



Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices



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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

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AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices

Structured Abstract

Objectives. To review important patient safety practices for evidence of effectiveness, implementation, and adoption.

Data sources. Searches of multiple computerized databases, gray literature, and the judgments of a 20-member panel of patient safety stakeholders.

Review methods. The judgments of the stakeholders were used to prioritize patient safety practices for review, and to select which practices received in-depth reviews and which received brief reviews. In-depth reviews consisted of a formal literature search, usually of multiple databases, and included gray literature, where applicable. In-depth reviews assessed practices on the following domains:

- How important is the problem?
- What is the patient safety practice?
- Why should this practice work?
- What are the beneficial effects of the practice?
- What are the harms of the practice?
- How has the practice been implemented, and in what contexts?
- Are there any data about costs?
- Are there data about the effect of context on effectiveness?

We assessed individual studies for risk of bias using tools appropriate to specific study designs. We assessed the strength of evidence of effectiveness using a system developed for this project. Brief reviews had focused literature searches for focused questions. All practices were then summarized on the following domains: scope of the problem, strength of evidence for effectiveness, evidence on potential for harmful unintended consequences, estimate of costs, how much is known about implementation and how difficult the practice is to implement. Stakeholder judgment was then used to identify practices that were “strongly encouraged” for adoption, and those practices that were “encouraged” for adoption.

Results. From an initial list of over 100 patient safety practices, the stakeholders identified 41 practices as a priority for this review: 18 in-depth reviews and 23 brief reviews. Of these, 20 practices had their strength of evidence of effectiveness rated as at least “moderate,” and 25 practices had at least “moderate” evidence of how to implement them. Ten practices were classified by the stakeholders as having sufficient evidence of effectiveness and implementation and should be “strongly encouraged” for adoption, and an additional 12 practices were classified as those that should be “encouraged” for adoption.

Conclusions. The evidence supporting the effectiveness of many patient safety practices has improved substantially over the past decade. Evidence about implementation and context has also improved, but continues to lag behind evidence of effectiveness. Twenty-two patient safety practices are sufficiently well understood, and health care providers can consider adopting them now.

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Appendix A. Original List of Patient Safety Practices

Appendix B. AMSTAR: A Measurement Tool To Assess Systemic Reviews

Appendix C. Literature Searches and Topic-Specific Methods

Appendix D. Supplementary Evidence Tables

(*NEW) refers to a new review that was not addressed in the 2001 report, “Making Health Care Safer: A Critical Analysis of Patient Safety Practices.”

Executive Summary

Background

The 1999 Institute of Medicine report “To Err is Human: Building a Safer Health System,” is credited by many with launching the modern patient safety movement.¹ A year after this report was published, as part of its initial portfolio of patient safety activities, the Agency for Healthcare Research and Quality (AHRQ) commissioned a group from the University of California, San Francisco-Stanford Evidence-based Practice Center (EPC) to analyze evidence behind a diverse group of patient safety practices (PSPs) that existed at that time.

The resulting 2001 report, “Making Health Care Safer: A Critical Analysis of Patient Safety Practices,”² hereafter referred to as “Making Health Care Safer,” was both influential and controversial. A significant number of copies of the report were distributed by AHRQ, and it became a cornerstone of other efforts (such as the National Quality Forum’s 34 “Safe Practices for Better Healthcare” list)³ to rank safety practices by strength of evidence. However, the low rankings given to some popular safety practices, such as computerized order entry, raised fundamental questions about the role of evidence-based medicine in quality and safety practices.

Since the “Making Health Care Safer” report was published, the safety field has matured. Regulators and accreditors encourage health care organizations to adopt “safe practices” and to avoid adverse events that are considered wholly or largely preventable. A significant amount of money and person-hours have been invested in efforts to improve safety, and almost all health-care delivery organizations regard safety as a primary strategic priority.

However, evidence indicates that progress has not matched the efforts and investment. Some patient safety practices (PSPs) have resulted in unintended consequences, whereas others have been shown to be highly context dependent, working effectively in a research setting but failing during broader implementation. In the past 2 years, three studies have found high rates of preventable harm in hospitals,⁴⁻⁶ one of which found no improvement in adverse event rates from 2003 to 2008.

Against this backdrop, AHRQ commissioned an updated research report on the state of PSPs. Because many of the project team members and much of the methodology were drawn from the initial “Making Health Care Safer” project, and because most of the relevant practices were reviewed then, we see this report as a natural sequel to the 2001 report. However, because of the burgeoning literature relevant to patient safety and the limits of budget and time, we chose to examine a subset of PSPs (chosen through methods described below). Moreover, part of the maturation of the safety field has included a deeper appreciation of the importance of context in patient safety practices, a topic examined by our research team in the 2010 report, “Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria,” hereafter referred to as “Context Sensitivity.”⁷ Accordingly, this report emphasizes matters of context and generalizability, as well as unintended consequences, to a greater degree than the 2001 “Making Health Care Safer” report.

Objectives

The goal of this project was to conduct a systematic literature review evaluating the evidence for a large number of patient safety practices.

Analytic Framework

For this report, we adopted the definition of a PSP used in the 2001 “Making Health Care Safer” report:

A Patient Safety Practice is a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.

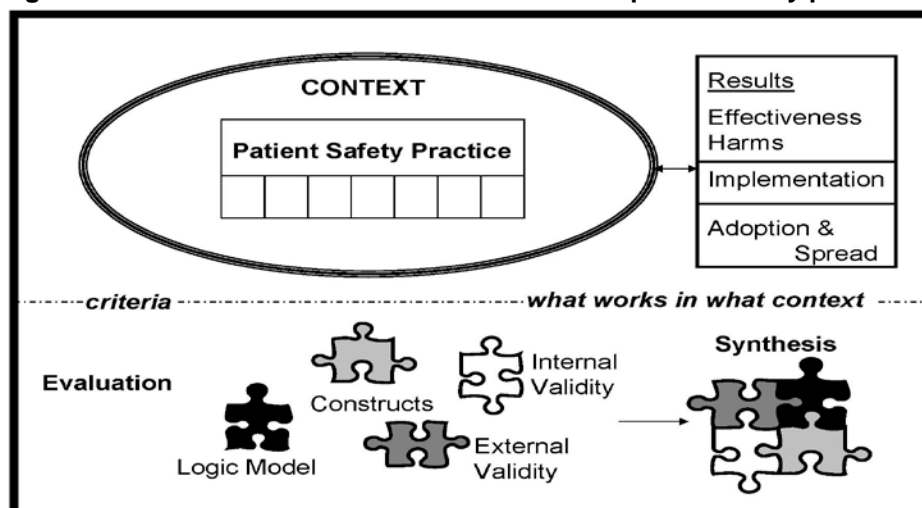
The framework for considering the evidence regarding a PSP was worked out as part of the report on “Context Sensitivity.”⁷ One of the principal challenges in the review of PSPs has been addressing the question of what constitutes evidence for PSPs. Many practices intended to improve quality and safety are complex sociotechnical interventions whose targets may be entire health care organizations or groups of providers, and these interventions may be targeted at rare events. To address the challenge regarding what constitutes evidence, we recognize that PSPs must be evaluated along two dimensions: the evidence regarding the outcomes of the safe practices, and the contextual factors influencing the practices’ use and effectiveness.

These dimensions are represented in Figure A, which depicts a sample PSP that consists of a bundle of components (the individual boxes), and the context within which the PSP is embedded. Important evaluation questions, as depicted on the right in the figure, include effectiveness and harms, implementation, and adoption and spread. We then apply criteria to evaluate the four factors that together constitute quality (depicted as puzzle pieces in the bottom half of the figure). They include:

1. Constructs about the PSP, its components, context factors, outcomes, and ways to accurately measure these constructs
2. Logic model or conceptual framework about the expected relationships among these constructs
3. Internal validity to assess the PSP results in a particular setting
4. External validity to assess the likelihood of being able to garner the same results in another setting

We then synthesize this information into an evaluation of the strength of the evidence for a particular PSP.

Figure A. Framework for evidence assessment of patient safety practices



The principal results of the “Context Sensitivity” report included the following key points.

- Whereas controlled trials of PSP implementations offer investigators greater control of sources of systematic error than do observational studies, trials often are not feasible in terms of time or resources. Also, controlled trials are often not possible for PSPs requiring large-scale organizational change or PSPs targeted at very rare events. Furthermore, the standardization imposed by the clinical trial paradigm may stifle the adaptive responses necessary for some quality improvement or patient safety projects. Hence, researchers may need to use designs other than randomized controlled trials to develop strong evidence about the effectiveness of some PSPs.
- Regardless of the study design chosen for an evaluation, components that are critical for evaluating a PSP in terms of how it worked in the study site, and whether it might work in other sites, include the following:
 - Explicit description of the theory for the chosen intervention components, and/or an explicit logic model for “why this PSP should work”
 - Description of the PSP in sufficient detail that it can be replicated, including the expected change in staff roles
 - Measurement of contexts
 - Explanation, in detail, of the implementation process, the actual effects on staff roles, and changes over time in the implementation or the intervention
 - Assessment of the impact of the PSP on outcomes and possible unexpected effects (including data on costs, when available)
 - For studies with multiple intervention sites, assessment of the influence of context on intervention and implementation effectiveness (processes and clinical outcomes)
- High priority contexts for assessing any PSP implementation include measuring and information for each of the following four domains:
 - Structural organizational characteristics (such as size, location, financial status, existing quality and safety infrastructure)
 - External factors (such as regulatory requirements, the presence in the external environment of payments or penalties such as pay-for-performance or public

- reporting, national patient safety campaigns or collaboratives, or local sentinel patient safety events)
- Patient safety culture (not to be confused with the larger organizational culture), teamwork, and leadership at the level of the unit
 - Availability of implementation and management tools (such as staff education and training, presence of dedicated time for training, use of internal audit-and-feedback, presence of internal or external individuals responsible for the implementation, or degree of local tailoring of any intervention)

These principles guided our search for evidence, and the way in which we presented our findings in this report.

Methods

We divided the project into three phases: topic refinement, the evidence review, and the critical review and interpretation of the evidence. The project team performed topic refinement and conducted the critical review of the evidence jointly with the Technical Expert Panel (TEP), which had also participated in the “Context Sensitivity” project. This TEP included many of the key patient safety leaders in the United States, Canada, and the United Kingdom: experts in specific PSPs and evaluation methods and persons charged with implementing PSPs in hospitals and clinics.

Topic Refinement

Because the goals of the project were to assess the evidence of the effectiveness of new safe practices and the evidence of implementation for current safe practices, most PSPs were eligible for this review. Thus, our first task was to refine the scope of the topic to fit within the timeframe and budget of the project, a task undertaken by the project team and the TEP. To accomplish this task, we created an initial list of 158 PSPs that we considered potentially eligible for inclusion. Through a process of internal team triage, group discussion with the TEP, and formal TEP votes, we narrowed the list to 41 PSPs for which a review of evidence was judged likely to be most helpful to providers, policymakers, and patients. However, this number of PSPs was still too large for us to review the evidence comprehensively within the timeframe. For that reason, we asked our TEP whether “breadth” or “depth” was likely to be more valuable for stakeholders; in other words, we asked whether the review should focus on fewer topics in more detail or cover all topics but with less detail. Our TEP recommended a “hybrid” approach, in which some topics would be reviewed in depth, whereas other topics would receive only a “brief review.” Topics could be considered as needing only a “brief review” for several reasons: the PSP is already well established; stakeholders need to know only “what’s new” since the last time a topic was reviewed in depth; new evidence suggests the PSP may not be as effective as originally believed, so it is no longer a priority PSP; or the PSP is emerging with little evidence accumulated. We ultimately ended up with 18 in-depth reviews and 23 brief reviews.

Evidence Reviews

In-Depth Reviews

Overall approach. For many of the 18 topics designated to receive an in-depth review, a systematic review was likely to exist. Thus, a search to identify existing systematic reviews was usually the project team’s first step. To assess the potential utility of such reviews, we followed the procedures proposed by Whitlock and colleagues,⁸ which essentially meant addressing the following two questions: (1) Is the existing review sufficiently “on topic” to be of use? (2) Is the existing review of sufficient quality for us to have confidence in the results?

If an existing systematic review was judged to be sufficiently “on topic” and of acceptable quality, we took one of two steps. We either performed an “update” search; that is, we searched databases for new evidence published since the end date of the search in the existing systematic review. Or, we conducted a search for “signals for updating.” Such searches generally followed the criteria proposed by Shojania and colleagues.⁹ The searches involved a search of high-yield databases and journals for “pivotal studies” that could be a signal that a systematic review is out-of-date. Any evidence identified via the update search or the “signals” search was added to the evidence base from the existing systematic review.

Some PSPs had no existing systematic reviews, while other PSPs had prior reviews that were either not sufficiently relevant or were not of sufficient quality to be used. In those situations, we conducted new searches using guidance as outlined in AHRQ’s “Methods Guide for Effectiveness and Comparative Effectiveness Reviews.”¹⁰

Evidence about context, implementation, and adoption are key aspects of this review. We searched for evidence on these topics in two ways:

- We looked for and extracted data about contexts and implementation from the articles contributing to the evidence of effectiveness.
- We identified “implementation studies” from our literature searches. “Implementation studies” focus on the implementation process, particularly the elements demonstrated or believed to be of special importance for the success, or lack of success, of the intervention. To be eligible, implementation studies needed to either report or be linked to reports of effectiveness outcomes.

Reporting format. We took the format for in-depth reviews from AHRQ’s “Context Sensitivity” report. Table A outlines the format of the in-depth reviews.

Table A. Format for in-depth reviews

How important is the problem?
This section briefly sketches the nature of the target for the Patient Safety Practice.
What is the Patient Safety Practice?
This section describes the practice or practices proposed and evaluated.
Why should this Patient Safety Practice work?
This section describes what has been written about the basis for a proposed Patient Safety Practice, such as an underlying theory, a logic model for how it should work, or prior data.
What are the beneficial effects of the Patient Safety Practice?
This section provides the review of the evidence of effectiveness, and is the section most similar to traditional Evidence-based Practice Center reports.
What are the harms of the Patient Safety Practice?
This section contains the evidence of harms. Unlike reviews of most clinical interventions, evaluating potential harms is not a routine part of Patient Safety Practice evaluations. Thus, for most topics, this section is underdeveloped.
How has the Patient Safety Practice been implemented, and in what contexts?
This section describes what has been reported about how to implement the Patient Safety Practice and the range of institutions or contexts of where it has been implemented. When there is sufficient evidence, implementation studies are evaluated qualitatively for themes regarding effective implementation.
Are there any data about costs?
This section describes the evidence of costs of implementing the Patient Safety Practice, or, in some cases, cost-effectiveness analyses that have been performed.
Are there any data about the effect of context on effectiveness?
This section describes the evidence about whether or not the Patient Safety Practice has been shown to have differential effectiveness in different contexts. The "Context Sensitivity" project defined important contexts for Patient Safety Practices in four domains: external factors (e.g., financial or performance incentives or Patient Safety Practice regulations); structural organizational characteristics (e.g., size, organizational complexity, or financial status); safety culture, teamwork, and leadership involvement; and availability of implementation and management tools (e.g., organizational training incentives). ¹¹

Brief Reviews

Brief reviews are not full systematic reviews. The goals of the brief reviews covered in this report varied by PSP according to the needs of stakeholders. The assessment could focus on either information about effectiveness of an emerging PSP or implementation of an established PSP; alternatively, the review could explore whether new evidence calls into question the effectiveness of an existing PSP. Thus, the methods for the brief reviews differed by topic. However, in general, brief reviews were conducted by a content expert who worked with the project team. The brief reviews involved focused literature searches for evidence relevant to the specific need. The evidence was then narratively summarized in a format that also varied with the particular goal.

Evidence Summary

We judged that users of this report would want a summary of the evidence for each topic. Such summary messages may facilitate an uptake of the findings. The project team developed the following summary domains with input from the TEP.

Scope of the problem. In general, we addressed two issues: the frequency of the safety problem, and the severity of each average event. For benchmarks, we regarded safety problems that occur approximately once per 100 hospitalizations as “common;” examples include falls, venous thromboembolism (VTE), potential adverse drug events, or pressure ulcers. In contrast, events an order of magnitude or more lower in frequency were considered “rare;” such events include inpatient suicide, wrong-site surgery, and surgical items being left inside a patient. The scope must also consider the severity of each event; for instance, most falls do not result in injury, and most potential adverse drug events do not result in clinical harm. However, each case of inpatient suicide or wrong-site surgery is devastating.

Strength of evidence for effectiveness. This assessment follows a framework for strength of evidence that the project team adapted from existing EPC Methods guidance¹² to increase the relevance to patient safety practices. This means we included in strength of evidence assessments evidence about context, implementation, and the use of theory or logic models, in addition to standard EPC criteria on inconsistency, in precision, and the possibility of reporting bias.

Evidence on potential for harmful unintended consequences. Most PSP evaluators have not explicitly assessed the possibility of harm. Consequently, this domain includes evidence of both actual harm and the potential for harm. The ratings on known or potential harms ranged from high risk of harm to low (or negligible) risk of harm; in some cases, the evidence was too sparse to provide a rating.

Estimate of costs. This domain is speculative, because most evaluations do not present cost data. However, we believed that providing at least a rough estimate of cost would be beneficial information to include in this report. Therefore, we used the following categories and benchmarks to provide a rough estimate of cost, noting, where necessary, the factors that might cause cost estimates to vary.

- **Low cost.** PSPs that do not require hiring new staff or large capital outlays but instead involve training existing staff and purchasing some supplies. Examples include most fall prevention programs, VTE prophylaxis, and medical history abbreviations designated as “Do Not Use.”
- **Medium cost.** PSPs that might require hiring one or a few new staff members, have modest capital outlays, or incur ongoing monitoring costs. Examples include some fall prevention programs, many clinical pharmacist interventions, and participation in the American College of Surgeons outcomes reporting system (\$135,000/year).¹³
- **High cost.** PSPs that require hiring substantial numbers of new staff, have considerable capital outlays, or both. Examples include computerized order entry (because it requires an electronic health record), having to hire many nurses to achieve a certain nurse-to-patient ratio, or facility-wide infection control procedures (estimated at \$600,000 year for a single intensive care unit).¹⁴

Implementation issues. This section summarizes how much we know about how to implement the PSP and how difficult it is to implement. To approach the question of how much we know, we considered the available evidence about implementation, the existence of data about the effect and influence of context, the degree to which a PSP has been implemented, and the presence of implementation tools, such as written materials and training manuals.

For the question of implementation difficulty, we used three categories: difficult, for PSPs that require large scale organizational change; not difficult, for PSPs that require protocols for drugs or devices, such as those needed to reduce radiation exposure or to help prevent stress-related gastrointestinal bleeding; and moderate, for PSPs falling between the extremes.

Critical Review and Interpretation of Evidence

The TEP reviewed the results of the evidence review performed by the project team both in a written draft document and at a face-to-face meeting in January 2012. One outcome of this review was a set of recommendations about priorities for PSP adoption.

Results

We completed 18 in-depth reviews and 23 brief reviews. Table B summarizes the findings according to the five main issues previously described (scope, strength of evidence, harms, costs, and implementation). The table is organized into two main sections: PSPs aimed at a specific (single) patient safety target, such as adverse drug events, or general clinical topics, such as preventing pressure ulcers; and PSPs designed to improve the overall system or to address multiple patient safety targets, such as nurse-staffing ratios or computerized provider order entry. In some cases, the text in the PSP column differs slightly from the chapter heading for that PSP. This is due to the desire by our TEP to include the target safety problem in the table (if targeted at a specific safety problem), more specification, or an example of the PSP (e.g., adding “such as a centralized display of consolidated data” to the PSP designated as “operating room integration and display systems”).

Table B. Summary table*

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much Do We Know?/How Hard Is it?
Practices Designed for a Specific Patient Safety Target					
Adverse Drug Events					
High-alert drugs: patient safety practices for intravenous anticoagulants; in-depth review	Common/Moderate	Low	Low-to-moderate	Low	Little/Moderate
Use of clinical pharmacists to prevent adverse drug events; brief review	Common/Low	Moderate-to-high	Low	High	Little/Moderate
The Joint Commission’s “Do Not Use” list; brief review	Common/Low	Low	Negligible	Low	Little/Probably not difficult
Smart infusion pumps; brief review	Common/Low	Low	Low	Moderate	Moderate/Moderate
Infection Control					
Barrier precautions, patient isolation, and routine surveillance for the prevention of healthcare-associated infections; brief review	Common/Moderate	Moderate	Moderate (isolation of patients)	Moderate-to-high	Moderate/Moderate
Interventions to improve hand hygiene compliance; brief review	Common/Moderate	Low	Low	Low	Moderate/Moderate

Table B. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much Do We Know?/How Hard Is it?
Reducing unnecessary urinary catheter use and other strategies to prevent catheter-associated urinary tract infections; brief review	Common/Moderate	Moderate-to-high	Low	Low	Moderate/Moderate
Prevention of central line-associated bloodstream infections; brief review	Common/Moderate	Moderate-to-high	Low	Low-to-moderate	Moderate-to-difficult/ Not difficult (implementation of a “bundle”)-to-moderate (understanding organization culture and context)
Ventilator-associated pneumonia; brief review	Common/High	Moderate-to-high	Low	Low-to-moderate	Moderate/Moderate
Interventions to allow the reuse of single use devices; brief review	Common/Low	Low	Low	Low	A lot/Not difficult
Surgery, Anesthesia, and Perioperative Medicine					
Preoperative checklists and anesthesia checklists to prevent a number of operative safety events, such as surgical site infections and wrong site surgeries; in-depth review	Common/Moderate	High	Negligible	Low	A lot/Moderate
The use of ACS-NSQIP report cards and outcome measurements to decrease perioperative morbidity and mortality; in-depth review	Common/High	Moderate-to-high	Low	Moderate	Moderate/Moderate
New interventions to prevent surgical items from being left inside a patient; brief review	Rare/Low	Low	Negligible	Low if it simply involves more frequent manual counting; high if RFID is used	Little
Operating room integration and display systems, such as a centralized display of consolidated data; brief review	Common/Low-to-high	Low	Negligible	Moderate	Moderate/Moderate
Use of beta blockers to prevent perioperative cardiac events; brief review	Common/High	High evidence harms may equal or exceed benefits	High (death, stroke, hypotension, and bradycardia)	Low	NA
Use of real-time ultrasound guidance during central line insertion to increase the proportion correctly placed on the first attempt; brief review	Common/Low-to-moderate	High	Negligible	Low-to-moderate	A lot/Moderate

Table B. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much Do We Know?/How Hard Is it?
Safety Practices for Hospitalized Elders					
Multicomponent interventions to prevent in-facility falls; in-depth review	Common/Low	High	Moderate (increased use of restraints and/or sedation)	Moderate	Moderate/Moderate
Multicomponent interventions to prevent in-facility delirium; in-depth review	Common/Low	Moderate	Low	Moderate	Moderate/Moderate
General Clinical Topics					
Multicomponent initiatives to prevent pressure ulcers; in-depth review	Common/Moderate	Moderate	Negligible	Moderate	Moderate/Moderate
Inpatient, intensive, glucose control strategies to reduce death and infection; in-depth review	Common/Moderate	Moderate-to-high evidence it doesn't help	High (hypoglycemia)	Low-to-moderate	NA
Interventions to prevent contrast-induced acute kidney injury; in-depth review	Common/Low	Low	Negligible	Low	Little/Not difficult
Rapid-response systems to prevent failure-to-rescue; in-depth review	Common/High	Moderate	Low	Moderate	Moderate/Moderate
Medication reconciliation supported by clinical pharmacists; in-depth review	Common/Low	Moderate	Low	Moderate	Moderate/Moderate
Identifying patients at risk for suicide; brief review	Rare/High	Low	Low	Moderate	Little/Moderate
Strategies to prevent stress-related gastrointestinal bleeding (stress ulcer prophylaxis); brief review	Rare/Moderate	Moderate	Moderate (pneumonia)	Moderate	Little/Not difficult
Strategies to increase appropriate prophylaxis for venous thromboembolism; brief review	Common/Moderate	High	Moderate (bleeding)	Low	Little/Moderate
Preventing patient death or serious injury associated with radiation exposure from fluoroscopy and computed tomography through technical interventions, appropriate utilization, and use of algorithms and protocols; brief review	Rare/High	Moderate	Negligible	Low	Moderate/Not difficult
Ensuring documentation of patient preferences for life-sustaining treatment, such as advanced directives; brief review	Common/Moderate	Moderate	Low	Low	Moderate/Moderate
Increasing nurse-to-patient staffing ratios to prevent death; in-depth review	Common/High	Moderate	Low	High	A lot/Not difficult

Table B. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much Do We Know?/How Hard Is it?
Practices Designed To Improve Overall System/Multiple Targets					
Increasing nurse-to-patient staff ratios to prevent falls, pressure ulcers, and other nursing sensitive outcomes (other than mortality); in-depth review	Common/High	Low	Low	High	A lot/Not difficult
Incorporation of human factors and ergonomics in the design of health care practices by hiring an expert or training clinicians in human factors; in-depth review	Potentially applicable to all patient safety problems	Not assessed systematically, but moderate-to-high evidence for some specific applications	Negligible	Moderate	A lot/Moderate
Promoting engagement by patients and families to reduce adverse events (such as patients encouraging providers to wash their hands); in-depth review	Common	Emerging practice (few studies available)	Uncertain	Low	Little/Moderate
Interventions to promote a culture of safety; in-depth review	Common/Low-to-high	Low	Uncertain	Low-to-moderate (varies)	Moderate/Not difficult-to-moderate (varies with intervention)
Patient safety practices targeted at diagnostic errors; in-depth review	Common/High	Emerging practice (few studies available)	Uncertain	Varies	Varies
Monitoring patient safety problems; in-depth review	Common/Low-to-high	Low	Negligible	High	Moderate/Difficult
Interventions to improve care transitions at hospital discharge; in-depth review	Common/Moderate	Low	Negligible	Moderate-to-high	Little/Difficult
Use of simulation-based training and exercises; in-depth review	Common/Moderate-to-high	Moderate-to-high for specific topics	Uncertain	Moderate	Moderate
Obtaining informed consent from patients to improve patient understanding of potential risks of medical procedures; brief review	Common/Moderate	Moderate	Negligible	Low	Moderate/Not difficult
Team-training in health care; brief review	Common/High	Moderate	Low	Moderate	Moderate/Moderate-to-difficult
Computerized provider order entry (CPOE) with clinical decision support systems (CDSS); brief review	Common/Moderate	Low-to-moderate	Low-to-moderate	High	Moderate/Difficult
Interventions to prevent tubing misconnections; brief review	Common/Moderate	Low	Low	Low	Moderate/Not difficult

Table B. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much Do We Know?/How Hard Is it?
Limiting trainee work hours; brief review	Common/Moderate	Low	Moderate (at least); includes lack of training time	High	Moderate/Difficult

Abbreviations: ACS NSQIP=American College of Surgeons National Surgical Quality Improvement Program; NA = not available; PSP: Patient Safety Practice; RFID = radio-frequency identification.

*In some cases, the text in the “PSP” column differs slightly from the chapter heading for that PSP. This difference is attributable to our Technical Expert Panel’s desire to include the target safety problem (if the practice is in fact targeted at a specific safety problem), more specification, or an example of the PSP (e.g., adding “such as a centralized display of consolidated data” to the PSP designated as “operating room integration and display systems”).

Rating Scales:

Scope of the problem targeted by the PSP (frequency/severity): frequency = rare or common; severity = low, moderate, or high.

Strength of evidence for effectiveness of the PSPs: low, moderate, or high.

Evidence or potential for harmful unintended consequences: negligible, low, moderate, or high.

Estimate of cost: low, moderate, or high.

Implementation issues: How much do we know? = little, moderate, or a lot; How hard is it? = not difficult, moderate, or difficult.

Discussion

Since the 2001 report, “Making Health Care Safer,” a vast amount of new information on PSPs has emerged. Compared with a decade ago, more agreement is now evident on what constitutes evidence of effectiveness and the importance of implementation and context. In this review, we determined that the strength of evidence was at least moderate for 20 PSPs, or about half of those reviewed. For 26 of the PSPs, we judged that evidence of at least moderate strength was available on how to implement them.

Thus, sufficient evidence exists about effectiveness and implementation to permit our TEP members to conclude that some PSPs are ready to be “strongly encouraged” for adoption by health care providers. Their assessments were based explicitly on the combination of the available evidence with their expert judgment in interpreting the evidence. The 10 “strongly encouraged” PSPs are listed in Table C.

Table C. Strongly encouraged patient safety practices

<ul style="list-style-type: none"> • Preoperative checklists and anesthesia checklists to prevent operative and post-operative events • Bundles that include checklists to prevent central line-associated bloodstream infections • Interventions to reduce urinary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols • Bundles that include head-of-bed elevation, sedation vacations, oral care with chlorhexidine, and subglottic-suctioning endotracheal tubes to prevent ventilator-associated pneumonia • Hand hygiene • “Do Not Use” list for hazardous abbreviations • Multicomponent interventions to reduce pressure ulcers • Barrier precautions to prevent healthcare-associated infections • Use of real-time ultrasound for central line placement • Interventions to improve prophylaxis for venous thromboembolisms

The TEP members concluded that several other PSPs had sufficient evidence of effectiveness and implementation, and that they should be “encouraged” for adoption. The 12 “encouraged” PSPs are listed in Table D.

Table D. Encouraged patient safety practices

- Multicomponent interventions to reduce falls
- Use of clinical pharmacists to reduce adverse drug events
- Documentation of patient preferences for life-sustaining treatment
- Obtaining informed consent to improve patients' understanding of the potential risks of procedures
- Team training
- Medication reconciliation
- Practices to reduce radiation exposure from fluoroscopy and computed tomography scans
- Use of surgical outcome measurements and report cards, like the American College of Surgeons National Surgical Quality Improvement Program
- Rapid response systems
- Utilization of complementary methods for detecting adverse events/medical errors to monitor for patient safety problems
- Computerized provider order entry
- Use of simulation exercises in patient safety efforts

The 22 PSPs in Tables C and D represent practices that health care providers can consider for adoption now. This recommendation particularly applies to the 10 “strongly encouraged” practices. For these practices, at least in the judgment of our TEP, there is sufficient knowledge to implement them, and that doing so will likely result in safer care. Future evaluations will likely further the knowledge of how best to implement the practices to make them most effective. However, in the meantime, our TEP believes that providers should not delay their consideration of adopting these practices, as enough is known now to permit health care systems to move forward.

Limitations

Because of limited resources and time, the current report does not cover the entire patient safety field, which has grown exponentially since the last report, both in the number of potential PSPs and in the amount of data about individual PSPs. For that reason, we used an explicit and transparent process to select which PSPs to evaluate, and our final list of 41 (from the more than 150 candidates) included the PSPs we felt were of highest priority to policymakers and providers.

Secondly, we did not perform in-depth reviews for all 41 PSPs. To maximize use of the available time and resources, we tailored our methods to the needs of our stakeholders. In particular, we targeted the 18 PSPs that were of the greatest interest to our stakeholders, or for which we likely had the most new information for in-depth reviews. The remaining 23 PSPs received brief reviews. It is important to note that the decisions about which PSPs would receive which level of scrutiny and analysis were made by a broadly representative stakeholder committee.

Thirdly, the in-depth reviews, although thorough, did not conform to all of the criteria for conducting an evidence review as presented in the Institute of Medicine’s report, “Finding What Works in Health Care: Standards for Systematic Reviews,”¹⁵ or to all the criteria in AHRQ’s “Methods Guide for Effectiveness and Comparative Effectiveness Reviews”⁹; for example, we did not publicly post a protocol for each of the individual reviews. We used our collective experience as EPC team members to adapt existing EPC methods that best preserved the essence of a systematic review, while allowing for the completion of 18 in-depth reviews within 9 months and within the available budget.

Additionally, over time, we will likely improve our methods for assessing evidence regarding how patient safety interventions affect health care processes and outcomes. The methods we used

for this report incorporate new perspectives regarding the importance of implementation and context, which was the focus of the “Context Sensitivity” report; likewise, in the future, we expect to increase our understanding of the interactions between multiple intervention, implementation, and organizational variables and how the variables influence safety outcomes. If future research reveals that these variables interact in ways that our current understanding of theory and logic models cannot explain, we will need to modify the methods for evaluating PSPs again.

Lastly, we relied on the judgment of our TEP at every important step of the project. Therefore, the results are as much a product of these judgments as are our systematic review methods. Hence, our results might be sensitive to the selection of particular experts on our TEP. However, we mitigated this potential bias by including more than double the number of experts on our TEP as we typically would for an EPC review, which allowed us to include a diverse set of stakeholders from the U.S., Canada, and the United Kingdom. Stakeholders included PSP developers and evaluators, patient safety policymakers, and experts in design and evaluation methods. Rather than regarding the tight linkage between the needs of the stakeholders and the work of the EPCs as a limitation, we view it as a strength that increases the likelihood that the results of the review will be meaningful to providers, payors, and patients, and that the report’s results will lead to meaningful change.

Future Research Needs

Despite over a decade of effort, there is little evidence that patient outcomes (broadly measured) have significantly improved, yet there has been some success (generally in efforts to reduce one type of harm, usually using one method of improvement). For example, efforts have focused on reducing blood stream infections, improving teamwork, or enhancing patient engagement.

If health care is to make significant improvements in patient safety, research should inform and guide these efforts. We have learned much about how to improve safety, yet we need to learn much more. Acquiring this knowledge will require investments in patient safety research, including investing in “basic” methodological research. To date, investments in patient safety research have fallen far short of the magnitude of the problem.

To achieve progress in improving patient safety, research is needed in a number of areas, including the following:

- “Basic” patient safety research to develop new tools and measures, and research to ensure that the tool matches the problem
- A larger number of valid measures of patient safety
- Better methods to measure context and how an intervention was implemented
- Methods to identify and provide the necessary skills, resources, and accountability (e.g., a safety management infrastructure) at each level of the health care system

More effective and less burdensome methods of improvement so that clinicians, researchers, and administrators can work on reducing all potential patient harms, rather than a select few.

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Part 1. Overview

Chapter 1. Introduction

The modern patient safety movement is believed by many to trace its origins to the 1999 publication of the groundbreaking report, “To Err is Human” by the Institute of Medicine.¹ This report, which highlighted the 44,000 to 98,000 deaths per year from medical errors in the United States (U.S.) (the equivalent of the fatalities that would result from the crash of a “jumbo jet a day”), galvanized the public and resulted in the focus, of widespread media and legislative attention, for the first time, on the issue of patient safety. Parallel reports from other countries were similarly influential.²

As part of its initial portfolio of patient safety activities, the Agency for Healthcare Research and Quality (AHRQ) commissioned a team from the University of California, San Francisco (UCSF)-Stanford University Evidence-Based Practice Center to analyze the evidence behind a diverse group of patient safety practices (PSPs) in use—or conceptualized—at that time. The report—“Making Health Care Safer: A Critical Analysis of Patient Safety Practices”² (MHCS)—was published in 2001.³ The report analyzed nearly 80 different safety practices on several dimensions, including potential impact, supporting evidence, and costs and complexity of implementation. Based on these evidence reviews, practices were ultimately rated on both impact and evidence, as well as prioritization for future research.

MHCS was immediately both influential and controversial. Several hundred thousand copies of the report were distributed by AHRQ, and it became a lynchpin for other efforts (such as the National Quality Forum’s Safe Practices list) to describe PSPs through the lens of evidence-based medicine. The controversy was generated by the report’s rankings of PSPs—in particular, the relatively low rankings for certain popular practices such as computerized order entry—which raised fundamental questions about the role of evidence in assessing the value of quality and safety practices, questions that continue to be debated to this day.⁴⁻⁷

In 2001, hospitals and health care organizations were under relatively little pressure to implement safety practices. A decade later, the stakes have grown far higher.⁸ Regulators and accreditors are pushing health care organizations to adopt various “safe practices” or to avoid particular adverse events that are considered wholly or largely preventable. Many payers, including the Centers for Medicare & Medicaid Services, have embedded patient safety into pay-for-performance and “no pay for errors” initiatives. Billions of dollars and millions of person-hours have been invested in a variety of efforts to improve safety, and virtually every health care delivery organization now identifies patient safety as one of its top strategic priorities.

Yet the evidence indicates that our progress in eradicating medical errors has not matched the efforts and financial resources invested in implementing PSPs. Studies of some practices that have tremendous intuitive appeal, such as reducing resident duty hours and implementing rapid response teams, have yielded conflicting results.^{9,10} Many examples of unintended consequences of safety practices have emerged,¹¹ and the successful implementation of safety practices has been shown to be highly context dependent,¹² often working effectively in some hospitals but not others. Although a national initiative to improve safety in the United Kingdom found some evidence of improvement, control hospitals improved as much as those that participated in a vigorous intervention.¹³ Three recent U.S. studies have demonstrated continuing high rates of preventable harm in hospitals;¹⁴⁻¹⁶ one of these studies showed evidence of no improvement in adverse event rates from 2003 to 2008.¹⁴

Against this backdrop, AHRQ, believing that the time has come to re-examine the state of the evidence supporting a wide variety of PSPs, commissioned a team led by investigators at RAND Health, UCSF, and Johns Hopkins to reexamine the evidence behind key PSPs. Many of the individuals engaged in this task participated in producing the original MHCS report, the MCHS methodology formed the cornerstone of the present effort, and many of the practices examined for this report were those previously reviewed in 2001. Thus, we see the present report as a natural sequel to MHCS.

Because of the burgeoning literature relevant to patient safety and the limits of budget and time, we selected a subset of PSPs to examine for this present report (chosen through methods described in Chapter 2) rather than attempt, as we did in 2001, to review all PSPs. Moreover, the maturation of the safety field has led to a deeper appreciation of the importance of context in PSPs, a topic examined by our research team in our 2010 report, “Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria.”¹⁷ Accordingly, this report emphasizes matters of context and generalizability, as well as unintended consequences, to a greater degree than did MHCS.

Who Will Use This Report, and for What Purpose?

We envision that this report will be useful to a wide audience.

Policymakers may use its contents and recommendations to promote or fund the implementation of particular practices. Similarly, leaders of local health care organization (including hospitals, medical groups, or integrated delivery systems) may use the data and analyses to choose which practices to consider implementing or further promote at their institutions. Because of consumers’ keen interest in patient safety, the connection between the emergence of an evidence-based practice and the enactment of an associated accreditation standard, regulation, public reporting requirement, or payment-based initiative is much tighter for PSPs than it is for clinical practices. This makes it particularly crucial that policymakers have good data on which to base their decisions.

Clinicians are increasingly being asked to participate in patient safety activities and want to know the evidence supporting PSPs that they are being asked to help implement. For *trainees and teachers*, patient safety is now seen as foundational to the education of doctors, nurses, pharmacists, health care administrators, and other ancillary health care personnel. We hope that trainees and practicing clinicians alike will find the material both interesting and relevant to their day-to-day practices.

Researchers will find a wealth of potential research opportunities. Those who fund research, including (but not limited to) AHRQ, will find that we explicitly identified future research needs. As our understanding of the patient safety field has matured, researchers have become increasingly aware of the complexity of PSPs. For example, the widespread enthusiasm for the use of checklists¹⁸ (which was largely absent in 2001) has led to cautionary notes from several patient safety leaders regarding the degree to which even seemingly simple PSPs are dependent on culture change and local context.^{19,20}

Patient safety professionals, meaning people directly involved in improving patient safety and those working in organizations focused on quality and patient safety, overlap with each of the

three groups above, but deserve their own designation here, as they may be the most frequent and intense users of this report as they seek to improve patient safety at their own institutions.

Finally, while this volume is not primarily written for *patients and their families*, both groups have become increasingly involved in patient safety efforts in a variety of ways. We welcome such engagement and believe that patients, families, and their advocates can help advance efforts to prevent harm.

A decade ago, our early enthusiasm for patient safety was accompanied by a hope—and some magical thinking—that finding solutions to medical errors would be relatively straightforward. Simply adopt some techniques drawn from aviation and other “safe industries,” build strong information technology systems, and improve culture, and, the hope went, patients would immediately become safer in hospitals and clinics everywhere.

We now appreciate the naivety of this point of view. Making patients safe will require ongoing efforts to improve practices, training, information technology, and culture. It will need top-down resources and leadership, accompanied by bottom-up wisdom and innovation. It will depend on a strong policy environment that creates appropriate incentives, while avoiding an environment in which providers’ enthusiasm and creativity are sapped by an overly rigid, prescriptive bureaucracy and set of rules.

While we have become more sophisticated about the challenges of keeping patients safe over the past decade, the fundamentals have not changed: we need good and well-trained people, armed with good data, operating under good policies, working under good leaders to do the right things for patients. We hope this report contributes to these efforts by helping to identify those right things.

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Chapter 2. Methods

Topic Development

This topic was nominated by leaders of the Agency for Healthcare Research and Quality's Patient Safety Portfolio, part of the Center for Quality Improvement and Patient Safety.

The original goals of the project were stated as follows:

The analysis shall build on and expand upon earlier evidence reports and current listing of Safe Practices by the National Quality Forum's (NQF) 'Safe Practices for Better Healthcare 2010 Update.' The analysis shall focus on the collection of evidence of the effectiveness of new safe practices that have been developed but not included in the 2010 update, evidence of implementation of current and new safe practices and the adoption of safe practices by health care providers. This analysis shall include the review of scientific literature, other appropriate analyses, and extensive peer review of the draft report. The final report of this project will be used by AHRQ for strategic planning in its patient safety portfolio for future project development, implementation of safe practices. The report will also be used by external organizations such and the NQF, Joint Commission and others in their patient safety efforts.¹

The preliminary Key Questions, pending topic refinement, were organized into three categories.

Design, Development and Testing of New Patient Safety Practices

- What new patient safety practices (PSPs) have been developed since 2001 and/or are not included in the NQF safe Practice list in 2010?
- What is the nature of the safety practice i.e. clinical, organizational, or behavioral?
- What is the intended risk that the practice is designed to prevent or mitigate?
- Describe how the practice is a bundle of individual components or practices, if applicable.
- What is the intended setting for the practice, i.e., in patient, ambulatory, combination, specialty, or clinical domain, and organizational setting?
- What are the nature, quality, and weight of evidence of the practice's effectiveness?

Implementation of Patient Safety Practice

- Was the safety practice implemented outside the developing institution?
- What were the contextual settings in which it was implemented?
- What were the issues, barriers, problems, successes, and failures in the implementation of the practice?
- What modifications and/or customizations were made (if any) in the implementation process?
- What are the different implementation settings outside the developing institution that have been reported for this practice?

- Describe how the practice has been sustained in its use after initial implementation.
- Was there any external support for the implementation process, e.g., AHRQ technical support, use by a collaborative, or quality improvement organization (QIO)?

Adoption/Diffusion

- What is the extent to which the practice has been adopted by multiple institutions or organizations outside the developing institution?
- Was there any organized activity or program to support the diffusion of this innovation or practice?
- What, if any, evidence exists on the sustained use of the practice?
- Has the practice become a requirement for use by any accreditation or credentialing agency or organization?

Project Overview

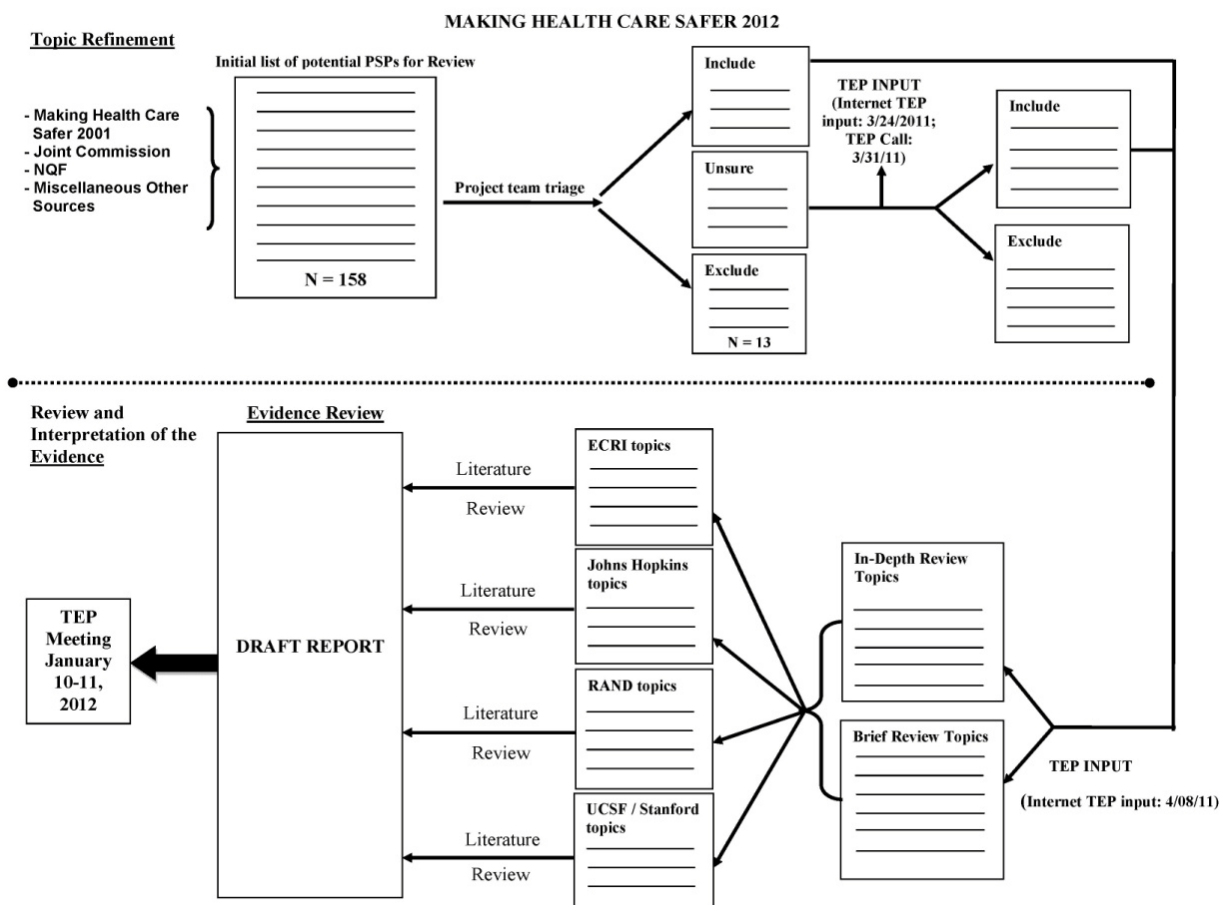
An overview of the project is depicted in Figure 1. A key aspect of this project is the active participation of a Technical Expert Panel (TEP) comprising a large number of patient safety stakeholders and evaluation methods experts. We retained the participation of the TEP that had participated in a prior AHRQ-supported project, “Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria” (hereafter referred to as “Context Sensitivity”). The TEP comprised many of the key patient safety leaders in the United States., Canada, and the United Kingdom, including experts in specific PSPs, as well as experts in evaluation methods and people charged with implementing PSPs in hospitals and clinics.

We divided the project into three phases: topic refinement, the evidence review, and the critical review and interpretation of the evidence. The project team conducted the topic refinement and the critical review and interpretation of the evidence jointly with the TEP; the project team performed the evidence review.

Topic Refinement

Because the goals of the project were to assess the “evidence of the effectiveness of new safe practices” and the “evidence of implementation of current...safe practices,” practically all PSPs were potentially eligible for inclusion in this review. Thus our first task was to refine the scope of the topic to something that was achievable within the timeframe and budget for the project; this task was undertaken by the project team and the TEP. Figure 1 presents an overview of how this task was accomplished. We first compiled a list of potential PSPs for the review, starting with the 79 topics in the MHCS report (2001)² and adding practices from the National Quality Forum’s 2010 Update, the Joint Commission, and the Leapfrog Group; practices identified in an initial scoping search; and those suggested by our TEP. This effort resulted in an initial list of 158 potential PSPs (see Appendix A).

Figure 1, Chapter 2. Overview of the project



We then conducted an internal project team process that included amalgamation of some topics and renaming of others, resulting in 96 PSPs. Internal project team triage resulted in our identifying 35 PSPs we believed must be included, 48 PSPs about which we were unsure, and 13 that we believed could be excluded or folded into other PSPs that were on our “include” list (Table 1). As indicated, we incorporated some of those 13 topics into other topics, such as the monitoring topics. We excluded others that we judged to represent more of a quality issue than a patient safety issue (such as pneumococcal vaccination interventions and regionalizing surgery to high volume centers), whereas we judged others to be too late (warfarin interventions, in light of the emergence of new oral anticoagulants) or too early in development (radio-frequency identification [RFID] devices attached to wandering patients) for consideration.

Table 1, Chapter 2. Initially excluded topics

Topic	Team Comment
Use of computer monitoring for potential ADEs (ADEs related to targeted classes (analgesics, potassium chloride, antibiotics, heparin) (focus on detection))	Seems this could be part of a broader focus on patient safety reporting systems.
Anticoagulation services and clinics for coumadin (Adverse events related to anticoagulation)	This is likely to become less important in the future with a move to non-coumadin-based anticoagulants such as dabigatrin, which do not require the same degree of monitoring.
Localizing specific surgeries and procedures to high volume centers (Mortality associated with surgical procedures)	We could include if the policy recommendation (i.e., the intervention) was to implement this type of policy. This became a “safety practice” when Leapfrog included it, but it’s just as easy to argue that it’s quality rather than safety.
Maintenance of perioperative normothermia (Surgical site infections)	Would bundle in preventing SSI.
Use of supplemental perioperative oxygen (Surgical site infections)	
Intraoperative monitoring of vital signs and oxygenation (Critical events in anesthesia)	Could add to info on OR data integration and display systems
Methods to increase pneumococcal vaccination rate (Pneumococcal pneumonia)	Seems more like a quality issue than a safety issue.
Pain management (overall topic)	Probably not a PSP.
Non- pharmacologic interventions to relieve post-operative pain (e.g., relaxation, distraction)	
Endoscope reprocessors (Healthcare-associated infections)	Include under reprocessing topic
Laser resistant endotracheal tubes (Surgical fire)	
Surgical and exam gloves (i.e., to prevent infection from clinician to patient)	Not sure if covered in other topic.
RFID-type tracking of patient location (e.g., for wandering) (Wandering and elopement in patients/residents with dementia, or infant abduction)	Interesting topic, but no evidence yet that the team knows of.

We then sought input from our TEP about these decisions, offering them the opportunity to change any of the “include/exclude” decisions, and asked for formal votes on the 49 PSPs classified an “Unsure.”

This effort resulted in 48 PSPs judged to be of highest priority in terms of the need for an evidence review of effectiveness, implementation, or adoption, still too large a number of topics to review comprehensively within the given timeframe. Therefore, we asked our TEP to assess whether “breadth” or “depth” was likely to be more valuable for stakeholders—in other words, we asked whether the review should focus on fewer topics in more detail or cover all topics but in less detail. Our TEP recommended a hybrid approach in which some topics would be reviewed in depth, whereas other topics would receive only a “brief review.” Topics could be considered to need only a “brief review” for several reasons: the PSP is already well-established; stakeholders need to know only “what’s new?” since the last time this topic was reviewed in depth; new evidence suggests the PSP may not be as effective as originally believed, so it is no longer a priority safety practice to implement; or it is an emerging PSP with limited evidence yet accumulated about it.

For each of the 48 topics, we then solicited formal input from our TEP about the need for an in-depth review, a brief review, or no review at all. Table 2 presents the results in terms of the proportion of TEP members who recommended a topic undergo an in-depth review, a brief review, or no review at all. We designated all topics that received 50 percent or greater support for an in-depth review to be reviewed in depth; all other topics were designated for brief reviews.

No topic on the list received 50 percent or greater support for no review at all. The list underwent further modification, as some PSPs originally designated as separate topics were judged to be sufficiently similar to be covered together in one review; examples included the topics related to transitions in care and those related to monitoring.

A final set of modifications to this scope occurred during the course of the reviews.

- Our PSP topic on pressure ulcers was modified to focus solely on implementation, as an EPC review of the effectiveness of pressure ulcer prevention interventions is currently underway.
- We combined the topics, “diagnostic errors” and “notification of test results to patients” into a single in-depth review.
- The body of literature on simulation methods was sufficiently large that we treated it as an in-depth review.

The review topics were then divided among the participating EPCs. Weekly teleconference calls and email were used to promote common practices in the review process.

Table 2, Chapter 2. Proportion of technical expert panelists expressing a preference for the level of evidence review for each PSP

PSP*	In-Depth	Brief Review	No Review
In-Depth			
Handoff - (Transitions in care)	79%	21%	0%
Medication reconciliation	71%	29%	0%
Rapid response teams	67%	20%	13%
Fall prevention strategies and interventions to reduce the use of restraints	64%	29%	7%
Diagnostic errors - meta-cognition, computerized decision support	64%	21%	14%
Protocols for notification of test results to patients	64%	29%	7%
Geriatric/delirium programs	64%	7%	29%
Monitoring for patient safety problems	57%	36%	7%
Preventing ventilator-associated pneumonia	57%	21%	21%
Pressure ulcer prevention	57%	36%	7%
Promoting a culture of safety	53%	33%	13%
Universal protocol/preoperative checklist (surgical safety)	50%	43%	7%
Report cards/outcomes measurement like NSQIP (surgical safety)	50%	43%	7%
Nurse staffing patterns and ratios	50%	36%	14%
Other interventions targeting improved transitions in care – (Transitions in care)	50%	36%	14%
Intensive insulin therapy for glycemic control	50%	36%	14%
Use of preoperative anesthesia checklists (Complications due to anesthesia equipment failures)	50%	29%	21%
Protocols for high risk drugs, e.g., nomograms for heparin	50%	29%	21%
Interventions to prevent contrast-induced renal failure	50%	36%	14%
The patient’s role in preventing errors	50%	21%	29%

Table 2, Chapter 2. Proportion of technical expert panelists expressing a preference for the level of evidence review for each PSP (continued)

PSP*	In-Depth	Brief Review	No Review
Human factors – as a general topic, focus still to be more precisely defined	50%	13%	38%
Brief Review			
CPOE and clinical decision support systems (CDSS)	47%	47%	7%
Bundles and checklists as a general strategy (not just for specific indications)	47%	40%	13%
Simulator-based training	46%	31%	23%
Prevention of surgical items left inside patient (surgical safety)	43%	50%	7%
Medication administration	43%	50%	7%
Display systems	43%	43%	14%
Hand washing + interventions to improve hand washing compliance	36%	50%	14%
Perioperative beta- blockers	36%	57%	7%
VTE prophylaxis and methods for implementation	36%	50%	14%
Team training/team practices	36%	43%	21%
Limiting individual provider's hours of service	36%	50%	14%
Smart pumps and other protocols for infusion pumps	36%	50%	14%
Device-related strategies for preventing tubing misconnections	36%	43%	21%
Clinical pharmacist consultation services	36%	43%	21%
Prevention of nosocomial UTIs	33%	53%	13%
Use of real-time ultrasound guidance during central line insertion	33%	60%	7%
Patient understanding/informed consent (possibly includes health literacy)	29%	36%	36%
Interventions for central venous catheter-related blood infections	29%	50%	21%
Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose	29%	36%	36%
Death among surgical patients with serious treatable complications (failure to rescue)	29%	36%	36%
Barrier precautions, patient isolation, routine surveillance for patients at admission	21%	71%	7%
Identifying patients at risk for suicide	21%	64%	14%
"Sign your site" protocols - potentially part of checklists	14%	79%	7%
Processes related to reprocessing single-use medical devices	14%	50%	36%
Do not use abbreviations, acronyms, symbols, and dose designation campaign	14%	79%	7%
Ensure documentation of patients' preferences for life-sustaining treatment	7%	50%	43%
Strategies to prevent stress-related gastrointestinal bleeding	7%	50%	43%

*The topic titles listed in this table were the exact titles the TEP considered in their decision-making; some of these PSP topics or titles underwent further revisions to their final title between that assessment and this final report.

Evidence Assessment Framework

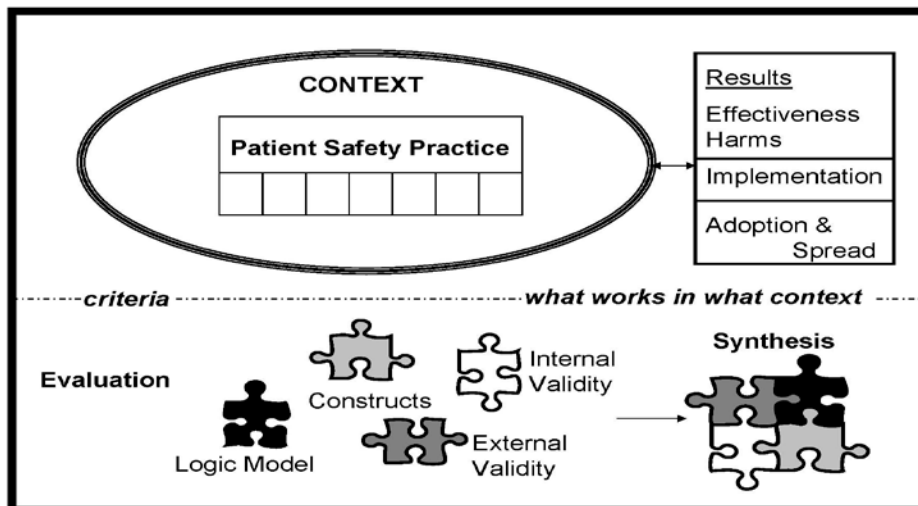
The framework for our consideration of the evidence regarding a PSP was worked out as part of the prior AHRQ “Context Sensitivity” project.³ A principal challenge in previous reviews of PSPs has been addressing the question of what constitutes evidence for PSPs. Many practices designed to improve quality and safety are complex sociotechnical interventions whose targets may be entire health care organizations or groups of providers, and these interventions may be targeted at extremely rare events. To address the challenge regarding what constitutes evidence, we recognize that PSPs must be evaluated along two dimensions: (1) the evidence regarding the outcomes of the safety practices, and (2) the contextual factors that influence the practices’ use and effectiveness.

Figure 2 presents this framework, depicting a generic PSP that consists of a bundle of components (the individual boxes) and the context within which the PSP is embedded. Important evaluation questions, as depicted on the right, concern effectiveness and harms, implementation, and adoption and spread. We then apply criteria to evaluate each of four factors that together constitute equality (depicted as puzzle pieces in the bottom half of the figure):

1. Constructs about the PSP, its components, context factors, outcomes, and ways to measure these constructs accurately;
2. Logic model or conceptual framework about the expected relationships among these constructs;
3. Internal validity to assess the PSP results in a particular setting; and
4. External validity to assess the likelihood of being able to garner the same results in another setting.

We then synthesize this information into an evaluation of the strength of the evidence about a particular PSP.

Figure 2, Chapter 2. Framework for evidence assessment of patient safety practices



The principal results of the “Context-Sensitivity” project included the following key points.

- Whereas controlled trials of PSP implementations offer investigators greater control of sources of systematic error than do observational studies, trials often are not feasible, in terms of time or resources. Also, controlled trials are often not possible for PSPs

requiring large-scale organizational change or PSPs targeted at very rare events. Furthermore, the standardization imposed by the clinical trial paradigm may stifle the adaptive responses necessary for some quality improvement or patient safety projects. Hence, researchers need to use designs other than RCTs to develop strong evidence about the effectiveness of PSPs.

- Regardless of the study design chosen for an evaluation, components that are critical for evaluating a PSP in terms of how it worked in the study site and whether it might work in other sites include the following:
 - Explicit description of the theory for the chosen intervention components, and/or an explicit logic model for “why this PSP should work;”
 - Description of the PSP in sufficient detail that it can be replicated, including the expected change in staff roles;
 - Measurement of contexts;
 - Explanation, in detail, of the implementation process, the actual effects on staff roles, and changes over time in the implementation or the intervention;
 - Assessment of the impact of the PSP on outcomes and possible unexpected effects (including data on costs, when available); and
 - For studies with multiple intervention sites, assessment of the influence of context on intervention and implementation effectiveness (processes and clinical outcomes).
- High-priority contexts for assessing any PSP implementation include measuring and information for each of the following four domains:
 - Structural organizational characteristics (such as size, location, financial status, existing quality and safety infrastructure);
 - External factors (such as regulatory requirements, the presence in the external environment of payments or penalties such as pay-for-performance or public reporting, national patient safety campaigns or collaboratives, or local sentinel patient safety events);
 - Patient safety culture (not to be confused with the larger organizational culture), teamwork, and leadership at the level of the unit; and
 - Availability of implementation and management tools (such as staff education and training, presence of dedicated time for training, use of internal audit-and-feedback, presence of internal or external people responsible for the implementation, or degree of local tailoring of any intervention).

These principles guided our search for evidence and the way we present our findings in this report (see Table 3).

Table 3, Chapter 2. Format for in-depth reviews

How important is the problem?
This section briefly sketches the nature of the target for the Patient Safety Practice.
What is the Patient Safety Practice?
This section describes the practice or practices proposed and evaluated.
Why should this Patient Safety Practice work?
This section describes what has been written about the basis for a proposed Patient Safety Practice, such as an underlying theory, a logic model for how it should work, or prior data.
What are the beneficial effects of the Patient Safety Practice?
This section provides the review of the evidence of effectiveness, and is the section most similar to traditional Evidence-based Practice Center reports.
What are the harms of the Patient Safety Practice?
This section contains the evidence of harms. Unlike reviews of most clinical interventions, evaluating potential harms is not a routine part of Patient Safety Practice evaluations. Thus, for most topics, this section is underdeveloped.
How has the Patient Safety Practice been implemented, and in what contexts?
This section describes what has been reported about how to implement the Patient Safety Practice and the range of institutions or contexts of where it has been implemented. When there is sufficient evidence, implementation studies are evaluated qualitatively for themes regarding effective implementation.
Are there any data about costs?
This section describes the evidence of costs of implementing the Patient Safety Practice, or, in some cases, cost-effectiveness analyses that have been performed.
Are there any data about the effect of context on effectiveness?
This section describes the evidence about whether or not the Patient Safety Practice has been shown to have differential effectiveness in different contexts. The "Context Sensitivity" project defined important contexts for Patient Safety Practices in four domains: external factors (e.g., financial or performance incentives or Patient Safety Practice regulations); structural organizational characteristics (e.g., size, organizational complexity, or financial status); safety culture, teamwork, and leadership involvement; and availability of implementation and management tools (e.g., organizational training incentives). ⁴

Evidence Review Process

As already noted, this report presents two types of evidence reviews: in-depth reviews and brief reviews. In this section, we describe the general methods for each type of review. The details of the review processes for individual topics (for example, the search strategies and flow of articles) varied by topic and are described in Appendix C. The evidence reviews were conducted by the project team. Figure 3 presents an outline of the general methods for each type of review.

In-Depth Reviews

Many of the 18 topics designated for an in-depth review were likely to have been the subject of a previous systematic review; thus, the review process usually began with a search to identify existing systematic reviews. To assess their potential utility, we followed the procedures proposed by Whitlock and colleagues⁵ which essentially meant addressing the following two questions:

- Is the existing review sufficiently “on topic” to be of use? and
- Is it of sufficient quality for us to have confidence in the results?

Assessment of whether a review was sufficiently “on topic” was a subjective judgment based on the patients-intervention-comparators-outcomes-timeframe (PICOT) focus of the existing review. To assess the quality of the systematic review, we, in general, used the AMSTAR criteria (see Appendix B).⁶ If an existing systematic review was judged to be sufficiently “on topic” and of acceptable quality, then based on that review, the following searches were undertaken:

- A full update search, in which databases were searched for new evidence published since the end date of the search in the existing systematic review; and/or
- A search for “signals for updating,” according to the criteria proposed by Shojania and colleagues,⁷ which involved a search of high-yield databases and journals for “pivotal studies” whose results might be a signal that a systematic review is out-of-date.
- Based on the results of these searches, the existing review was supplemented with newer evidence or considered to be up-to-date.

Any evidence identified via the update search or the “signals” search was added to the evidence base from the existing systematic review.

For some topics, no systematic review could be identified, or those that were identified were either not sufficiently relevant or not of sufficient quality to be used. In those situations, new searches were done using guidance as outlined in the EPC Methods Guide.⁸

As indicated above, evidence about context, implementation, and adoption are key aspects of this review. We searched for evidence on these topics in two ways:

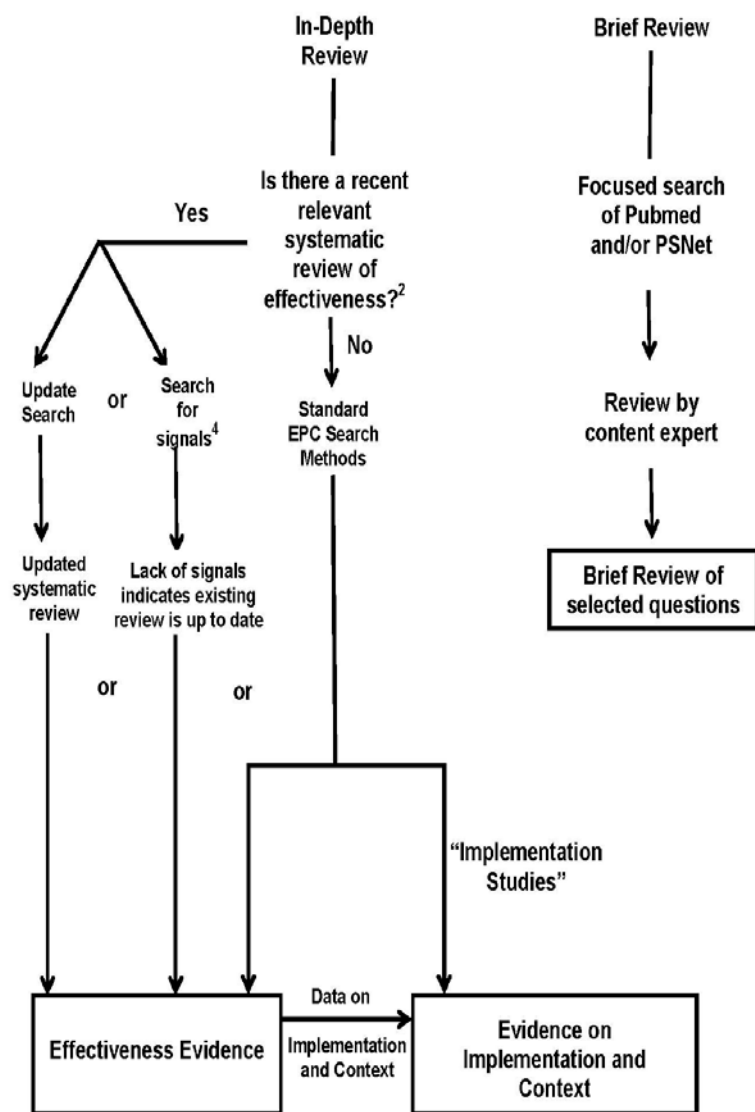
We looked for and extracted data about contexts and implementation from the articles contributing to the evidence of effectiveness;

We identified “implementation studies” from our literature searches. “Implementation studies” focus on the implementation process, especially those elements of the implementation demonstrated or believed to be of particular importance for the success, or lack of success, of the intervention. To be eligible, implementation studies needed to either report, or be linked to reports of, effectiveness outcomes.

Brief Reviews

Brief reviews are explicitly not full systematic reviews or updates. The goals of the brief reviews varied by PSP, according to the needs of stakeholders. The assessment could focus primarily on information about effectiveness of an emerging PSP or implementation of an established PSP; alternatively, the review could explore whether new evidence calls into question the effectiveness of an existing PSP. Thus, the methods used to conduct the brief reviews varied according to the various goals of the reviews. . However, in general, brief reviews were conducted by an expert in the topic in collaboration with the project team, and involved focused literature searches for evidence relevant to the specific need. This evidence was then narratively summarized in a format that also varied with the particular goal.

Figure 3, Chapter 2. Evidence review process



Assessing Quality of Individual Studies

In general, to assess the quality, or risk of bias, of individual studies contributing evidence of effectiveness to in-depth reviews, we used the criteria published on the Cochrane Effective Practice and Organisation of Care (EPOC) Web site.⁹ This Cochrane Group is devoted to reviews of interventions designed to improve the delivery, practice, and organization of health care. Thus, it uses quality/risk of bias assessment instruments that are applicable to numerous study designs; criteria are available for controlled-before-and-after studies and for time series studies, as well as for randomized trials.

For the many topics included in this review for which we identified an existing systematic review as a starting point for our review, we accepted the original review's assessment of the quality/risk of bias of included studies. In other words, we did not re-score the original studies included in an existing systematic review for risk of bias. A consequence of this decision is that we did not apply the EPOC criteria to assess quality/risk of bias for some topics in this report,

but instead relied on the criteria originally chosen for that review, for example the criteria of the U.S. Preventive Services Task Force.

Implementation studies were not assessed for their quality, as we lacked evidence or expert opinion about the criteria for such an assessment.

Assessing Strength of Evidence for a Patient Safety Practice

Table 4 shows the scheme we employed for assessing the strength of the body of evidence regarding a specific PSP. This scheme starts with elements taken from the EPC Methods Guide on strength of evidence,¹⁰ which itself borrows largely from the GRADE scheme,^{11,12} and incorporates elements about theory, implementation, and context taken from the prior AHRQ “Context Sensitivity” report.³ It includes an assessment of the risk of bias, by whatever criteria were used for a particular PSP, and then adjusts the strength up or down based on standard GRADE criteria and on criteria about the use of theory and description of implementation. The points for scoring are meant only as a guide. Implementation studies were not assessed for strength of evidence.

Table 4, Chapter 2. Criteria for assigning strength of evidence for effectiveness/harms questions

What does the evidence show about the effectiveness of this PSP among those at risk?

Individual study risk-of-bias score: Low (+4); Moderate (+3); High (+2); for Cochrane/EPOC Risk of Bias instrument, suggest zero “No” answers = Low risk, one to two “No” answers = Moderate risk, and three or more “No” answers = High risk; suggest taking the median or average as the overall risk of bias for the evidence base.

Across all study types, decrease score if:

- Important inconsistency across studies (-1)
- Serious imprecision (-1)
- High probability of reporting bias (-1)
- No explanation in any of the studies of why the PSP might work, either in terms of theory, logic models, or prior success in other fields or in pilot studies (-1)
- PSP not described in sufficient detail to permit replication (-1)

Across all study types, increase score if:

- Very strong effect in majority of studies (+1)
- All plausible residual confounding would reduce a demonstrated effect or would suggest a spurious effect if no effect was observed (+1)
- Use of theory/logic models, assessment of contexts, reporting of implementation process, and fidelity of implementation (+1)

For observational studies, increase score if:

- Use of observational study designs of stronger internal validity (controlled before-and after, time series, statistical process control) (+1)

If evidence allows a conclusion, then strength of evidence should be scored as follows:

- $\geq +4$ = High
- +3 = Moderate
- +2 = Low

If evidence does not permit a conclusion then the strength of evidence = insufficient

Summarizing the Evidence

We expected that users of this report would want a summary of the evidence for each topic. Such summary messages may facilitate uptake of the findings. We summarized the evidence according to the following domains:

Scope of the problem. In general, we addressed two issues: (1) the frequency of the safety problem, and (2) the severity of each average event. For benchmarks, we regarded safety problems that occur approximately once per 100 hospitalized patients, as “common;” examples include falls, venous thromboembolism (VTE), potential adverse drug events, or pressure ulcers. In contrast, events an order of magnitude or more lower in frequency were considered “rare;” such events include inpatient suicide and surgical items left inside the patient. The scope must also consider the severity of each event: most falls do not result in injury, and most potential adverse drug events do not result in a clinical harm. However, each case of inpatient suicide or wrong site surgery is devastating.

Strength of evidence for effectiveness. In general, this assessment follows the framework for strength of evidence presented above.

Evidence on potential for harmful unintended consequences. Most PSP evaluators have not explicitly assessed the possibility of harm. Consequently, this domain includes evidence of both actual harm and the potential for harm. The ratings on known or potential harms ranged from high risk of harm to low (or negligible); in some cases, the evidence was too sparse to provide a rating.

Estimate of costs. This domain is speculative, because most evaluations do not present cost data. However, we judged that readers would want at least a rough estimate of cost. Therefore, we used the following categories and benchmarks, noting in places the factors that might cause cost estimates to vary.

- Low cost: PSPs that did not require hiring new staff or large capital outlays, but instead involved training existing staff and purchasing some supplies. Examples would include most falls prevention programs, VTE prophylaxis, or medical history abbreviations designated, “Do Not Use.”
- Medium cost: PSPs that might require hiring one or a few new staff, and/or modest capital outlays or ongoing monitoring costs. Examples would include some falls prevention programs, many clinical pharmacist interventions, or participation in the American College of Surgeons Outcomes Reporting System (\$135,000/year).
- High cost: PSPs that required hiring substantial numbers of new staff, considerable capital outlays, or both. Examples would include computerized order entry (because it requires an electronic health record), having to hire many nurses to achieve a certain nurse-to-patient ratio, or facility-wide infection control procedures (estimated at \$600,000 year for a single intensive-care unit [ICU]).

Implementation issues. This section summarizes how much we know about how to implement the PSP, and how difficult it is to implement. To approach the question of how much we know, we considered the available evidence about implementation, the existence of data about the effect of context and the influence of context, the degree to which a PSP has been implemented,

and the presence of implementation tools such as written implementation materials or training manuals.

For the question of implementation difficulty, we use three categories: difficult for PSPs that required large scale organizational change; not difficult for PSPs that required protocols for drugs or devices such as those to reduce radiation exposure or to help prevent stress-related gastrointestinal bleeding; and moderate for PSPs falling between the extremes.

Setting Priorities for Adoption of Patient Safety Practices

After obtaining critical input from our TEP about the dimensions and benchmarks used for summarizing the evidence, we next solicited their views on whether the evidence was sufficient at present to encourage wider adoption of some of the PSPs. Specifically, we asked our TEP the following questions:

We are asking for your global judgment of the priority for adoption of the PSPs that are included in our report. By “global judgment,” we mean that you will be making a summary judgment, which considers all the factors discussed in the chapters and listed in the summary table (the magnitude of the current safety problem [in terms of frequency and severity], the degree to which the PSP can improve safety outcomes, any potential for unintended consequences, what we know and how hard it is to implement the PSP, and the cost) plus your own experience as a researcher, provider, policymaker, or PSP developer. We have chosen a four-category scheme for this judgment:

THIS PSP SHOULD BE STRONGLY ENCOURAGED—We know enough now that if we were choosing a hospital (or nursing home or ambulatory care center, etc.) to get care from, we would choose a hospital (or nursing home or ambulatory care center, etc) that was implementing this PSP over one which was not. Another way of thinking about this might be: unless the hospital (or nursing home or ambulatory care center, etc) knows its outcomes for this safety problem are already excellent (or the safety problem is not relevant for the setting, such as failure-to-rescue in an ambulatory care center), then it ought to be implementing this PSP. We would expect over the next 3 years that most organizations would implement this PSP, even if it has substantial cost. “Most” does not have a precise definition but it does not mean 51% nor does it mean 95%. Let’s say it means about 70-80%.

THIS PSP SHOULD BE ENCOURAGED—This is a PSP that we’d like to be implemented at the hospital (or nursing home or ambulatory care center, etc.) where we would receive our care, but there’s just enough uncertainty about the effect, or concern about the cost, or some other factor, to keep us from putting it on the “strongly encouraged” list. We would expect that over the next 3 years many organizations would implement this PSP, and high cost might be a significant factor in an organization’s decision.

THIS PSP IS STILL DEVELOPMENTAL—There’s still more that needs to be known about this PSP before we should be encouraging health care providers to adopt it. Organizations implementing these PSPs should be encouraged to publish evaluations of their implementation and effectiveness in order to increase the evidence base for the PSP.

THIS PSP SHOULD BE DISCOURAGED—This PSP is one where we’re pretty sure the cost or difficulty implementing it is not worth the potential benefit, or even that the harms or potential for harms exceeds the evidence of benefit.

As in prior group judgment processes, we also provide a response option **“I DO NOT WANT TO RATE THIS PSP”** so that people are not forced to make decisions about PSPs they feel unprepared to assess, AND we can distinguish between that decision and an inadvertent “skipped” PSP.

We received input from 19 of the 21 members of the TEP; the remaining two declined to rate the PSPs because they judged that making these kinds of clinical and policy decisions was not within their area of expertise. Based on the judgments of the panelists, we classified the PSPs according to the following rules:

- **Strongly Encouraged:** To be classified as “strongly encouraged,” a PSP had to receive a rating of “strongly encourage” or “encourage” from 75 percent or more of the technical experts, no TEP member could rate the PSP as “this PSP should be discouraged,” and a majority of the “strongly encourage/encourage” ratings had to be “strongly encourage.”
- **Encouraged:** To be classified as “encouraged,” a PSP had to receive a rating of “strongly encourage” or “encourage” from 75 percent or more of the technical experts, and a majority of the “strongly encouraged/encourage” ratings had to be “encourage.”

In any such process, the thresholds are somewhat arbitrary and can magnify the apparent impact of small differences in ratings. Therefore, we also assessed PSP at the threshold between “strongly encourage” and “encourage” (two PSPs received equal numbers of votes for each category) and the threshold between “encourage” and no rating (four additional PSPs). For these additional ratings, we used a four-person subset of our TEP, the people actually responsible for policymaking or implementing PSPs. For each of our “threshold” PSPs, we judged that three of these four technical experts needed to either “encourage” or “strongly encourage” the PSP, to retain its “strongly encouraged” or “encouraged” Classification. This determination resulted in one PSP being down-rated from “strongly encouraged” to “encouraged,” and affirmed that all four PSPs that made it by one vote should be classified as “encouraged.”

Future Research Needs

To assess future research needs with respect to PSPs, we first devoted 2 hours of discussion time at the face-to-face meeting of the TEP to this topic. Two project team members recorded both general and specific topics for future research that the TEP discussed. From these notes we obtained themes or domains that we used to organize the future research needs. To these we added future research needs for specific PSPs suggested by the individual team members who reviewed the literature on those PSPs. We then sought input from the TEP regarding which

future research needs were highest priority, and classified as high priority those topics receiving more than 50 percent support.

Peer and Public Review Process

The draft of this report was posted for public comment and sent to six peer reviewers and our TEP for review.

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Part 2. Evidence Reviews of Patient Safety Practices

The following pages contain the evidence reviews for 41 patient safety practices or approaches to care. They are organized as follows:

- **Practices designed for a specific patient safety target**
- **Practices designed to improve the overall system/multiple targets**

Within the section “Practices Designed for a Specific Patient Safety Target” the topics are organized according to the target:

- **Adverse drug events**
- **Infection control**
- **Surgery, anesthesia, and perioperative medicine**
- **Safe practices for hospitalized elders**
- **General clinical topics**

Within each subsection, the topics are organized as follows:

- **In-depth reviews**
- **Brief reviews**

In-depth reviews are presented in the following format:

How important is the problem?
This section briefly sketches the nature of the target for the Patient Safety Practice.
What is the Patient Safety Practice?
This section describes the practice or practices proposed and evaluated.
Why should this Patient Safety Practice work?
This section describes what has been written about the basis for a proposed Patient Safety Practice, such as an underlying theory, a logic model for how it should work, or prior data.
What are the beneficial effects of the Patient Safety Practice?
This section provides the review of the evidence of effectiveness, and is the section most similar to traditional Evidence-based Practice Center reports.
What are the harms of the Patient Safety Practice?
This section contains the evidence of harms. Unlike reviews of most clinical interventions, evaluating potential harms is not a routine part of Patient Safety Practice evaluations. Thus, for most topics, this section is underdeveloped.
How has the Patient Safety Practice been implemented, and in what contexts?
This section describes what has been reported about how to implement the Patient Safety Practice and the range of institutions or contexts of where it has been implemented. When there is sufficient evidence, implementation studies are evaluated qualitatively for themes regarding effective implementation.
Are there any data about costs?
This section describes the evidence of costs of implementing the Patient Safety Practice, or, in some cases, cost-effectiveness analyses that have been performed.
Are there any data about the effect of context on effectiveness?
This section describes the evidence about whether or not the Patient Safety Practice has been shown to have differential effectiveness in different contexts. The “Context Sensitivity” project defined important contexts for Patient Safety Practices in four domains: external factors (e.g., financial or performance incentives or Patient Safety Practice regulations); structural organizational characteristics (e.g., size, organizational complexity, or financial status); safety culture, teamwork, and leadership involvement; and availability of implementation and management tools (e.g., organizational training incentives).*

* Taylor SL, Dy S, Foy R, et al. What context features might be important determinants of the effectiveness of patient safety practice interventions? *BMJ Qual Saf.* 2011;20(7):611-7.21617166

Brief reviews use a different format, that varies somewhat depending on the topic. The general format for brief reviews is: What is (are) the patient safety practice(s)?; How has the patient safety practices been implemented?; What have we learned about the practice(s)? Brief update reviews are topics that were covered in “Making Health Care Safer” 2001 and use a format designed for reader to identify what’s new since then.

References. Each chapter is individually referenced for convenience.

Part 2a. Practices Designed for a Specific Patient Safety Target

Section A. Adverse Drug Events

Chapter 3. High-Alert Drugs: Patient Safety Practices for Intravenous Anticoagulants

Elizabeth Pfoh, M.P.H.; David Thompson, D.N.Sc., M.S., R.N.; Sydney Dy, M.D., M.Sc.

How Important Is the Problem?

High-alert medications are defined as medications that are the most likely to cause significant patient harm, even when used correctly. These medications are more likely to be associated with harm due to issues such as narrow therapeutic ranges (increasing the potential for a prescribing error), and also cause more significant harm when an error does occur because of the significant nature of the potential adverse effects such as bleeding or hypoglycemia.^{1,2} Many of these medications are also more likely to be associated with dosing errors, due to issues such as the need to frequently calculate dosing based on weight. A study evaluating adverse drug events found that high-alert medications accounted for 48 percent of the events.³

The Institute of Safe Medical Practices identifies the top high-alert medications to be insulin, opioids, injectable potassium chloride (or phosphate), intravenous anticoagulants (heparin), and sodium chloride solutions above 0.9 percent, due to both common use and significance of associated harm.¹ Other high-alert medications include chemotherapeutic agents and sedatives.

From 1997 to 2007, 9.3 percent of all hospital sentinel events were medication-related, and anticoagulants made up 7.2 percent of medication events. Unfractionated heparin was the anticoagulant most frequently involved in these events.⁴ Administration errors (e.g., dosing and timing), omission, and prescribing errors constituted approximately 70 percent of heparin errors.⁵

What Is the Patient Safety Practice?

In the 2001 “Making Health Care Safer report,” this PSP was conceptualized as “Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants.”⁶ The rationale for focusing on anticoagulants was that, although a number of other classes of medications have been identified as “high-risk,” and some recommendations to reduce risks apply to multiple classes of medications, the effectiveness of interventions to reduce risks associated with other medications have not been as extensively evaluated as interventions to reduce risks associated with heparin. Because interventions to reduce adverse events may differ significantly by drug type, and the focus on anticoagulants in the inpatient setting is mainly on heparin, this review focused on heparin, the most commonly used intravenous anticoagulant, as an illustrative example rather than addressing issues for high-alert medications overall.

The original report reviewed two types of interventions for heparin:

- The implementation of dosing protocols or nomograms, which normally include standard initial doses and instructions for monitoring and adjusting doses
- Inpatient anticoagulation services, which provide pharmacist input on dosing and monitoring

Weight-based nomograms use actual patient body weight to calculate an optimum dose that is patient-specific. In contrast, physician dosing without nomograms often does not account accurately for patient characteristics.

This current report systematically reviewed the literature to identify effectiveness studies of any intervention with a goal to reduce adverse events related to intravenous heparin in the inpatient setting that had a comparison group and was not a qualitative study. Since this PSP is currently most often conceptualized as focusing on intravenous administration as the most high-risk route, we did not include subcutaneous or oral anticoagulant administration in this review. Intravenous anticoagulants are particularly high risk because dosing is complex and the therapeutic range is particularly narrow. This narrow range increases the opportunity for harm.⁶⁻⁹ Although bleeding can occur even at therapeutic doses of heparin, it is much more likely when the dose is excessive or inadequately monitored. Unfractionated heparin, which is given intravenously, is widely used as the drug of choice for a variety of clinical conditions where rapid and closely monitored anticoagulation is needed, such as acute coronary syndromes.¹⁰ However, since the 2001 publication of “Making Health Care Safer,” low-molecular-weight heparins—which have a less complex dosing regimen, are given subcutaneously, and have been shown to have equivalent efficacy for many indications—have widely replaced unfractionated heparin for some clinical conditions such as venous thromboembolism (VTE) prophylaxis.

A wide variety of safety practices are recommended to increase patient safety for intravenous anticoagulants in general. These practices include limiting the number and dosage of high alert drugs prescribed (to ensure that only patients who are most likely to benefit receive the medications or that lower-risk options are used whenever possible), having independent system checks and balances in place to identify and prevent dosing errors, and having a transparent error reporting system to aid in the development and implementation of system changes.^{1,2} Other practices include removing high-alert medications from nursing units and floor stock, standardizing medication doses, using single doses or pre-mixed solutions, labeling different strength solutions clearly to avoid mixups (e.g., Heplock packaging), provider education and drug-administration protocols and decision support tools that involve double-checking of the drug and dosing, pump-setting, and dosage.⁴ Health information technology tools may help reduce errors associated with high-alert medications by preventing significant overdoses (e.g. tenfold errors in dosing) and verifying that the correct medication is being administered.^{11,12} However, the level of effectiveness of health information technology may vary.^{13,14} Specific heparin patient-safety practices reviewed here include dosing nomograms and weight-based dosing interventions, with and without the use of health information technology tools as part of the intervention.

Why Should This Patient Safety Practice Work?

Numerous patient factors, particularly patient weight, can influence the dosing needs for heparin. Bleeding risk increases as the dose increases and with inappropriately high dosing. Patients on intravenous heparin have multiple risk factors for bleeding that may also affect dosing needs: they often have high acuity conditions such as recent stroke, or are undergoing high-risk procedures such as coronary artery bypass or continuous hemodialysis. In addition, dosing ranges for heparin vary by indication; physicians often tend to be conservative and underdose heparin when not using standard nomograms.¹⁰ For these reasons, standardization of dosing and monitoring of subsequent anticoagulation are vital.

Heparin-induced adverse effects not related to dosing issues (e.g., heparin-induced thrombocytopenia) are also important considerations in heparin use, but are not generally considered patient safety events and were not included in the scope of this review.

What Are the Beneficial Effects of the Patient Safety Practice?

The original “Making Health Care Safer” report⁶ found six studies, mostly of low quality, on heparin nomograms. All showed a statistically significant improvement in time to achievement of, or proportion of patients with, appropriate anticoagulation. Two low-quality studies of inpatient anticoagulation services also showed statistically significant improvements in anticoagulation. All studies either did not evaluate bleeding outcomes or did not have a sufficient sample size to measure these outcomes. Four of the six studies of nomograms did show a statistically significant increase in the proportion of patients with partial thromboplastin time (PTT) values above the normal range (and therefore at increased risk for over-anticoagulation and bleeding complications).

For this review, a total of 1,960 unique abstracts were captured by the search strategy. Of these, 1,936 were excluded during the abstract screening phase. Seven articles met the inclusion criteria for intervention studies evaluating the effectiveness of interventions to improve the safety of intravenous heparin administration, published after the “Making Health Care Safer” report (Table 1). We did not identify any additional recent systematic reviews of high-alert medications or heparin. We identified five studies evaluating the use of weight-based nomograms, all published between 2001 and 2005. The only randomized, controlled trial was by Toth and colleagues, who developed a weight-based nomogram for heparin dosing in transient ischemic attack (TIA) and/or stroke.¹⁵ Out of 206 patients, total complications were significantly reduced using the nomogram (9 pre [8.5%] vs. 2 post [2%] $p=0.04$). Additionally, time to suprathreshold activated PTT (aPTT) (i.e., adequate anticoagulation) was reduced (1.1 with nomogram vs. 1.6 without nomogram; $p=0.01$) and time to therapeutic-range aPTT (i.e., therapeutic anticoagulation) was reached with fewer adjustments (18 with the intervention vs. 13 for the control group; $p<0.01$). Zimmermann and colleagues also used a pre-post design to assess the effect of a weight-based nomogram for 173 patients with acute coronary syndromes.¹⁶ Median time to first therapeutic aPTT was reduced from >24 to 8.75 hours ($p<0.001$) and the mean number of aPTT tests decreased from 4.15 (SD.83) to 3.62(SD.85) ($p=0.002$). Oyen and colleagues conducted a pre-post study of 419 patients evaluating the implementation of a computerized nomogram for acute coronary syndromes targeted at nurses and found improvements in anticoagulation outcomes (percentage of a PTT in goal range 44% with the nomogram vs. 27% without); data on complications were not reported. Baird and colleagues¹⁷ used a pre-post study design in a small patient sample ($n=68$) to test an evidence-based nomogram that was developed with a team of nurses, doctors, and a pharmacist; no statistics were reported. Finally, Fraipont et al developed a nurse-directed weight-based nomogram in a very small study (total $n=38$); the study found that there were no statistically significant differences in anticoagulation outcomes or complications between the intervention and control groups.¹⁸

The remaining two, more recent, papers assessed the impact of technology along with processes and procedures for the use of the technology on heparin administration safety. A 2011 study by Prusch and colleagues aimed to improve medication safety through the use of intelligent infusion devices (IIDs), a bar-code-assisted medication administration system, and an electronic medication administration record system using a pre-post design. Monthly compliance with the

telemetry drug library increased from 56.5 percent (SD: 1.5%) pre-intervention to 72.1 percent (SD: 2.1%) post-intervention ($p < 0.001$), and the number of telemetry manual pump edits decreased (56.9 [SD: 12.8] to 14.7 [SD: 3.9]; $p < 0.001$).¹³ Finally, Fanikos and colleagues assessed the impact of a smart infusion device with a hospital-determined drug library and programmable software on anticoagulation errors using a pre-post design. After reviewing a total of 14,012 administered doses of heparin in 3,674 patients, the software generated a total of 501 heparin alerts in 246 patients. No significant difference in anticoagulation errors was found as a result of the intervention (49 pre- vs. 48 post-intervention).¹⁴

Table 1, Chapter 3. Summary table—heparin effectiveness studies

Author, Year	Description of PSP	Study Design	Outcomes: Benefits
Baird, 2001 ¹⁷	Single protocol for heparin administration	Pre-post	Dosing and time to anticoagulation: No statistics reported
Fanikos, 2007 ¹⁴	Smart pump; drug library with point-of-care decision support; programmable alert	Pre-post	Anticoagulation medication errors: No significant differences
Fraipont, 2003 ¹⁸	Nurse-directed weight-based nomogram	Pre-post	Time to therapeutic anticoagulation, complications: not significant
Oyen, 2005 ¹⁹	Computerized nomogram for acute coronary syndromes	Pre-post	Therapeutic anticoagulation significantly improved, complications not reported
Prusch, 2011 ¹³	Intelligent infusion devices (IIDs), bar-code-assisted medication administration system, and electronic medication administration record system	Pre-post	Telemetry drug library monthly compliance and manual pump edits: Statistically significant improvement
Toth, 2002 ¹⁵	Weight-based nomogram for transient ischemic attack and/or stroke	RCT	Total complications, overanticoagulation, time to anticoagulation – all statistically significant improvement
Zimmermann, 2003 ¹⁶	Weight-based nomogram for acute coronary syndromes	Pre-post	Time to anticoagulation significant; complications not significant

In terms of evidence grading, the strength of evidence for this topic was low. Risk of bias was high due to study design issues: Only one study was an RCT.¹⁴ Results were inconsistent, with half of the studies reporting no statistically significant findings; several studies were too small to measure outcomes meaningfully. Many studies did not report patient safety outcomes, but instead reported the outcomes for process measures such as time to therapeutic anticoagulation or compliance with a drug library; many studies that did report complications or errors did not have sufficient sample size. Finally, regarding precision, a number of different outcome measures were used, so no conclusions could be made (see Evidence Table on risk of bias in Appendix D).

What Are the Harms of the Patient Safety Practice?

Neither the original report nor our updated review found studies that reported on harms of the Patient Safety Practice.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

The effectiveness studies included older studies on weight-based nomograms and anticoagulation services and newer studies on intelligent infusion devices and other electronic medication systems, in various populations and types and sizes of hospitals (e.g., community and teaching). One United States study from 2000 that evaluated the use of a weight-based nomogram found that utilization was extremely low at approximately 10 percent. Further, utilization was not improved after an intervention that included education as well as configuring the computerized order entry system to allow physicians to choose either the weight-based nomogram, or traditional heparin ordering.²⁰

Are There Any Data About Costs?

Implementation of heparin nomograms is feasible, although institutions often develop their own systems rather than adapting existing nomograms. The original report found one study that concluded that the costs of frequent monitoring were offset by the reduction in the number of heparin boluses required.⁶ One of the nomogram studies identified in our update search¹⁶ found a statistically significant decrease in the number of monitoring blood tests required, which would reduce the costs to manage patient care.

Are There Any Data About the Effect of Context on Effectiveness?

Data regarding the impact of context on effectiveness is limited. The evidence found in the studies mentioned above could be divided into three categories: leadership, organizational characteristics, and administration tools.

Two studies commented on the impact of leadership on the effectiveness of the intervention. Baird and colleagues reported that leadership was important for protocol development.¹⁷ Prusch and colleagues reported that executive sponsorship and oversight as well as the support of the pharmacy and therapeutics committee were key to effectiveness.¹³

Regarding organizational characteristics, one study cited the impact of a multidisciplinary team and a relationship between the hospital and the intelligent diffusion device vendors on the development of interoperability between systems.¹³ Another study¹⁹ found that a computerized nomogram provided greater levels of standardization than a paper-based form, since the paper-based form was altered by providers more than 50 percent of the time. Additionally, the computerized version was able to provide feedback on patient states, which improved patient monitoring and the evaluation of the nomogram. Therefore, through the implementation of the computerized nomogram, the heparin dosing protocols and monitoring practices were standardized.

Three studies mentioned external implementation tools, but no details of how these implementation tools affected effectiveness (overall effectiveness results are described above in the section on beneficial effects). Prusch and colleagues used new medication administration technology developed with frontline nurses and pharmacists. Historical data were analyzed to ensure the drug library had optimal dosing limits and medications. Finally, the technology was pilot tested prior to implementation.¹³ Fanikos and colleagues used the software in the smart infusion device to establish limits for rates programmed into the.¹⁴ Fraipont and colleagues used the previously developed Raschke nomogram²¹ in their study.¹⁸

Finally, we identified one additional study which did not meet our inclusion criteria for reporting effectiveness data but took a broader human factors approach to improving heparin safety by improving administration. Harder and colleagues evaluated the human factors associated with improving the safety of heparin administration.²² After completing interviews with the staff, the authors offered suggestions for improving the heparin administration process in order to make the computerized heparin dosing interface more user-friendly (e.g., automatically converting English and metric measurements.) Iterative refinements were made to the system after the initial modifications, and an educational program was rolled out to inform providers about the new heparin administration process.²²

Conclusions and Comment

In conclusion, we found low strength of evidence that patient safety practices, including nomograms and new intelligent medication administration, dosing, and monitoring technology, can improve outcomes for the use of intravenous heparin (Table 2). Through our systematic review, we identified no studies of nomograms published after 2005 and no studies of inpatient anticoagulation services published since 2000, although both the use of protocols (e.g., computerized order entry) and indications for heparin have changed dramatically since that time including concerns regarding dosing in obese patients.²³ Only two studies evaluated new technology, and no studies evaluated other types of interventions to improve heparin safety. Study quality was generally low, and many studies had small sample sizes, usually insufficient for the detection of the impact of interventions on complications of heparin administration. We did not identify any studies evaluating the harms of these patient safety practices, although there could be some potential harm from errors caused by misunderstanding of protocols or miscommunication with anticoagulation services, which could also lead to errors in dosing.

Although the standardization of dosing protocols, accomplished with the input of front-line personnel, is an important component of increasing safety and has been shown to improve the effectiveness of heparin administration, few studies have evaluated these protocols and had sufficient sample size for patient safety outcomes. Significant barriers also exist to implementing these protocols, and no studies have demonstrated the impact of interventions to increase their use by health care providers. Only a few, small, low-quality studies evaluated other types of interventions to improve the safety of inpatient anticoagulation, such as human factors, anticoagulation services, or new technology, such as computerized order entry or intelligent infusion devices. Because intravenous anticoagulants are one of the most common sources of patient harm from safety issues with high-alert drugs, research on interventions to improve their safety should be a priority. Further study is needed to evaluate the implementation, effectiveness, and context factors for patient safety practices for intravenous heparin, especially in regards to use of new technological tools.

Table 2, Chapter 3. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Low	Low-to-moderate	Low	Little/Moderate

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Chapter 4. Clinical Pharmacist's Role in Preventing Adverse Drug Events: Brief Update Review

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Introduction

In our original report, “Making Health Care Safer” 2001, Kaushal and Bates noted that over 770,000 people were harmed or died in hospitals annually from adverse drug events (ADE),¹⁻⁴ with incidence rates in hospital-based studies ranging from 2 to 7 per 100 admissions.^{1,5-7} In the outpatient setting, as they also noted, one study on adults estimated the ADE incidence rate at 3 percent.⁸ The purpose of this review is to update the data on the incidence of ADEs in hospital settings and to review measures aimed at preventing these events, including the role of the clinical pharmacist. We searched the literature from 2001 to 2011 and included studies most relevant to clinical pharmacist interventions on medication errors and adverse drug events in various health care settings. Our focus was on studies that to some degree addressed the possible association between clinical pharmacist activities and improved prescribing practices and/or assessed whether such activities might lead to reduced medication errors and adverse drug events.

What is the Role of the Clinical Pharmacist in Preventing Adverse Drug Events?

There have been various patient safety initiatives implemented that involve pharmacists with the goal of reducing ADEs. These initiatives are often based on the premise that clinical pharmacists can play an important role in intercepting and acting on possible prescribing errors and/or recognizing drug-related problems before injury, or further injury, can occur. This concept has been tested in a variety of settings in a variety of ways.

In the original report, Kaushal and Bates⁴ noted that in a seminal study by Leape and colleagues,⁹ a clinical pharmacist participating in an intensive care unit team led to “a statistically significant 66% decrease in preventable ADEs due to medication ordering.” Another study suggested that ward-based clinical pharmacists may benefit inpatient medication use safety and quality.¹⁰ A single study in a geriatric population found a decrease in medication errors at the time of inpatient discharge when clinical pharmacists were involved.¹¹ Based on a meta-analysis, clinical pharmacists were considered to have a modest effect on maintaining acceptable drug ranges.¹² In the ambulatory setting, the authors noted that clinical pharmacists may have positive impacts on a variety of chronic diseases (hypertension, hypercholesterolemia, chronic heart failure, and diabetes).¹³ However, these ambulatory studies had significant limitations and potential biases, making generalizations problematic.⁴

At the time of the first review,⁴ the authors noted that, in two studies, physicians were receptive to and often acted on clinical pharmacist interventions^{9,14} attesting to the often collaborative relationship between the two groups. Overall, Kaushal and Bates concluded that, “Given the other well-documented benefits of clinical pharmacists and the promising results in the inpatient setting, more focused research documenting the impact of clinical pharmacist interventions on medication errors and ADEs is warranted.”⁴

What Have We Learned About the Role of Clinical Pharmacists?

Recent Reviews and Systematic Evaluations Suggest Clinical Pharmacists Improve Medication Management

Since the 2001 report, several new systematic reviews, have addressed the role of clinical pharmacists in different clinical settings. The largest such review was Kaboli and colleagues¹⁵ (AMSTAR score 7 positive of 9 relevant domains). This review included studies from 1985 to 2005 that assessed clinical pharmacists' interventions in inpatient care. Eligible studies were those using concurrent controls or time series design, and measuring a number of different outcomes.

Thirty six studies contributed evidence to the review, including 10 studies of pharmacists' participation on rounds, 11 studies of their participation in medication reconciliation, and 15 studies of drug-specific services (e.g. coumadin, antibiotics). The review was narrative, and concluded that the evidence "supports the use of clinical pharmacists in the inpatient setting to improve the quality, safety and efficiency of care," although noting that the evidence base is still limited by small sample size, many studies were conducted at only a single institution, and most studies have differing measures of outcome.

Three other reviews dealt with clinical pharmacists benefit in the care of elderly adults, in nursing homes, and pediatric patients.

Hanlon and colleagues¹⁶ found a number of benefits for elderly adults, in a variety of settings, in optimizing prescribing (i.e., improving quality of pharmaceutical care) and reducing drug-related problems. While there was scant evidence on reducing adverse drug events, they commented on the difficulty in designing a study that would show ADR reduction, noting that to detect a 25% decrease in adverse effects, due to a pharmacist intervention, would require randomizing at least 800 to 1400 elderly patients. This review scored 4 of 9 relevant AMSTAR domains. In a narrative review of interventions in nursing homes, Marcum and colleagues included five randomized controlled studies assessing the impact of clinical pharmacists on various outcomes, including drug-related adverse events; they also included two studies with a pharmacist or pharmacologist as part of a multidisciplinary approach. While some studies showed significant differences in the numbers and/or choices of (or changes in) drugs, clinical outcomes--measured in various ways--were mixed, tending overall to show inconsistent and/or nominal impacts.¹⁷ This review scored 6 of 9 relevant AMSTAR domains. Sanghera and colleagues¹⁸ noted that pharmacists provide important improvements on drug therapy for children. Many of the 18 studies in the review were older, and methodologies differed (e.g., measuring outcomes in various ways, by various designs and definitions), but an overall positive impact was consistently seen in the studies reviewed. Most of the studies were in the inpatient setting, and only three were in the outpatient area. Even so, the review highlighted that pharmacists play a crucial role in detecting and correcting medication errors, such as dosing mistakes, sometimes potentially lethal ones. The authors concluded, "...pharmacists reviewing medication charts is very important in identifying medication-related problems; hence it is likely to be the most effective factor in improving drug therapy in children." It should be kept in mind that many of the studies pre-dated the electronic era. This review scored 7 of 9 relevant AMSTAR domains.

Another review, by Cohen and colleagues,¹⁹ included 16 studies of pharmacist activities in the Emergency Department (AMSTAR score 6 positive of 9 relevant domains). Again noted was the wide diversity of tasks in which pharmacists were engaged, including (but not limited to)

providing drug information, patient counseling, precepting, toxicology case assistance and various forms of therapeutic consultations, interventions and managements, including medication error prevention (though included studies were limited in this latter regard).

By and large, these reviews support clinical pharmacist activities in improving medication management. In general, three issues emerge from the literature. First, clinical pharmacists are engaged in a multitude of patient level activities, including recognizing, intercepting, and documenting drug-related problems, as well as assisting in optimizing pharmaceutical choices for patients and, in some cases, engaging in specific interventions or in specific disease management practices. Second, it is problematic to accurately capture all that pharmacists do at either an individual patient level or at an organization level,²⁰ which makes it that much more difficult to assess their impact, especially since clinical pharmacists do not work in isolation but rather with other clinicians and, frequently, within hospitals or health care systems or settings. Third, studies that attempt to show the benefit of pharmacists engaged in various activities from a larger vantage point (e.g., assessing whether adding a pharmacist to a ward team reduces medication errors or adverse drug events) often have challenges in their interpretation, including lack of concurrent control groups, indeterminate definitions of suboptimal prescribing, varying definitions of medication errors and preventable adverse drug events, different methods of error and event capture and reporting, and varying clinical outcome assessments. Even so, while individual studies do not always demonstrate benefits from an organizational perspective, the body of work suggests that pharmacists provide substantial value to patient care, clinical teams, institutions, and health care organizations.

Original Studies Not Included in the Systematic Reviews Show that Interventions With Clinical Pharmacists Tend to Reduce Adverse Events

As with the systematic reviews we again focused on studies that attempted to address the relationship between clinical pharmacist activities and improved prescribing and/or a reduction in adverse events. We identified eight new studies not included in the systematic reviews already discussed. Of note, many of the more recent studies have had limited success in overcoming some of those methodological issues seen in some of the older studies. As above, we focused on studies from the United States and other English speaking countries. The studies are summarized in Table 1, Chapter 4.

Table 1, Chapter 4. Summary of studies

Study, Year	Population and Controls	Intervention	Outcomes Measured and Timing	Findings
Kaushal, 2008 ²¹	Pediatric ICU or general ward with paper charting; matched units did not receive intervention	Part or full-time clinical pharmacist rounding and monitoring drug dispensing, storage, and administration	Medication errors and adverse events pre/post, identified by nurse and reviewed by 2 blinded physician reviewers; 6-8 weeks baseline, 3-month intervention period	Full-time clinical pharmacist decreased medication errors (29 to 6 per 1000 patient days); increase in medication errors in controls; part-time pharmacists did not decrease error rate.

Table 1, Chapter 4. Summary of studies (continued)

Study, Year	Population and Controls	Intervention	Outcomes Measured and Timing	Findings
Wang, 2007 ²²	Pediatrics unit of a community teaching hospital	Addition of CPOE to existing clinical pharmacist system	Medication errors, near misses, and adverse events over a 3-month period	Clinical pharmacist intercepted 78% of 111 potentially serious prescribing errors but none of 32 harmful administrative errors and few of the transcribing (6/25) or monitoring errors (3/7)
Rivkin, 2011 ²³	General medical ICU	Inclusion of clinical pharmacist in rounding	Clinically important drug-drug interactions pre/post over a 10-week period	Drug interaction rates decreased significantly (65%) when compared retrospectively (historically) to a 10-week period earlier in the year
LaPointe, 2003 ²⁴	Cardiac ICU	Rounding and participation in patient-oriented activities (e.g., taking medication histories, discharge counseling), and provider level activities (e.g., giving in-service talks to house staff and communicating with physician and nursing staff)	Medication error interventions (e.g., dose or medication changes, missing medications, allergy-drug contraindications) pre/post over 5 years	Incidence of medication errors increased from around 15 to nearly 24 per 100 admissions, and a higher trend was seen during times of house staff transition
Stoner, 2000 ²⁵	Outpatient psychiatric setting (235 sets of evaluations in 83 patients on anti-psychotics)	Pharmacist testing/ recommendations regarding patients on antipsychotics who had movement disorder complaints or who were taking drugs to counter movement disorders	Movement disorder (extrapyramidal) symptoms	A majority of recommendations (82% of 130 evaluations) were followed by clinicians; of these, 93% led to a resolution or reduction in extrapyramidal symptoms
Simpson, 2004 ²⁶	Neonatal ICU	Pharmacist-run education program on medication orders and IV fluid review implemented at month 4 of 12 months plus other process changes	Medication errors pre/post; case finding by incident reporting	Significant decrease in medication errors (from 24 to 5 per 1,000 neonatal activity days/month); error rate increased during summer staffing change

Table 1, Chapter 4. Summary of studies (continued)

Study, Year	Population and Controls	Intervention	Outcomes Measured and Timing	Findings
Bond, 2006 ²⁷	584 hospitals encompassing >35,000 Medicare patient stays	Pharmacy staffing and presence or absence of various pharmacy services	Adverse drug reactions (ADRs)	Pharmacist involvement in 8 services (in-service education, drug information services, adverse drug reaction management, drug protocol management, cardiopulmonary resuscitation teams, medical rounds and completing admission drug histories) as well as higher staffing rates decreased ADRs; however, pharmacist participation in total parenteral nutrition teams increased ADRs
Bond, 2007 ²⁸	885 U.S. hospitals with data on 2.8 million Medicare patients	14 different clinical pharmacy services and several staffing models	Severity-adjusted mortality rates	In-service education, drug information, adverse drug reaction monitoring; participation in drug protocol management, cardiopulmonary resuscitation teams and medical rounds; and completing admission drug histories were associated with reduced mortality as were two staffing variables
Brown, 2008 ²⁹	Large rural hospital Emergency Department	Review of medication orders and identification of errors via retrospective review by an independent reviewer. Pharmacists also documented their interventions.	Medication Errors, 1 month when pharmacist was not present to check medication orders versus 1 month when pharmacist (s) was (were) present; time periods for assessment were one year apart	Pre-post analysis showed significant decrease (66.6%) from error rates of approximately 16 to 5 per one hundred medications orders

Table 1, Chapter 4. Summary of studies (continued)

Study, Year	Population and Controls	Intervention	Outcomes Measured and Timing	Findings
Rothschild, 2010 ³⁰	Four academic Emergency Departments	Observational study in which pharmacy residents conducted 226 sessions (787 hours) of observing pharmacist activities; the study included over 17,000 medications ordered or administered to nearly 6,500 patients	Identification of medication errors at various stages of prescribing or administration by unblinded, continuous observation. Data collection was via templated forms. Captured elements included errors of interest, ranging from those intercepted before reaching the patient to caught after reaching the patient but before harm could occur to ameliorated adverse events (collectively these together were known as recovered medication errors) . Case reviewers independently assessed suspected error interventions.	Pharmacists identified over 500 recovered medication errors, with an overall rate of about 3 per 100 medications or about 8 per 100 patients. Approximately 90% were intercepted before reaching the patient.
Cesarz, 2012 ³¹	An academic medical center's 32-bed Emergency Department, serving pediatric and adult populations	Prospective observational study looking at activities of four pharmacists during relevant shifts in reviewing discharge prescriptions. Data collection was over a 3 week period and used standardized forms for reporting interventions. All recommendations were provided to the ordering physician who made the determination to change a prescription	Self-report of interventions on discharge prescriptions. An independent reviewer determined whether the intervention was categorized as error prevention or therapeutic optimization	Of 674 discharge prescriptions reviewed, ED pharmacists intervened on about 10%; roughly half of the 68 interventions (54%) concerned error prevention.

A number of the studies contained design flaws that prevented ruling out the contribution of other process modifications or even secular changes to the observed results. Nevertheless, overall, these newer studies continue to support the important roles of clinical pharmacists in reducing prescribing mishaps as well as in improving several patient-level outcomes in various

settings. With the exception of one study, studies in which pharmacists participated in a greater number of clinical processes seemed to show stronger effects.

Clinical Pharmacist Interventions Show Little Potential for Harm

Virtually no study has shown an outright potential for harm, apart from an occasional isolated finding such as an ADR rate increase with pharmacist participation on total parenteral nutrition teams (a result that, given its oddity, must remain questionable).²⁷ Theoretically speaking, as noted in the original report,⁴ involvement of clinical pharmacists and implementation of their review processes may result in some delays in dispensing medications. But if these interventions reduce errors (and/or clarify prescribing), this outcome cannot truly be considered a harm, though perhaps it is bothersome and time consuming for patients or providers.

Benefits of Implementation May Outweigh Costs

In terms of resource utilization and costs, the decrease in ADRs that should result from improved prescribing practices should lead to financial savings and/or mitigations in the costs of care. However, information in that regard is limited and generally unclear. Of the two primary studies noted in the 2001 report that estimated annual savings, one based on interventions in an intensive care unit and another based on pharmacist activities in a large university hospital, estimated savings ranged from \$270,000 to almost \$400,000 per year.^{4,9,32} Because of differences in outcomes and how they are measured, true costs and/or savings are hard to gauge and, not surprisingly, vary widely. For example, in a review of economic benefits from hospital-based interventions by De Rijdt and colleagues,³³ financial outcomes, generally stated in estimated annualized savings, ranged anywhere from less than \$10,000 to over \$500,000, depending on the study and the clinical or interim outcome measured as well as the method of financial evaluation and whether pharmacist costs were included.³³ From another perspective, Bond and Raehl²⁸ estimated that the legal settlement costs avoided by the reduction in preventable deaths in the patient population they studied (Medicare) would be nearly \$2.4 billion for hospitals that incurred adverse events. While cost or savings estimates depend on a set of assumptions as well as the financial costs of pharmacists' time and effort, these widely varying estimations bring home the point that reduction in medication errors or preventable ADEs can have subsequent "down the line" effects and that financial changes may accrue at a variety of levels depending on the intervention and the seriousness of clinical outcomes (or outcomes avoided).³³ A major driver of the cost-effectiveness of a clinical pharmacist intervention is whether new pharmacists need to be hired or if the program can be implemented by reallocation of existing resources and/or the use of lower cost pharmacy technicians for some roles, and thus increase the availability of clinical pharmacists to directly interact with patients and physicians.

Conclusions and Comment

Clinical pharmacists play important roles in a variety of health care settings, and their activities appear to benefit individual patients as well as health care organizations in a multitude of ways, many of which are difficult to isolate when studying whether these interventions objectively lower medication errors or ADEs. Many of the studies are not methodologically strong, and the literature lacks consistency and comparability. Nevertheless, systematic reviews and recent evidence generally supports that pharmacist involvement in intensive care units, particularly when engaging in bedside rounds improves medication management and/or reduces

medication errors and preventable ADEs. The existing data for other inpatient and for outpatient care settings are also supportive of a role for pharmacists but less robust than in intensive care units. Data from nursing homes are not as clear as for other settings, but, logically speaking, since medication and prescribing errors occur in this setting, and patients are elderly and more prone to polypharmacy, it is likely by analogy that drug safety in nursing homes will be improved by clinical pharmacist interventions. Similarly, evidence from emergency departments is limited but given the high intensity of care activities and of prescription utilization, it is logical that benefits will accrue from pharmacist interventions. More and better designed studies should help determine the magnitude of the benefit(s), to the extent that such benefits exist, in various health care settings. A summary table is located in Table 2, Chapter 4.

Table 2, Chapter 4. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Moderate-to-high	Low	High	Little/Moderate

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Chapter 5. The Joint Commission’s “Do Not Use” List: Brief Review (NEW)

Peter Glassman, M.B.B.S., M.Sc.

Introduction

Medication errors stem from a variety of causes, including miscommunication between prescribers and pharmacists in the form of misunderstood and/or illegible abbreviations. The potential hazards of certain abbreviations started receiving heightened attention approximately twenty years ago.¹ Most notably, as one of its National Patient Safety Goals, the then named Joint Commission on Accreditation of Healthcare Organizations (JCAHO, hereinafter referred to as the Joint Commission for consistency) in 2003 announced that nine abbreviations and/or shorthand notations—a Do Not Use list—should be banned in its accredited hospitals by April 2004.^{2,3} The list included the following inappropriate abbreviations: “U” or “u” instead of unit; “IU” instead of International Unit; “Q.D.” or similar instead of once daily; “Q.O.D” or similar instead of every other day, “MS”, “MSO₄” and “MgSO₄” instead of writing morphine sulfate or magnesium sulfate; and use of zeros, either when trailing an ordinal number (1.0 instead of 1) or lack of a zero before a decimal point (.9 instead of 0.9)^{2,4} (See Figure 1).

Figure 1, Chapter 5. Official “do not use” list

Official “Do Not Use” List¹

Do Not Use	Potential Problem	Use Instead
U, u (unit)	Mistaken for “0” (zero), the number “4” (four) or “cc”	Write “unit”
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write “International Unit”
Q.D., QD, q d., qd (daily)	Mistaken for each other	Write “daily”
Q.O.D., QOD, q.o.d, qod (every other day)	Period after the Q mistaken for “I” and the “O” mistaken for “I”	Write “every other day”
Trailing zero (X.0 mg) [*]	Decimal point is missed	Write X mg
Lack of leading zero (.X mg)		Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write “morphine sulfate” Write “magnesium sulfate”
MSO ₄ and MgSO ₄	Confused for one another	

¹ Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.

Exception: A “trailing zero” may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

Additional Abbreviations, Acronyms and Symbols
(For possible future inclusion in the Official “Do Not Use” List)

Do Not Use	Potential Problem	Use Instead
> (greater than)	Misinterpreted as the number “7” (seven) or the letter “L”	Write “greater than”
< (less than)		Write “less than”
Abbreviations for drug names	Confused for one another Misinterpreted due to similar abbreviations for multiple drugs	Write drug names in full
Apothecary units	Unfamiliar to many practitioners	Use metric units
@	Confused with metric units Mistaken for the number “2” (two)	Write “at”
cc	Mistaken for U (units) when poorly written	Write “mL” or “m” or “milliliters” (“mL” is preferred)
µg	Mistaken for mg (milligrams) resulting in one thousand-fold overdose	Write “mcg” or “micrograms”

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Figure taken from the JCAHO Web site.⁴

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Avoiding potentially hazardous abbreviations was initially intended to pertain to handwritten documents (e.g., written prescriptions), but the over-riding plan was to extend this stipulation to all forms of patient-specific communications including printed, electronic or handwritten materials, with targeted compliance rates of 90% for handwritten and electronic formats and 100% for printed material by 2005.^{2,8}

As part of the initial Joint Commission safety program, health care organizations were to add three abbreviations to their specific banned list, depending on the type of organization and their own experiences with abbreviation errors; the Joint Commission provided an additional list of abbreviations, symbols and acronyms for consideration.⁴ The Joint Commission is not the only organization to provide lists or recommendations. The Institute for Safe Medication Practices provides an even more extensive list for consideration⁵ and in 2006 began collaborating with the Food and Drug Administration to reduce hazardous abbreviations.^{6,7}

The magnitude of harm due to abbreviations and other shorthand notations such as acronyms and symbols is not entirely clear. In a study completed after the Joint Commission's patient safety goal was disseminated, Brunetti et al., using data from the United States Pharmacopeia MEDMARX™ program—which in turn uses the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Medication Errors, found that between 2004 and 2006 a total of 29,974 medication errors out of 643,151 (4.7%) reported to the MEDMARX program were associated with abbreviations.⁹ Of those with sufficient information to ascertain a description of the error (n = 18,153), about 43% were due to using the term “QD” (once daily). In addition, roughly 13% involved the abbreviation “U” (units), and approximately 13% “cc” (milliliter); nearly 10% used MSO4 or MS (morphine sulfate), and 3% “HS” (at bedtime); almost 4% were attributed to decimal errors (e.g., no leading zero or a trailing zero). Of the errors assessed, 0.3% led to patient harm, and most of those involved the abbreviation “U” in some manner.

Most errors (81%) occurred during prescribing; not surprisingly, medical staff were responsible for roughly 79% of abbreviation errors. Abbreviation use varied among staff groups, with physicians often using “sc”, “hs” and “cc.” While the study was limited by the constraints of voluntary reporting, the data suggest that relatively few abbreviations and notations are responsible for perhaps 5% of related medication errors—and this number may well be larger since not all errors are likely to be reported.

The purpose of this narrative literature review is to understand the degree to which health care organizations have succeeded in implementing procedures to prevent inappropriate abbreviations, and to identify which method(s) work well. We searched PubMed in October 2011 using major heading search terms “abbreviation and safe or unsafe or adverse or harm” for English language articles published starting in the year 2000. Titles and abstracts were retrieved, and relevant articles were retained for review. We expanded the search by using Google to search for possibly pertinent articles and links; we identified additional articles by looking at cited references from various publications. We focused on United States-based studies. Clinical trials, observational studies, reviews, and anecdotal reports on implementation were our primary resources and given priority in the order above.

What Are the Procedures for Reducing Prescribing Errors?

As Kuhn (2007) noted, there are three primary methods for addressing the safety issues posed by abbreviations: “education, enforcement and leadership.”⁸ In addition, the advent of electronic prescribing with clinical decision support may impact on abbreviation use.

Unfortunately, in all of these areas, the relevant United States' literature is sparse, and implementation efforts have had mixed results.

How Effective Have These Procedures Been?

Educating Providers to Reduce Potentially Unsafe Abbreviations. Abushaiqa et al. studied the strategy to decrease six specified unsafe abbreviations (unit instead of U; microgram instead of μg ; 3 times a week for TIW; avoiding the degree symbol for hour, and avoiding trailing zeros and lack of leading zeros).³ The setting was a 340-bed hospital in Detroit. Educational materials included pocket cards, chart dividers in patient charts, and traffic sign look-alike stickers. Providers were sent memorandums and electronic mail. In-service programs were also completed: prescribers using banned abbreviations or symbols were asked to clarify their orders and received instruction on why to avoid banned abbreviations.

The evaluation period, including a baseline assessment, lasted from September 2003 to April 2004. Unsafe abbreviations dropped from about 20% in the pre-intervention phase to about 3% by the end of the intervention period, with a total of over 20,000 orders reviewed. Sustainability of the program was not addressed, but the authors noted that in April 2004 the facility started utilizing the Joint Commission's Do Not Use list and in July 2004 the hospital no longer accepted orders with unsafe abbreviations.³

On the other hand, Garbutt et al. focused on 20 "safe prescribing behaviors" using a multi-faceted educational intervention at an urban teaching hospital in St Louis. The prescribing errors included dangerous abbreviations such as potential dosing errors (e.g., trailing zeros, leading zeros) and frequency measures (e.g., QD, QOD, TIW, HS). The intervention program included an academic component (e.g., grand rounds or lecture format) as well as reminders and prompts to emphasize desired prescribing practices. Overall, prescribing errors for surgical house staff declined but paradoxically increased for medical house staff. Notably, neither group decreased use of potentially hazardous abbreviations.¹⁰

Leonhardt and Botticelli studied an effort in Milwaukee, in 2003 to 2004, involving seven independent health care organizations.¹¹ The safety collaborative included local hospitals that partnered with the local business community as well as retail pharmacies. The goal was to completely eliminate nine abbreviations/shorthand notations from hospital medication orders and five abbreviations/shorthand notations from outpatient prescriptions (including abbreviations associated with units, once daily, every other day, trailing zeros and lack of leading zeros). Interventions and strategies included banning the prohibited abbreviations, educational programs (at various times during the intervention period) and providing informational materials (e.g., printed documents, wallet cards, posters); in addition, there was feedback to physicians who continued to use banned abbreviations. In outpatient clinics the intervention was passive education (i.e., newsletters).

The program improved prescribing for hospital-based medication orders but not for outpatient-based prescriptions. More specifically, appropriate documentation (i.e., no banned abbreviations or notations) rates, evaluated at thirteen hospitals, increased from approximately 62% at baseline to about 81% after the intervention ($P < 0.0001$). For clinic-based prescriptions, evaluated at nine retail pharmacies, rates of appropriate prescriptions increased a non-significant amount, from about 69% to 73% ($P = 0.11$).¹¹

Leadership and Enforcement Effects on Abbreviation Use

We found no formal studies that isolated enforcement and/or leadership efforts, although the Abushaiqa study clearly included some enforcement. There were some anecdotal success stories, mostly after lack of success with educational programs. For example, at Children’s Hospitals and Clinics in Minneapolis, prescribers were mandated to re-write orders with prohibited abbreviations; no details were provided on the magnitude of the effect(s). Another hospital in Tennessee contacted providers to ask for clarification of orders with designated abbreviations, and a medical staff chairperson discussed abbreviations with individual prescribers identified as using such; abbreviations in medication orders reportedly declined from around 30% to 6%. An Ohio hospital retrospectively routed prescriptions that contained designated abbreviations (apparently after filling the prescription) back to prescribers with feedback that the order had an unacceptable abbreviation(s). This program reportedly had “no noticeable decrease” in abbreviation use.¹²

Impact of Electronic Prescribing on Hazardous Abbreviations

Electronic prescribing provides a ready venue for focusing on abbreviation misuse. First, electronic prescribing eliminates illegible handwriting. Second, clinical decision support may be configured to prompt providers to avoid abbreviations and/or to auto-correct or translate abbreviations to preferred terms (e.g., using Q.O.D. would yield “every other day” on the prescription). However, there are limited data on how using electronic prescribing affects abbreviation use.

In a small study of faculty providers practicing in an outpatient setting, Galt et al. conducted a prospective, randomized controlled trial looking at how a personal digital assistant (PDA) affected prescribing by 78 office-based primary care physicians.¹³ Practices were randomized to either usual handwritten prescribing or to entering prescriptions using a PDA-based clinical drug application. However, intervention offices could, when desired, use handwritten prescriptions. Duplicate prescriptions were gathered by printing an extra electronic prescription or by using carbon copies of written ones. The analysis compared the intervention group pre and post PDA use—that is, during the period when handwritten prescriptions were used, and then during the PDA use period, when physicians entered 43% of prescriptions via electronic means.

The study found that illegibility decreased from about 9% to 3% (though not to zero since not all prescriptions were via PDA) and, among other errors, various abbreviations and shorthand methods fell numerically (P-values not provided) including abbreviations for drug name (from about 3% to 2% of errors), administration route (from about 63% to 37%), frequency (from roughly 86% to 51%), and symbols on the prescription (from about 77% to 47%). In both time periods, issues with zeros were relatively rare (< 1%); interestingly dosing abbreviations rose from 61% to approximately 71%, as some of these were allowed in the application.¹³

Devine et al. studied the impact of a basic computerized provider order entry program in a multispecialty clinic system in Washington State. Using a pre/post study design, evaluating handwritten (pre-intervention) prescriptions from January to March to 2004 and electronic prescriptions (post-intervention) from July 2005 to April 2006 at three retail pharmacies, they found that illegible prescriptions decreased from just under 3% to less than 0.1% and inappropriate abbreviations fell from around 5% to 0.4%.¹⁴

In a small prospective study of faculty providers practicing in an outpatient setting, Abramson et al. found that reducing abbreviation error rates was the primary driver in reducing overall prescribing errors when transitioning from an older to a newer electronic prescribing

system. The older, locally derived system had automatic conversion of inappropriate abbreviations installed on some computers; it also allowed for free text entries on the ordering template. It had minimal clinical decision support and did not send prescriptions directly to pharmacies. The newer system had a commercially available clinical decision support package, but did not auto-correct abbreviations. The system was able to send prescriptions to pharmacies. The newer system included two alerts to providers when they entered and completed a prescription containing an inappropriate abbreviation. In this yearlong study, data were available on seventeen physicians in the academically affiliated clinic. Rates of inappropriate abbreviations (per 100 prescriptions) fell from about 24 at baseline to just under 11 at 6 months and then to approximately 6 at 1 year after implementation (p-values < 0.001). Interestingly, non-abbreviation error rates rose at 12 weeks, but were similar at one year post-implementation.¹⁵

What Have We Learned About Procedures for Reducing Prescribing Errors?

The U.S. literature on programs designed to reduce prescribing errors is sparse. Studies that assessed the success of programs to educate providers report mixed results. We found no studies that focused specifically on enforcement or leadership, but anecdotal reports are also mixed. No studies address sustainability.

Electronic prescribing systems may hold promise. However the data on avoiding abbreviations are limited, and it is not clear which technology or technologies will work best for reducing shorthand methods of prescribing.

Conclusions and Comment

Abbreviations and other shorthand notations on prescriptions and orders increase the risk of medication errors, and the majority of errors and subsequent harms are caused by relatively few abbreviations or notations, and more specifically, “QD” (once daily), “U” (units), “cc” (milliliter); MSO₄ or MS (morphine sulfate), and “HS” (at bedtime); in addition, decimal errors (e.g., no leading zero or a trailing zero) are also troublesome. Various organizations, most notably the Joint Commission in the form of its “Do Not Use” list, have taken a strong stand against using certain abbreviations. However, the available literature on various implementation efforts is limited, and no clear route to success has been described. Moreover, we found no studies that address sustainability of efforts and no studies on whether reducing abbreviations leads to less patient harms, though logically this would seem to be the case.

All in all, abbreviations can lead to misunderstandings and miscommunications between the prescribers and the pharmacists and in turn may lead to incorrect prescriptions being given to patients. Most errors are caused by relatively few abbreviations. Harms from such errors are uncommon but preventable. Although it is not clear how the Joint Commission’s “Do Not Use” List (or any other list of hazardous abbreviations) can best be implemented across the spectrum of U.S. health care organizations it is important to note that there is no obvious patient harm to implementing such a list and data, to the extent that it exists, suggests that avoiding certain heightens prescribing safety. The cost and burden of implementation will depend on the stringency and/or comprehensiveness of the method(s) used. For example, electronic prescribing and decision support tools may offer the best chance of successfully reducing abbreviations on the “Do Not Use” list. However, it will take some time before prescribers are universally using

these systems and the cost and effort is not insubstantial to newly utilizing electronic prescribing. Another alternative would be enforcing a zero tolerance policy on handwritten prescriptions and medication orders. However, this might create a substantial burden for prescribers and pharmacists, particularly in the outpatient and retail pharmacy areas, not to mention mail out facilities. In the meantime, a low-cost approach of implementation, such as through ongoing education and/or feedback, focused on avoiding selected harmful abbreviations whenever and wherever possible seems reasonable and feasible. A summary table is located at Table 1, Chapter 5.

Table 1, Chapter 5. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Low	Negligible	Low	Little/Probably not difficult

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Chapter 6. Smart Pumps and Other Protocols for Infusion Pumps: Brief Review (NEW)

James Reston, Ph.D., M.P.H.

Introduction

Medication errors represent a serious issue affecting the U.S. health care system, accounting for the largest category of patient safety incidents within the larger category of medical errors. One report estimated that at least 1.5 million preventable medication errors occur in the U.S. each year.¹ A list of high-alert medications (those with the highest potential for patient harm if used in error) published by the Institute for Safe Medication Practices (ISMP) includes several medications delivered by intravenous (IV) infusion (e.g., insulin, propofol, heparin).²

Because IV delivery is more rapid and leads to higher systemic concentrations of drugs compared with other delivery methods, adverse drug effects tend to be more rapid and severe when associated with IV infusion. Because traditional infusion pumps are typically programmed in milliliters per hour (mL/hr) and volume-to-be-infused (VTBI) in mL, they are particularly vulnerable to errors in drug administration and monitoring.¹ Such errors include administration of the wrong dose or the wrong drug as well as erroneous infusion to the wrong patient.

What Are the Practices for Reducing IV Medication Errors?

To address the shortcomings of infusion pumps, manufacturers have added technology to recent models of general-purpose (large volume),³ syringe,⁴ and patient-controlled analgesia (PCA) pumps⁵ specifically designed to prevent medication errors. Smart pumps include a software program (also referred to as a dose error reduction system [DERS]) that provides a customized drug library alerting users to predetermined minimum and maximum dose limits for each drug.

The program provides soft alerts (also known as soft stops) that prompt users to reconsider a given drug dosage but allow them to administer that dosage if they choose, as well as hard alerts (or hard stops) that prevent users from going beyond the stated dose limits.¹ These systems permit the development of dosing limits for continuous and bolus deliveries, as well as clinical advisories (point of care notifications) and area-wide default settings for alarm thresholds.

In addition, some smart pumps have incorporated barcode technology that allows verification of patient identity, thereby preventing delivery of the wrong drug or delivery to the wrong patient.^{6,7} One PCA pump offers an integrated bar code scanner for automatically locating the correct drug entity (e.g., drug name and concentration), and a handful of hospitals have created interfaces between their general purpose pump servers, barcode-enabled point of care (BPOC) systems, and documentation systems to make sure that the pump is programmed according to the medication order and that administration is automatically documented.⁶

Unlike traditional infusion pumps, smart pumps can alert health care workers when they have selected inappropriate dosages for a given drug. Soft alerts have the shortcoming that they are merely reminders that can be overridden by the user although overrides are captured in a DERS log and can frequently be associated with a user. Hard alerts have the potential to be more effective because they do not allow easy circumvention, although they can still be circumvented by determined users (e.g., by bypassing the drug library and entering the infusion rate and

volume manually).⁸ A significant drawback is that inappropriately programmed hard alerts may impede delivery of care, and circumvention of hard alerts can lead to serious errors.⁹

Smart pumps with DERS plus BPOC can additionally prevent drug delivery to the wrong patients.^{10,11} As long as users comply with such alerts and prompts, smart pumps have the potential to reduce the number of infusion errors. Compliance with safety features can be improved by programming prompts that increase ease of use, and by emphasizing a culture of safety within the organization. Smart pumps also contain a data log that can be used to identify programming errors or show that the pump prevented adverse events.⁹

However, the basic limitation of smart pumps is that they can correct only errors of administration; other types of medical errors can occur during ordering or prescribing, dispensing, transcribing, and monitoring of patient response.¹⁰ For this reason, smart pumps function best not as standalone devices but when integrated into a larger medication safety system that connects them with computerized provider order entry (CPOE), BPOC, and electronic medication administration records (eMARs).⁹ Such interconnected systems can target not only errors of administration but also errors of ordering, dispensing, and transcription.¹⁰

How Have These Practices Been Implemented?

A recent systematic review by Hertzell and Sousa (2009) identified nine studies published from 2003 to 2008 that assessed the use of smart pumps for prevention of medication errors. The majority of studies evaluated smart pumps with soft alerts. The review summarized the study findings and identified lack of user compliance with soft alerts as an important factor that compromised the efficacy of smart pumps in the majority of studies. The authors concluded that “well-designed research is still lacking with respect to the effectiveness of smart pumps in preventing medication errors.”¹ The most relevant studies mentioned in this review are summarized in more detail below, along with more recent studies published subsequent to the review’s publication date.

Smart Pumps With Soft Alerts

Nuckols et al. (2007) performed a retrospective review of 4,604 critically ill patients in ICUs at two hospitals to determine how often preventable IV adverse drug events (ADEs) matched smart pump safety features. These consisted of drug libraries with dose limits that triggered soft alerts, which could be addressed or overridden. The study evaluated ADEs before and after smart pump implementation. Of 100 preventable ADEs, only four (two before and two after smart pump implementation) matched the safety features of smart pumps.¹²

Rothschild et al. (2005) performed a prospective time series study of smart pumps with intervention (decision support on) and control (decision support off) periods to determine the impact of integrated decision support on the incidence of medication errors and adverse drug events in 735 cardiac surgery patients. Preventable adverse events (11 intervention, 14 control) and non-intercepted potential adverse events (82 intervention, 73 control) did not differ significantly between groups. Serious medication error rates were 2.41 and 2.03 per 100 patient-pump days in the intervention and control periods, respectively ($P = 0.124$). Caregivers violated infusion practice 25% of the time (571 infusions) by bypassing the drug library during the intervention periods. Medications were administered without physician documentation 7.7% of the time (intervention and control periods combined). The smart pumps were not programmed to give hard alerts, which cannot be easily overridden; therefore, it was easy for caregivers to override alerts or bypass the drug library. Poor caregiver compliance with the drug library and

dosage limits may have explained the lack of advantage of smart pump decision support in this study.¹³ This study used an early version of smart pump technology that was opt-in rather than opt-out, which made it easier for users to skip the library rather than look for it.

Larsen et al. (2005) performed a retrospective before-after study in pediatric patients that compared medication infusion errors 12 months before and 12 months after adopting a new protocol using a combination of smart pumps, standard drug concentrations, and human-engineered (user-friendly) medication labels. The smart pumps included a modifiable drug library and provided soft alerts to users who attempted to use doses that exceeded the safety limits. The infusion error rate dropped from 3.1 to 0.8 per 1000 doses from the pre-intervention to the post-intervention period, a risk reduction of 2.3 (95% CI 1.1-3.4, $P < 0.001$).¹⁴ However, since this was a combination of three interventions, it is unclear what percentage of the error reduction can be attributed to smart pumps alone. Data were obtained from the hospital-wide-incident-reporting system, which tends to underreport errors, but the reported pre- and post-intervention error rates should be representative of the relative number of errors.¹⁴

Adachi and Lodolce (2005) conducted a retrospective before-after study (one year pre-intervention, one year post-intervention) to determine whether a new intervention (revised standard order sets and smart pumps with soft alerts) could reduce IV dosing and administration errors. Although they found that only a small reduction occurred in overall dosing errors (59 to 46), a larger reduction occurred in pump-related errors (24 to 10, or from 41% to 22% of dosing errors). Standard concentrations eliminated errors related to the wrong drug concentration. Nine out of the 10 post-intervention pump programming errors occurred because users did not use the pump software.¹⁵

Three uncontrolled studies illustrate compliance issues associated with smart pump soft alerts. Eckel et al. (2006) reported a high frequency of programmings (44.4%) due to users bypassing the drug library when selecting a drug. Furthermore, users overrode 88.5% of soft alerts.¹⁶ Fields and Peterman (2005) reported 506 medication errors due to users overriding soft alerts.¹⁷ However, a third study (Breland 2010) reported that a community hospital was able to improve compliance with pump alerts from 33% (when smart pumps were first introduced) to 97% three years later.¹⁸

Smart Pumps With Soft and Hard Alerts

Schilling and Sandoval (2011) performed a retrospective before-after study (4 months pre- and 4 months post-intervention) of smart pumps with soft and hard alerts in a community hospital setting. Use of rescue medications and heparin infusions decreased substantially from pre- to post-intervention, and length of stay in patients receiving antimicrobial agents also decreased substantially. Regarding dosage alerts, 86.2% were soft alerts and 13.8% hard alerts. About 61% of soft alerts were overridden by users and 39.% were modified to comply with accepted rates; users complied with every hard alert.¹⁹

Fanikos et al. (2007) conducted a retrospective before-after study evaluating the impact of a smart pump with soft and hard alerts in an academic medical center. After reviewing anticoagulation errors in 3,674 patients, the authors found no significant decrease in errors post-intervention (49 pre vs. 48 post). This lack of difference may reflect the fact that only a relative minority of events were infusion-related errors (19/97 total events). Infusion errors were substantially higher in the period prior to smart pump implementation (15 errors) compared with the post-intervention period (4 errors).²⁰

Smart Pumps With Soft and Hard Alerts Plus Barcode Technology

Trbovich et al. (2010) conducted a simulation study comparing nurses' ability to avoid medication errors using a traditional pump, a smart pump, and a pump with an integrated barcode scanner (the latter two had soft and hard alerts). The study was conducted in a laboratory setting using patient mannequins with bar-coded wristbands and medication bags with bar-coded labels containing patient ID; errors were assessed by type. Wrong drug errors did not differ significantly by pump type. Patient ID errors were remedied by significantly more nurses using pumps with barcode scanners (88%) than with the smart pumps without barcode scanners (58%) or traditional pumps (46%). Significantly more nurses remedied critical overdose errors when using pumps with barcode scanners (79%) and smart pumps without barcode scanners (75%) due to hard alerts than with traditional pumps (38%). Wrong dose soft alerts did not result in significant differences in fixing overdose errors among different pumps (errors remedied by 75% of nurses using pumps with barcode scanners, 63% with smart pumps without barcode scanners, and 50% with traditional pumps). This was because many nurses overrode soft alerts.⁷ While this study provides perspectives on error rates, it does not faithfully simulate a clinical environment: auto-programming in a clinical setting is limited at this time but is typically accomplished through interfaces with BPOC systems instead of through printing medication labels with patient ID.

Smart Pumps With Soft and Hard Alerts Integrated With Barcode Technology and eMARs

Prusch et al. (2011) conducted a prospective before-after study evaluating a program integrating intelligent infusion devices (IIDs) with a BPOC system and an eMAR system.²¹ Monthly compliance with the telemetry drug library increased from 56.5% pre to 72.1% post intervention ($p < 0.001$) and the number of telemetry manual pump edits decreased (56.9 to 14.7; $p < 0.001$). Pump programming errors related to i.v. unfractionated heparin occurred at a rate of 16.9 events/10,000 opportunities pre-implementation and 11.3 events /10,000 opportunities post-implementation, but the rate decrease was not statistically significant ($P = 0.17$). However, smart pumps were used before and after the implementation period, the only difference being that the smart pumps became fully integrated with BPOC and eMAR in the post-implementation period. Therefore, the true impact of smart pumps on infusion error rates is unclear from this study.

None of the studies described above identified harms to patients that could be attributed specifically to the use of smart pumps in place of traditional infusion pumps.

What Have We Learned About These Practices?

Implementation of smart pump technology by health systems and hospitals generally requires considerable planning, including identification of stakeholders, evaluation of software capabilities, evaluation of hospital-specific practices, decisions regarding standard operating systems and procedures, building of drug libraries, and education of staff before the pumps can be deployed.²² Successful implementation usually involves multidisciplinary teams that include pharmacists, nurses, and physicians. With minor variations, this overall process has been described in several published studies.^{17,18,23,24}

In their guidelines for safe implementation and use of smart infusion pumps, ISMP identifies several key steps necessary for implementation. These include:

- Ownership of the process at the executive level (assessment of culture and budget resources, forming a multidisciplinary team, performing a Failure Mode and Effects Analysis [FMEA] to identify barriers to compliance)
- Technological readiness (ensure that information technology [IT] systems can interface with pumps and that IT staff levels are sufficient, update drug libraries and download medication safety information efficiently [preferably via a wireless network], consider wireless network communication upgrade if it is unavailable prior to smart pump implementation)
- Physical environment and equipment (ensure sufficient number of pumps, policies for cleaning, storage, and distribution, short-term pump rental from outside vendors [if necessary], ensure rental pumps are programmed with the renting facility's drug library and dose limits, ensure sufficient number of electrical outlets for pump operation in patient areas and for recharging internal batteries when not in use)
- Staff education (plan for several weeks of staff education, train super-users, ensure ongoing education, explain purpose of and procedures for soft and hard stops, inform staff about drug library updates, develop champions in each clinical area devoted to safety culture, do smart-pump simulation exercises, emphasize benefits of smart pump technology)
- Specialized patient care areas (make plans to address needs of specific therapies or patient care areas such as pediatrics/nursery, pain management, operating room, oncology, emergency department, and patient transport)
- Vendor support (to help define implementation timetable, provide sample drug libraries, online tutorials, live telephone assistance, post-implementation follow-up visits, assistance in data evaluation, and external support groups)
- Rollout (prioritize sequence of patient care areas receiving pumps, select areas with adequate staff and resources, select educators and champions from pilot units, vendor support should be available, evaluate rollout process)⁸

Creation of safe and effective customized drug libraries is essential for proper utilization of smart pumps. Institutions must evaluate their clinical practice when determining what drugs and dosage limits to select for their library. Drug libraries should at least include all high-alert drugs with standard concentrations as well as soft and hard stops for various dosage limits. Once drug libraries have been developed, considerable time must also be devoted to maintaining and updating the libraries. Wireless communication technology in an organization's infrastructure allows easier adjustment or updating of drug libraries, which otherwise would require manually updating each pump separately.⁸

Breland (2010) reported that a community hospital was able to increase compliance rates with pump alerts from 33% at baseline (when smart pumps were first introduced) to 97% three years later. This was done by having nursing directors and managers stress the importance of the safety software and how it could improve patient safety. Compliance data were shared with staff nurses and unannounced twice-weekly inspections were performed by pharmacy to determine why safety software was not being used in individual cases. Continual reeducation and customization of drug libraries for the needs of specific critical care areas (CCAs) also helped to improve compliance. Compliance rates for individual CCAs were distributed to nursing directors, who also emphasized to the staff the legal liability entailed in noncompliance. In addition, a review of edits and overrides led to a drug library revision to eliminate unnecessary

alerts by changing some dosage limits to reflect actual dosing practices (which were determined to be safe).¹⁸

Conclusions and Comment

The evidence supporting efficacy of smart pumps for prevention of medical errors is limited by the relatively small number of studies and the use of observational study designs with inherent susceptibility to bias (Table 1). In addition, most published studies have evaluated only smart pumps with soft alerts; study findings are somewhat variable, ranging from suggesting no effect to a limited effect of soft alerts in reducing the rate of medical errors. This appears to be partly due to user compliance, which although somewhat variable among different institutions, is usually low because users can easily override soft alerts. Hard alerts and barcode technology should theoretically have more impact on error rates, but too few studies have evaluated these features to judge their relative effectiveness. Smart pumps have the most potential to reduce medication errors when integrated into a larger medication safety system that connects them with CPOE, BPOC, and eMARs.

Implementation of smart pump technology by health systems and hospitals generally requires considerable planning, including identification of stakeholders, evaluation of software capabilities, evaluation of hospital-specific practices, decisions regarding standard operating systems and procedures, building of drug libraries, and education of staff before the pumps can be deployed. Successful implementation usually involves multidisciplinary teams that include pharmacists, nurses, and physicians. Once drug libraries have been developed, considerable time must also be devoted to maintaining and updating the libraries. Wireless communication technology in an organization's infrastructure allows easier adjustment or updating of drug libraries, which otherwise would require manually updating each pump separately.

Table 1, Chapter 6. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Low	Low	Moderate	Moderate/Moderate

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Section B. Infection Control

Chapter 7. Barrier Precautions, Patient Isolation, and Routine Surveillance for Prevention of Health Care-Associated Infections: Brief Update Review

Marin Schweizer, Ph.D.

Introduction

Healthcare-associated infections are linked to high morbidity, mortality, and costs worldwide. In 2002, an estimated 1.7 million healthcare-associated infections were seen in U.S. hospitals, resulting in approximately 99,000 deaths.¹ In 2005, 18,650 patients with methicillin-resistant *Staphylococcus aureus* (MRSA) died, more than the number of Americans who died from HIV/AIDS in that same year.² In 2007, *Clostridium difficile* was ranked among the 20 leading causes of mortality among Americans over 65 years of age.³ Despite decades of infection control interventions, health care-associated infections continue to be a major burden on U.S. hospitals.⁴

Currently, there is a rising wave of new emergent healthcare-associated infections, including multi-drug resistant strains of *Acinetobacter baumannii* and *Klebsiella pneumoniae*. Additionally, reports of vancomycin-resistant *S. aureus* have appeared sporadically across the Nation.⁵⁻⁷ No effective antibiotics are available for some strains of these pathogens, and few new antibiotics are in the developmental pipeline. For example, since 2007, only two new antibiotics have been developed. Thus, prevention, not treatment, is the most sustainable strategy to control health care-associated infections.

Findings of Original Report

When “Making Health Care Safer” was first published in 2001, the main healthcare-associated pathogens of interest were vancomycin-resistant enterococci (VRE) and *C. difficile*. Three types of barrier precaution interventions were actively being studied, including (1) gowns and gloves for all contact with patients with VRE or *C. difficile* followed by immediate hand hygiene, (2) use of dedicated or disposable examining equipment for patients with VRE or *C. difficile*, and (3) patient and/or staff cohorting for patients with VRE or *C. difficile*.

Nearly all of the studies that assessed the effectiveness of barrier precautions were simple before-after studies with small cohorts of patients. Additionally, these studies usually assessed a large bundle of practices to prevent infections, thus it was difficult to elucidate which components of the bundle were effective.

Although results varied, the majority of the studies demonstrated significant reduction in the incidence of VRE or *C. difficile* following barrier precaution interventions. A review of the literature published just before the publication of “Making Health Care Safer” noted that there had been little progress in assessing the psychological effects of contact isolation. However, it was noted that attending physicians may examine patient on barrier precautions less often. The barrier precautions chapter of “Making Health Care Safer” concluded that barrier precaution interventions are effective and called for future studies of the long-term efficacy of barrier precaution interventions as well as the cost-effectiveness of barrier precaution interventions.

This update review focuses on what we have learned about infection prevention measures and their effectiveness since the publication of the original report. We conducted a search of the health care and health services literature for the time interval 2001 to 2011 and reviewed all studies relevant to this topic.

What Are Infection Prevention Measures?

The reservoir for many healthcare-associated infections is primarily colonized or infected patients. Transiently colonized health care workers and contaminated items in the environment are often intermediates in the patient-to-patient transmission of these pathogens. Thus, breaking transmission from these reservoirs is the most important strategy to prevent healthcare-associated infections. Multiple interventions can prevent transmission. Vertical interventions, in which specific organisms are targeted, include active surveillance plus contact isolation or nurse cohorting. Horizontal interventions, in which all healthcare-associated infections are targeted, include universal contact precautions in high-risk settings.⁸

Active Surveillance and Isolation

Active surveillance is the process of testing patients for asymptomatic colonization. Active surveillance is usually only performed for MRSA or VRE, since these organisms have established reservoirs and valid screening tests.⁹ *Universal active surveillance* entails testing all admitted patients for colonization, while *targeted active surveillance* only tests patients at high risk for colonization (e.g., patients who recently received antimicrobials).

Patients found to be colonized through active surveillance are then isolated from other patients in order to prevent transmission. Isolation can be performed through nurse cohorting or contact isolation. Nurse cohorting is defined as physical segregation of colonized or infected patients from patients not known to harbor the specific pathogen in a distinct area of the same ward, and nursed by designated staff.¹⁰ When a patient is placed on *contact precautions*, health care workers are required to wear a gown and gloves when they come in contact with the patient then remove the gown and gloves and wash their hands after the contact, to prevent transmission to other patients via their hands or clothing.

Contact isolation includes contact precautions but the patient is also placed in a single room. If a single room is not available, contact isolation can be performed by cohorting patients colonized or infected with the same pathogen in the same room. Currently, most of the studies that assess active surveillance or universal contact precautions have only assessed these interventions in intensive care units (ICUs), since ICU patients are at high risk of healthcare-associated infections.¹¹⁻¹³

What Have We Learned About Infection Control Practices Since the Original Report?

Increasing Resistance and Changing Epidemiology Among *Staphylococcus aureus*

Since the publication of the “Making Health Care Safer” report in 2001, *Staphylococcus aureus* has gained considerable attention due to a number of factors. First, healthcare-associated

methicillin-resistant *S. aureus* infections increased rapidly with a high mortality rate.^{2,7} However, since 2007 rates of healthcare-associated MRSA have begun to decline.¹⁴ Second, community-associated MRSA infections caused by the USA300 clone emerged between 1999 and 2001.¹⁵ USA300 MRSA has caused severe infections in previously healthy people with no prior contact with the health care system, thus alarming both health care professionals and the general public.¹⁵ Additionally, USA300 MRSA infections have not replaced healthcare-associated MRSA infections (e.g. USA100), rather they have occurred as a separate epidemic leading to an increasing number of MRSA infections.¹⁶ Third, isolated cases of vancomycin-resistant *S. aureus* (VRSA), first recognized in 2002, have led to fears that failure to control VRE and MRSA transmission may lead to a new epidemic of VRSA, which will be very difficult to treat.⁵⁻⁷

Hypervirulent Strains of *Clostridium difficile* Have Emerged

The epidemiology of *C. difficile* has also changed since the publication of the “Making Health Care Safer” report. A ‘hypervirulent’ strain known as PCR ribotype 027, restriction endonuclease analysis group BI, and North American PFGE pulsotype 1 (027/BI/NAP1) has emerged worldwide and is associated with increased morbidity and mortality.^{17,18} In fact, U.S. mortality due to *C. difficile* increased from 793 deaths in 1999 to 6,372 deaths in 2007.³ Many countries, including the United States, have also reported an increased incidence of community-associated *C. difficile* infections among previously healthy people.^{17,19}

What Methods of Infection Control Are Currently Being Studied?

There is great debate in the field of infection control over whether vertical or horizontal approaches should be used to prevent healthcare-associated infections.⁸ Active surveillance, a vertical approach because it focuses only on one organism, has been credited with the low rates of morbidity and mortality from MRSA in northern Europe and in Western Australia.^{20,21} Proponents of active surveillance argue that active surveillance and isolation, which has prevented spread of other nosocomial pathogens such as smallpox and severe acute respiratory syndrome, can also be used to contain MRSA or VRE.^{20,22,23} Proponents of active surveillance acknowledge that a single-pathogen approach is not ideal; however, current horizontal approaches have not decreased healthcare-associated infection rates significantly.²⁰ Furthermore, active surveillance and isolation for asymptomatic carriers could prevent transmission of MRSA or VRE through multiple routes such as directly from one patient to another, via health care workers’ contaminated hands or clothing, and via the environment.²⁴

In contrast, proponents of a horizontal approach argue that hospitals should implement interventions that will decrease the spread of all healthcare-associated infections, which would decrease the overall rate of healthcare-associated infections.^{8,25,26} Advocates of a horizontal approach also argue that strategies focusing on active surveillance and contact isolation for MRSA or VRE will not prevent spread of susceptible *S. aureus* or *enterococcus*, spread of other resistant organisms, or endogenous infections in patients already colonized with MRSA or VRE. Also, active surveillance programs that only assess one body site will miss colonization of other body sites.²⁵ The increasing burden of antibiotic-resistant infections, including highly transmissible pathogens such as *Acinetobacter baumannii*, cannot currently be prevented through active surveillance.^{27,28} Furthermore, the costs for active surveillance may decrease the funds available to implement other important infection prevention interventions.²⁶

Even current guidelines disagree over the use of active surveillance for MRSA or VRE. The Society for Healthcare Epidemiology of America (SHEA) Guideline for Preventing Nosocomial

Transmission of Multidrug-Resistant Strains of *Staphylococcus aureus* and *Enterococcus*, as well as Dutch and British guidelines, recommend routine screening of high-risk patients for MRSA or VRE. However the Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee (CDC HICPAC) Guideline on Management of Multidrug-Resistant Organisms in Healthcare Settings, as well as an Australian guideline, recommend active surveillance as a targeted measure to be implemented only when the incidence or prevalence of MRSA or VRE is not decreasing despite other infection control strategies.^{7,29-32}

Evidence for Effectiveness of Infection Control Practices

Multiple systematic literature reviews concluded that the evidence for interventions for the prevention and control of multidrug-resistant organisms were of poor quality and that definitive recommendations could not be made.^{10,33-35} However, a large number of new articles have been published on these topics including multiple studies with large patient populations and have not been included in these systematic reviews.^{13,24,36,37}

Four large studies have assessed the effectiveness of active surveillance plus contact isolation for preventing spread of MRSA or VRE. Robicsek et al. performed a three-phase quasi-experimental study in three hospitals. Phase one was a baseline assessment in which no intervention was performed. Phase two included surveillance for MRSA in ICUs and contact isolation for MRSA carriers. Phase three expanded to whole-hospital universal surveillance for MRSA, contact isolation for MRSA carriers, and decolonization of MRSA carriers with topical mupirocin. These investigators demonstrated that the aggregate hospital-associated MRSA disease prevalence density decreased by 36.2% (P=0.17) from baseline to ICU surveillance and by 69.6% (P =0.03) from baseline to universal surveillance.³⁶

Similarly, investigators in the Veterans Health Administration performed a quasi-experimental study to assess their nationwide MRSA Prevention Initiative. This initiative was composed of an MRSA prevention bundle which included (1) hand hygiene promotion, (2) an infection prevention culture change, and (3) whole-hospital universal surveillance for MRSA and contact isolation for MRSA carriers. In their analysis of all 153 Veterans affairs hospitals, they found that the rates of healthcare-associated MRSA infections declined by 45% in non-ICUs and by 62% in ICUs after the Initiative was implemented.²⁴

In contrast, Harbarth et al. implemented active surveillance for MRSA carriers in six surgical wards while six other surgical wards served as a control. After a washout period, the intervention and control wards were switched. MRSA carriers identified by active surveillance received a bundled intervention which included contact isolation, adjustment of perioperative antibiotic prophylaxis, and topical decolonization (nasal mupirocin ointment and chlorhexidine body washing). This study did not find a significant change in MRSA infections (adjusted incidence rate ratio, 1.20; 95% confidence interval, 0.85-1.69; P=0.29).³⁷

Finally, the STAR*ICU Trial was a cluster-randomized trial of 18 ICUs. This study randomized eight ICUs to standard of care and ten ICUs to a bundle that included universal surveillance for MRSA and VRE, contact isolation for MRSA or VRE positive patients, and universal gloving until surveillance culture results were negative for all other ICU patients. That study found no difference between the intervention and control groups in terms of mean ICU-level incidence of colonization or infection with MRSA or VRE per 1,000 patient-days (40.4±3.3 and 35.6±3.7 in the two groups, respectively; P = 0.35).¹³

These four studies differed in multiple ways. First, the two studies with positive results assessed their interventions both in the ICUs and universally throughout the health care

institutions, while the two studies with negative results only assessed their interventions in ICUs or surgical wards. Each study implemented a unique bundle in which the only common factor in all four bundles was active surveillance plus contact precautions. For example, both the Harbarth and Robicsek included nasal decolonization while the other two studies did not. The studies also varied in how their laboratory testing was performed. For example, in the Veterans Health Administration study, surveillance samples were tested at the local clinical microbiology laboratory. In contrast, in the Star*ICU study, all surveillance samples were mailed to the Clinical Microbiology Laboratory of the National Institutes of Health Clinical Center. Interestingly, when comparing all four of these studies, the studies with negative results had stronger study designs.

The studies above assessed active surveillance among ICU patients. Admission to the ICU is a large risk factor for healthcare-associated infections, therefore, it may be cost-effective to target only ICU patients for active surveillance rather than the entire hospital.³⁸ The high cost of active surveillance has led to multiple cohort studies with the goal of establishing a rule to predict which patients are at high risk for MRSA or VRE colonization.³⁹ A prediction rule would help infection prevention staff determine which patients are likely to carry MRSA or VRE and, thus, could transmit MRSA or VRE to other patients or could acquire an MRSA or VRE infection. Ideally, screening the patients identified as high risk of colonization would be more cost-effective and take less time than testing all patients for MRSA or VRE using traditional active surveillance. Many prediction rules include recent admission to the hospital, which is a strong predictor of MRSA and VRE colonization, with sensitivities ranging from 44% to 77% and specificities ranging from 46% to 98%.^{38,40-45} Prediction rules have also included risk factors for colonization such as prior operation, hemodialysis, prior history of MRSA or VRE, transfer from long-term care facility, age, antimicrobial use during the past year, and a current wound. If these prediction rules were applied, the proportion of MRSA or VRE colonized patients who would be missed ranged from 15% to 43%.^{38,40-45} Thus, current prediction rules have had varying success.

Similarly, three studies have created prediction rules to predict patients at high risk for *C. difficile* infection.^{46,47} The first prediction rule included age, *C. difficile* infection pressure, recent admission to the hospital, severity of illness score, days of high-risk antibiotic use, low albumin level, ICU admission, and receipt of laxatives, gastric acid suppressors or antimotility drugs.⁴⁶ The second rule only included the Waterlow score, a nursing tool routinely used to assess a patient's risk of developing a pressure ulcer.⁴⁷ The third rule included age, hemodialysis and length of ICU stay.⁴⁸ The sensitivity of the *C. difficile* infection prediction rules ranged from 60% to 70% and the specificity ranged from 89% to 95%.^{46,47}

Horizontal approaches to infection control could utilize contact precautions without the use of expensive laboratory surveillance tests. A single ICU, quasi-experimental study of a bundle which included universal contact precautions found that not only did this bundle stop an outbreak of multidrug-resistant *Acinetobacter baumannii*, it also led to a decrease in MRSA acquisition from 14% to 10%, and VRE acquisition from 21% to 9%.¹¹ Two quasi-experimental studies compared universal gloving (wearing a new pair of gloves for each patient) to active surveillance and contact precautions in a single ICU.^{49,50} Active surveillance and contact precautions included VRE and MRSA surveillance cultures on admission and every 4 days with contact precautions for patients colonized or infected with VRE or MRSA. Both studies found no difference in MRSA or VRE colonization no matter which intervention was implemented. However, one study

found an increase in nosocomial infection rates during the universal glove period, potentially due to decreased compliance with hand hygiene after removal of gloves.⁴⁹

Another horizontal approach would be to place patients at high risk for acquiring a healthcare-associated infection under pre-emptive contact precautions.^{51,52} One ICU found that their intubated patients were eight times more likely to acquire healthcare-associated MRSA compared with non-ventilated patients, thus they performed a quasi-experimental study to assess an intervention where all intubated patients were placed under pre-emptive contact precautions. In the first phase of the study, active surveillance for MRSA was performed at ICU admission and weekly with contact precautions for MRSA positive patients. In the second phase of the study, active surveillance and contact precautions for MRSA remained, however all intubated patients were also placed on contact precautions. This study found a decrease in healthcare-associated MRSA infections for both intubated patients ($p=0.02$) and in all ICU patients ($p<0.05$).⁵²

Less is known about optimal methods to prevent *C. difficile* transmission compared with VRE and MRSA.⁵³ Most studies of *C. difficile* prevention are simple quasi-experimental studies that test a bundled intervention. Multiple recommendations and guidelines suggest contact isolation for symptomatic *C. difficile* infected patients only.^{17,53,54} Contact isolation for *C. difficile* infected patients should include single rooms with private toilets if possible.¹⁷ According to the SHEA/IDSA Expert Panel, the only two approaches to preventing *C. difficile* with good evidence to support them are wearing gloves when caring for an infected patient and antimicrobial stewardship.^{17,54} No data currently support isolating asymptomatic *C. difficile* carriers.^{53,54} An unresolved issue is whether to place symptomatic patients with a history of *C. difficile* infection under contact precautions.¹⁷

Some Potential for Harm Is Associated With Contact Precautions

At the time that “Making Health Care Safer” was published, very few studies assessed the potential harm associated with contact isolation. Recent studies, including a systematic literature review, found that contact precautions have been associated with less patient-to-health care worker contact, changes in systems of care that produce delays and more noninfectious adverse events (e.g., falls, pressure ulcers), increased symptoms of depression and anxiety, and decreased patient satisfaction with care.⁵⁵⁻⁵⁹

Costs and Implementation of Infection Prevention Interventions Have Been Examined

Both vertical and horizontal interventions to prevent healthcare-associated infections require upfront investments to pay for components of the intervention such as supplies (e.g., gowns and gloves) and laboratory resources (e.g., tests, personnel).⁹ However, a business case can be made for these interventions since the estimated median cost of a healthcare-associated infection ranges from \$26,424 to \$34,657 for MRSA and from \$17,1438 to \$36,380 for VRE.⁶⁰⁻⁶⁴ Two studies found that clinical active surveillance of ICU patients for VRE or MRSA colonization was cost effective compared with the cost savings of preventing these infections.^{63,65} Similarly, another study found that active surveillance and isolation for VRE colonization among high-risk patients cost effective.⁶⁶ A mathematical model compared whole hospital universal active surveillance for MRSA to targeted active surveillance for MRSA and found that targeted surveillance was more cost effective.⁶⁷

The cost-effectiveness studies estimated that the cost of active surveillance and contact isolation strategies for MRSA or VRE to range from \$1,913 to \$10,545 per month.^{63,65,66} The mathematical model found that the average cost of targeted active surveillance of high risk patients ranged from \$4,100 to \$12,508 per infection averted depending on MRSA prevalence and screening test used, while the average cost of universal active surveillance ranged from \$5,799 to \$21,195 per infection averted.⁶⁷ When these costs were itemized, 13% to 99% of the total cost was spent on specimen collection and laboratory testing while the remaining proportion was spent on isolation (e.g., gowns, gloves, nurse time to don gowns and gloves).^{63,65-67} The vast differences in these proportions were due to how labor costs were accounted for. Studies varied as to how they assessed the cost of laboratory technologists, cost of nursing time to collect swabs, and cost of nursing time to don and remove gowns and gloves.

Although cost-effectiveness analyses have not been performed for universal contact precautions to prevent healthcare-associated infections, an analysis by Wenzel et al., compared the cost-effectiveness of active surveillance and contact precautions for MRSA to a population-based infection control approach. This analysis assumed that active surveillance for MRSA would cost approximately \$600,000 while the population-based approach would cost approximately \$300,000. If the active surveillance program reduced MRSA infections by 50% and the population-based approach reduced healthcare-associated infections by 50%, then the active surveillance program would save \$245 million to \$980 million nationally while the population-based intervention would save \$1.75 billion to \$7 billion nationally.²⁶

As with all health care interventions, health care worker support and implementation of the intervention is necessary for the intervention to be successful. The STAR*ICU trial noted suboptimal implementation of their interventions. That study demonstrated that when contact precautions were specified, gloves were used for 82% of contacts, gowns for 77% of contacts, and hand hygiene was performed after gloves were removed for 69% of contacts. Additionally, when universal gloving was specified, gloves were used for 72% of contacts and hand hygiene was performed after gloves were removed for 62% of contacts.¹³ The Veterans Health Administration's MRSA initiative includes a dedicated MRSA coordinator at each acute care hospital responsible for implementation of the initiative. From the beginning of the initiative in 2007 to the end of the study period in 2010, compliance with surveillance nasal screening for MRSA increased, with the percentage of patients who were screened at admission rising from 82% to 96%, and the percentage who were screened at transfer or discharge rising from 72% to 93%. However adherence to contact precautions was not reported.²⁴ Two studies by Bearman and colleagues found that observed compliance was higher during a universal glove intervention compared with observed compliance with contact precautions (gowns and gloves) during an active surveillance plus contact precaution intervention. However, the studies found conflicting results as to when hand hygiene compliance was greater. The first study found that the active surveillance and contact precautions intervention was associated with greater compliance with hand hygiene compared with hand hygiene compliance during the universal gloving intervention.⁴⁹ The second study, which included hand hygiene in-service trainings, found that compliance with hand hygiene was higher during the universal gloving phase compared with the active surveillance and contact precautions phase.⁵⁰

Upcoming Studies

Of late, two multicenter cluster-randomized trials of contact precautions have been implemented. The Cluster Randomized Trial of Hospitals to Assess Impact of Targeted versus

Universal Strategies to Reduce MRSA in ICUs (REDUCE – MRSA trial) recently finished collecting data on the effectiveness of the following strategies: (1) MRSA active surveillance of ICU admissions, followed by contact isolation if positive, (2) MRSA active surveillance of ICU admissions followed by nasal decolonization if positive, and (3) universal nasal decolonization of ICU admissions without screening.⁶⁸ The Benefits of Universal Glove and Gowning Study (BUGG Study) is currently comparing the effectiveness of universal contact precautions to standard of care in multiple ICUs in order to determine whether universal gowns and gloves decrease the overall burden of healthcare-associated pathogens in the ICU setting. The results of these studies should be available soon and will add to the growing body of evidence on interventions to control healthcare-associated infections.¹²

Conclusions and Comment

Although many studies have been performed since the “Making Health Care Safer” report, there is still much debate as to which interventions should be implemented to prevent healthcare-associated infections. Vertical interventions, such as active surveillance for MRSA or VRE, have been studied the most; however, these studies have had conflicting results. Horizontal approaches, such as universal gloving, have the potential to reduce the burden of all health care-associated pathogens; however these approaches have been understudied. Current evidence should be considered by individual institutions to determine which interventions are right for their institution based on their patient population, problem pathogens, and ability to implement interventions.⁶⁹ For example, universal active surveillance for MRSA may be optimal for hospitals with endemic MRSA throughout their hospital, whereas ICU-level universal contact precautions may be recommended for hospitals with multidrug-resistant *Acinetobacter baumannii* transmission in their ICU. Interventions such active surveillance, contact precautions, and contact isolation should not be performed alone. Rather, these interventions must be performed in conjunction with other infection control interventions such as hand hygiene and antimicrobial stewardship. In conclusion, high quality studies are still needed to determine the optimal interventions to reduce healthcare-associated infections. A summary table is located at Table 1, Chapter 7.

Table 1, Chapter 7. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate	Moderate (isolation of patients)	Moderate-to-high	Moderate/Moderate

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Chapter 8. Interventions To Improve Hand Hygiene Compliance: Brief Update Review

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Introduction

Healthcare-associated infections account for approximately 80,000 deaths per year in the United States.¹⁻³ A worldwide systematic review found that the incidence of healthcare-associated infections ranged from 1.7 to 23.6 per 100 patients. Hospital costs directly related to healthcare-associated infections ranged from \$28.4 to \$33.8 billion in 2007 U.S. dollars.⁴ Yet these infections are frequently preventable through hand hygiene.

Substantial epidemiologic evidence supports that hand hygiene reduces the transmission of healthcare-associated pathogens and the incidence of health-care associated infections.⁵ The link between hand hygiene and improvements in healthcare-associated infections is hard to prove definitively in modern-day health care. However, the importance of hand hygiene is universally acknowledged by organizations such as the Joint Commission, World Health Organization (WHO) and Centers for Disease Control (CDC), which recommend or require hand hygiene practices and interventions to improve hand hygiene compliance in order to reduce health care-acquired infections.⁵⁻⁷ This review will therefore focus on interventions to improve compliance with hand hygiene, rather than on the efficacy of hand hygiene for reducing healthcare-associated infections.

Compliance with hand hygiene practices among health care workers has historically been very low, averaging 39 percent.⁵ The review on hand hygiene compliance and interventions aimed at improving it that was conducted for the original 2001 “Making Health Care Safer” report found that poor compliance has been documented in studies across hospital unit types and in various other settings. Workers tend to underestimate the importance of compliance and often overestimate their compliance with hand hygiene procedures.¹ The report concluded that future research studies needed to identify reasons for poor compliance and design sustainable interventions that target these factors. The aim of this review is to assess the evidence for the impact of interventions on hand hygiene compliance since that report.

What Is Hand Hygiene Compliance?

Hand hygiene is a general term for removing microorganisms with a disinfecting agent such as alcohol or soap and water.¹ Hand hygiene should be conducted by health care workers before seeing patients, after contact with bodily fluids, before invasive procedures, and after removing gloves.⁶ The WHO offers a slight variation by recommending five key moments when health care workers should practice hand hygiene: before patient contact, before an aseptic task, after bodily fluid exposure risk, after patient contact, and after contact with patient surroundings.⁵ The National Quality Forum’s “Safe Practices for Better Healthcare 2010 Update” and the Joint Commission recommend that organizations should implement CDC or WHO guidelines, encourage staff compliance with guidelines with category II evidence, and ensure staff comply with organizational rules regarding hand hygiene (see section below on implementation for details).^{6,7}

Monitoring health care workers' compliance with hand hygiene practices is vital for evaluating whether interventions are successful. WHO recommends using a validated methodology for training observers to directly monitor hand-hygiene using "My five moments for hand hygiene."⁵ Other methods for monitoring include patient-observations, measuring of hand hygiene product consumption (either by volume of product used or through electronic counting devices), and electronic hand hygiene compliance monitoring systems (e.g. real-time location systems, dedicated monitoring systems or video monitoring).⁸

Hand hygiene interventions include both single and multi-level interventions. These interventions include staff and/or patient education and involvement, feedback initiatives, cultural change, organizational change, social marketing, additional sinks or alcohol dispensers, or a combination of the above.^{1,9}

Advocates of hand-hygiene improvement interventions recommend that multimodal interventions are needed to induce sustained hand-hygiene practice improvements, and should be based on theories of behavior change. On the individual level, the intervention should target provider education and motivation regarding hand-hygiene practices; on the interpersonal level, patient empowerment and cues to action should reinforce proper hand-hygiene practices; and on the organization level, organizational structure and philosophy needs to be supportive of proper practices.⁵

How Have Interventions To Improve Hand Hygiene Compliance Been Implemented?

Several major hand hygiene compliance programs have been developed and made publicly available from the CDC, Institute for Healthcare Improvement, Joint Commission, and WHO, and are widely implemented in health care institutions.

The CDC has published a guideline, interactive training and educational materials, and posters for hand-hygiene compliance.¹⁰ The guideline provides suggestions for health care worker educational and motivational programs; these suggestions include stating a rationale for, and providing information regarding, when hand-hygiene is required; and providing proper hand hygiene techniques, methods to maintain skin health, expectations of managers, and indicators for glove use.¹¹ The interactive tools include a set of PowerPoint® slides and speaker notes that provide background information on the importance of hand-hygiene, indications on when to use hand-hygiene practices and how to properly clean ones' hands, and educational/motivational programs.¹² Promotional posters aiming to demonstrate proper hand-hygiene and remind health care workers of the importance of hand-hygiene are also available.⁶

The Institute for Healthcare Improvement, in collaboration with the CDC, the Association for Professionals in Infection Control and Epidemiology, and the Society of Healthcare Epidemiology of America, created a how-to guide on improving hand-hygiene among health care workers for organizations. This guide includes evidence-based interventions, goal-setting suggestions, evaluation suggestions, and measurement tools. The intervention is a multi-faceted approach with four key aims: (1) to improve knowledge of proper hand hygiene practice; (2) to have workers demonstrate hand hygiene knowledge; (3) to ensure the availability of alcohol-based rub and gloves at the point of care; and (4) to ensure that competency in hand hygiene is regularly verified, compliance is monitored, and appropriate feedback loops are in place.¹³

The Joint Commission created a monograph to help health care organizations properly measure hand hygiene performance. Content for the monograph came from examples of methods and tools submitted through the Consensus Measurement in Hand Hygiene Project and published

literature.¹⁴ The monograph includes a comprehensive review of three measurement methods, including surveys, measuring product use, and directly observing hand hygiene. Additional information includes a review of ways to display data, intervention strategies, and additional supplementary resources.

In 2009, the WHO published an extensive report, including a background on transmission of infections, guidelines for proper hand-hygiene protocol; social, cultural, and behavioral aspects of hand-hygiene; consensus recommendations; process and outcome measurement; and patient involvement in hand-hygiene.⁵ A multimodal strategy was found to be necessary to improve compliance; therefore recommendations for proper hand hygiene span different levels. For providers, washing hands when visibly dirty, and using alcohol-based hand rub before and after contact with a patient, contaminated surface, or medicine is critical. Additionally, they should not wear artificial nails. Organizations should provide information to workers regarding hand-hygiene practices that reduce skin irritation and provide lotions or creams to minimize the occurrence of skin irritation. When designing an intervention to increase proper hand hygiene, a multi-faceted, multi-modal intervention should be used, practices should be monitored, and feedback loops should be implemented. Health care administrators should ensure structural and cultural factors are conducive to hand-hygiene practices, including ensuring access to alcohol-based hand-rub and/or a continuous water supply at the point of care, and making compliance with a multi-faceted intervention an institutional priority.⁵ Individual factors, such as normative beliefs (peer behavior), perceived control, and attitude (awareness of being observed) should also be addressed since they were found to be important predictors of hand hygiene adherence. The WHO provides training and education tools such as a template for creating an action plan, an observation form for monitoring hand-hygiene compliance, training films, and educational brochures. All tools were tested in eight official pilot sites in seven countries before being finalized.⁵

What Have We Learned About Hand Hygiene Interventions?

A recent review determined that a successful hand hygiene educational program has several key features. These features include reinforcement of hand hygiene messages; knowledge of health care workers' perceived importance of hand hygiene and its role in prevention of healthcare-associated infections; monitoring and feedback of hand hygiene practices; practical education tools; role-modeling by senior staff; and supportive infrastructure and management. Interventions should be multimodal, and teaching methodology should be progressive and include different types of methods. The educational program itself should be designed to include local structure, priorities, and resources.¹⁵ Additionally, as stated above, across several studies, the 2009 WHO report found hand hygiene practices should be multimodal, and structurally and culturally tailored to improve compliance with hand hygiene.⁵

What Methods Have Been Used To Improve Hand Hygiene Compliance?

The 2001 "Making Health Care Safer" report discussed studies that aimed to improve hand hygiene through education, feedback, installation of sinks and alcohol-based solution, and organizational changes.¹ "Making Health Care Safer" included 14 non-randomized controlled or before-after studies, 13 of which measured hand hygiene compliance through direct observation, most in the intensive care unit setting. Interventions included increasing sink or alcohol-based

solution availability, education, and multifaceted interventions, including feedback. Ten studies found a statistically significant increase in compliance, and four did not. Three studies evaluated longer-term results and found that compliance rates decreased after the intervention ended.¹

Impact of Interventions on Hand Hygiene Compliance

Since 2001, two major systematic reviews have been published on the impact of interventions on hand-hygiene compliance.

A 2010 Cochrane systematic review (an update of a 2007 review) found insufficient evidence that hand-hygiene interventions improve hand hygiene in the hospital setting.⁹ The review included randomized controlled trials, controlled clinical trials, controlled before and after studies, and interrupted time series analyses that met the criteria of the Cochrane Effective Practice and Organization of Care Group from 1980-2009. Eligible outcomes included indicators of compliance with hand hygiene or proxy indicators such as use of product; operating room studies were excluded. Four studies were included, with one study finding a statistically significant improvement in hand hygiene 4 months post-intervention, two studies finding a statistically significant increase in product use which was sustained at one site for 2 years, and one study finding no effect in the intervention compared with the control group 3 months post-intervention. Studies focused on educational campaigns and promotion of guidelines, as well as a multifaceted intervention to improve compliance. Simple substitution of a product with alcohol-based hand rub did not significantly increase product use.⁹

A 2008 systematic review addressed studies evaluating hand-hygiene interventions and healthcare-associated infections in acute and long-term care settings (not the impact of the interventions on compliance with hand hygiene).¹⁶ Studies included multifaceted initiatives, introduction of new hand-hygiene products, and implementation of infection control practices and policies, surveys, and electronic monitoring. The review included before and after studies with and without control groups and cohort studies with no controls. Eighteen of 31 included studies (58%) reported a statistically significant reduction in healthcare-associated infections with the intervention compared with the control group; some studies also included other factors that may have influenced the reductions in healthcare-associated infections.

Patient Engagement

A 2011 review by McGuckin and colleagues found evidence of the importance of patient engagement or empowerment and multi-model strategies in hand-hygiene interventions. The authors found that patient empowerment comprised patient participation, knowledge, skills, and a facilitating environment for their participation in hand hygiene. The majority of patients agreed that they would ask their health care workers to wash their hands (80% to 90%), especially if encouraged to ask. However, the authors found scarce literature on the efficacy of patient empowerment interventions to improve health care worker hand hygiene and were unable to conduct a traditional evidence-based review.¹⁷

Conclusions and Comment

In conclusion, although it is well-accepted that hand hygiene is a critical patient safety practice for reducing healthcare-associated infections, compliance with this practice is often low. Well-developed tools are available for implementing hand hygiene interventions, although high-quality evidence demonstrating which interventions are most effective is lacking. Reviews have found that the results of hand hygiene compliance interventions were mixed, with effectiveness

waning over the long term. A recent systematic review focusing on higher quality evidence found only four studies, three of which showed a significant impact. Another recent review found mixed results for the impact of hand hygiene interventions on rates of healthcare-associated infections. A variety of interventions to improve hand hygiene are being implemented and promoted by various U.S. and international organizations, particularly educational programs, monitoring, and feedback. Interventions should be multimodal, addressing providers' knowledge, attitudes, and beliefs regarding hand hygiene, as well as strategies for behavioral change, and should ideally be tailored to institutional needs as well as different provider groups and health care situations. Health care administrators embarking on a hand hygiene intervention should take advantage of the tools developed by the CDC and the WHO. New strategies, such as patient engagement in hand-hygiene interventions, are an emerging area with only a few studies assessing their effectiveness, and need further research on how best to implement them effectively. Finally, research may be directed toward understanding the effectiveness of specific elements of hand hygiene interventions, and the context in which they are implemented, in order to understand which combinations lead most reliably to success. A summary table is located in Table 1, Chapter 8.

Table 1, Chapter 8. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Low	Low	Low	Moderate/Moderate

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Chapter 9. Reducing Unnecessary Urinary Catheter Use and Other Strategies To Prevent Catheter-Associated Urinary Tract Infections: Brief Update Review

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Introduction

Urinary tract infection has long been considered the most common healthcare-associated infection (HAI), with the vast majority of these infections occurring after placement of the convenient, often unnecessary,¹⁻³ and easily forgotten urinary catheter.⁴ With an estimated one million catheter-associated urinary tract infections⁵ (CAUTIs) per year, associated with an additional cost of \$676 per admission (or \$2836 when complicated by bacteremia),⁶ it is not surprising that CAUTIs were among the first hospital-acquired conditions selected for non-payment by Medicare as of October 2008,⁷ and have been further targeted for complete elimination⁸ as a “never event,” with a national goal to reduce CAUTI by 25% and reduce urinary catheter use by 50% by 2014.^{9,10} These national initiatives renewed public and research interest in the prevention of CAUTI, prompting updates of several comprehensive guidelines¹¹⁻¹⁴ and reviews of strategies to prevent CAUTI released since the 2001 “Making Health Care Safer” report.¹⁵

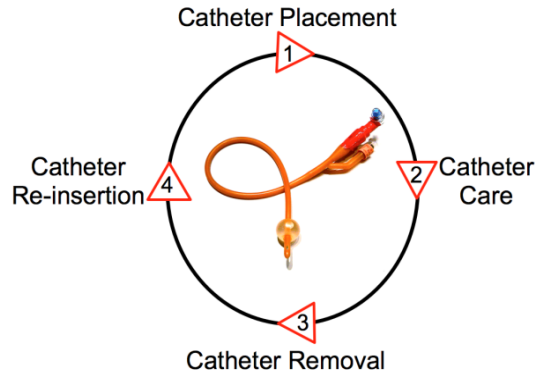
What Strategies May Prevent Catheter-Associated Urinary Tract Infections?

Similar to other hospital-acquired infections — such as central line-associated blood stream infection (CLABSI) — many CAUTI prevention strategies have been “bundled” into multi-modal sets of interventions known as “bladder bundles,”¹⁶ consisting of educational interventions to improve appropriate use and clinical skill in catheter placement, behavioral interventions such as catheter restriction and removal protocols, and use of specific technologies such as the bladder ultrasound. Despite some early success in implementing a “bladder bundle”¹⁶ to reduce urinary catheterization rates,¹⁷ CAUTI prevention has proven challenging for several important reasons. For example, monitoring urinary catheter use and CAUTI rates to inform and sustain urinary catheter-related interventions is very resource intensive. Perhaps more importantly, improving practice regarding urinary catheter placement and removal also requires interventions to change the expectations and habits of nurses, physicians, and patients about the need for urinary catheters.

To help organize and prioritize the many potential interventions to prevent CAUTI, we use the conceptual model of the “lifecycle of the urinary catheter”¹⁸ to highlight that the highest yield interventions to prevent CAUTI will target at least one of the four “stages” of the catheter’s “life.” As illustrated in Figure 1, the “lifecycle” of the catheter (1) begins with its initial placement, (2) continues when it remains in place, day after day, (3) ceases when it is removed, and (4) may start over if another catheter is inserted after removal of the first one.

Figure 1, Chapter 9. Lifecycle of the urinary catheter¹⁸

This conceptual model illustrates four stages of the urinary catheter lifecycle as targets for interventions to decrease catheter use and catheter-associated urinary tract infections.



Meddings J, Saint S. Disrupting the Life Cycle of the Urinary Catheter. *Clin Infect Dis*. 2011; 52(11): 1291-3 by permission of Oxford University Press.

Because avoiding unnecessary urinary catheter use is the most important goal in prevention of CAUTI, this chapter reviews the evidence on two types of interventions that target unnecessary urinary catheter use: (1) protocols and interventions to decrease unnecessary *placement* of urinary catheters (catheter lifecycle stage 1), and (2) interventions that prompt *removal* of unnecessary urinary catheters (catheter lifecycle stage 3).

The evidence summarized in this chapter was generated using a literature search conducted for a prior systematic review and meta-analysis¹⁹ along with a focused update of the published peer-reviewed literature (from August 2008 to February 2012) through a MEDLINE search for intervention studies to reduce use of unnecessary urinary catheters in the acute care of adults. A CINAHL database search was also performed for interventions developed and implemented by nurses related to urinary catheter use. Studies were included if at least one outcome involving catheter use or CAUTI events (Table 1) was reported as a result of the intervention, and with a comparison group (either pre- vs. post-intervention or a separate control group).

Table 1, Chapter 9. Description of outcomes evaluated (adapted from the prior meta-analysis¹⁹)

Measures of Catheter-Associated Urinary Tract Infection (Cauti) Development	Number of CAUTI episodes per 1,000 catheter-days was recorded and a rate ratio was calculated to compare pre- vs. post-intervention. When rates of both asymptomatic and symptomatic CAUTI were reported separately, ²⁰ the rates of symptomatic CAUTI were used for the meta-analysis. ¹⁹
	Cumulative risk of CAUTI during hospitalization (i.e., the percentage of patients who developed CAUTI) was also extracted for each study, and a risk ratio was calculated to compare risks before and after the intervention for the meta-analysis. ¹⁹
Measures of Urinary Catheter Use	Mean number of days of urinary catheter use per patient was recorded before and after the intervention, and a standardized mean difference (SMD) was calculated to compare the two groups for the meta-analysis. ¹⁹
	Percentage of patient days in which the catheter was in place was calculated before and after the intervention, and a standardized mean difference (SMD) was determined for each study for the meta-analysis. ¹⁹
	Daily catheter prevalence , defined as the number of patients with catheters in place during a specific time period, is reported for some of the more recent studies.
Need for Catheter Replacement	Re-catheterization need was extracted as the number and percent of patients who required replacement of a catheter after prior removal of an indwelling catheter.

The table in Appendix D summarizes the intervention studies described in this review, including study designs, patient populations, and the interventions employed to avoid unnecessary catheter placement or to prompt catheter removal. Meddings J, Rogers MA, Macy M, et al. Systematic review and meta-analysis: reminder systems to reduce catheter-associated urinary tract infections and urinary catheter use in hospitalized patients. Clin Infect Dis. 2010;51(5):550-60 by permission of Oxford University Press.

What Strategies May Reduce Unnecessary Catheter Use?

Strategies To Avoid Unnecessary Placement of Indwelling Urinary Catheters

Simply put, patients without urinary catheters do not develop CAUTI. Yet, multiple studies show that between 21 and 63 percent^{1,3,21-24} of urinary catheters are placed in patients who do not have an appropriate indication and therefore may not even need a catheter. Over the past decade, several studies have employed interventions to decrease unnecessary catheter placement (described in Appendix D Table). Although educational interventions are a common and important first step to decrease inappropriate catheter use, more effective and potentially more sustainable interventions go a step further by instituting restrictions on catheter placement. Protocols that restrict catheter placement can serve as a constant reminder for providers about the appropriate use of catheters, can suggest alternatives to indwelling catheter use (such as condom catheters or intermittent straight catheterization), but perhaps most importantly, can generate accountability for placement of each individual urinary catheter. A fairly typical approach for developing a catheter restriction protocol is to begin with a basic list of appropriate catheter uses (such as provided in the Centers for Disease Control and Prevention’s Healthcare Infection Control Practices Advisory Committee (HICPAC) guideline¹¹); this list (Table 2) can then be tailored to include other indications based on local opinion and specialized patient populations.

Table 2, Chapter 9. Indications for indwelling urethral catheter use (from the 2009 CDC's guideline¹¹)

A. Examples of <i>Appropriate</i> Indications for Indwelling Urethral Catheter Use
Patient has acute urinary retention or bladder outlet obstruction
Need for accurate measurements of urinary output in critically ill patients
Perioperative use for selected surgical procedures: <ul style="list-style-type: none"> • Patients undergoing urologic or other surgery on contiguous structures of genitourinary tract • Anticipated prolonged surgery duration; catheters inserted for this reason should be removed in post-anesthesia care unit • Patients anticipated to receive large-volume infusions or diuretics during surgery • Need for intraoperative monitoring of urinary output
To assist in healing of open sacral or perineal wounds in incontinent patients
Patient requires prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures)
To improve comfort for end of life care if needed
B. Examples of <i>Inappropriate</i> Uses of Indwelling Catheters
As a substitute for nursing care of the patient or resident with incontinence
As a means to obtain urine for culture or other diagnostic tests when patient can voluntarily void
For prolonged postoperative duration without appropriate indications (e.g., structural repair of urethra or contiguous structures, prolonged effect of epidural anesthesia, etc.)

The technology required to implement catheter placement restrictions ranges from low technology strategies such as a hospital or unit policy on appropriate catheter placement or pre-printed catheter orders with limited indications to higher technology strategies such as computerized orders^{22,23,25} for catheter placement. Catheter restriction protocols have been a common component of successful multi-modal interventions to decrease catheter use and/or CAUTI rates, including hospital-wide²³ interventions and interventions tailored for specific environments such as the emergency department,^{21,26} inpatient units¹⁷ (including general medical^{25,27,28}-surgical²⁹ wards and ICU²⁹⁻³³), and in the peri-procedural³² setting. Urinary retention protocols^{22,28,29,32-34} are a type of catheter restriction protocols that often incorporate the use of a portable bladder ultrasound^{22,28,32,34,35} to verify retention prior to catheterization, and recommend use of intermittent catheterization rather than indwelling catheters to manage a common and often temporary issue.

Strategies To Prompt Removal of Unnecessary Urinary Catheters

Urinary catheters are commonly left in place when no longer needed.^{3,24} In most hospitals, four steps are required to remove a urinary catheter:¹⁸ (1) a physician recognizes the catheter is in place, (2) the physician recognizes the catheter is no longer needed, (3) the physician writes the order to remove catheter, and (4) a nurse removes the catheter. Thus, by default, hours and sometimes days may pass before an unnecessary catheter is recognized and removed. Because every additional day of urinary catheter use increases the patient's risk of infectious and non-infectious catheter-related complications, interventions that facilitate prompt removal of unnecessary catheters can have a strong impact. We describe below the evidence regarding strategies that may accelerate or bypass some of these four steps to prompt catheter removal.

Perhaps the most important CAUTI prevention strategy after placement of the catheter is to maintain awareness of the catheter's existence (in lifecycle stage 2 of Figure 1), as health care providers commonly forget the catheter is in place.⁴ Thus, a key step in prompting removal of unnecessary catheters is frequently (by day or by shift) reminding nurses and physicians that the catheter remains in place. Catheter reminder interventions include a daily checklist^{23,32,33,36,37} or verbal/written reminder^{31,38-42} to assess continued catheter need, a sticker reminder on the patient's chart^{35,43,44} or catheter bag,⁴⁵ or an electronic²³ reminder that a catheter is still in place.

Reminder interventions can be generated by nurses, physicians or electronic order sets, and can be targeted to remind either nurses or physicians about the catheter. Some reminder interventions have employed nurses dedicated to detecting unnecessary catheters.^{23,35} Reminder interventions can also serve to remind clinicians of appropriate catheter indications.

Unfortunately, reminder interventions can also be easy to ignore⁴³ and catheters may remain in place without action. The next type of intervention to prompt removal of unnecessary catheters, which goes a step further, is a “stop order” that requires action. Stop orders prompt the clinician (either nurse or physician) to remove the catheter by default after a certain time period has elapsed or condition has occurred, unless the catheter remains clinically appropriate. For example, catheter stop orders can be configured to “expire” in the same fashion as restraint or antibiotic orders, unless action is taken by a clinician. Stop orders directed at physicians^{23,25,28,30,42} require an order to be renewed or discontinued on the basis of review at specific intervals, such as every 24 to 48 hours after admission or post-procedure. Stop orders directed at nurses either require the nurse to obtain a catheter removal order from physicians,^{27,32,46} or can empower nurses to remove the catheter without requesting a physician order^{20,28,30,34,47-49} on the basis of an appropriate indication list. Admittedly, implementing a nurse-empowered catheter removal protocol may be less effective than anticipated, as early qualitative research of nurse-empowered interventions indicate some nurses are uncomfortable with this autonomy⁴⁹ and might not remove catheters as expected.

What Is the Impact of Strategies To Avoid Unnecessary Urinary Catheter Use?

Impact of Interventions To Avoid Unnecessary Catheter Placement

Multiple before-and-after studies of interventions to decrease inappropriate catheter placement (such as catheter placement restrictions and urinary retention protocols) have resulted in a decrease in the use of urinary catheters,^{21-23,28,29,31,33} a lower proportion of catheters in place without a physician order^{21,23,25,26} and a reduction in the proportion of catheters in place without an appropriate indication.^{21,23,26,28}

Impact of Reminder and Stop Order Interventions on Catheter Use and CAUTIs

A systematic review and meta-analysis of 14 studies¹⁹ published prior to August 2008 (including nine reminder interventions and five stop order interventions) demonstrated that the rate of CAUTI (episodes per 1,000 catheter-days) was reduced by 52 percent ($p < 0.001$) with the use of either a reminder or stop order. Based on this meta-analysis, reminders and stop orders could result in large numbers of avoided CAUTI episodes per 1,000 catheter-days, particularly when baseline rates of CAUTI are high (Table 3, adapted from a previous meta-analysis¹⁹).

Table 3, Chapter 9. Number of avoided CAUTI episodes per 1,000 catheter-days

Baseline rate of CAUTI episodes per 1,000 catheter-days	Number of avoided CAUTI episodes per 1,000 catheter-days anticipated by the type of intervention to prompt catheter removal		
	Reminder	Stop order	Overall
5	2.8	2.0	2.6 (95%CI, 1.6–3.6)
10	5.6	4.1	5.2 (95%CI, 3.2-7.2)
20	11.2	8.2	10.4 (95%CI, 6.4-14.4)

This meta-analysis¹⁹ also suggested that the mean duration of urinary catheterization decreased by 37 percent, with 2.61 fewer days of catheterization per patient in the intervention vs. control groups. The pooled standardized mean difference (SMD) in the duration of catheterization was -1.11 overall (p=0.070); a statistically significant decrease in duration was observed in studies that used a stop order (SMD -0.30; p=0.001) but not in those that used only a reminder intervention (SMD -1.54; p=0.071).¹⁹ An update of the literature review since this meta-analysis yielded 12 additional studies with reminder and/or stop order interventions. Figure 2 illustrates the major findings of the 14 studies for catheter use and CAUTI events as reported in the prior meta-analysis;¹⁹ Figure 3 illustrates the major findings for the 12 subsequent studies, including eight that reported measures of catheter use, and eight that reported CAUTI events.

Figure 2, Chapter 9. Summary of CAUTI and urinary catheter outcomes from 14 studies

■ Before Intervention or Control ■ After Intervention

First Author, Year	CAUTI Outcomes		Urinary Catheter Use Outcomes	
	CAUTI episodes per 1000 catheter days	% Patients who developed CAUTI	Mean Days of Urinary Catheter Use per Patient	% Patient Days with Catheter in Place
Apisarnthanarak, 2007	21.5 5.2 *		11.0 3.0 *	
Cornia, 2003		8.8 13.8	8.0 5.0 *	
Crouzet, 2007	12.3 1.8 *	10.6 1.1 *	8.4 6.7	
Dumigan, 1998	14.3 9.2			74 76
Fakih, 2008				20 16 *
Huang, 2004	11.5 8.3 *	3.8 2.4 *	7.0 4.6 *	
Jain, 2006	3.8 2.4			
Loeb, 2008		2.1 2.1	5.0 3.7 *	
Murphy, 2007	"Reduced UTI rates by 30%," other details not given			
Reilly, 2008			4.7 3.0	96 86
Saint, 2005			0.6 0.4 *	14 13 *
Stephan, 2006	45.8 18.6 *		5.0 3.9 *	
Topal, 2005	36.0 19.0 *	19.5 12.3		16 10 *
Weitzel, 2008		37 6.7	8.6 4.5	

Note: Summary comes from the 14 studies^{20,25,28-30,33,36-41,43,45} included in the 2010 meta-analysis.¹⁹

*Difference of p<0.05 reported between intervention and comparison group.

Figure 3, Chapter 9. Summary of CAUTI and urinary catheter outcomes from 12 additional studies

■ Before Intervention or Control ■ After Intervention

First Author, Year	CAUTI Outcomes		Urinary Catheter Use Outcomes		
	CAUTI episodes per 1000 catheter days	% Patients who developed CAUTI	Mean Days of Catheter Use per Patient	% Patient Days with Catheter	Daily Catheter Prevalence%
Bruminhent, 2010	7.02 2.08 *				
Elpern, 2009	4.7 0 *				
Fuchs, 2011	2.88 1.46				
Gotelli, 2008					24.0 17.0
Knoll, 2011					15.2 12.1 *
Robinson, 2007		40.0 13.3	8.6 4.5		
Rothfield, 2008	3.2 2.4			33 19 *	
Schultz, 2011				90-95 76-84	
Seguin, 2010	5.0 4.9	4.3 3.0	5.0 4.0 *		
van den Broek, 2011		12.6 12.7	ICU/CCU Medicine* Neuro Surgery* 0 15 30		ICU/CCU Medicine Neuro Surgery* 0 45 90
Voss, 2008			4.9 3.9	26 10	
Wenger, 2010	2.26 1.02 *				

Note: Summary comes from 12 additional studies^{23,27,31,32,34,35,42,44,46-49} since the prior meta-analysis.¹⁹

*Difference of p<0.05 reported between intervention and comparison group.

Potential for Unintended Harm by Catheter Removal Interventions

Interventions that facilitate removal of urinary catheters do pose the risk of premature urinary catheter removal, with patients then requiring unnecessary recatheterization; any catheterization event is associated with procedure-related discomfort and other potential complications. Thus, monitoring the need for re-catheterization is important to avoid unintended patient harm. In the meta-analysis of reminder and stop order studies, only four of the 14 studies reported rates of re-catheterization^{20,25,39,43} with low re-catheterization rates noted in both intervention and control groups. None of the 12 more recent studies involving reminders or stop orders to prompt catheter removal reported data on potential patient harm, such as premature removal.

Summary of Other Strategies To Prevent CAUTI

Several recent evidence-based guidelines¹¹⁻¹⁴ have focused on preventing CAUTI and have assessed the evidence and provided recommendations for implementing prevention strategies. Key recommendations in the CDC guideline,¹¹ in addition to appropriate catheter use (Table 2), include (1) aseptic insertion of urinary catheters by properly trained personnel, using aseptic technique and sterile equipment (with an exception being that clean technique is appropriate for chronic intermittent catheterization), and (2) proper urinary catheter maintenance with a sterile, closed drainage system permitting unobstructed urine flow. Aseptic insertion is primarily recommended as a standard of care for which limited evidence exists. Stronger evidence (epidemiological and clinical) supports the importance of a sterile, closed, unobstructed urinary drainage system.

A more controversial topic is the use of antimicrobial catheters. Based on the current evidence, the CDC guideline recommends¹¹ that antimicrobial catheters should not be used routinely to prevent CAUTI. It also suggests that further research is needed both on the effect of silver-alloy coated catheters in reducing the risk of clinically significant CAUTI outcomes and on the benefit of silver-alloy coated catheters in selected patients at high risk of infection.

Bundles of interventions are also an important strategy, as part of a multi-modal approach that focuses efforts on high-yield interventions. For example, one strategy that includes several of the components from the “Bladder Bundle” implemented by the Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety & Quality is the “ABCDE” approach:¹⁶

- Adherence to general infection control principles is important (e.g., hand hygiene, surveillance and feedback, aseptic insertion, proper maintenance, education).
- Bladder ultrasound may avoid indwelling catheterization.
- Condom catheters or other alternatives to an indwelling catheter such as intermittent catheterization should be considered in appropriate patients.
- Do not use the indwelling catheter unless you must!
- Early removal of the catheter using a reminder or nurse-initiated removal protocol appears warranted.

What Is the Cost of Implementing a CAUTI Prevention Program?

The cost of implementing a CAUTI prevention program will vary based on the level of technology used (e.g., computerized vs. pre-printed catheter orders, and whether portable bladder ultrasounds are purchased) and the time invested in implementing and evaluating the interventions. Saint and colleagues, in their study of a written urinary catheter reminder

generated by a research nurse to remind physicians which of their inpatients had urinary catheters,⁴³ found that the intervention was either cost-neutral or modestly cost-saving depending on the assumptions made. More recently, a study³⁵ of five hospitals in the Netherlands employed a multi-modal intervention including reminders in four hospitals, and a stop order in the fifth hospital. The program was found to be cost-saving, with the mean amount saved being €537 (or ~\$700) per 100 hospitalized patients.

What Methods Have Been Used To Improve the Implementation of Interventions To Prevent Catheter-Associated Urinary Tract Infections?

Because reducing unnecessary catheter use often requires changing well-established habits and beliefs of nurses and physicians, the challenge of implementation should not be underestimated. To facilitate implementation of practices to prevent CAUTI, the Michigan Keystone Bladder Bundle Initiative¹⁶ used the Johns Hopkins University collaborative model for transformational change. This model is based in part on the “four E’s”: Engage, Educate, Execute, and Evaluate.⁵⁰ During the “Engage” and “Educate” steps, hospitals were provided information in multiple formats and a toolkit describing the intervention steps and outcomes measures. In the “Execute” step, the hospital was strongly encouraged to choose one nurse champion⁵¹ (for example, a case manager, nurse coordinator, or clinical nurse specialist) to lead the initiative and organize a bladder bundle team, including at least one physician, and to participate in workshops and conference calls with other participating hospitals to provide additional expert content and practical coaching. Also during the “Execute” step, daily patient rounds (which in some hospitals were called a “catheter patrol”) were recommended to assess catheter presence and necessity, and provide feedback to specific units and re-evaluate strategies in progress. Hospitals were also encouraged to implement more active strategies for prevention, such as a catheter reminder system or promoting the use of catheter alternatives by developing protocols or making sure the necessary supplies were readily available. In the “Evaluate” phase, hospitals were asked to conduct a baseline assessment of catheter use (point prevalence) and appropriate use according to specified indications and to conduct periodic reassessments to assess progress and sustainability.

Implementation challenges within CAUTI prevention should be expected⁵² and managed accordingly. Qualitative assessment focusing on HAI prevention has identified two important potential barriers to healthcare-associated infection preventive efforts: “active resisters” and “organizational constipators.”⁵³ Active resisters are hospital personnel who vigorously and openly oppose changes in practice, as a matter of habit or culture (e.g., “just not how they were trained”). Management of active resisters often requires those in authority to mandate compliance, collect data, and provide feedback.⁵³ A “champion” who is influential or a peer of the resisting staff may also help to overcome active resistance.^{51,52} “Organizational constipators” are usually mid- or high-level executives who act as barriers to change by preventing or delaying certain actions needed to implement new practices.⁵³ Strategies to address an organizational constipator are to include this person in early discussions to improve buy-in and motivation, working around the person, or replacing the constipator.

A unique challenge to expect when implementing urinary catheter removal strategies is reluctance by some nurses to remove the catheter,⁵² even when the nurse is “empowered” to do so. In some cases, nurses may be active resisters due to disagreement with the catheter policy

and/or a desire to avoid the inconveniences and increased frequency of patient contact required for the care of incontinence and catheter alternatives. Other nurses report they simply do not feel comfortable⁴⁹ removing the catheter without explicit orders from the physician, which is ironic considering that many nurses place catheters without orders. Nursing comfort with catheter removal can be increased⁴⁹ with peer support and education, and may be facilitated by directly addressing the workload concerns associated with the removal of indwelling catheters. Indeed, a survey of nurses²⁷ during implementation of a nurse-empowered catheter removal protocol indicated increased nursing and patient satisfaction, despite the expected increase in workload.

Even though CAUTI is a very common healthcare-associated infection, Krein and colleagues reported that CAUTI preventive practice use is lagging behind efforts to prevent central line-associated bloodstream infection and ventilator-associated pneumonia,⁵⁴ with room for improvement in adopting catheter removal and CAUTI preventive strategies demonstrated again in two recent large surveys of hospitals⁵⁵ and ICUs.⁵⁶ Fortunately, many resources exist (www.Catheterout.org) to help hospitals develop and implement programs to decrease catheter use and prevent CAUTI, including a range of tools and educational materials to address implementation challenges. Hospital and unit-level leadership also play a key role in preventing infection.⁵⁷

Monitoring and Providing Feedback on Catheter Use and CAUTI Rates

Inappropriate urinary catheter use is an easy habit to start and a difficult one to break.¹⁸ Consequently, many studies^{17,30} have emphasized the importance of on-going surveillance and feedback as an intervention to reduce healthcare-associated infections such as CAUTI and sustain prevention efforts. New national efforts to reduce CAUTI (www.onthecuspstophai.org/stop-cauti/) incorporate periodic feedback to participating units on urinary catheter use and CAUTI rates. The CAUTI rates evaluated include the National Healthcare Safety Network (NHSN) and the newly described population-based rates.⁵⁸ The population-based CAUTI rate incorporates both the NHSN rate and the device utilization ratio, to account for interventions focused on reduction in catheter use and improvements in placement and maintenance.

Important next steps to address CAUTI involve developing strategies to decrease the effort and resources required to monitor catheter use and CAUTI rates. Advanced informatics tools have recently been shown to increase the impact of this feedback loop to the extent that rates of CAUTI were lower in facilities that deployed these tools compared with those that did not.⁵⁹ Careful selection or development of datasets used for implementing hospital payment changes and public reporting for CAUTI events is also recommended. Unfortunately, the current administrative data used to implement non-payment⁷ for hospital-acquired CAUTIs and to publicly report hospital performance likely captures few CAUTI events, given documentation and coding challenges⁶⁰ to translate a urinary tract infection event from a medical record into hospital-acquired CAUTI in the administrative datasets.

Conclusions and Comment

In summary, hospitals should strongly consider employing interventions to avoid unnecessary catheter placement and to prompt removal of unnecessary catheters. These interventions appear to be low cost, low risk and effective strategies to address a common

hospital-acquired infection in the United States, with some unique but not impossible challenges for implementation. Furthermore, reducing indwelling catheter use addresses the noninfectious complications of urinary catheter use such as catheter-related patient discomfort and immobility (Table 4).

Table 4, Chapter 9. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate-to-high	Low	Low	Moderate/Moderate

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Chapter 10. Prevention of Central Line-Associated Bloodstream Infections: Brief Update Review

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Introduction

Central venous catheters (CVCs) are intravascular access devices that terminate within the great vessels of the neck (superior or inferior vena cava, brachiocephalic veins, subclavian vein or internal jugular vein), or a site proximal to the heart. CVCs are vital for the care of hospitalized and critically ill patients, as they provide reliable venous access for clinical activities such as blood sampling, infusion of medications, and hemodynamic measurement. However, CVCs are also the leading cause of healthcare-associated bloodstream infections (BSIs) and are frequently implicated in life-threatening illnesses.^{1,2} Infections associated with CVCs are categorized in the literature as either “central-line associated bloodstream infection” (CLABSI), or “catheter-related bloodstream infection” (CRBSI), based on whether surveillance or ascertainment of infection is the desired goal. For instance, the Centers for Disease Control and Preventions’ (CDC) National Healthcare Safety Network (NHSN) uses the CLABSI definition for surveillance purposes, defining the term as a laboratory confirmed BSI in any patient with a CVC present either at the time of, or within a 48-hour period before the detection of infection.^{3,4} Thus, the CDC-NSHN definition overestimates the true incidence of CRBSI, as some BSIs may be due to infection at other sites (e.g., pneumonia or urinary tract infection) or at sites that are difficult to detect (e.g., translocation from the gastrointestinal tract or mucositis following chemotherapy). In contrast, CRBSI is a more precise and rigorous definition that requires either (a) isolation of the same organism from the catheter and the peripheral blood, (b) simultaneous quantitative blood cultures with a ratio of 5:1 or higher of those from the indwelling CVC compared with peripheral blood, or (c) a differential time to positivity of CVC-derived versus (vs.) peripheral blood culture positivity of more than 2 hours.⁵ The CRBSI definition is thus largely used within the context of clinical care and research, whereas the term, CLABSI, is implemented for epidemiologic surveillance.⁶ For the purposes of this review, we use the term CLABSI to encompass both of these operational definitions.

Of the approximately 249,000 BSIs that occur in U.S. hospitals each year, 80,000 (32.2%) occur in intensive care unit (ICU) settings.² Because CVCs are more frequently used in ICUs than in other areas of the hospital, and the strongest predictor of developing a BSI is the presence of a CVC, the epidemiology of CLABSI has traditionally focused on the critically ill. With over 15 million catheter days in ICUs annually, the potential impact of CLABSI is substantial in this population alone.^{6,7} However, in a survey of major medical centers, CVC use was identified in 24.4 percent of patients outside the ICU.⁸ Thus, millions of patients both in and out of ICU settings are potentially at risk of developing CLABSI. Although the frequency of CLABSI outside the ICU is largely unknown, Weber and colleagues found that the incidence of CLABSI decreased when patients transitioned from ICUs to step-down units or non-ICU floors.⁹ Data from the CDC-NHSN also suggest lower CLABSI rates in patients on hospital wards compared with those in an ICU setting.¹⁰ Furthermore, recent evidence suggests that the incidence of CLABSI in ICUs is significantly lesser than reported in 2001, likely due to a number of efforts aimed at preventing this infection.¹¹ These efforts notwithstanding, the increasing use of CVCs

such as peripherally inserted central catheters (PICCs) outside of ICUs may reflect an important shift in the epidemiology of CLABSI to non-ICU settings.¹² This change is highly relevant, as lack of a uniform patient-care team and absence of comprehensive surveillance efforts in non-ICU settings represent substantial obstacles to addressing CLABSI in these areas.

The economic burden of CLABSI is substantial. A recent analysis estimated that each CLABSI episode independently increases length of hospitalization from 7 to 21 days, and adds an attributable cost of about \$37,000 (2002 dollars) per patient.¹³ The annual national cost of caring for patients who develop CLABSI is estimated to range from \$0.67 to \$2.68 billion.¹³⁻¹⁵ Similar trends exist in European nations, where the incremental expenditure related to CLABSI is estimated at €1,154 (€18,241 [\$24,558 in 2012 dollars vs. €1,087 [\$12233]) per patient.¹⁶ Given this clinical and economic cost, investigators, policy-makers, and regulatory agencies in the U.S. and abroad have devoted great efforts to curtail CLABSI over the past decade.¹⁷⁻¹⁹

CLABSIs are potentially preventable through the use of evidence-based practices.²⁰ The original “Making Health Care Safer” report examined the prevalence, strategies, and costs associated with CLABSI prevention, and found that certain practices (e.g., the use of maximal sterile precautions) were associated with both a decrease in CLABSI risk and reduced cost, whereas others (e.g., intravenous antimicrobial prophylaxis) added expense without clear benefit.^{21,22} In this review, we provide an update to the original report by highlighting the most clinically and cost effective strategies associated with CLABSI prevention. To compile this report, we performed a systematic review of the literature and searched multiple databases to identify relevant studies published between 2000 and 2012 using terms such as “Bacteremia,” “Catheterization, Central Venous,” and “central line-associated bloodstream infection.” Our search strategy yielded a total of 1,087 unique manuscripts of which 337 articles were relevant for this report.

What Practices Are Associated With CLABSI Prevention?

One of the most important advances in the science of CLABSI prevention has been the identification of individual risk factors associated with this condition. These include (a) lengthy hospitalization before venous catheterization; (b) prolonged duration of catheterization; (c) heavy microbial colonization at the insertion site; (d) heavy microbial colonization of the catheter hub; (e) femoral or internal jugular vein insertion (rather than subclavian vein); (f) operator-inexperience or lack of implementation of best practices during CVC insertion; (g) presence of neutropenia; (h) total parenteral nutrition provided through the catheter; (i) inadequate care/maintenance of the CVC after insertion; and (j) type of CVC.²³⁻³⁰ Strategies to prevent CLABSI have evolved from targeting these variables.

The CD’s Healthcare Infection Control Practices Advisory Committee (HICPAC) recently updated their guidelines to summarize the evidence behind a number of practices associated with CLABSI reduction.²⁰ As with prior iterations, the update provides levels of recommendation for each clinical practice based on the theoretical rationale, scientific data, applicability and impact of the intervention. Based on the level of evidence in their support, recommendations are divided into five categories, ranging from practices that are strongly recommended and supported by well-designed experimental, clinical, or epidemiologic studies to those that are of unclear value owing to insufficient evidence or lack of consensus regarding efficacy (Table 1). From a conceptual standpoint, these practices can be classified as (a) interventions that may be implemented at the time of CVC insertion; (b) practices best utilized after placement of a CVC; and (c) institutional initiatives to reduce CLABSI.

Table 1, Chapter 10. Categories and recommendations for CLABSI reduction practices from the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention*

Recommendation	Description	Category of Recommendation
Hand hygiene prior to catheter insertion	Decontaminate hands with either antiseptic-containing soaps or alcohol-based gels/foams before inserting, repairing, replacing, or dressing a CVC	Category IB
All inclusive catheter carts or kits	A catheter kit or cart contains all the equipment necessary for CVC insertion (needle, guidewire, introducers, etc.), and ensures sterility by minimizing interruptions during line placement	Category IB
Maximal sterile barrier precautions	Use a cap, mask, sterile gown, sterile gloves, and a sterile full body drape when inserting CVCs and PICCs or performing guidewire exchange(s)	Category IB
Chlorhexidine for skin anti-sepsis	Prepare clean skin with chlorhexidine preparation with alcohol before CVC insertion and during dressing changes	Category IA
Antimicrobial catheters	Chlorhexidine/silver sulfadiazine or minocycline/rifampin-impregnated CVCs are recommended only if the catheter is expected to remain in place 5 days or more <u>AND</u> the CVC will be inserted in an environment where the CLABSI rate remains high despite a comprehensive reduction strategy	Category IA
Subclavian vein insertion	Whenever possible, use the subclavian site, rather than the jugular or femoral sites in adults	Category IB
Disinfect hubs and needle-less connectors	Minimize contamination risk by scrubbing the access site with an appropriate antiseptic (chlorhexidine, povidone iodine, or 70% alcohol) prior to accessing the CVC	Category IA
Remove non-essential CVCs	Daily evaluation and prompt removal of CVCs that are no longer clinically warranted is an important aspect of CLABSI prevention; routine replacement of CVCs, PICCs, or hemodialysis catheters is not recommended	Category IA
Chlorhexidine cleansing	Daily cleansing using a 2% chlorhexidine solution or impregnated washcloth rather than soap and water in ICU- and hemodialysis patients is recommended	Category II
CVC dressing	Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the CVC site	Category IA
Chlorhexidine sponge dressing	The use of chlorhexidine-impregnated sponge dressings is recommended for patients ≥ 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis and use of maximal sterile barrier precautions	Category 1B
Topical antibiotic use	Topical antibiotic use may promote fungemia or bacteremia in non-dialysis populations and is recommended only for hemodialysis catheter dressing	Category IB
Antibiotic or anti-infective “locks”	Instillation of supra-physiologic doses of an intravenous antibiotic or anti-infective solution into a catheter lumen between periods of CVC access is recommended only in those at high baseline risk for CLABSI	Category II
Systemic antibiotic prophylaxis	The use of oral or intravenous antibiotic therapy either during insertion or following placement of a CVC is not recommended	Category IB

Table 1, Chapter 10. Categories and recommendations for CLABSI reduction practices from the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention* (continued)

Recommendation	Description	Category of Recommendation
Educational interventions	Education regarding appropriate indications, method of placement, and surveillance for CLABSI are a critical component of a comprehensive CLABSI prevention program	Category IA
Catheter bundles or “checklists”	The use of five practices in unison at the time of CVC insertion, “the bundle,” is recommended. These interventions include hand hygiene prior to insertion; use of maximal sterile barrier precautions; chlorhexidine for skin antisepsis; avoidance of the femoral site of insertion; and prompt removal of catheters when no longer indicated	Category IB
Use of specialized CVC insertion teams	The use of trained personnel dedicated to the placement of CVCs in ICU and hospitalized patients is recommended	Category IA

*Categories of recommendations:

Category IA: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies;

Category IB: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence.

Category IC: Required by State or Federal regulations, rules, or standards.

Category II: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

Unresolved Issue: No specific recommendations exist due to conflicting or insufficient evidence.

Abbreviations: CLABSI = central line-associated bloodstream infection; CVC = central venous catheter; PICC = peripherally inserted central catheter.

Note: Adapted from O’Grady, et al.²⁰

Measures To Prevent CLABSI at Time of Central Venous Catheter Insertion

Hand hygiene before catheter insertion. Hand hygiene is an important practice in the prevention of CLABSI.³¹ Hand decontamination with either antiseptic-containing soaps or alcohol-based gels/foams has consistently been shown to reduce CLABSI rates.³²⁻³⁴ A key strategy in promoting hand hygiene involves educating staff who insert CVCs on the importance of this practice. In a before-and-after study assessing the impact of an educational initiative on hand hygiene, the incidence of CLABSI decreased from 3.9 per 1,000 catheter days to 1.0 per 1,000 catheter days ($P < 0.001$) following education on this topic in an ICU setting.³⁵ As the most common cause of CLABSI is entry of skin pathogens during CVC insertion and maintenance, ensuring best practice during catheter placement and handling is crucial for CLABSI prevention (Category IB).^{20,36}

All-inclusive catheter-carts or kits. A study by Young and colleagues found that a systems-based intervention featuring a catheter kit (that contained a large sterile drape and 2% chlorhexidine gluconate) led to a significant reduction in CLABSI rates (11.3 per 1,000 CVC-days vs. 3.7 per 1000 CVCs, $P < 0.01$) in a medical-surgical ICU.³⁷ This approach has been expanded upon by a number of other investigators to include not only a kit of essential items, but a mobile cart that contains all of the equipment needed to insert CVCs.^{38,39} The use of an all-inclusive cart or catheter kit minimizes interruptions related to non-availability of necessary equipment and thus lends itself to CLABSI reduction by ensuring maintenance of a sterile field during catheter insertion. Furthermore, the use of carts encourages a consistent approach to CVC insertion by standardizing catheter types, guide-wires, needles, and other essential supplies. Although the use of catheter-carts and kits is not specifically endorsed by the recent HICPAC guidelines,²⁰ they are pragmatic, relatively low-cost innovations that have been associated with lower CLABSI rates.

Maximal sterile barrier precautions. Several studies have demonstrated that the use of maximal barrier precautions including a cap, mask, sterile gown, gloves, and a sterile full-body drape when inserting CVCs reduces CLABSI.^{6,37,40,41} Current HICPAC guidelines thus recommend that maximal sterile barriers are used during insertion of all CVCs (Category IB).²⁰ The cost-effectiveness of this practice in preventing CLABSI has been established, as the expense of sterile barriers is dwarfed by the additional expense of CLABSI and its subsequent care, even in resource-poor environments.⁴² Despite this evidence, a study of 10 ICUs in major academic medical centers published in 2006 reported that fewer than 30 percent had systematically adopted maximal sterile barrier precautions.⁴³ However, a more recent national survey of infection preventionists, which examined the use of evidence-based practices (including maximal sterile barriers) in Federal and non-Federal hospitals between 2005 and 2009, found that the reported use of this practice is on the rise.⁴⁴ This more recent finding highlights the fundamental role of translating evidence into practice regarding CLABSI prevention.

Chlorhexidine for skin antisepsis. In a systematic review and meta-analysis of 8 trials involving 4,143 unique catheter insertions, skin antisepsis with chlorhexidine was found to be

associated with a 50 percent reduction in the subsequent risk of CLABSI compared with povidone iodine.⁴⁵ A formal economic evaluation by the same authors projected that although costlier initially, the use of chlorhexidine over povidone iodine for insertion site disinfection and CVC care would lead to a 1.6 percent decrease in the incidence of CLABSI, a 0.23 percent decrease in the incidence of death, and a savings of \$113 per catheter.⁴⁶ Existing HICPAC guidelines endorse the use of chlorhexidine gluconate for skin antisepsis prior to CVC insertion (Category IA).²⁰

Antimicrobial catheters. The utility of catheters impregnated with a variety of substances including chlorhexidine-silver sulfadiazine, minocycline-rifampin, benzalkonium chloride, and silver have been evaluated in more than 20 randomized controlled studies and four recent systematic reviews and meta-analyses.⁴⁷⁻⁵¹ Meta-conclusions from these reviews remain limited, due to heterogeneity arising from differences in the population, design, and conduct of the pooled studies. For example, in a study involving a pediatric burn population, Weber and colleagues found significant reductions in CLABSI with the use of minocycline and rifampin antimicrobial coated catheters over non-coated catheters.⁵² However, a prospective, double-blinded, randomized study in adults failed to show a reduction in CLABSI with a second-generation CVC coated with chlorhexidine and silver sulfadiazine.⁵³ Due to the initial acquisition cost, variation in benefit according to patient populations, and potential concern for inducing antimicrobial resistance, routine use of antimicrobial CVCs is not recommended.^{20,54} However, in facilities where high-rates of CLABSI persist despite deployment and compliance with comprehensive CLABSI prevention efforts, the use of antimicrobial CVCs is considered reasonable by current HICPAC guidelines (Category IA).²⁰

The subclavian vein as the insertion point of choice. The site of CVC placement may influence the risk of CLABSI, owing to the differing density of bacterial skin colonization at each entry site. In a multicenter study of 289 patients randomized to undergo venous catheterization using either the femoral or subclavian site, CVC placement in the femoral area was associated with a substantially greater risk of CLABSI than was subclavian insertion (20 versus 3.7 per 1,000 catheter days).⁵⁵ In a recent Dutch multicenter study involving 3,750 CVCs and 29,003 CVC days, insertion into the femoral and jugular vein was independently associated with an increase in the risk of subsequent CLABSI.⁵⁶ In a study directly comparing the subclavian to the internal jugular and femoral sites, the subclavian site was associated with the lowest risk of infection (0.97 versus 2.99 and 8.34 per 1,000 catheter days, respectively).²⁴ For this reason, whenever medically feasible, the subclavian vein is the preferred site for venous catheterization in the current HICPAC guidelines (Category IB).^{6,20,57-59} However, this recommendation remains the subject of on-going debate, as some rigorous studies have found that the risk of CLABSI from femoral vein CVC insertion is not greater than that associated with insertion into the subclavian or internal jugular veins.⁶⁰⁻⁶²

Measures To Prevent CLABSI After Central Venous Catheter Insertion

Following the insertion of a CVC, several practices may decrease the risk of developing CLABSI. These “maintenance” practices are important aspects of CLABSI prevention, especially in CVCs that remain in place for an extended period of time.

Disinfect hubs, needleless connectors, and injection ports prior to CVC use. Contamination of the catheter hub due to non-sterile access technique is a recognized path for developing CLABSI. Minimizing contamination by wiping the catheter hub with an appropriate antiseptic specifically recommended by the device manufacturer, or swabbing the membranous septum of a CVC with 70% alcohol have been shown to reduce both risk of catheter contamination and incidence of CLABSI.⁶³⁻⁶⁵ The practice of disinfecting access sites prior to CVC use, colloquially dubbed “scrub the hub,” is linked to decreases in both bacterial colonization at access sites and rates of incident CLABSI.⁶⁶⁻⁶⁸ Educational efforts targeting providers responsible for CVC care (such as bedside nurses) are an important component in ensuring dissemination and compliance with this practice.⁶⁹ Although current HICPAC guidelines emphasize minimizing the risk of contamination by scrubbing the hub with an appropriate antiseptic (Category IA),²⁰ several *in vitro* studies have demonstrated that even with strict attention to decontamination, pathogenic organisms can persist in crevices or inside CVC access valves and/or require prolonged duration of contact with an antimicrobial to significantly decrease the level of colonization of CVC valves.⁶⁹⁻⁷² In response, innovative technologies such as those that incorporate antimicrobial compounds in the matrix of the CVC access valve, or devices that bathe the valve with antimicrobials are being developed and tested.^{70,72-74} In the absence of significant clinical experience with these novel devices, recommendations regarding their widespread use are not possible.

Remove nonessential CVCs. Each day with a CVC increases the risk of developing CLABSI.^{75,76} Prompt removal of CVCs that are no longer warranted is thus an important practice to reduce CLABSI. This action necessitates both awareness of CVC presence and an ongoing risk-benefit assessment of continued central venous access. In a study tracking temporary CVC use in hospitalized patients, Chernetsky-Tejedor and colleagues reported that patients who underwent PICC placement for venous access paradoxically also had 5.4 concurrent days with a peripheral intravenous line (P<0.001), and had more days in which the only justification for the CVC was intravenous administration of antimicrobial agents (8.5 versus 1.6 days; P=0.0013). The authors therefore concluded that a substantial proportion of CVC-days might have been unjustified in this cohort.⁶⁵ In a recent survey conducted in a European hospital, neither the bedside nurse nor the treating physician knew why a CVC was in place for 8.3 percent of non-ICU patients.⁷⁷ Importantly and relatedly, routine replacement of CVCs at pre-determined time intervals has not been shown to reduce the risk of CLABSI and is not recommended based on the available evidence (Category IA).²⁰

Chlorhexidine cleansing. Daily bathing of patients with a chlorhexidine-based solution in ICU- or advanced care settings may lower CLABSI incidence. In a crossover study conducted in a medical ICU, daily washing with a 2% chlorhexidine-impregnated washcloth significantly reduced subsequent BSI compared with using soap and water (4.1 vs. 10.4 per 1,000 patient-days, P<0.05).⁷⁸ A study in a surgical ICU also found that daily bathing with a 2% chlorhexidine gluconate impregnated cloth led to significant reductions in CLABSI (12.07 vs. 3.17 CLABSIs per 1,000 days; 73.7% rate reduction, P= 0.04).⁷⁹ The benefits of chlorhexidine baths may also extend to high-risk patients outside of ICU settings. In a quasi-experimental before and after study of the effect of daily washing with 2% chlorhexidine solution on CLABSI incidence, Munoz-Price and colleagues reported a 99 percent reduction in the CLABSI rate in a long-term acute care facility.⁸⁰ However, a recent retrospective study involving patients in a surgical ICU

suggested that the benefit from chlorhexidine bathing might not apply to all patients.⁸¹ As the evidence base for this practice is limited and conflicting, current HICPAC guidelines cautiously endorse the use of chlorhexidine washes (either in solution form or as a chlorhexidine impregnated wash cloth), for daily skin cleansing as a means to prevent CLABSI with a Category II recommendation.²⁰ However, the level of evidence for this recommendation may soon be upgraded, as a recent meta-analysis pooling 12 studies found significant reductions in CLABSI risk in studies that evaluated chlorhexidine cleansing in a medical ICU setting (OR 0.44, 95% confidence interval, 0.33 to 0.59).⁸²

CVC dressing, chlorhexidine sponges and topical antibiotic use. The type of dressing and use of topical antibiotic ointments or creams at the catheter site may affect the risk of CLABSI. In a meta-analysis of seven studies comparing clear dressings to gauze for CVCs, transparent dressings were associated with greater risk of catheter tip colonization (Relative Risk [RR] 1.78, 95% confidence interval [CI] 1.30 to 2.30, $P < 0.05$), but not CLABSI (RR 1.63, 95% CI 0.76 to 3.47).⁸³ Another meta-analysis of randomized controlled trials comparing gauze and tape to transparent dressings found no significant differences between dressing type and risk of CLABSI.⁸⁴ Thus, for CLABSI prevention, existing guidelines do not endorse one type of dressing over the other and leave the choice of CVC dressing to provider/patient preference and clinical scenario.²⁰

The use of a chlorhexidine gluconate sponge over the site of CVC insertion has been associated with a decrease in the frequency and cost of CLABSI. In a study involving 1,636 patients with venous and arterial catheters, Timsit and colleagues reported that chlorhexidine gluconate sponge placement at the site of catheter insertion substantially reduced the incidence of CLABSI (1.4 to 0.6 per 1,000 catheter days, hazard ratio 0.39, $P < 0.03$). However, severe contact dermatitis was observed in eight low birth-weight infants (5.3 per 1,000 catheter days), and the potential for this adverse effect remains an important limitation in the use of chlorhexidine gluconate sponges in this population.⁸⁵ In a recent economic evaluation, chlorhexidine-impregnated sponge use in patients with CLABSI was estimated to save \$197 per patient using a 3-day dressing change strategy vs. \$83 using a 7-day standard dressing change strategy.⁸⁶ In another cost-benefit analysis, a hypothetical 400-bed hospital inserting 3,078 CVCs annually would avoid a projected average of 35 CLABSIs, 145 local infections, and 281 ICU days with the systematic use of a chlorhexidine-impregnated foam dressing; potential annual hospital net savings were projected at over \$895,000.⁸⁷ Owing to important differences in study design and outcomes involving primarily pediatric populations, current guidelines recommend the use of chlorhexidine-impregnated sponge dressings only in situations where the CLABSI rate is not decreasing despite adherence to other prevention measures (Category IB).²⁰

The use of topical antibiotic ointment or creams at the insertion site (e.g. povidone iodine) is recommended only for patients with hemodialysis catheters, where its use has been associated with suppression of BSI.^{88,89} Interestingly, a recent prospective, non-blinded crossover study found that chlorhexidine sponge dressings were not protective against BSI in patients with hemodialysis catheters.⁹⁰ Conversely, topical antibiotic dressings are not recommended for CLABSI prevention in non-dialysis patients as their use may paradoxically increase fungemia and antimicrobial resistance in this category of patients (Category IB).^{20,91,92}

Antibiotic/anti-infective “locks” in high-risk patients. A catheter lock refers to the instillation of supra-physiologic doses of an intravenous antibiotic or anti-infective solution into a catheter

lumen between periods of CVC access. Several studies have examined both the utility of specific antibiotic or anti-infective agents (e.g. vancomycin, cephalosporins, taurolidine, EDTA, ethanol) and the targeted use of antibiotic locks in high-risk patient populations. In a systematic review and meta-analysis, vancomycin-based antibiotic locks in patients deemed high-risk for CLABSI (planned, long-term central venous catheter duration or those with a history of prior CLABSI) significantly decreased the risk of this outcome (RR 0.34, P=0.04).⁹³ A more recent systematic review also reported reductions in the risk of subsequent CLABSI using this approach as an adjunctive treatment, specifically in patients with poor venous access where catheter salvage was key.⁹⁴ In view of concerns regarding the potential for inducing antibiotic resistance, several novel compounds have been tested as anti-infective locks. For example, a recent study found a solution containing minocycline and EDTA to be highly efficacious in preventing CLABSI in patients with hemodialysis catheters.⁹⁵ In patients receiving prolonged home parenteral nutrition via a CVC, the antineoplastic compound taurolidine was found to reduce the risk of CLABSI when used as a catheter lock in a before and after study.⁹⁶ Even though several studies have found reductions in CLABSI incidence in specific populations, generalizations beyond these groups are difficult and not appropriate.⁹⁷⁻¹⁰⁰ Thus, due to important differences in study design, type of catheter, agent used, and patient population, the use of antibiotic locks should be limited to those who are at high baseline risk for CLABSI (Category II).²⁰

Systemic antibiotic prophylaxis. Routine systemic antibiotic prophylaxis during or after CVC insertion to reduce the risk of CLABSI is not recommended (Category IB).²⁰ A recent Cochrane meta-analysis involving patients with cancer found no convincing evidence that prophylactic peptidoglycan administration prior to CVC insertion was associated with reduced CLABSI incidence.¹⁰¹ A recent study examining the effect of prophylactic cefazolin on CLABSI following port placement similarly found no benefit associated with antibiotic treatment.¹⁰²

Institutional Initiatives To Reduce CLABSI

Educational interventions. Educational programs that emphasize appropriate indications for CVC placement and programs that review proper procedures for catheter insertion and maintenance have both been shown to reduce the incidence of CLABSI in various settings.¹⁰³⁻¹⁰⁷ Although teaching CVC insertion using simulation techniques is a growing phenomenon, a recent systematic review found that this practice was associated with less frequent mechanical complications, but not CLABSI.¹⁰⁸ Reporting and monitoring for infections through a structured infection control program is a critical component of CLABSI prevention. Consequently, education and training regarding how to implement and assess infection control measures and periodic reassessment of this knowledge has also been shown to reduce CLABSI.^{20,35,109} Despite these important studies, a recent survey found that knowledge regarding which practices are most associated with CLABSI prevention remains variable.¹¹⁰ Educational initiatives thus represent an important area of opportunity for institutions and health systems interested in controlling CLABSI (Category IA).²⁰

Use of catheter checklists or “bundles.” A standardized approach to CVC placement that utilizes a set of evidence-based practices represents an important innovation in CLABSI prevention. In the Michigan Keystone ICU study, Pronovost and colleagues enrolled 103 ICUs in 67 hospitals to test whether an intervention consisting of five evidence-based practices

implemented at the time of CVC insertion could reduce CLABSI. Notably, these five practices were selected because they each had strong evidence supporting their efficacy in CLABSI reduction and the lowest barriers to implementation. These five practices were hand hygiene prior to insertion; use of maximal sterile barrier precautions; chlorhexidine for skin antisepsis; avoidance of the femoral site of insertion; and prompt removal of catheters when no longer indicated. Following implementation of this intervention, the mean rate of CLABSI dropped from 7.7 per 1,000 catheter days at baseline to 1.4 per 1,000 catheter days at 16 months across participating sites.³³ The use of these five interventions in unison has been called the “checklist” or “the bundle.” The use of the bundle and variations thereof has been associated with a sustained decrease in the incidence of CLABSI, not only within the U.S., but internationally as well.^{38,111-116} The bundle has also been found to be cost-effective both in the U. S. and abroad, leading to its widespread acceptance as a key strategy with which to reduce CLABSI.^{20,117} The HICPAC guidelines categorize the use of bundled interventions during CVC insertion as performance improvement initiatives and recommends this practice to reduce CLABSI (Category IB).²⁰

Specialized CVC insertion teams. Data from several studies suggest that CVC placement by specialized teams dedicated to this role leads not only to greater placement skills and reduced insertion complications, but also to reduced rates of institutional CLABSI.^{25,33,38,111} The use of dedicated and trained staff ensures predictable adherence to evidence-based practices such as hand hygiene and maximal sterile barriers. The advent of nursing-led PICC teams represents an important transformation in the placement of CVCs in both critically ill and hospitalized patients. Preliminary studies suggest that these teams are associated with high rates of insertion success and low rates of mechanical complications in a variety of patient settings.¹¹⁸⁻¹²⁰ However, no data comparing the risk of CLABSI in patients who undergo PICC placement by nursing PICC teams compared with other providers (such as hospitalists or radiologists) are currently available. The HICPAC guidelines recommend the use of trained personnel to insert CVCs (Category IA).²⁰

How Has CLABSI Prevention Been Implemented?

With the realization that CLABSI can be curtailed by the use of evidence-based practices, CLABSI prevention has increasingly become an attainable goal for hospitals, health care systems, and payors. The Michigan Keystone ICU study underscored how both technical (e.g., asepsis during insertion, standardized surveillance), and adaptive (e.g., buy-in from leadership, a culture of safety) components were needed to successfully implement a CLABSI prevention initiative.¹²¹ The identification of these two distinct, yet complementary, realms highlights how engagement and education of staff, consistent execution of the bundle, and rigorous evaluation of process—critical activities embodied within the CLABSI bundle—are fundamental components of CLABSI reduction.¹²² To ensure validity outside of Michigan, this model was replicated and tested in Rhode Island and in the Adventist multistate health care system, where declines in CLABSI at participating sites were also observed.^{122,123}

Fueled by these successes, the U.S. Department of Health and Human Services prioritized CLABSI reduction by designating it as Tier I of a comprehensive national healthcare-associated infection prevention program. Ambitiously, the program aimed to reduce the incidence of CLABSI by 50 percent in ICUs and specific patient populations over a period of 5 years, primarily by encouraging the use of insertion bundles. A 2011 interim analysis found that providers are on track with meeting this target, although continued opportunities remain for

patients in non-ICU settings and those receiving hemodialysis.¹²⁴ In similar fashion, the Agency for Healthcare Research and Quality (AHRQ) funded and launched an implementation program called “On the CUSP: Stop BSI.” This national venture includes Federal agencies (e.g., CDC), State organizations, and various professional societies, and aims to reduce the mean CLABSI rate to less than 1 per 1,000 catheter days in each of the 50 United States.

What Have We Learned About CLABSI Prevention?

A decade’s worth of quality improvement, clinical research and policy change has led to greater understanding of a number of pivotal aspects of prevention and control of CLABSI. These important lessons and ongoing challenges are summarized below.

Importance of Organizational Context

CLABSI reduction efforts using bundles have been successful at some sites, but not at others. This variable success has led to a renewed appreciation of organizational complexities (e.g., local culture, clinical care team engagement) that influence the implementation of evidence-based practices in health care settings. In a study that sought to answer why certain hospitals were more likely to succeed in CLABSI reduction efforts than others, Krein and colleagues found that themes involving structure and hierarchy within hospitals, politics and relationships between key stakeholders, a missing sense of mission and value, and lack of commitment and passion explained why some hospitals were not as successful at implementing CLABSI reduction practices as others. The authors suggest that the use of externally-facilitated initiatives (e.g., infection prevention measures, technology-based solutions or a quality collaborative), may provide the motivation, and sometimes resources, needed for implementation needed to implement CLABSI prevention measures and overcome these major obstacles.¹²⁵ In another article studying the influence of context on outcomes, Dixon-Woods and colleagues examined the Michigan Keystone ICU-initiative to develop an ex-post theory of why this quality improvement program was so successful.¹²⁶ These investigators posited that a number of components ensured the success of the program: (a) recruitment of a large number of ICUs that created pressure for others to join (e.g., isomorphic pressure), (b) the use of scheduled teleconferences and meetings that created a sense of a densely networked community, (c) reframing of CLABSI as a social problem (e.g., one that involved human action and behavior, not a technical fix), which convinced stakeholders that they should organize to solve this issue, (d) influencing hospital culture through checklists and integration of nursing and management, and (e), robust measurement of outcomes as a means to enforce practice.

Similar themes emerged from a multi-ICU study involving the Department of Veterans Affairs (VA) health care system, one of the largest integrated health care systems in the world. Render and colleagues studied the effects of a centralized inpatient evaluation center that supported not only bundle implementation, but also provided support by recruiting leadership, and providing feedback, learning tools, and mentoring at VA ICUs. Although the bundle was implemented in all ICUs, the investigators found marked declines in CLABSI specifically at sites where the additional support tools were well received. In contrast, sites that struggled with CLABSI reduction lacked a functional improvement team, forcing functions, or real-time feedback systems, underscoring the importance of these factors in CLABSI reduction.¹²⁷

In a national study of 1,212 health care professionals from 33 different hospitals, Flanagan and colleagues conducted an open-ended survey and also found that poor adherence to guidelines, lack of culture change, no impetus to change, insufficient resources, and issues

related to education were perceived barriers to achieving success in CLABSI improvement programs.¹²⁸ In the context of the work by Krein, Dixon-Woods, and others, these findings highlight the importance of understanding, appreciating, and addressing contextual factors in the quest to control CLABSI throughout the world.

Need for Accurate and Reliable Reporting

AHRQ has emphasized the reduction of CVC-associated BSI by designating it as Patient Safety Indicator (PSI)-7 on nationally reported scorecards. Although a technical brief outlining specifications of measurement for this PSI is publicly available,¹⁸ variations in measurement of this indicator have led to consternation in the literature. In a criterion validity study, Zrelak and colleagues conducted a retrospective cross-sectional study of 23 U.S. hospitals using trained abstractors and found that among 191 cases that met PSI-7 criteria, only 104 (positive predictive value [PPV] 54%; 95% CI, 40% to 69%) represented true CLABSI.¹²⁹ In another study examining the validity of PSI-7, Cevasco and colleagues used similar methodology and found that only 42 of 112 reviewed cases represented true CLABSI events (PPV 38%; 95% CI, 29% to 47%).¹³⁰ In both studies, coding-related issues and present-on-admission diagnoses explained a large fraction of incorrect reporting. Inaccurate measurement is further compounded by continued variation in public reporting of PSI-7. In a study of 14 states with mandatory CLABSI monitoring laws, Aswani and colleagues found numerous disparities in how participating sites selected the time span of their data collection, variably presented their infection rates, used inconsistent methods of risk adjustment, chose which locations and care settings to report, and demonstrated significant time lag to reporting.¹³¹ Using a standard definition of CLABSI to retrospectively study institutional variation in reporting bloodstream infections, Lin and colleagues found marked variability among 20 ICUs when comparing infection preventionists-reported CLABSI rates to those from a computer-generated algorithm.¹³² In a provocative study, Niedner and colleagues showed that more-aggressive surveillance using stricter definitions and written policies was associated with higher CLABSI reporting rates in 16 pediatric ICUs.¹³³ This variability in reporting has profound implications in pay-for-performance and benchmarking applications that use this measure, as those most likely to accurately report CLABSI stand to be the most penalized. This dilemma underscores the need to standardize, audit, and constantly evaluate this system of quality measurement.

Importance of Continued Performance Improvement Efforts

Despite major strides involving knowledge generation and dissemination over the past decade, important gaps remain in the practice of CLABSI prevention. In a cross-sectional survey of 1,000 randomly selected physician-members of the American College of Physicians-American Society of Internal Medicine, the reported use of maximal sterile barriers and chlorhexidine gluconate at the time of CVC insertion remained low among internists who identified themselves as having recently inserted a CVC.¹³⁴ Similarly, around 15 percent of U.S. hospitals report routinely changing CVCs at predetermined time intervals despite abundant evidence that this practice should be discontinued.^{43,135} In an audit of staff practice and awareness of post-insertion catheter care, Shapey and colleagues found multiple breaches involving knowledge about dressing and catheter hub decontamination.¹³⁶ Are these behaviors and practices remediable? In a 36-month followup study of the Keystone Project, zero incidents of CLABSI were found in participating sites, despite completion of the original study. The durability of this effect suggests that not only can behaviors be changed, but engagement, education, monitoring, and feedback

can sustain these behaviors beyond the intervention stage.¹¹³ Ongoing performance measurement and process improvement must thus come to represent a fundamental facet of national and local efforts directed towards CLABSI prevention.

Identification of New Challenges

Most BSIs related to CVCs occur not in those with long-term CVCs, but in patients with short-term CVCs.¹³⁷ A major shift in the landscape of short-term CVCs, the remarkable growth of PICC use in hospitalized and critically ill patients, may therefore bring new challenges to CLABSI prevention.^{12,76,120} Despite the rapid growth in the use of PICCs, little is known about the indications, prevalence, and patterns of use of this device. Consequently, little is known regarding the adherence to or appropriateness of CLABSI prevention techniques when inserting and maintaining PICC lines. As PICCs are frequently placed in vulnerable populations such as children and those with cancer¹³⁸ and are associated with important complications, further study of this technology and its association with CLABSI is needed.^{139,140} In addition, considerably less attention has been devoted to the study and testing of best practices in maintaining long-term CVCs, such as PICCs. As the risk of CLABSI is greatly influenced by the manner in which a CVC is handled and treated following insertion, this knowledge gap represents an important area for future study.

Conclusions and Comment

The intervening decade between the original “Making Health Care Safer” report^{18,21,22} and this update has borne witness to a number of practices, approaches, and technologies that have controlled and eliminated CLABSI in specific settings. Despite this progress, a number of important policy, knowledge, and implementation gaps remain. While a CLABSI bundle that incorporates five practices that have reasonable evidence underlying their use appears to be successful in reducing CLABSI within ICUs, the extent to which this bundle is effective at preventing and reducing CLABSI outside of the ICU is unknown. As the majority of CVCs are now found in non-ICU settings, a research agenda that targets this population is necessary. Understanding how best to assess and address the complexities of culture and behavior are critical in this context, as these factors are likely to vary to a greater extent than ICU settings. A summary table is located in Table 2, Chapter 10.

Table 2, Chapter 10. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard is It?
Common/Moderate	Moderate-to-high	Low	Low-to-moderate	Moderate-to-difficult/ Not difficult (implementation of a “bundle”)-to-moderate (understanding organization culture and context)

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Chapter 11. Ventilator-Associated Pneumonia: Brief Update Review

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Introduction

Ventilator associated pneumonia (VAP) is defined as a hospital-acquired pneumonia that develops within 48 to 72 hours after endotracheal intubation; the diagnosis hinges on a lack of evidence suggesting that the infection developed prior to intubation. VAP is the most common intensive care unit (ICU)-acquired infection, accounting for 25 percent of all ICU infections and 50 percent of ICU antibiotic use. At least 250,000 VAPs occur in the United States (U.S.) each year. This condition causes complications in 8 to 28 percent of mechanically ventilated patients and carries a mortality risk of approximately 10 percent (range 6% to 27%), resulting in a possible 25,000 VAP-attributable deaths every year. Patients who develop VAP stay, on average, 4 days longer in the ICU. The per-case cost of VAP is estimated to be \$23,000, and the total incremental costs to the U.S. health care system are high: \$2.19 to 3.17 billion USD per year¹⁻³ The wide range of these estimates results from the lack of universally accepted, reliable diagnostic criteria for VAP is present. The diagnosis of VAP may be based on any of a variety of definitions, including a surveillance definition, a clinical definition, a microbiologically confirmed definition, or a combination of the three methods. Microbiologically confirmed definitions also may be differentially based on blind tracheal aspirates, directed bronco-alveolar lavage, or even protected brush specimens.²

The original “Making Health Care Safer” report examined four interventions related to VAP: variation of position (semi-recumbent positioning and continuous oscillation), continuous subglottic suctioning, selective decontamination of the gastro-intestinal tract and the use of sucralfate. While the data in favor of semi-recumbent positioning was limited (reduced VAP but did not change mortality), the practice was judged to be easy to implement and had essentially no cost or adverse effects. Oscillation was less clear in its benefit secondary to poor methodological quality of the studies. While no evidence for harm was found, there were increased costs, estimated to be about \$100/day at the time of that report. Subglottic suctioning was judged to be a promising strategy. At the time of the report, it was infrequently used and there were only a few studies. Harmful effects were felt to be negligible but there were incremental costs for the specialized endotracheal tubes required for this strategy. Selective gastro-intestinal decontamination was found to have strong benefit for reducing VAP, though cost-effectiveness was unclear. Of the trials examined, none reported adverse events from this practice; however, there is continued concern that this practice may have a deleterious effect on antibiotic sensitivity in general, leading to more resistant organisms over time in individuals as well as on a population basis. Sucralfate as a VAP prevention strategy was judged to be inconclusive. Additionally, sucralfate is inferior compared with H-2 blockers for preventing gastro-intestinal bleeding. Given the increased risk of mortality with gastrointestinal bleeding and the increased costs should this complication occur, sucralfate can no longer be recommended for VAP prevention and H-2 blockers are the preferred agent for preventing gastro-intestinal bleeding in critically ill patients.

This updated review focuses on four strategies as well; elevation of the head of the bed, sedation vacations, oral care with chlorhexidine and subglottic suctioning.

What Are the Patient Safety Practices for Preventing Ventilator-Acquired Pneumonia?

We conducted a systematic review of the literature to update a 2001 review conducted for the original report. A recent study estimates that 14,000 to 20,000 lives could be saved each year in the U.S. if best practices to prevent VAP were universally applied to all patients on mechanical ventilation.³ The four primary recommended practices include: elevating the head of the bed to 30 degrees, sedation vacations, oral care with chlorhexidine (CHG), and subglottic suctioning endotracheal tubes. Ventilator “bundles” usually include other elements such as deep venous thrombosis (DVT)/pulmonary embolism (PE) prophylaxis and Peptic Ulcer Disease prophylaxis, but these procedures are designed to prevent other ventilator-associated conditions and do not address VAP prevention specifically. In fact, Peptic Ulcer Disease prophylaxis may increase the risk of VAP. Other VAP-specific preventive interventions may include use of closed suctioning circuits, scheduled circuit changes and a preference for orotracheal over nasotracheal intubation. The remainder of this section describes the evidence in support of the four primary VAP specific practices.

Head-of-Bed Elevation

The practice of head-of-bed elevation to prevent VAP has been recommended by several medical groups including the Canadian Critical Care Trials Group, the American Thoracic Society and Infectious Diseases Society of America, and the Centers for Disease Control and Prevention. This recommendation is based on early data showing that being supine was an independent risk factor for VAP.⁴ Importantly, a study in 1999 by Drakulovic and colleagues⁵ demonstrated a reduction in VAP with patients in the semi-upright position.⁵

A recent systematic review by Niel-Weisse and colleagues that applied strict inclusion criteria (randomized or quasi-randomized trial, published as a full paper and not an abstract, state the outcome measures used and present data sufficient to calculate the risks in both groups) and included only three of 208 potential studies, representing a total of 337 patients questioned whether patients’ head elevation can be maintained continuously above 30 degrees in ICUs, and point prevalence assessments used in many studies may overstate how often the goal is met.⁴ The effect of head-of-bed elevation on the incidence of both clinically diagnosed and microbiologically confirmed VAP was found to be non-significant (RR = 0.47, 95% CI = 0.19 to 1.17 and RR = 0.67, 95% CI = 0.23 to 2.01, respectively). A second study used broncho-alveolar lavage, and the other two used tracheal aspirates for the microbiological assessment. The third study found no significant increase in harm (decubitus ulcers); other potential harms (such as DVT) were not assessed. These same three trials also found no significant impact on mortality (pooled RR = 0.90, 95% CI = 0.64 to 1.27). The data were also judged to be of low quality for methodological reasons. Despite these findings, an evaluation of the results using an online Delphi process recommended the practice of keeping the head of the bed elevated by greater than 30 degrees to prevent VAP (most studies had actually used 45 degrees as their target).⁴ The favorable point estimates (all favored the intervention despite lack of statistical significance) and the lack of measurable harm may have influenced this recommendation.

Sedation Vacations

The use of sedation vacations, or sedation holds, has been shown to help patients wean from mechanical ventilation more quickly than when these techniques are not employed.^{6,7} Further, sedation vacations reduce patients’ exposure and subsequent risk of VAP as well as several other

mechanical ventilation-associated complications,^{6,7} and are, themselves, considered to be safe⁷. One pre-post study that examined a sedation protocol that specified daily interruption of sedatives in combination with spontaneous breathing trials demonstrated reduced ventilator days and reduced length of hospital stay. Although the sedation interruption group had a higher rate of self-extubation, the proportion of patients that required re-intubation was similar pre- and post intervention.⁷ These findings suggest that sedation vacations should be part of all ventilator and VAP prevention bundles.

Oral Care Using Chlorhexidine

Oral care using chlorhexidine (CHG) to reduce VAP is based on evidence that in intubated patients, gingival and dental plaque become rapidly colonized with bacterial overgrowth due to loss of natural mechanical elimination and poor hygiene. This microbiological burden becomes a source for aspiration of bacteria around the endotracheal tube cuff, resulting in pulmonary infection. Instituting meticulous oral care can reduce this microbiological burden and the potential for VAP. A systematic review in 2007⁸ that included seven randomized controlled trials (RCTs; 1,650 patients) evaluating CHG found a statistically significant reduction in the risk for VAP using a fixed effects model (RR=0.74 95% CI=0.56-0.96). Although the effect was found to be non-significant when a random effects model was applied, the absolute risk reduction was slightly better (RR=0.70, 95% CI= 0.47-1.04).⁸ A sub-group analysis of oral care using CHG in cardiac surgery patients did support the finding of a statistically significant reduction in the risk for VAP (RR=0.41, 95% CI=0.17-0.98)⁸

In 2008, the Canadian VAP Prevention Guidelines⁹ advised that oral care with CHG should be considered for VAP prevention, and the SHEA guidelines¹⁰ recommended regular oral care with an antiseptic solution. Although the SHEA guidelines did not specifically recommend CHG, all three of the studies that were cited as a basis for the recommendation used CHG.¹⁰

A 2011 systematic review of the effects of CHG¹¹ that included 12 RCTs (2,341 patients) further supported the previous findings. The relative risk of VAP after oral care with CHG was reduced 28 percent for all patients (RR, 0.72; 95% CI, 0.55 to 0.94); 59 percent for cardiac surgery ICU patients (RR, 0.41; 95% CI, 0.17 to 0.98); 33 percent for trauma/surgical ICU patients (RR, 0.67; 95% CI, 0.50-0.88); and 28 percent for mixed ICU patients (RR, 0.77; 95% CI, 0.58-1.02 for mixed ICUs). Evidence has also shown that using a 2% solution of CHG is superior to a 0.2% solution, which is superior to 0.12%.¹¹

Subglottic Suctioning Endotracheal Tubes

Subglottic suctioning tubes address the tendency for nasal-oral secretions and debris to pool above the endotracheal tube cuff and below the vocal cords. This pooling creates a rich culture medium for micro-organisms found in the nasal-opharynx, which leads to overgrowth and is thought to be a major cause of VAP. Subglottic suctioning endotracheal tubes use a port or ports just above the cuff to allow removal of this pooled material so it cannot act as a culture medium or be aspirated. Some of the systems use a simple single suctioning port, whereas others use an active lavage system with an inflow and outflow port to “wash “out the material. Our review identified no studies that directly compared these types of subglottic suctioning tube design (or continuous vs. intermittent suction); nevertheless, the evidence is strongly in favor of these devices for the reduction of VAP. Among 13 RCTs (2,442 patients) identified for a recent systematic review,¹² 12 of the RCTs found that subglottic suctioning reduced VAP; the pooled risk-reduction was 0.55 (95% CI=0.46 to 0.66, $p<0.00001$) with no heterogeneity in the studies.

This practice also significantly reduced the duration of mechanical ventilation and length of stay in the ICU, although it had no impact on ICU- or hospital mortality.

How Have Practices To Prevent Ventilator-Acquired Pneumonia Been Implemented and What Has Been Learned?

Practices to prevent VAP are usually “bundled” into a care package of several elements as described above. The package may also incorporate elements beyond the four discussed above, including closed in-line endotracheal suctioning systems, humidification systems, and non-VAP specific interventions such as DVT/PE prophylaxis, for which ventilated patients are at increased risk. In a 2005 pre-post study, Resar and colleagues reported a 45 percent reduction in VAP across 35 ICUs that used such a bundled approach in a collaborative. This particular bundle used only sedation vacations and head-of-bed elevation as VAP-specific elements.¹³ Subsequent pre-post studies have also found that bundled elements synergistically reduced the rate of VAP by as much as 40 percent in both adult and pediatric patient populations.^{14,15}

One factor that has been noted in most of these publications is the difficulty of ensuring that all patients who qualify for the bundle and the individual elements within the bundle (e.g., for some patients—such as spine surgery patients with a dural tear—head-of-bed elevation may be contraindicated,) actually receive the bundle’s elements consistently. The Michigan Keystone Project addressed this quality gap through a process of developing and applying technical tools such as checklists and ensuring their use through improvements in teamwork and the safety climate within 112 ICUs. This pre-post study found a 71 percent risk reduction in VAP, while at the same time demonstrating an increase in the adherence to evidence-based practices from 32 percent at baseline to 84 percent after 30 months.¹⁶ This finding suggests that a combination of effective evidence-based bundle elements reinforced with strategies to improve teamwork and safety can ensure that patients receive appropriate care and that outcomes improve substantially.

Others have also noted this positive effect of collaboratives on closing the quality gap. In their evaluation of the routine use of VAP prevention practices, Krein and colleagues (2008)¹⁷ found that use of semi-recumbent positioning was much more prevalent than the use of subglottic drainage (73% vs. 21% of hospitals that reported use of VAP practices). They also found that use of semi-recumbent positioning was strongly influenced by participation in collaboratives (such as the Keystone Project) and is considered primarily a responsibility of nursing staff. In contrast, use of subglottic suctioning endotracheal tubes is not influenced very much by collaboratives and is primarily a physician decision. It is unclear whether these differences are secondary to the participation in collaboratives, depend on who has the primary responsibility for decisionmaking, or both. Interestingly, the authors also noted that whereas the prevalence of semi-recumbent positioning was dramatically higher than that of subglottic drainage, when the effectiveness of the techniques was compared, the supportive evidence for subglottic drainage was found to be much stronger than for semi-recumbent positioning (five randomized studies vs. two). More recently, Krein (2011)¹⁸ reported that the prevalence of use of VAP prevention measures was also strongly influenced by the threat of non-payment for this hospital-acquired infection, although the use of any one bundle component for preventing VAP varied across respondents to their survey. This finding would suggest that efforts to close the quality gap and improve the prevalence of use of prevention practices will need to be multi-factorial.

The cost-effectiveness of several VAP prevention practices—both subglottic suctioning endotracheal tubes and VAP bundles—has been assessed. For subglottic suctioning tubes, it is

estimated that 11 people need to be treated (number needed to treat) in order to prevent one VAP. Although the cost of these endotracheal tubes is approximately \$18 USD, one model of continuous washing tubes (inflow/outflow ports with pumping system) costs about \$200 USD. In comparison, the cost of a standard endotracheal tube is approximately \$1 USD. If the number needed to treat is accurate, these special endotracheal tubes (even the most expensive versions) are cost-effective, especially if reserved for patients likely to remain intubated for more than 48 to 72 hours (the risk for VAP in those requiring intubation less than 48- to 72 hours is considered low). This conclusion is further supported by Hallais and colleagues,¹⁹ who compared the cost of these tubes to the cost of VAP, using very conservative values. The authors found that averting only three VAPs would offset the cost of the special tubes. Based on this cost analysis, any ICU with at least 3 VAPs per year would find that switching to these tubes reduces harm as well as costs.

Ventilator bundles have also recently been evaluated for their cost-effectiveness. A Danish study²⁰ retrospectively examining ventilated patients in a single ICU found that the cost of preventing one VAP was 4451 €(approximately \$6,000 USD), and the cost of preventing one death was 31792 €(approximately \$42,000 USD). While the cost and incidence of each VAP varies across patient populations, the study concluded that the ventilator bundle would likely be cost-effective in most environments.

Conclusions and Comment

In conclusion, of the four key practices for preventing VAP, subglottic suctioning endotracheal tubes have strong evidence to support their ability to reduce VAP and to do it cost-effectively, based on a systematic review of multiple RCTs. Strong evidence from a recent systematic review of multiple RCTs also supports oral care using CHG. Evidence from a few non-randomized studies supports sedation vacations directly. This evidence is of moderate strength. The maintenance of a head-of-bed elevation of at least 30 degrees (a ubiquitous element of VAP prevention bundles) is supported by very little evidence, yet remains part of virtually all recommendations by U.S. quality and safety organizations. This tacit support is likely a result of its ease and lack of evidence of harm, although the ability to effectively implement this element consistently has been questioned. Other elements often advocated for VAP prevention but not specifically addressed in this chapter include using antimicrobial-coated endotracheal tubes (evidence supports effectiveness),²¹ closed circuit in-line suctioning systems (evidence does not support their effectiveness)²² and humidification circuits on ventilators (evidence does not support their benefit).²³

Evidence from multiple large pre-post studies also supports the effectiveness of VAP bundles. While the evidence for each specific VAP prevention bundle element may vary, two principles are clear. First, VAP is most effectively reduced by the bundling of several elements together for a potentially synergistic effect, and bundles should be developed locally based on both institutional expertise and evidence, with ongoing evaluation of the success of the interventions. Second, the consistent application of each of the bundle elements to all patients who qualify for them is essential to success. The use of teamwork tools and strategies to ensure this consistency can have a tremendous impact on closing this quality gap and improving patient outcomes. Technical work (the bundle) needs to be supported by adaptive work (the processes needed to apply the bundle consistently) for the best success.¹⁸ A summary table is located below (Table 1).

Table 1, Chapter 11. Summary table

Scope of the Problem targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Moderate-to-high	Low	Low-to-moderate	Moderate/Moderate

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Chapter 12. Interventions To Allow the Reuse of Single-Use Devices: Brief Review (NEW)

Meredith Noble, M.S.

Introduction

Many hospitals choose to reprocess single-use devices (SUD)—those intended by the manufacturer to be discarded after one use—for reuse in additional patients.¹ Reprocessing includes cleaning, sterilization, and if necessary, refurbishing. Specific information on the size of the reprocessing industry is not available.² According to the Association of Medical Device Reprocessors Web site, disciplines that commonly use reprocessed devices include: cardiovascular; arthroscopic/orthopedic; general surgery; gastroenterology; laparoscopic surgery.

A wide variety of SUDs are reprocessed. Commonly reprocessed SUDs include: arthroscopic shavers; biopsy forceps; blood pressure cuffs; clamps and dissectors; compression sleeves; electrophysiology catheters; external fixation devices; laparoscopic scissors and forceps; opened but unused items; orthopedic drill bits and burrs; phaco tips; pneumatic tourniquet cuffs; pulse oximeter sensors; scissors and staplers; soft tissue ablaters; trocars.¹ Opened but unused items are not technically reused but also must be reprocessed.

Using SUDs is money-saving and generally thought to be safe.¹ However, SUDs are only required to be demonstrated to the Food and Drug Administration (FDA) as safe for one use; some manufacturers and the Medical Device Manufacturer's Association contend that reusing SUDs is unsafe because the devices are frail and cannot be adequately cleaned and resterilized.^{1,3} Potential risks to patients include infection, toxicity, particulate contamination, and mechanical failure.¹

Although reuse of single-use devices is common and perhaps even pervasive, little evidence on its safety and efficacy has been published. To gather the available evidence, a literature search of PubMed was conducted for English language articles published between January 1, 2001 and November 2, 2011.

What Are the Practices for Assuring the Safety of Reused Devices?

Reprocessing used SUDs is subject to FDA oversight. On August 14, 2000, FDA issued a policy on the reuse of single-use medical devices making hospitals and third-party reprocessors subject to all the requirements of the Federal Food, Drug, and Cosmetic Act—a requirement formerly imposed only on original equipment manufacturers (OEMs).⁴ In response, many hospitals that had been reprocessing SUDs in-house began using third parties to reprocess the devices. Unused items are not subject to FDA oversight.⁵

The Medical Device User Fee and Modernization Act of 2002 expanded regulatory requirements. Premarket notification submissions (510(k)s) for certain reprocessed SUDs identified by FDA must now include validation data. Validation data include cleaning, sterilization, and functional performance data, which confirm that each SUD will remain substantially equivalent to a predicate device after the maximum number of times the device is reprocessed.⁴ In addition, the reprocessor must be indicated with a mark or label for each reprocessed SUD.

According to FDA regulations, “a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers, including:

- Submitting documents for premarket notification or approval for each device and model reprocessed
- Registering as a manufacturer with FDA and listing all products
- Submitting adverse event reports
- Tracking devices whose failure could have serious outcomes
- Correcting or removing from the market unsafe devices
- Meeting manufacturing and labeling requirements.”⁴

The FDA considers hospitals that reprocess devices as device manufacturers subject to the requirements of the Quality System (QS) Regulation.⁶ However, most hospitals who use reprocessed SUDs obtain them from third parties who perform the reprocessing.⁴ An estimated 95% of reprocessing in the U.S. is completed by two firms,¹ Stryker Sustainability Solutions (formerly Ascent Healthcare Solutions, Phoenix, AZ) and SteriMed Inc. (Minneapolis, MN).³ According to their Web site, Stryker claims the majority of the reprocessing market and has over 2,000 hospital members. Their service includes delivering orders and picking up used equipment (which hospital personnel leave in marked bins), and at their facility, sorting, cleaning, refurbishing/repairing, repackaging, and resterilizing equipment. The FDA has cleared or approved a variety of sterilizing agents that can be used in reprocessing⁷ and inspects reprocessing facilities for compliance with regulations, with steep penalties for violators.⁵

How Have These Practices Been Implemented?

Reprocessing protocols in the peer-reviewed published literature vary but generally include cleaning and sterilization. Cleaning may consist of manual or automated washing with water and detergent or enzymatic solution. Sterilization may entail pressurized steaming (i.e., in autoclave), ethylene oxide (especially for heat sensitive items) or gamma radiation. Quality assurance is intended to verify sterilization success. The FDA urges the use of biological indicators to verify that test organisms are killed.⁶ Chemical indicators verify that sufficient temperatures were achieved or sterilant was present in the sterilizer in each sterilization run. Repairs and part replacements should be made as necessary. The FDA does not require the use of particular protocols, but may prefer standard procedures such as those recommended by the Association for the Advancement of Medical Instrumentation.⁶

Reprocessing is performed in hospitals or by independent third parties at separate facilities. Data suggest the majority of hospitals that reprocess devices use third parties.¹ When such a vendor is used, implementation for the hospital should not pose challenges. Personnel must remember to place used devices in bins provided by the reprocessing vendor; the vendor provides pick up, reprocesses the items, and delivers ready-to-use items. Ordering reprocessed devices should not differ from ordering new devices.

What Have We Learned About These Practices?

Cleaning. Theoretically, cleaning should remove all debris and sterilization should inactivate potentially infective viruses, bacteria, and fungi. Literature searches performed for this review identified nine laboratory studies published in the last 10 years that tested an array of reprocessed SUDs for microbiological contamination. Devices studied included laparoscopic instruments,^{8,9}

various catheters,¹⁰⁻¹² trocars,¹³ sphincterotomes,¹⁴ diathermy pencils,¹⁵ and tracheostomy tubes.¹⁶ While most studies could not demonstrate microbial contamination after reprocessing, four found that reprocessed SUDs were contaminated.^{9,11,15,16} Two of the studies also reported damage, incomplete kits, and/or compromised functioning.^{9,16} Another study assessed cleaning to remove test soils from biopsy forceps and found up to 95% of the material was removed.¹⁷

Effect on patient outcomes. The literature search spanning the last 10 years identified only one randomized controlled study that compared new and reprocessed SUD laparoscopic instruments used to perform cholecystectomy; the study found no significant differences in outcome.²¹ This study is small (125 patients) and may be underpowered to detect rare events. A single study may not be representative of outcomes in general; devices and protocols will vary.

A meta-analysis of nine studies that compared new and reprocessed hemodialyzers found reuse was associated with an increased risk of hospitalization but no difference in mortality.²⁰

The U.S. Government Accountability Office (GAO) published a report in January 2008 discussing FDA oversight of reprocessed SUDs and the available information on the potential health risks of using reprocessed SUDs. The report concluded:

“The limited number of peer-reviewed studies related to reprocessing that we identified were insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. Despite the limitations of available data, FDA’s analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk.”²

Cost savings. If using reprocessed SUDs is as safe as using new devices, saving costs on materials would free hospital resources for other uses without compromising patient safety. Our searches identified four cost studies published in the last 10 years. A modeled European study found that the cost savings for reprocessing cardiac electrophysiology catheters was 33% for ablation applications and 41% for diagnostic.¹⁸ A modeled Canadian study found savings of \$0 to \$739 per year per patient when hemodialyzers were reprocessed.¹⁸ Hemodialyzers are typically reused only by the same patient. A meta-analysis of nine studies in which various devices were used had an overall savings rate of 49%, but stipulated that the few studies identified were of poor quality and had missing data, including adverse event cost data.¹⁹ A meta-analysis of nine studies that compared new and reprocessed hemodialyzers found reuse was associated with small cost savings, an increased risk of hospitalization, and no difference in mortality.²⁰ The Stryker Web site states that member hospitals can save 50% over purchasing new equipment in acquisition costs, and 70%–80% in operating room medical waste disposal costs. Reusing devices should also reduce wastes for landfill.

What Methods Have Been Used To Improve These Practices?

Healthcare Risk Control (HRC) is a service ECRI Institute offers for risk managers. HRC provides resources for a variety of patient safety issues, and specifically recommends that hospital systems considering use of reprocessed SUDs should “at a minimum, establish written policies, procedures, and policies for such practices... [and] should be widely circulated throughout the organization.”¹ They further recommend establishing a reuse committee comprised of individuals from multiple departments, including materials management, risk management and/or hospital legal counsel, infection control, clinical and/or biomedical

engineering, administration, central sterile supply, surgery, finance, and physician(s) advocating reuse.¹ A third party reprocessor should be selected based upon registration with the FDA and compliance with FDA regulations; the types of devices to be reprocessed; and support (including logistical support such as device pickup).¹ Reprocessors usually provide template policies and procedures to hospitals to support implementation.¹

Conclusions and Comment

Reprocessing SUDs with appropriate quality controls should theoretically guarantee sterilization. Less information is available on the integrity of the devices themselves after reprocessing; the FDA recommends that reprocessors test all devices to ensure that functionality is maintained.

Some laboratory studies in the clinical literature found that various devices were not sterile; however, quality assurance should prevent unsterile devices from being reused. Some devices remained unsterile after multiple attempts; use of the protocols or reuse of the particular device warrants reconsideration in such circumstances.

Clinical literature and data on real-world use are currently not robust enough for the GAO or independent authors to firmly conclude that reused SUDs are safe. However, one systematic review found an increased rate of adverse events in patients treated with reused SUDs. The protocols in the peer-reviewed literature may differ from those used by third party reprocessors. A summary table is located below (Table 1).

Table 1, Chapter 12. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Low	Low	Low	A lot/Not difficult

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Section C. Surgery, Anesthesia, and Perioperative Medicine

Chapter 13. Preoperative Checklists and Anesthesia Checklists

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How Important Is the Problem?

Surgical operations greatly benefit the public health; however, they can also be directly responsible for substantial morbidity and mortality. In industrialized countries, the rate of perioperative death directly due to inpatient surgery has been estimated at 0.4 percent to 0.8 percent, and the rate of major complications has been estimated at 3 percent to 17 percent.^{1,2} Sources of these complications are numerous, including wrong-patient/procedure/site surgery, anesthesia equipment problems, lack of availability of necessary equipment, unanticipated blood loss, non-sterile equipment, and surgical items (e.g., sponges) left inside patients. The complexity of most surgical procedures requires a well-coordinated team to prevent these events.

The medical community recognizes that anesthesia has reached a high level of safety; however, with increased awareness, it is believed that the risk, particularly morbidity risk, can be further reduced.³ As an example of increasing awareness, in June 2010, the European Board of Anesthesiology (EBA) and the European Society of Anesthesiology (ESA) jointly adopted the “Helsinki Declaration on Patient Safety in Anaesthesiology.”⁴ Also, the journal *Health Devices* listed, “Anesthesia hazards due to incomplete pre-use inspection” as one of the top ten technology hazards for 2012.⁵

What Is the Patient Safety Practice?

Preoperative checklists can help prevent errors and complications related to surgery. Checklists are often implemented within a multifactorial strategy of interventions; therefore they usually cannot be judged alone as a patient safety practice. The World Health Organization (WHO) Surgical Safety Checklist is a prominent example of a preoperative checklist intended to ensure safe surgery and minimize complications; it has been translated into at least six languages.⁶ Because of its prominence and importance, the majority of our review for this PSP details the WHO checklist: its development, pilot testing, context and implementation at different sites, and degree of adoption and diffusion around the world.

In addition to the WHO checklist, we also reviewed evidence on three other types of checklists:

- The SURPASS checklist.⁷⁻¹⁰ The checklist encompasses not only the operation itself, but all events from admission to surgery to discharge
- Checklists specifically intended to prevent wrong-site surgery. Two items on the WHO checklist address wrong-site surgery (“Has the patient confirmed his/her identity, site, procedure, and consent?” and “Is the site marked?”). In 2004, the Joint Commission created the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.¹¹ It comprises three sets of steps: pre-operative verification process, marking the operative site, and a “time out” immediately before the operation. A

checklist can potentially be used to clarify the details of these three steps. The Universal Protocol is intended to prevent wrong surgery not just in the operating room but anywhere an invasive procedure is performed (e.g., interventional radiology unit).¹²

- Checklists specifically intended to check anesthesia equipment. The WHO checklist also contains a specific item about preoperative anesthesia (“Is the anaesthesia machine and medication check complete?”). This single item could itself be addressed by a sub-checklist. In 2008, the American Society of Anesthesiologists provided general guidelines about items that should be checked before surgery, and institutions can implement the guidelines to tailor the checklist to their specific equipment and clinical settings.¹³

Checklists have also been developed, implemented, and assessed outside of the realm of surgery. The Michigan ICU checklist (also referred to as the Keystone project) has been shown to prevent central line-associated bloodstream infections (CLABSI).^{14,15} This program involved a multifactorial intervention at 108 Michigan ICUs. Data showed a reduction in CLABSI from 7.7 infections per 1,000 catheter-days before the program to only 1.4 infections per 1,000 catheter-days at 16 to 18 months after program initiation follow-up. A 2001 study by Dixon-Woods and colleagues¹⁵ proposed six reasons for this reduction, including “creating a densely networked community with strong horizontal links that exerted normative pressures on members” and “harnessing data on infection rates as a disciplinary force.” A recent systematic review of this program (and other PSPs to prevent hospital-associated infections) was conducted by the Blue Cross and Blue Shield Evidence-based Practice Center; please refer to that report for further information about the Keystone project.¹⁶

Background Information About Preoperative Checklists

In January 2007, the WHO Patient Safety group started work on the Second Global Patient Safety Challenge: Safe Surgery Saves Lives. This group of international experts identified four areas of potential improvement in surgical safety: surgical site infection prevention, safe anesthesia, safe surgical teams, and measurement of surgical services.¹⁷ Based on that work, in early 2008, the WHO published a guideline for safe surgery.¹⁸ This guideline was used as the basis for the WHO Surgical Safety Checklist, which was launched in June 2008.

The checklist, which was included as a Supplementary file in the original publication,⁶ contained 19 items in three phases with collaborative involvement of the surgeon, the anesthetist, and the nursing team:

- Before induction of anesthesia (“Sign In”), covering areas such as patient identification, anesthesia equipment check, and a pulse oximetry check
- Before skin incision (“Time Out”), covering areas such as team introductions, review of critical steps, and antibiotic prophylaxis
- Before patient leaves operating room (“Sign Out”), covering areas such as checking counts of instruments, specimen labeling, and concerns for recovery

The SURPASS checklist (SURgical PATient Safety System)⁷⁻¹⁰ is intended to address any events that occur between patient admission and discharge. Thus, it encompasses more potential areas of safety than the WHO checklist, which is focused only on the operating room. An estimated 53 percent to 70 percent of surgical errors occur outside the operating room.^{8,19,20} Within the operating room itself, the SURPASS checklist is less specific than the WHO checklist

(for example, the SURPASS checklist does not specifically mention any of the following: pulse oximetry, difficult airway, risk of blood loss (although it asks whether blood products are available), team introductions, and anticipation of critical events).

In January 2004, the Joint Commission launched the first version of the Universal Protocol (UP) for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.^{11,21} It comprises three sets of steps: pre-operative verification process, marking the operative site, and a “time out” immediately before the operation. The preoperative verifications (of person, procedure, and site) are supposed to occur not only in the operating room, but also (if applicable) when the procedure is scheduled, when the patient enters the health care facility, and anytime care is transferred between caregivers. Site marking should involve only the operative site and should be visible before the patient is draped. The “time out” is to occur before incision and involve the entire operating room team. The Universal Protocol is not a checklist,¹² but it could be implemented using one or more checklists. Both steps 1 and 3 specifically mention the potential use of a checklist.

Anesthesia safety guidelines and standards are actively reviewed and modified globally through organizations such as the WHO and the World Federation of Societies of Anaesthesiologists (WFSA).²² The latest WFSA standard, which was developed as part of the “Safe Surgery Saves Lives” project, recommends that an appropriate “pre-list check” be performed prior to the start of each operating list and an appropriate “pre-patient check” be performed prior to each anesthetic. In addition, individual anesthesia societies are developing guidelines for pre-anesthesia checks, including the American Society of Anesthesiologists (ASA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI). The latest U.S. pre-use checkout guidelines, entitled “Recommendations for Pre-Anesthesia Checkout (PAC) Procedures,” were published in 2008 by the ASA.¹³ These guidelines were a result of a multi-year effort by an ASA task force consisting of members from the ASA, the American Association of Nurse Anesthetists (AANA), the American Society of Anesthesia Technicians and Technologists (ASATT), and major anesthesia system manufacturers. The latest AAGBI revision was published in 2004 and has been adopted by many institutions around the country.²³ Similar to the WFSA guideline checklist, the full ASA and AAGBI checklists were designed to be used at the start of the day with a subset of the full checklists performed prior to each procedure. These societies’ sample checklists were developed as a basis for institutions to develop their individual checklists.

Additional background information about preoperative checklists, including how they were developed and modified, and the overlap between different checklists, appears in Appendix A.

Why Should This Patient Safety Practice Work?

No formal “model” exists for why preoperative checklists should reduce surgical errors, but studies have cited several common reasons. These reasons include ensuring that all critical tasks are carried out, encouraging a non-hierarchical team-based approach; enhancing communication; catching near misses early, anticipating potential complications, and having technologies to manage anticipated and unanticipated complications. With regard to anesthesia checklists, Staender and Mahajan³ attribute the reduced anesthesia-related mortality rates to a combination of interventions, including incident reporting, simulations, and checklists.

What Are the Beneficial Effects of the Patient Safety Practice?

In this section, the primary issues surrounding checklists involve implementation, rather than whether they are effective. Consequently, we briefly summarize the primary results, and the bulk of our work appears later in detailed assessments of the implementation efforts.

World Health Organization Checklist

The 2008 WHO Surgical Safety Checklist was tested at eight sites (Prince Hamzah Hospital in Amman, Jordan; St. Stephen's Hospital in New Delhi, India; University of Washington Medical Center in Seattle, U.S.; St. Francis Designated District Hospital in Ifakara, Tanzania; Philippine General Hospital in Manila, Philippines; Toronto General Hospital in Toronto, Canada; St. Mary's Hospital in London, England; and Auckland City Hospital in Auckland, New Zealand).⁶ These settings varied greatly in the number of beds (range 371 to 1800), the number of operating rooms (range 3 to 39), and the income level of the country (four low, four high). Surgical safety policies prior to implementation of the WHO Checklist also differed regarding the use of routine intraoperative monitoring with pulse oximetry (six of eight sites), oral confirmation of patients' identity and surgical site in the operating room (only two of eight sites), and routine administration of prophylactic antibiotics in the operating room (five of eight sites). None of the eight sites had a "standard plan for intravenous access for cases of high blood loss," or formal team briefings preoperatively or postoperatively.

Baseline data were obtained at each site for 3 months prior to checklist introduction, involving a total of 3,733 surgical procedures. In the subsequent 3- to 6-month period after checklist introduction, involving 3,955 procedures, data showed decreases in patient mortality (from 1.5% to 0.8%) and inpatient complications (from 11% to 7%). No single site was driving the findings, as evidenced by the persistence of findings after the removal of any single site in a sensitivity analysis. Authors found that the performance rates for six specific safety indicators (e.g., using a pulse oximeter) also increased after checklist introduction, suggesting that the safety indicators may have been responsible for the lower rates.

In discussing the results, authors acknowledged that the underlying reasons for the improvements were "most likely multifactorial" and included explanations such as the following:

- The checklist itself
- A Hawthorne effect (i.e., rates may have decreased because operating room personnel knew they were being measured). The authors argued against this possibility based on two aspects of their data: (1) that this knowledge was in place both before and after checklist introduction, and (2) the subset of procedures for which study personnel were present in the operating room had the same reductions in complications as procedures where study personnel were absent from the operating room.
- The simple existence of a formal pause or preoperative briefing (which could be done without a "checklist"). Such a pause is a necessary component of the checklist.
- Increased uptake of safety technologies (e.g., administering antibiotics in the operating room rather than in preoperative wards). This change could be considered a byproduct of checklist introduction (i.e., hospitals made more antibiotics directly available in the operating room because of the presence of an antibiotics-related item on the checklist)
- A broad change in safety culture and teamwork at that site, an explanation supported by the finding that greater increases in safety attitudes at the pilot sites were associated with greater reductions in complications.²⁴

In a subsequent, 2010, publication, Weiser and colleagues²⁵ presented a subgroup analysis of the 2009 NEJM publication that was focused on urgent surgery (defined as surgery required to be performed within 24 hours of assessment in order to be beneficial). Complications dropped from 18 percent in the pre-intervention phase to 12 percent in the post-intervention phase, and death dropped from 3.7 percent to 1.4 percent. Also, a 2011 study by Haynes and colleagues²⁴ reported data on the Safety Attitudes Questionnaire (SAQ) in the eight pilot sites before and after checklist introduction. The SAQ is scored on a 1 to 5 scale, where a 5 represents the most safety-conscious attitude. Scores on the SAQ were only slightly higher in the phase after checklist introduction than before introduction (4.01 vs. 3.91, representing an increase of only 2.5 percent of the scale range; this small difference was nevertheless statistically significant). However, the change in SAQ scores was associated with reduced complication rates (Pearson $r=0.71$), meaning that sites with greater improvements in safety attitude tended to have greater reductions in complications. The publication also reported that 80 percent of respondents considered the checklist easy to use, 20 percent believed it took too long, and when respondents were asked if they would want the checklist used if they were undergoing surgery, 93 percent said yes.

SURPASS Checklist

An empirical test of the 90-item SURPASS checklist was reported in a 2010 study by DeVries and colleagues.⁷ The design was a 6-month interrupted time series with concurrent controls; six hospitals using the checklist were matched with five other hospitals that did not, and researchers measured the rates of surgical complications in both groups. The 11 hospitals were distributed through the Netherlands and comprised six tertiary hospitals, three academic hospitals, and two regional hospitals; numbers of beds per hospital ranged from 380–1002. These hospitals had already been measured for their safety performance, so the potential Hawthorne effect is lower than it would have been in hospitals just starting to be measured. Regarding implementation, authors stated that the SURPASS checklist involved extensive time and effort. A random sample of cases generally revealed good compliance with the checklist (median 80%).

The 3-month period after the checklist was initiated (compared with the 3 months before) saw numerous improvements: decreases in the percentage of patients with complications (from 15% to 11%), in-hospital mortality (1.5% to 0.8%), patient temporary disability (9.4% to 6.6%), and reoperations (3.7% to 2.5%). No such improvements were found among the control hospitals. Interestingly, the extent of improvement was associated with greater compliance with the checklist: the 566 patients whose surgery involved greater checklist compliance had 7.1 complications per 100 patients, which was considerably lower than the 18.8 per 100 experienced by the 580 patients whose surgery involved less checklist compliance. This finding provided greater confidence that the checklist itself was the reason for the improvements. A subsequent retrospective review of 294 medical claims¹⁰ estimated that 40 percent of deaths and 29 percent of liability incidents might have been prevented if the SURPASS checklist had been used.

Wrong-Site Surgery Checklists

Wrong-site surgery is relative rare: Estimates for various procedures range from 1 in 13,000 procedures for wrong-site anesthesia block to 1 in 4,200 for wrong-side ureteral stents.²⁶ A general systematic review estimated that the overall rate was 1 to 5 per 10,000 procedures.²⁷ Given the rarity, demonstrating a statistical reduction would require an unfeasibly large study. A systematic review searched for literature and concluded there was “no literature to substantiate the effectiveness of the current JC [Joint Commission] Universal Protocol in decreasing the rate

of wrong site, wrong level surgery.”²⁷ Therefore, the preventive benefits of a checklist to prevent wrong-site surgery, are generally assumed based on clinical expertise.

Anesthesia Equipment Checklists

In evaluating beneficial effects, the same limitations apply to anesthesia checklists as apply to wrong-site surgery checklists. The rate of mortality associated with malfunction of anesthesia equipment is 1:100,000, and the rate of severe morbidity ranges between 1:170 and 1:500.³ Future research may be possible to evaluate the severe morbidity rate; however, addressing the benefits on mortality would require an unfeasibly large study.

A 2000 randomized cross-over study by Blike and Biddle²⁸ compared the effectiveness of the 1994 hard-copy version of the FDA-approved AACR to a researcher-designed electronic checklist. Machine faults were purposely entered into an Ohmeda Modulus II Plus Anesthesia System. Participants using the electronic checklist were first given a researcher-drafted “philosophy of anesthesia apparatus checkout,” which outlined basic strategies to reduce anesthesia apparatus-related patient injury. They reported that the electronic checklist greatly improved the detection of prearranged anesthesia equipment faults. For 19 of the 20 faults studied, the electronic checklist was either equal or superior to the AACR. However, the electronic checklist missed 30 percent of the “difficult” faults (e.g., breathing circuit leak). While this percentage was better than when the AACR was used (60%), it is still substantial. Studies like these provided the basis for revising the AACR. For additional references to the effectiveness of the AACR, we refer the reader to the 2008 ASA guideline; most of this literature was published prior to 2000.

Ben-Menachem and colleagues²⁹ performed a simulation study, published in 2011 that used the 2008 ASA guideline to measure the performance of anesthesia residents of Sheba Medical Center (Israel). The residents were instructed to complete the ASA checklists during simulation-based scenarios, which included two pre-arranged equipment failures. The study showed that 25 of 28 participants correctly performed 70 percent or more of the items on the checklist that is used before the first-morning case, and 27 of 30 participants correctly performed 70 percent or more of the items on the between-case checklist. Regarding the pre-arranged equipment failures, 30 of 31 participants identified O₂ supply and pressure alarms and 30 of 30 participants recognized an abnormal capnograph waveform.

What Are the Harms of the Patient Safety Practice?

Direct harms of preoperative checklists have not been reported. In 2011, Sewell³⁰ reported that after WHO implementation, the rate of lower respiratory tract infections actually increased from 2.1 percent to 2.5 percent. Whether this increase was caused by the checklist is unclear; however the authors attributed rate *reductions* to the checklist, so they could also have attributed rate *increases* to the checklist. In 2011, Kearns³¹ reported that 3 months after WHO checklist implementation, 30 percent believed it was an inconvenience in emergency cases; however, this percentage was lower than it had been prior to implementation of the checklist when staff were asked hypothetically whether they believed it would be an inconvenience in emergency cases (53 percent said it would be). In 2010, Thomassen and colleagues³² reported user experiences with their pre-induction anesthesia checklist. In this qualitative study, focus group interviews were conducted amongst the participating nurses and physicians. Users reported that checklist use could divert attention from the patient and that it interfered with doctor-nurse workflow, although the latter improved with increased use.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

World Health Organization Checklist

In 2011, one of the eight pilot sites that piloted the WHO Checklist reported checklist-related opinions of surgical team members 18 months after checklist introduction.³³ Team members reported high levels of agreement with the questions “Do you think the use of the checklist has improved patient safety?” “Are you comfortable in reminding other members of the team to carry out the checklist?” “If you were to undergo surgery would you want the checklist to be used?” and “Do you think that use of the checklist generally has improved communication among members of the Operating Room team?” Team members generally estimated that it took about two minutes to complete the checklist.

We identified nine reports of the implementation of the WHO checklist at other sites; implementation details at each site appear in Table 1 in Appendix D in the section titled “Evidence Tables for Chapter 13.” Eight studies used the 2008 WHO checklist as a basis, and one did not say which version was used. Six studies modified the WHO checklist, according to either surgical specialty (three studies) or country (three studies). Of six studies that modified the checklist, five provided their modified checklist within the paper, and of these five, four included all of the WHO items and one did not (they had deleted some items).

Six studies were case series, and three were before-after studies. Regarding a theory or logic model, eight of nine provided some statements about why a checklist should work to reduce complications (e.g., “Checklists may be used to improve patient safety by ensuring that all elements of a practice are instituted for each new clinical event”).³¹ Six studies were conducted in the UK, two in the U.S., and one in Finland. Four studies involved surgical specialties (pediatrics, OB-GYN, orthopedics, and otorhinolaryngology), and the other five were general surgery.

Only two studies reported on the pre-existing safety infrastructure: one stated that a core group of patient safety experts was in place before checklist implementation, and another stated that a hospital quality infrastructure had been in place for five years prior to implementation. Two studies reported information on the pre-existing safety culture, and they both measured staff attitudes specifically about checklist-related items. In one, some safety aspects were fairly good (knowledge of OR-teams’ names and roles, the rate of recording of postoperative follow-up instructions, and overall successful communication range from 61% to 93%); however the rate of discussing risks was only 24 percent. In the other study, most respondents (81% to 85%) believed that communication in the operating room could improve and that for elective surgery the checklist would be useful) and only 31 percent already felt familiar with other operating room team members. However, for emergency surgery, a slight majority (53%) believed that introducing the checklist would be inconvenient. All of these opinions were hypothetical as they were solicited before checklist introduction.

The results of the nine implementations appear in Table 2 in Appendix D in the section titled “Evidence Tables for Chapter 13.” Regarding checklist training, three sites mentioned educational sessions, three used posters in the operating room, two mentioned a hospitalwide publicity campaign, two mentioned that training was provided (however, no details were provided), and two either failed to mention training or stated that only limited training was provided. Four studies mentioned a pilot testing period; these pilot tests lasted 1 to 3 months and often involved minor modifications to the checklist. Three studies reported the degree of

compliance with the checklist; one simply reported 97 percent compliance, and the other two reported improvement over time (from approximately 60% to approximately 80% in one study, and from 85% to 95% in another study). One study reported that it took about two minutes to complete the checklist, and that 20 percent of respondents believed it caused an unnecessary time delay.

Feedback from surgical teams was generally positive, but support tended to be greater from nurses and anesthesiologists than from surgeons. Two studies reported increases in certain attitudinal variables such as the degree to which people felt familiar with others in the operating room, the quality of communication, the anticipated safety of patients, and the usefulness of the checklist in either elective or emergency cases. Behaviorally, one study reported that after 3 months, team briefings were occurring in 77 percent of operations and time-outs in 86 percent. Another study reported improvements in anesthesiologists' knowledge about patients, their check of anesthesia equipment, and staff knowledge of patient identity/procedure/site.

Reasons cited for success included good training and staff understanding, a local champion, support from upper management, being able to modify the checklist, distribution of responsibility, the feeling of ownership by team members, and enhanced communication and teamwork. Barriers to implementation included general surgeon resistance to changing habits, the belief that they were already checking those things, awkwardness of self-introductions, steep interpersonal hierarchy, and a fear of legal responsibility if a complication occurred after they had signed a form.

One ongoing research project, funded by the Agency for Healthcare Research and Quality, is entitled "Factors Associated with Effective Implementation of a Surgical Safety Checklist."³⁴ This 2010-2013 project "will examine implementation processes in a large group of U.S. and international hospitals to identify factors supportive of effective implementation." Further, the team will determine how teamwork helps explain the impact of the checklist.

The WHO Web site (www.who.int/patientsafety/safesurgery/en/) provides advice to hospitals for implementing the checklist.³⁵ This advice includes statements such as "The key to successful implementation is to start small. Start with a single operating room on day 1 and see how it works. This will guide you to strategies for altering the checklist to fit your needs, as well as identify potential barriers to adaptation."³⁵ Other implementation advice from WHO is available in the Frequently Asked Questions section

(www.who.int/patientsafety/safesurgery/faq_introduction/en/index.html), the 20-page "Starter Kit for Implementing the Surgical Safety Checklist"

(www.who.int/patientsafety/safesurgery/testing/participate/starter_kit-sssl.pdf), and the "Checklist Adaptation Guide"

(www.who.int/patientsafety/safesurgery/checklist_adaptation.pdf). Regarding checklist modification, the Web site states, "Do not hesitate to customize the checklist for your setting as necessary, but do not remove safety steps just because you are unable to accomplish them." Also, regarding feasibility, the WHO states that "It should take no more than a minute to complete each section of the checklist" (i.e., three minutes in total). The pilot study reported that at various sites, introduction of the checklist took only 1 week to 1 month.⁶

The Web site www.safesurg.org also provides additional materials relevant to the WHO checklist. Those interested in implementing the checklist are encouraged to register with the Web site. The Web site provides a template for the 2009 checklist (www.safesurg.org/template-checklist.html) in Microsoft Word format (Microsoft Corporation, Redmond, Washington, U.S.), and an implementation manual is available (www.safesurg.org/implementation-manual.html).

The Web site also provides a list of other institutions' modified checklists (www.safesurg.org/modified-checklists.html), where institutions can submit their modifications of the WHO checklist to be made publically available. On October 3, 2011, the publically-available list contained 79 checklists from 25 countries.

The site also provides several downloadable videos (www.safesurg.org/videos.html): one on how to use the WHO checklist; one on how *not* to use it; two from the National Patient Safety Agency in the United Kingdom; one from University Health Network Hospital in Toronto; one from the Surgical Care and Outcomes Assessment Program in Washington State; two from Great Ormond Street Hospital in the United Kingdom; one in French from Fattouma Bourguiba Hospital in Monastir, Tunisia; one in Spanish from la Agencia de Calidad de Andalucia; one Spanish translation of the WHO how-top video; and two from Auckland City Hospital in New Zealand.

SURPASS Checklist

We performed a citation search to determine if the SURPASS checklist has yet been attempted outside the Netherlands; however, no such attempts were identified. The SURPASS Web site (www.surpass-checklist.nl/home.jsf?lang=en) describes an electronic version of the checklist (called SURPASS Digital) that can be used by any web-connected computer. The electronic version allows one to modify the checklist, although the designers of SURPASS strongly encourage users to avoid modification (www.surpass-checklist.nl/content.jsf?pageId=FAQ&lang=en).

Wrong-Site Surgery Checklists

No implementation advice was found on the Joint Commission Web site or in other published documents. In August 2010, the Joint Commission conducted an online survey of over 2,100 people.³⁶ The Web site did not report how many questions were asked or the wording of any given question. The Web site reports five findings from the survey: 1) 88 percent agreed that their organizations could fully implement the Universal Protocol; 2) 87 percent to 92 percent agreed that the three steps are appropriate; 3) More than 90 percent agreed that "there is benefit" in using it in the operating room, ambulatory surgery, and hospital units performing invasive procedures, but the rates of agreement of benefit were lower for ambulatory clinics and physician offices; 4) the need to modify policies and procedures varied greatly across respondents; and 5) no differences were found between different types of respondents (e.g., type of hospital, bed size).

We identified four sites describing pertinent checklists (see Table 3 in Appendix D in the section entitled "Evidence Tables for Chapter 13"). These sites were located in Switzerland, Sweden, the United Kingdom, and North Carolina:

The Swiss study³⁷ was conducted in a large anesthesiology service and focused on verifying two key aspects: patient identity and surgical site. The protocol was developed by an interdisciplinary team and required patient participation in the verification of identity and surgical site (answering open-ended questions rather than closed-ended questions). Compared with the first 3 months of implementation, the next 3 months saw better compliance in checking patient identity (63% up to 81%) and proportion of surgical site checks performed (77% up to 93%). Compliance was stable in subsequent periods. Barriers to implementation included 1) surgeons saying they already knew the patients or the surgical site was obvious, and 2) the failure to include the input of all surgical services in developing the protocol.

The Swedish study³⁸ involved two hospitals, each of which had a recent wrong-site surgery incident, and a root-cause analysis suggested that a time-out procedure might help. A time-out checklist was implemented, and one year later, a questionnaire was sent to all 704 team members. Of the 331 responders, 93 percent expressed the belief that the checklist contributes to increased patient safety (either “without a doubt,” or “probably”). When asked about eight specific components of the time-out checklists, the percentage of respondents who believed the component was “very important” varied widely, from a low of 14 percent for the introduction of team members to highs of over 80 percent for patient identity, correct procedure, and correct side.

The English study³⁹ was conducted at a children’s hospital in which staff had incorporated an eight-item correct-site surgery checklist into an existing preoperative checklist. Five people were required to sign the documentation: marking surgeon, operating surgeon, ward nurse, scrub nurse, and anesthetist. Comparing 2008 to 2006, correct completion was unimproved for four of the eight items (ward nurse signed, operating surgeon signed, scrub nurse, signed, and operating department practitioner signed) but was improved for the other four (mark site documented, no mark required documented, entries legible, and marking surgeon signed).

The North Carolina study³⁷ implemented a checklist to prevent wrong-site surgery that was tailored to the hospital’s preferences and procedures. Previously, the staff was using a cumbersome form to document their compliance with the Universal Protocol. Champions demonstrated the checklist during educational staff meetings, and new staff were given a primer. Staff commented favorably that they no longer had to remember everything.

The Association of PeriOperative Registered Nurses (AORN) Comprehensive Surgical Checklist (www.aorn.org/uploadedImages/Images/Images/comprehensive_surgical_checklist_RGB961.jpg) was a collaborative effort between AORN, the developers of the WHO checklist, and the Joint Commission. The Web site states that the checklist, created in April 2010, was “created to support a facility’s need to use a single checklist that includes the safety checks outlined in the World Health Organization’s (WHO) Surgical Safety Checklist, while also meeting the safety checks within The Joint Commission’s Universal Protocol in order to meet accreditation requirements.” Our searches identified no empirical studies of this checklist.

Another combined checklist (called a “crosswalk”) combining the WHO checklist and the Universal Protocol was published in November 2011 by the Pennsylvania Patient Safety Reporting System.⁴⁰ This document also addresses checking preparedness for surgical fires, as well as two intraoperative checks specifically for spinal surgery involving precise locations. Due to the recency, no studies exist yet on this crosswalk.

Anesthesia Equipment Checklists

The ASA guidelines identify 15 items: 7 to be performed *only before the first procedure* of the day, and 8 to be performed prior to *each procedure*. Similarly, the AAGBI guideline recommends that 11 items be checked prior to each operating session and that 3 of these items are to be checked again prior to each new patient procedure. These guidelines are to be implemented by individual hospitals and tailored to their departmental needs. As stated by the ASA on their Web site (ASA, 2011), “the updated recommendations are intended to serve as general guidelines for individual departments and practitioners to design pre-anesthesia checkout procedures specific for the delivery systems and the needs of the local practice.” Further, they state, “Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted,

modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert opinion, open forum commentary, and clinical feasibility data.”⁴¹

The ASA encourages institutions to submit their version of the Pre-Anesthesia Checkout (PAC) for publication on the ASA Web site (www.asahq.org/For-Members/Clinical-Information/2008-ASA-Recommendations-for-PreAnesthesia-Checkout/Sample-Procedures.aspx). Currently, sample PACs are posted for the following anesthesia system models: (1) General Electric AESTIVA[®], (2) Draeger Apollo, (3) Draeger Narkmoed GS, (4) Draeger 6000, (5) Draeger B/C/GS, and (6) Draeger Fabius GS. Eight U.S. hospitals are currently represented on the ASA collection of sample checkouts.

As an additional international example of implementing anesthesia checklist guidelines, the Columbian 2009 version of their “Minimum Safety Standards in Anaesthesia” states that anaesthesiologists and surgeons must collaborate in completing an overall check list, which is to include at least the items in the WHO checklist. In addition, before applying anaesthetic, the anaesthesiologist must complete a pre-anaesthetic checklist.⁴²

In referencing earlier implementation strategies for aviation checklists, a 2000 article by Blike and Biddle²⁸ propose the “three P’s” for successful implementation of their anesthesia machine electronic checklist. They refer to the three P’s as “a guiding *philosophy*, with *procedures* designed to achieve the goal of the philosophy using consistent *policies* for implementation.” They concluded that the earlier AACR was deficient in that the associated published checklist had no supporting philosophy.

Regarding staffing, the 2008 ASA guidelines identify particular aspects of the PAC that could be performed by a qualified anesthesia and/or biomedical technician. However, “regardless of the level of training and support by technicians, the anesthesia care provider is ultimately responsible for proper function of all equipment used to provide anesthesia care.”¹³

Are There Any Data About Costs?

Costs of implementing a checklist mostly involve checklist development (or checklist modification if the WHO checklist is used), formal staff notification that use of the checklist is expected, staff training, and additional operating room time. In 2010, Semel and colleagues⁴³ performed a hypothetical decision analysis of checklist introduction in a U.S. hospital. The cost of implementing the checklist was estimated using the “opportunity cost of the work that would have otherwise been performed by the three department checklist champions and the implementation coordinator,” which was an estimated \$12,635 in 2008 dollars; per-use cost was only \$11. The cost of a major surgical complication was estimated at \$13,372. In the base-case analysis, checklist introduction actually saved money. Regarding time, Sewell 2011³⁰ reported that 20 percent of staff thought the WHO checklist caused an unnecessary time delay. However, in 2011, Taylor and colleagues³³ reported that the WHO checklist took only about two minutes on average.

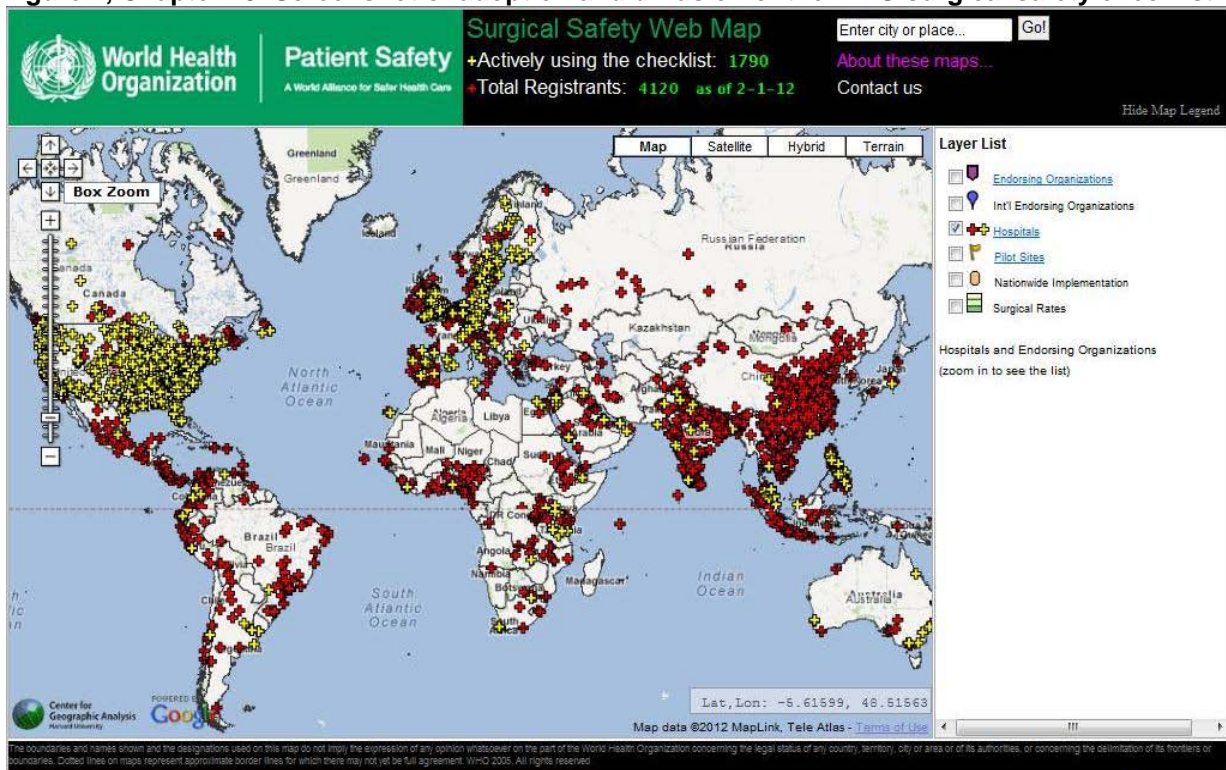
With regard to operating room time, a 26-item anesthesia checklist developed in 2010 by Thomassen and colleagues⁴⁴ was completed with a median time of 88.5 seconds (n=502 patients). Additionally, when cases were compared before and after implementation, checklist completion did not cause any significant difference in pre-induction time (25.1 vs. 24.3 minutes).

An additional potential cost benefit relates to reduced litigation claims. With regard to anesthesia, comparing the period prior to the 1990s to the period from 1990 to 2003, the proportion of claims with substandard care decreased (from 39% to 22%), and payments were made less frequently (from 58% to 42% of the time).³

Are There Any Data About Adoption and Diffusion of This Patient Safety Practice?

On February 22, 2012, the WHO's Surgical Safety Web Map indicated that as of February 1, 2012, 4,120 hospitals had expressed interest in using the checklist and 1,790 of these hospitals have used the checklist in at least one operating theatre (Figure 1). On the map, red crosses represent those expressing interest, and yellow crosses represent previous/current users.

Figure 1, Chapter 13. Screenshot of adoption and diffusion of the WHO surgical safety checklist



Note: This figure is a screenshot taken on 2/22/2012 of the WHO Surgical Safety Web Map (<http://maps.cga.harvard.edu:8080/Hospital/>). Red crosses represent hospitals who have expressed interest in using the WHO Surgical Safety Checklist (as of 2/1/2012); yellow crosses represent hospitals that have used the checklist in at least one operating theatre. Using the right-hand panel, the map can also be configured to display locations of endorsing organizations, international endorsing organizations, pilot sites, and countries with nationwide implementation. Granted permission by the World Health Organization.

Our searches found that a number of professional organizations have recommended adoption of the WHO checklist (Table 1).

Table 1, Chapter 13. Governmental and nongovernmental organizations adopting or recommending adoption of the WHO checklist

Organization	Web site	Details
The Institute for Healthcare Improvement (www.ihi.org)	www.ih.org/offerings/MembershipsNetworks/MentorHospitalRegistry/Pages/SurgicalSafetyChecklist.aspx	In December 2008, then-president Donald Berwick issues the Surgical Safety Checklist Challenge: to have each hospital use the checklist in at least one operating room by April 1, 2009. To assist facilities in implementing the checklist, the IHI Web site provides a list of eight “mentors” throughout the United States who have already implemented the checklist. The demographics of these eight sites are provided to enable facilities to match themselves up with similar mentor facilities.
National Patient Safety Agency (NPSA) in the UK	www.nrls.npsa.nhs.uk/alerts/?entryid45=59860	NPSA mandated in February 2010 the use of the checklist in all of its Trusts in England and Wales. ⁴⁵ The NPSA Web site contains downloadable materials, videos, and three tailored WHO surgical checklists (for radiological interventions, cataract surgery, and maternity cases). Also, the Surgical Checklist Implementation Project, funded by the National Health Service (NHS), involves four studies of implementing the WHO checklist at 20 NHS Trusts (www.safesurgery.org.uk). ⁴⁶ The topics of the four studies are (1) perception of the checklist and possible barriers to use; (2) additional quantitative data on staff perceptions of the checklist; (3) how the checklist is actually used in operating rooms; (4) the impact of checklist use on clinical outcomes. ⁴⁶
France	NA	France mandated the use of the WHO checklist in all its 8000 hospitals in 2010. ⁴⁷
Canadian Patient Safety Institute (CPSI)	NA	The CPSI has endorsed the checklist, and checklist implementation is now an accreditation standard for Canadian hospitals. ⁴⁸ The Canadian province of Ontario mandated use of the checklist in 2011. ⁴⁷
Washington State Surgical Care and Outcome Assessment Program (SCOAP) ⁴⁹	www.scoap.org/checklist/index.html	SCOAP stated a goal of having all of its hospitals use the WHO checklist in every operating room by the end of 2009. The February 2010 SCOAP version of the WHO checklist is available on the Web site. The Web site also states that “According to the Washington State Hospital Association, 100% of Washington State hospitals have either implemented a standardized surgical checklist or are in the process of doing so.” Hospitals can also order a 2x3 foot laminated SCOAP checklist from the Web site.
The South Carolina Hospital Association (SCHA)		The SCHA, in the fall of 2010, planned to institute the checklist in all the state’s hospitals over the next few years. ⁴⁷
Ireland and Jordan		Ireland and Jordan each plan to require checklist implementation in all its hospitals. ⁵⁰
Spanish Ministry of Health and Spanish Association of Surgeons	NA	The Spanish Ministry of Health and the Spanish Association of Surgeons have joined the initiative. ⁵¹

Table 1, Chapter 13. Governmental and nongovernmental organizations adopting or recommending adoption of the WHO checklist (continued)

Organization	Web site	Details
Australia and New Zealand: the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, the Royal Australian and New Zealand College of Obstetricians and Gynecologists, the Australian College of Operating Room Nurses, and the Australian Commission for Safety and Quality in Health Care	NA	These organizations developed a modified version of the WHO checklist. ⁵² The checklist was launched in August of 2009 with the endorsement of national government health departments in both countries.

The webcast event “Check a Box, Save a Life” was launched on October 22, 2009 to promote the use of the WHO checklist.⁵³ The event, run mostly by medical students, involved 182 hosting sites from 121 medical institutions and an estimated 1,400 online viewers. A Facebook page had enrolled 111 medical students who agreed to host the event at their institutions. At the Institute for Healthcare Improvement forum 6 weeks later, 15 case reports were presented that detailed checklist-related projects.

In January 2010 in the UK, just before the mandatory requirement to use the WHO checklist was instituted by the NPSA, Sivathanan and colleagues⁵⁴ conducted telephone interviews with 238 hospitals in the UK (randomly selected from some 540 hospitals, therefore representing about 44% of UK hospitals). Almost all (99%) of the hospitals had heard of the checklist, and its use was already compulsory in 65 percent of them. In hospitals where it was not required, 81 percent used it voluntarily, and 75 percent had a plan to make it mandatory in the future. However, some operating rooms reported partial use of the checklist, i.e., intentionally skipping items or skipping the entire checklist because of time constraints.

In June 2009, the journal *OR Manager* received online data from 136 subscribers regarding use of the WHO checklist.⁵⁵ About half (48.5%) said they had implemented the checklist, and 64 percent said the checklist has improved safety in the operating room. However, 11 percent of respondents stated that the checklist was not well accepted by surgeons, and another 63 percent said surgeons did accept it but “with reservations.” Nurses were believed to have a somewhat greater degree of acceptance, with only 2 percent “not well accepted” and 52 percent “accepted with reservations.”

A survey in October/November 2009 of 12 oral and maxillofacial consultants in Yorkshire England found that all were aware of the WHO checklist, but only 5/12 were actually using it.⁵⁶ Ten of 12 expressed the belief that it would improve patient safety, but four of 12 said it would not improve team communication.

Regarding the Universal Protocol, accredited hospitals are required to comply. Therefore the “diffusion” of the Universal Protocol is large, by mandate. However, as stated earlier, the Universal Protocol is not a checklist. We found no published information on how many hospitals actually use a checklist in their efforts to comply.

Regarding anesthesia checklists, in 2009, Winters and colleagues⁵⁷ at Johns Hopkins University republished the AAGBI checklist and discussed resistance of physicians to adopting anesthesia checklists in general. They cited the cases of some physicians who claimed to be insulted, whereas others expressed doubt that a checklist will prevent a medical mistake. They counter this argument by mentioning the complexity of modern medicine, which may inadvertently introduce devastating risks. In 2000, Thomassen and colleagues⁴⁴ of Haukeland University Hospital in Norway developed an anesthesia checklist designed to identify “pre-induction deficiencies” (i.e., missing equipment or inadequate preparation). The checklist was improved over the course of 502 inductions. They reported that in 17 percent of the cases, missing items were identified, the most critical being lack of availability of a second laryngoscope, the introducer not having been fitted to the endotracheal tube, the endotracheal tube cuff not having been tested, and no separate ventilation bag available. Thomassen’s 2010 study³² reported user experiences: Some of the senior physicians were skeptical of the usefulness of the checklist. They concluded that the success of implementation of the checklist depends on physician leaders having a positive attitude. The checklist itself improved confidence in unfamiliar contexts (see Table 4, Chapter 13 in Appendix D).

Conclusions and Comment

Several prominent authorities in the field of patient safety have proposed checklists in an attempt to prevent mistakes related to surgery. These checklists have been developed carefully by experts in the field, and have evolved over time to capture only the most essential considerations. Numerous implementation issues remain, including how to modify a given checklist to a specific hospital setting, or to a specific anesthesia system, or to a specific surgical staff. A recurrent theme in the literature on preoperative checklist is the explicit encouragement of a *team-based approach*. Further adoption and diffusion of these checklists will depend on the continued demonstration of effectiveness in preventing errors, checklist modifications to improve clarity and prevent misuse, proof that the benefits are worth the added time and cost, and flexibility to changes as needs arise. A summary table is located below (Table 2).

Table 2, Chapter 13. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	High	Negligible	Low	A lot/Moderate

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Chapter 14. Use of Report Cards and Outcome Measurements To Improve Safety of Surgical Care: American College of Surgeons National Quality Improvement Program (NEW)

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How Important Is the problem?

Over 40 million operative procedures are performed in the United States (U.S.) each year.¹ Postoperative adverse events occur all too commonly. Mortality for complex operations in the Medicare population ranges from 7.5 percent to as high as 17.7 percent for gastrectomy and 3.1 percent to 13.3 percent for pancreatectomy.² Overall morbidity for three complex procedures combined ranged from 44.3 percent to 38.9 percent. Even in less complex cases such as colectomy (250,000 cases are performed each year), surgical site infections occur approximately 10 percent of the time.³ These adverse events increase hospitalization length and cost. A surgical site infection is estimated to add \$27,631 to the cost of a surgical stay.⁴ Even a simple wound opening is estimated to cost \$1,426. A urinary tract infection can add \$675 or up to \$2,800 if accompanied by bacteremia.⁵ Following respiratory complications, length of stay increases attributable to post-operative complications range from 3 to 11 days.⁶ A single case of ventilator-associated pneumonia adds \$50,000 to the baseline cost of a surgical admission.^{7,8} Patients who develop postoperative pulmonary embolism/deep venous thrombosis require readmission in 44 percent of cases, with annual cost ranging from \$7,594 to \$16,644.⁶

What Is the Patient Safety Practice?

The largest and best known intervention for measuring and reporting surgical outcomes in the U.S. is the American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP), now implemented at 431 sites. This multicomponent intervention grew out of efforts initiated by Veterans Affairs (VA) Health System researchers and clinicians in the late 1980s. The original idea for VA NSQIP was to feedback data to facilities and surgeons on their performance as a stimulus for quality improvement. To implement that original idea a number of elements needed to be developed: methods to collect data consistently across sites, methods for data sharing, and models for calculations observed-to-expected outcomes. Later, in VA NSQIP, the need to bring sites together for learning and sharing across sites was recognized as necessary to catalyze improvement and this was added to the “intervention.” Thus, the “intervention” has changed over time in the components used to implement the original idea of feedback for performance data. An example of observed to expected ratio reporting for ACS NSQIP is located in Figure 1.

The current ACS NSQIP collects prospective, clinical data that are used to provide risk-adjusted assessments of outcomes that are fed back to the hospitals and surgeons for comparative purposes, with the ultimate goal of quality improvement. A benchmarked, peer-controlled database allows hospitals to compare 30-day outcomes across hospital types. With support from ACS NSQIP, individual sites work to design quality initiatives to achieve better outcomes and care in the areas of need.

The intervention comprises five basic components. First, a trained surgical clinical reviewer (SCR) prospectively collects data on preoperative and clinical variables and on 30-day outcomes (outcomes are described in more detail, below). The number of variables depends on the particular Program option chosen (which in turn depends on the needs and size of the particular hospital) but is typically 46 or 69 for each case. A predetermined number of cases is reported, which again depends on the Program option (also referred to as Use Option) the hospital has elected to use. The second component is development and maintenance of models of expected mortality and morbidity by risk and types of procedures performed. The third component is the calculation of the observed-to-expected (O/E) 30-day mortality and morbidity ratios. Data are then fed back to individual sites as observed-to-expected ratios of, typically, 21 morbidities, such as wound, respiratory, central nervous system, urinary and cardiac complications, as well as mortality. Data are provided alongside blinded national results from the other participating sites. Sites are designated as being a high (worse than expected) or low outlier (better than expected) for each category of morbidity and for mortality.

Figure 1, Chapter 14. Example of observed to expected ratio reporting for American College of Surgeons national surgical quality improvement program

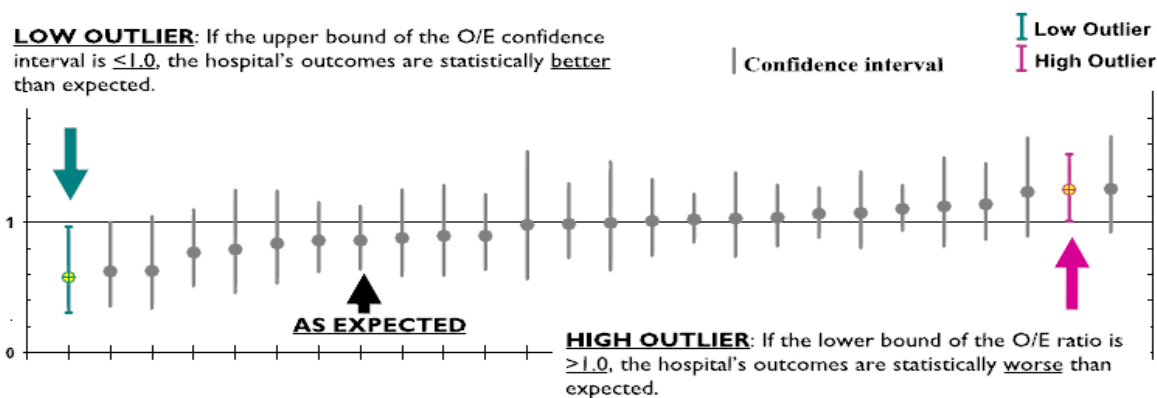


Figure 1 accessed from the ACS NSQIP Web site, December 2011. Reprinted by permission of American College of Surgeons NSQIP.

Lastly, institutions then identify areas where they are a high outlier and improvement is needed. Auditing by the ACS NSQIP staff occurs randomly and for cause, that is, site reports many high risk patients but a low complication rate. Individual surgeon-level data are provided to the participating hospital if they request it. While the responsibility for making changes and addressing areas in need of improvement remains with the individual sites, the administrative ACS NSQIP body provides support in terms of case reports, best practices, national meetings, and monthly supportive conferences calls with the surgeon champions and surgical clinical reviewers.

Why Should This Patient Safety Practice Work?

The concept that measurement and reporting of hospital outcomes can be useful for improving quality and safety goes back more than 100 years. E.A. Codman in 1913 told the Philadelphia Medical Society “We must formulate some method of hospital report showing as nearly as possible what are the results of the treatment obtained at different institutions. This report must be made out and published by each hospital in a uniform manner, so that comparison will be possible. With such a report as a starting point, those interested can begin to ask

questions as to the management and efficiency.”⁹ In 1914, Codman started his own hospital in Boston, the End-Result Hospital, to study the quality of surgical care.

Two precedents helped inform the rationale for ACS NSQIP. In 1994, in response to concerns about high complication rates in the VA, a system to collect and report clinical variables and outcomes across all VA sites was established (ultimately coined VA NSQIP).^{10,11} To compare results to non-VA hospitals or among VA sites fairly, these investigators needed to correct for how sick patients were. Lisa Iezzoni coined the phrase, the “algebra of effectiveness,” which means that outcomes are a function of patient factors, effectiveness of the care provided, and random variation.¹² Patient factors include the severity of target illness plus their comorbidities. Thus, the VA developed a database of preoperative risk factors (severity of illness and comorbidity) along with the database used to collect postoperative outcomes. In an attempt to level the playing field for cross-institutional comparisons, the investigators developed risk-adjustment models. The perceived success of the VA program led to its adaption for non-VA hospitals, now known as the ACS NSQIP.

The second precedent for ACS NSQIP was the apparent success of programs like the New York State Cardiac Surgery Reporting System (CSRS).¹³ In this program, which began about 20 years ago, the State Department of Health collects and distributes data from all New York State hospitals performing coronary artery bypass grafting, with the aim of promoting accountability and quality improvement. While originally envisioned as a confidential feedback system, public and court pressure led to the public release of results, and the CSRS became a public reporting system. Evaluation of the impact of the CSRS has been complicated by secular trends and the lack of a widely-accepted comparison group, but systematic reviews of public reporting have in general concluded that the preponderance of the evidence supports a causal relationship between the CSRS and greater declines in cardiac surgery morbidity and mortality than would be expected from the long-established secular trends alone.^{14,15} The basic concepts of the New York State CSRS have been adopted by other states (California, Pennsylvania) and have expanded across the U.S. through the efforts of the Society of Thoracic Surgery (STS) Registry, which incorporated public reporting. Measurement and reporting of cardiac surgery outcomes has also spread to England.¹⁶

The rationale for how NSQIP improves care is multifaceted. To improve care and reduce complications, surgeons must first know the outcomes of their own procedures. The data used to provide this feedback must be high quality and reliable, and the method of risk-adjustment must be adequate to allay concerns about comparing “apples to oranges.” Lastly, the program must establish an impetus for change: In this case, it is the comparison of care at one’s own site to that of other representative sites, that is sites with similar elements and the same risk-adjustment. This comparison allows surgeons and hospitals to see how they compare in terms of poor outcomes, which in turn promotes accountability and stimulates work to correct the problems. Most sites, 59 percent of those surveyed, were unaware of their hospital’s adverse event rates, let alone how they compare to other hospitals, until after they enrolled in ACS NSQIP.⁴

One of the great strengths of the ACS NSQIP program is that it relies on prospective clinical data. Administrative and claims data are limited, as they lack sufficient clinical data elements and vary considerably in terms of quality (coder variations, subjective reporting, focus on payment rather than on outcome reporting). A study comparing administrative and claims data collected by the University Health System Consortium (UHC) program showed that the ACS NSQIP identified 61 percent more total complications than were identified by UHC, including 97 percent more surgical site infections and 100 percent more urinary tract infections.¹⁷

Furthermore, NSQIP focuses on 30-day outcomes and is not limited to adverse events associated with the index admission. Studies show that more than 50 percent of complications happen after discharge. For colectomies, 45 percent of deep surgical site infections, 39 percent of organ space infections, and 28 percent of deep venous thrombosis (DVT) occur after patients have left the hospital.¹⁸ Identifying complications that occur outside the hospital is the prerequisite first step to developing changes in care to help prevent those complication, which in turn should result in reduced morbidity and mortality and save costs.¹⁹

What Are the Beneficial Effects of the Patient Safety Practice?

Evaluating the effect of the measurement and reporting of outcomes is complicated by the fact that these measurement systems have almost always resulted from policy decisions that affect large geographic areas; thus, with no access to natural control institutions, investigators are relegated to using time-series data within interventions sites, observational comparisons to non-intervention sites, and focused process-and-outcome evaluations seeking to explain observed changes in outcomes over time. As alluded to earlier, the first such evaluations emanated from a congressional mandate in 1986 for the VA to perform a National VA Surgical Risk Study (NVASRS), with the aim of developing surgical risk-adjustment models to predict outcomes and compare the quality of surgical care among facilities. Between 1991 and 1993, 44 VA medical centers used clinical nurse reviewers to collect preoperative and intraoperative clinical data and 30-day outcomes on major surgical procedures. Variations in the 30-day morbidity and mortality outcomes were identified across VA facilities.²⁰⁻²² The success of this initial study led to VA NSQIP, which was officially launched in 1994 and has provided continuous monitoring of the outcomes of surgical care in the VA. A review of over 400,000 cases performed between 1991 and 1997 showed that 30-day mortality and morbidity rates for major surgery fell 9 percent and 30 percent, respectively.²³ Reductions in one post-operative complication alone, surgical pneumonia, are estimated to have saved the VA \$9.3 million annually, and the overall reduction in postoperative morbidity may have saved \$46 billion over the lifetime of the program.

In the late 1990s, non-VA hospitals became interested in applying the VA experience to their data reporting and quality improvement programs. A pilot study in three civilian hospitals (University of Michigan, Emory University, University of Kentucky) showed the feasibility in the private sector.²⁴ Following this pilot, in 2001, the American College of Surgeons took the lead to expand efforts to a broader group of hospitals (14 sites), and in 2004, the formal ACS NSQIP began.²⁵

The potential impact of participating in ACS NSQIP on complication rates and mortality has been reported by individual hospitals and collaboratives and posted on the ACS NSQIP site. Although reported improvements in morbidities have been large, improvements in mortality have ranged from none to modest. However, many general and vascular surgery procedures tend to have low 30-day mortality rates to start. Most of the reports of improvement in single institutions or collaborative have not been published but have been presented in other venues. At the most recent ACS NSQIP national meeting in July 2011, 20 presentations reported reductions in morbidity following an intervention. In all these cases, ACS NSQIP data enabled the hospital or hospitals to target an area with worse-than-expected outcomes and to intervene, with resulting improvement. Eleven additional examples of programs that have recently begun participating in NSQIP, have identified areas of need, and are in the process of implementing change, although results are not yet available (see Table 1 for examples). An advantage of the annual national

conference is the opportunity it provides to network and collaborate on quality improvement planning and projects.

Table 1, Chapter 14. Example of interventions and associated impact on outcomes in American College of Surgeons national surgical quality improvement program for hospitals/collaboratives

Hospital	Complication	Intervention	Impact
Hershey Medical Center, Penn State ²⁶	19.3% SSI in diabetics; 8% in non-diabetics VTE 3.4% (2008)	Glucose control protocol VTE risk assessment and order set	Reduction of SSI O/E 1.31 to 0.78 Reduction of VTE rate 3.4% to 0.2% (2008-2009)
University of Virginia ²⁷	17.6% SSI (national average 8.1%) colorectal resections. High BMI was a risk factor.	Protocol for wound wicking for BMI >25 kg/m ² , SCIP measures, glycemic control	Reduction of SSI from 17.6% to 11.2% (36% reduction) (2003-2006)
Massachusetts General Hospital ²⁷	Vascular surgery morbidity O/E ratio=1.19, [99% CI 0.93 to 1.48] UTI rate 7.0% vs 4.7% (P<0.087)	physician order entry templates, foley catheter removal algorithm, silver-coated catheters for select patients, identify procedures not requiring a catheter, educational campaign for clinicians	Reduction of UTI 7.0% to 1.8%. Morbidity O/E ratio went from 1.19 [99% CI 0.93 to 1.48] to 0.93[99% CI 0.67 to 1.48] (76% reduction) (2003-2004)
Hospital A	Identified a rise in organ space infections	Standardized orders, proper antibiotic use, morbidity conference presentations, skin preparation changes	Organ space infection increase attributed to increased leak rates and identified surgical technique issues and saw improvements, but rate still high. (2005-2010)
Hospital B	VTE 17.6%	Risk stratification, best practices, standardized orders	VTE decreased from 17.6 to 2.3%; O/E 1.88 to 1.05 (2006-2010)
Hospital C	Unplanned reintubation 3% (O/E=1.56) Ventilator >48 hrs 3.84% (O/E=1.71)	Tracking tool, risk assessment, improved pulmonary toilet intervention	TBD
Hospital D	Ventilator >48 hrs 2.24% (O/E=1.7)	Tracking tool, standardized orders, patient teaching	Ventilator >48 hrs 2.24% to 1.19% (O/E=1.7 to 0.83) (2008-2010)
Hospital E	Overall orthopedic DVT 3.1% Knee Arthroplasty DVT rate 10.1%	Identified variations in DVT prophylaxis practice, surgeon specific review, standardized care	Reduction of overall orthopedic DVT rate 3.1% to 1.1% Reduction of knee arthroplasty DVT rate 10.1% to 1.6% (2008-2010)

Notes: DVT, deep venous thrombosis; VTE, venous thromboembolism; Hospital A-E are representative examples taken from ACS NSQIP Data Portal Web site, accessed December, 13, 2011. Reprinted by permission from the American College of Surgeons NSQIP.

Almost all these studies have a pre-post design, with no control groups, and therefore have all the limitations common to studies of that design, including regression to the mean. Yet, in aggregate, these reports consistently show that hospitals identified as high outliers in some particular outcome that respond by implementing a targeted intervention experience a decrease in that outcome. The magnitude of some of these decreases cannot be explained by regression to the

mean or confounding; for example the decrease in DVT rate from 10 percent to 1 percent in one study or from 3.2% to 0.2% in another study.

Two published longitudinal studies have reached divergent conclusions on the effects of reporting. The first study looked at changes over three years (2005 to 2007) in ACS NSQIP-participating sites (N=183) for all outcomes measured and surgical specialties using risk-adjustment and accounting for hospital procedure volume (Hall B, 2009).¹⁹ For the most recent time period, 2006 to 2007, 118 hospitals were enrolled and were participating long enough to produce clinically useful data. The authors found that 82 percent (97 of 118) of hospitals had improved morbidity and 66 percent (78 of 118) had improved mortality. The adjusted absolute difference in observed to expected (O/E) ratio was -0.114 for morbidity and -0.174 for mortality (negative numbers meaning less morbidity and mortality). Similar results were seen when the researchers accounted for institutional volume. They also found that the number of high outliers (those with worse outcomes) decreased over time and the number of low outliers (those with better outcomes) increased. Additionally, high outliers were more likely to improve and had larger mean changes in outcomes. For large hospitals, it was estimated that an average of 200 to 500 complications and 12 to 36 deaths may have been avoided.¹⁹ This study was conducted by investigators affiliated with ACS NSQIP.

The other study compared ACS NSQIP to another private sector collaborative, which was based at the University of Michigan Medical Center.²⁸ The data file provided by ACS NSQIP included Michigan and non-Michigan hospitals. The Michigan Surgical Quality Collaborative (MSQC) includes 34, largely community (68 percent) hospitals, unlike the ACS NSQIP-participating hospitals, which are primarily academic/teaching. Sixteen MSQC hospitals were included in the analysis, which assessed two time periods: April 2005 to March 2007 compared with April 2007 to December 2007. Results were also compared with the 126 non-Michigan NSQIP hospitals over the same time period. All hospitals used a similar data reporting system. This analysis found that the MSQC hospitals had a decrease in morbidity from 10.7 percent to 9.7 percent (9% reduction, P=.002; odds ratio=.898) over the 3 years, whereas morbidity did not change for the ACS NSQIP hospitals in either time period (12.4%; odds ratio=1.0). Mortality rates did not change for either group of hospitals.²⁸ This study was conducted by investigators affiliated with MSQC. One possible explanation for the difference in results between the two studies is that the length of time the hospitals were enrolled in the program may have been too short to see improvements, especially in the larger hospitals, which predominated among the non-Michigan ACS NSQIP hospitals.

What Are the Harms of the Patient Safety Practice?

Few published studies have assessed the potential and actual harms of this program. Most of the concerns are speculative. A primary concern has always been that surgeons will avoid high-risk cases for fear of adversely affecting their observed-to-expected outcomes assessments. This issue was raised early in the process of implementing report cards when anecdotal evidence appeared to suggest that as the result of implementing the New York CSRS, high-risk CABG patients were being diverted instead to the Cleveland Clinic.²⁹ However, subsequent and more comprehensive analyses could not document any systematic exclusion of high-risk patients from CABG operations, and that, on the contrary, the severity of illness and comorbidities of operated patients has increased over the years.^{30,31} The longitudinal ACS NSQIP study also supported this finding, showing that the risk profile and illness severity for surgical patients has increased over time.¹⁹ Another concern is that the outcomes for outpatient cases or for a hospital or surgeon who

performs a small volume of procedures might need longer follow-up, possibly more than a year, to accurately assess quality.³² Concerns have also been raised that surgeons could alter treatment plans or surgical options for patients based on their operative risk rather than give the patient the option of a procedure with a potentially better long-term functional outcome. An example would be in vascular surgery, where a high-risk patient eligible for a distal bypass would be recommended an amputation instead.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Detailed steps for hospital enrollment are provided on-line (acsnsqip.org) or can be requested directly from ACS NSQIP. The steps are also summarized here.

The first step is to review the program requirements (information can be requested on-line) and contact the ACS to ask questions or schedule a teleconference. The program information needs to be presented to a surgeon champion, quality improvement personnel, and administrators, and permission to proceed must be granted by those on-site. Budget approval must be made for the surgical clinical reviewer and the annual administrative fee. The annual cost is estimated to be \$135,000 per year, which includes the full time employment (FTE) of the data collector (meaning the surgical clinical reviewer).^{26,33} The online program application form needs to be submitted and approved by the ACS. A Hospital Participation Agreement and surgical clinical reviewer job description are given to the hospital and a surgical clinical reviewer should be recruited. Experience from the program has shown that the person best qualified for this position will have a bachelor of science degree in nursing or an advanced degree as well as surgical clinical experience (meaning in the operating room, surgical intensive care unit, or cardiac surgery). The candidate should ideally have additional experience with quality improvement and the clinical hospital system. Full-time effort in the initial phases of implementation is required.

The surgical clinical reviewer then undergoes training (online modules with a test). ACS NSQIP assists with implementing the program on-site. The complete process of enrollment and training ranges from a few weeks to months in duration. Six to 12 months is needed to obtain results that are acceptable for quality assessment.

The program requirements include site administrative support, a surgeon champion, and participation in a series of conference calls and the national ACS NSQIP meeting. Commitment from a surgeon champion (Chief of Surgery or appointed surgeon) is needed to oversee the program. Their involvement includes quarterly conference calls and attendance at the national meeting. Data reporting is mandated to follow particular rules, such as accrual of particular data; complete 30-day follow-up on participating patients, including follow-up attempts; and searches of public death records. ACS NSQIP personnel perform audits to help maintain data quality. For small hospitals, the effort and cost may be less than for larger facilities, depending on the volume of cases.

ACS NSQIP has been implemented in a variety of settings including large academic hospitals, smaller community hospitals, and statewide consortia (both large and small scale). As the need became apparent for new program models to accommodate differing clinical needs, four program options have evolved (Table 2). Program options vary in terms of number of variables collected, surgical specialty, if procedures are specifically targeted, and case sampling required. The percent of the FTE for the surgical clinical reviewer varies by program option, as the smaller

program can use less effort. FTE calculators are available on-line to calculate the amount required.

Table 2, Chapter 14. Comparison of American College of Surgeons national surgical quality improvement program use options

Elements	Classic	Essential	Small & Rural	Procedure Targeted
Eligibility	Any hospital	Any hospital	<1680 cases per year or Rural (RUCA) data code 7.0-10.6	Any hospital
Variables Collected	69 clinical variables	46 clinical variables (subset of Classic)	46 clinical variables (same as Essential)	Core of 46 clinical variables + Procedural specific variables (same as Essential)
Surgical Specialty Versions	General/Vascular Multispecialty	General/Vascular Multispecialty	Multispecialty	General/Vascular Multispecialty
Case Volume Requirements	General/Vascular =1680 cases/yr (or all if <1680) Multispecialty=20% case volume by specialty	General/Vascular =1680 cases/yr (or all if <1680) Multispecialty=20% case volume by specialty	Maximum=1680 cases/yr	Minimum =1680 cases/yr (depends on # and volume)
Case Sampling	General/Vascular =40 cases/8 day cycle Multispecialty=may be >40 per 8 day cycle	General/Vascular =40 cases/8 day cycle Multispecialty=may be >40 per 8 day cycle	All cases (100%)	15 Core cases per 8 day cycle 25 Procedure targeted cases per 8 day cycle
FTE requirement	1 FTE May be more for Multispecialty (#cases required /1680=# FTE required)	1 FTE May be more for Multispecialty (#cases required /1680=# FTE required)	¼ FTE ≤ 400 cases ½ FTE ≤ 800 cases ¾ FTE ≤ 1200 cases 1 FTE ≤ 1680 cases	1 FTE (minimum) May be more if target more than 1,000 procedures per year

Adapted from ACS NSQIP Information Sheet dated January 1, 2011. Reprinted by permission from the American College of Surgeons NSQIP.

The minimum number of cases the surgical clinical reviewer will enter is 1,680 (however, this number may be smaller or larger, depending on the program chosen). If data can be entered automatically from the electronic medical record, then an estimated 2,000 to 2,300 cases can be reviewed per year.

Currently, 431 sites are enrolled in ACS NSQIP, which represents roughly 10% of the almost 4,500 hospitals in the United States. A geographic map of 258 sites that had reported clinically useful data (from the July 2011 semi-annual NSQIP report) shows the distribution within and outside of the U.S. (Figure 2).

Figure 2, Chapter 14. Geographic distribution of American College of Surgeons national surgical quality improvement program participating sites

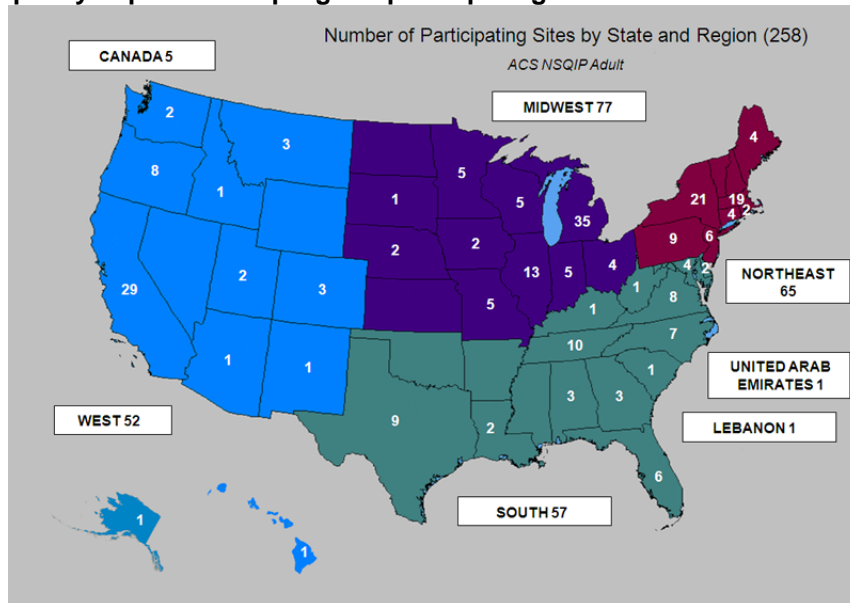


Figure 2 provided from ACS NSQIP Web site, from July 2011 semi-annual NSQIP report, accessed December, 2011
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Of participating sites, 49 percent are teaching or academic centers. The majority of these hospitals are high volume, as only 3 percent perform fewer than 100 cases per year, 7 percent perform 100-299 cases per year, 43 percent perform 300-499 cases per year, and 47 percent perform more than 500 cases per year. This skewed distribution of hospital size means that the 10 percent of hospitals participating in ACS NSQIP represent 32 percent of the procedures performed (based on Medicare data from ACS NSQIP, personal communication with Clifford Ko). Certain complex procedures are captured at an even higher rate, for example 57 percent of esophagectomies and 53.4 percent of pancreatectomy cases billed to Medicare are performed at ACS NSQIP sites (Table 3).

Table 3, Chapter 14. Percent of Medicare surgical cases covered by the national surgical quality improvement program

Procedure	MC cases in NSQIP	MC cases NOT in NSQIP	Total MC cases	Percent covered by NSQIP
Esophagectomy	1158	875	2033	57.0
Cystectomy	3346	4501	7847	42.6
Abdominal Aortic Aneurysm Repair	3762	6448	10210	36.8
Pancreatectomy	3901	3399	7300	53.4
Colectomy	32444	103056	135500	23.9
Proctectomy	6745	15767	22512	30.0
Aortolliac bypass	2255	4974	7229	31.2
LEB	12203	30100	42303	28.8
Liver Resection	2465	2201	4666	52.8
Hip Fracture Repair	40030	151140	191170	20.9
Abdominoplasty	1058	1829	2887	36.6
Lung Resection	16065	27391	43456	37.0

Table 3, Chapter 14. Percent of Medicare surgical cases covered by the national surgical quality improvement program (continued)

Procedure	MC cases in NSQIP	MC cases NOT in NSQIP	Total MC cases	Percent covered by NSQIP
Endovascular Abdominal Aortic Aneurysm Repair	8944	17324	26268	34.0
Nephrectomy	9727	16375	26102	37.3
Hysterectomy	17954	45108	63062	28.5
Total Hip Arthroplasty	56700	195528	252228	22.5
Laminectomy	60650	154858	215508	28.1
TURP	11345	42928	54273	20.9
Ventral Hernia	19360	57735	77095	25.1
Carotid Endarterectomy	20588	59710	80298	25.6
Total Knee Arthroplasty	72916	279642	352558	20.7
Prostatectomy	10677	18808	29485	36.2
Breast recon	455	700	1155	39.4
Appy	8802	31635	40437	21.8
Thyroid	5358	12598	17956	29.8
Gastrectomy	3782	7382	11164	33.9
Carotid stent	3648	7883	11531	31.6
Small Bowel Resection	10784	30836	41620	25.9
Mastectomy	6417	21378	27795	23.1
Cholecystectomy	29386	117327	146713	20.0
Total				32.0

Notes: LEB=Lower extremity bypass; TURP= Transurethral resection of the prostate.

Collaboratives are a main feature of the ACS NSQIP. The collaboratives have taken many different forms—a handful of geographically close hospitals or all of the hospitals in a state—that work together as a team to implement the program and initiate quality improvement. They also can represent a disease or patient population; thus a collaborative of hospitals need not be geographically close. Collaboratives provide a collective voice for bargaining with potential sources of funding. One reported approach is for the main insurer for the hospitals in the collaborative to pay for 50 percent of the cost of the program over a set number of years. Sometimes an option to renew the financial support is given if certain milestones are met or improvements are shown. Some payors have judged there to be a business case for helping support ACS NSQIP participation due to perceived cost-savings (detailed below). Table 4 shows the current list of active collaboratives in ACS NSQIP.

Table 4, Chapter 14. List of American College of Surgeons national surgical quality improvement program collaboratives including type, number of sites, and payor

Group	Type	# of Sites	Payor Involvement
Canadian National Surgical Quality Improvement Collaborative (CAN-NSQIP)	Regional	6	Canadian Health Authorities
Connecticut Surgical Quality Coalition (CTSQC)	Regional	5	None at this time
Department of Defense/TRICARE	System-wide	16	Department of Defense/TRICARE
Florida Surgical Care Initiative (FSCI)	Regional	63	BlueCross BlueShield of Florida

Table 4, Chapter 14. List of American College of Surgeons national surgical quality improvement program collaboratives including type, number of sites, and payor (continued)

Group	Type	# of Sites	Payor Involvement
Fraser Health Systems (Canada)	System-wide	3	Fraser Health Authority
Illinois Surgical Quality Improvement Collaborative (ISQIC)	Regional	12	None at this time
Kaiser Permanente Northern California Regional NSQIP Collaborative (KPNCRNC)	System-wide	21	Kaiser Permanente Northern California
Kaiser Permanente Southern California Regional NSQIP Collaborative (KPNCRNC)	System-wide	8	Kaiser Permanente Southern California
MaineHealth Collaborative	System-wide	6	MaineHealth
Mayo Clinic Surgical Quality Consortium (MCSQC)	System-wide	5	Mayo Clinic
Northern California Surgical Quality Collaborative (NCSQC)	Regional	4	None at this time
Nebraska Collaborative	Regional	2	BlueCross BlueShield of Nebraska
Oregon NSQIP Consortia	Regional	8	None at this time
Pennsylvania NSQIP Consortia	Regional	10	None at this time
Partners HealthCare	System-wide	5	BlueCross BlueShield Massachusetts
Surgical Quality Action Network – British Columbia, Canada (SQAN)	Regional	21	BC Patient Safety & Quality Council
Tennessee Surgical Quality Collaborative (TSQC)	Regional	10	BlueCross BlueShield of Tennessee Health Foundation
Upstate New York Surgical Quality Initiative	Regional	7	Excellus
ACS NSQIP Colectomy Collaborative	Virtual	36	None at this time
ACS NSQIP Glucose Control Collaborative (Pending)	Virtual	4	None at this time
ACS NSQIP Rural Collaborative (Pending)	Virtual	5	None at this time
ACS NSQIP Residency Training Collaborative (Pending)	Virtual	TBD	None at this time
Indiana Collaborative (Pending)	Regional	7	None at this time
Maryland Collaborative (Pending)	Regional	3	None at this time
Texas Collaborative (Pending)	Regional	16	None at this time
Virginia Collaborative (Pending)	Regional	11	None at this time
Wisconsin Collaborative (Pending)	Regional	6	None at this time

Abbreviation: TBD= to be determined

Adapted from ACS NSQIP Annual Meeting, July 2011

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A pilot pediatric collaborative for ACS NSQIP collects data for patients under age 18.^{34,35} Variables have been modified to pediatric surgery practices and needs.

Henry Ford hospital recently reviewed their lessons learned after implementing ACS NSQIP over 5 years ago.³⁶ Their findings were summarized into 12 steps (Figure 3).

Figure 3, Chapter 14. The 12 steps to implement the national surgical quality improvement program

-
- Secure multi-area leadership support
 - Develop the infrastructure
 - Develop a surgical quality improvement team
 - Encourage surgeon buy-in through data transparency
 - Map the patient's surgical experience
 - Understand where problems lie through data review
 - Use data analysis to select a target for improvement
 - Communicate the target selection at the surgical quality improvement conference
 - Engage surgeons and hospital administration throughout the process
 - Embrace additional support
 - Engage other specialties in the quality improvement process
 - Communicate and celebrate success
-

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Are There Any Data About Costs?

The costs of participation vary depending on the program type in which the hospital enrolls. An annual administrative fee varies by hospital size and level of participation, salary for the surgical clinical reviewer, and sometimes additional bonus to support the effort of the surgical champion or quality improvement team. This fee ranges from \$10,000 (rural and hospitals that perform <2000 cases/year) to \$25,000 (>2,000 cases). Hospitals have opportunities to lower their costs by participating in a collaborative or in a hospital system. The annual fee covers the 2-day training for the surgical clinical reviewer, audits, and the semi-annual data report, as well as the additional support provided by the ACS NSQIP in terms of materials and help with quality improvement.

The salary for the surgical clinical reviewer, who collects data and assists with the quality improvement, makes up the bulk of the expense of participation. Previously, the clinical reviewer had to be a nurse, but because individuals without nursing degrees have turned out to be some of the best surgical clinical reviewers, that requirement was dropped. As such, the full time employment (FTE) for this person will vary, based on their experience, level of training, and the region. For example, an FTE for an experienced person with a bachelor's degree may be around \$40,000 per year, but may be somewhat less for someone with experience but without a degree, or may be upwards of \$100,000 for a registered nurse (with benefits).

Many hospitals suggest that paying the surgeon champion (such as \$5,000 annually) is helpful in increasing their interest and efforts, although, a recent survey of surgical champions (109 respondents) found that 72.5 percent did not receive salary support to compensate their time.³⁸

The total cost of participating has been estimated at \$135,000, which includes the full time employment (FTE) in addition to \$10,000-\$25,000 annual administrative fee; however, this would be the high end estimate for a large hospital that hires a registered nurse as the surgical clinical reviewer.^{33,37} Most participating hospitals in fact pay considerably less than this estimate.

Since the overarching goal of ACS NSQIP is to reduce complications, which are costly, the business case for participating is that the cost of the program translates into cost savings to the

hospital. Examples of such savings reported by NSQIP sites are shown in Table 5. Shown are pre-post data without control groups; thus, inference of a causal relationship is limited by the study design.

Table 5, Chapter 14. Example of reductions in complications and associated costs

Hospital	Complication Reduction	Savings
Surrey Memorial Hospital ³⁷	Reduced SSI over four years: 13%, 10%, 7.5%, 7.2%	\$2.54 million savings
Henry Ford Hospital ³⁶	Reduced LOS by 1.54 days over 4 years for general surgery, vascular and colorectal procedures	\$2 million annual savings (increased billing by \$2.25 million/yr as underbillings were identified)
VA ²²	Surgical pneumonia alone	9.3 million in savings annually
University of Michigan Medical Center ⁷	Respiratory complication	\$51,409 per event. A reduction of two such complications per year pays participation.
Hershey Medical Center; Penn State ²⁶	Additional cost attributable to a postoperative complication=\$16,371.	Avoiding one postoperative complication equals cost savings of \$9052

One cost-effectiveness analysis of participation in ACS NSQIP has been published. It compared costs and outcomes for 2,229 general surgery and vascular surgery cases at one large academic hospital between two pre-intervention time periods and two post-intervention times, the first post-intervention period being the 6 months following implementation and the second being the 12 months following implementation. The perspective was the hospital's costs. The study found that the incremental cost of the program were \$832 and \$266 per patient for the two time periods, meaning the cost per patient of the program declined after the initial 6 months of implementation. Postoperative events also declined over time, from 17% to 13%. The incremental cost-effectiveness ratio to avoid 1 postoperative event was \$25,471 in the first 6 months, declining to \$7,319 in the second time period, meaning that the longer the institution participated in the program, the more cost-effective the program became.²⁶

Are There Any Data About the Effect of Context on Effectiveness? Lessons Learned From Implementation at Different Sites.

Many examples are available of successful program implementation as well as the challenges facing different hospital types, including varieties of collaboratives. The collaboratives are proving to be an effective approach for many hospitals, as the group can bargain for financial support from a variety of sources, shape the program for their own specific needs, and work together to make quality improvement changes. One example of the experience faced by a community of hospitals in starting a small state-wide collaborative, the Tennessee Surgical Quality Collaborative (TSQC), is detailed below. A second example is described of a group of hospitals across a state that embarked on constructing a collaboration, the Florida Surgical Care Initiative (FSCI).

During the recent national ACS meeting (October 2011), the Tennessee Surgical Quality Collaborative gave a detailed presentation of how they started. In 2004, after being introduced to the newly started ACS NSQIP at the national ACS meeting, a member of a community hospital in Tennessee returned home and approached his hospital's CEO. One year later they signed the contract to enroll in the program. Two other Tennessee hospitals started the application process

around the same time. Then at the State Chapter ACS meeting, the idea was posed to develop a statewide collaborative and use a funding mechanism modeled after that in Michigan, where some funding support would be provided from major payors in the area (in this case, Blue Cross/Blue Shield). Discussions with the payor were initiated, and the surgical leaders made a site visit to Michigan to learn more about developing a collaborative. The collaborative included the hospitals (and the chapter), Blue Cross/Blue Shield (BC/BS), and the Tennessee Hospital Association. Ultimately, it was decided that control of the collaborative (meaning the data) would remain with a leadership committee that comprised four surgeons who were appointed by the Chapter, along with two hospital CEOs and one member of the Tennessee Hospital Association. The proposal included funding for participation of eight hospitals (three hospitals that were currently enrolled and five new ones) estimated to be \$2,550,000 for 3 years. The money would cover half the expense of the surgical clinical reviewer at each site, and provide for some salary support for each site surgeon champion (\$5,000 each per year) and the cost of the administrative Tennessee Center for Patient Safety (TCPS), which would house the data. By 2008, three more hospitals wanted to join, and BC/BS increased their support to include them. This example highlights many of the key components to building a successful program—surgical leaders taking a role, supportive administration, collaborating with other hospitals.

A new and strikingly different collaborative is underway in Florida. The story of how this collaborative started was outlined at the national meeting. In brief, the drive to participate in NSQIP and improve care started with the hospitals. The Florida Hospital Association (FHA) was aware of the high surgical mortality demonstrated by the Dartmouth Atlas project (which is dedicated to identifying and showing disparities in access and utilization of health care) in their State. The FHA, along with the payor, BC/BS, collaborated to generate a financial incentive for hospital participation. According to the model, the first step was to identify the surgeon champions. In order to make the program financially viable to many of the smaller hospitals and to reach more hospitals, the ACS NSQIP along with the FHA devised a new version of the program that would collect only four outcomes, thus lowering costs. Currently, 64 hospitals are participating in the Florida Surgical Care Initiative (FSCI) and participation of 39 more is pending. This example demonstrates additional features that help encourage participation: individuals at the State level and hospital administration taking a lead, flexible program design to fit the needs of the collaborative, and the role of the local payor to incentivize hospital participation.

Conclusions and Comment

Although no randomized trials have assessed the use of outcomes measurements and reporting in surgery, the strength of the evidence that doing so improves operative mortality and morbidity has to be considered moderate or even high, given the strong theoretical rationale for why it should work, the evidence that outcome reporting has likely improved surgical outcomes in other settings (e.g., the New York State CSRS), the numerous reports from ACS NSQIP sites of implementation of quality and safety initiatives following identification of high outlier status, and the ensuing, sometimes dramatic, improvements in those outcomes. A great deal of experiential evidence exists on how to implement the ACS NSQIP—it has been implemented in more than 400 hospitals—suggesting that the program can be more widely implemented. Some of the key components of ACS NSQIP (collecting complications data, sharing models of observed-to-expected results, multi-site data collection systems across institutions that provide results back to the sites for benchmarking, contexts for learning and sharing tools that appear to

be effective across sites) are similar to those of other successful patient safety practices such as the Michigan Keystone ICU Project to reduce catheter-related bloodstream infections.³⁹ Despite ACS NSQIP and the Keystone ICU Project having started with different original “interventions” (the feedback of procedure-specific surgical outcome data to surgeons and a checklist of processes to reduce infections) the observation that the current version of the interventions include so many similar components probably suggests something generalizable about the implementation of certain kinds of practices across hospitals.

ACS NSQIP provides hospitals and providers with usable clinical data that are otherwise not available to them. Currently, all hospitals use administrative data to some degree to assess quality through the Centers for Medicare and Medicaid Services’ Hospital Compare program or the Surgical Care Improvement Project (SCIP). These data lack clinical information and are limited by the variables reported for claims. More importantly, the correlation between administrative data and actual complications or diagnoses is inadequate. For example, urinary tract infections are poorly reported in administrative data. Furthermore, studies show that adherence to SCIP measures do not correlate to better outcomes. ACS NSQIP has the power to show providers the most problematic clinical data.

The greatest benefit has been seen in the larger hospitals in the procedures with the higher complication rates. Whether the above improvements will translate to low risk but common procedures, such as out-patient procedures is unclear. Also, most of the early adopters have been large academically affiliated hospitals. How successfully and widely it can be implemented at smaller hospitals remains to be seen. A summary table is located below (Table 6).

Table 6, Chapter 14. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Moderate-to-high	Low	Moderate	Moderate/Moderate

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Chapter 15. Prevention of Surgical Items Being Left Inside Patient: Brief Update Review

Jonathan R. Treadwell, Ph.D.

Introduction

Leaving surgical items inside patients is a rare but potentially deadly mistake. The most common such item is a surgical sponge. Researchers at the Mayo clinic found that during the four-year period from 2003 to 2006, the rate of retained foreign objects was 1 in every 5,500 operations,¹ and 68 percent of the retained objects were sponges. The greatest subsequent risk to the patient is infection, which can be fatal. Other risks include perforations and granulomas.

Risk factors for such incidents were explored by Gawande and colleagues (2003),² who examined factors surrounding 42 retained sponges and 19 retained instruments. The majority required reoperation, and one patient died. Compared with control incidents, item retention was more likely to occur in the context of emergency surgery, an unexpected change in surgical procedure, high body-mass index (an x-ray is recommended), and the lack of item counts.

A review of the literature on the topic of retained surgical sponges conducted for the original report identified only one study (a case series) that attempted to assess the use of sponge and instrument counts to prevent retention.³ The goals of the present review were to identify interventions implemented since the previous review and to report on studies assessing their effectiveness. We conducted a review of the literature from 2001 to 2011 and reviewed all studies relevant to methods used to prevent surgical items from being left inside patients during surgical procedures.

What Are the Practices Aimed at the Prevention of Leaving Surgical Items Inside Patients?

To prevent leaving surgical items inside patients, the Association of periOperative Registered Nurses (AORN) recommends counting all sponges, sharps, and related miscellaneous items at five different times: (1) before the procedure to establish a baseline, (2) before closure of a cavity within a cavity, (3) before wound closure begins, (4) at skin closure, and (5) at the time of permanent staff relief of either the scrub person or the circulating nurse.⁴ In addition, specifically for surgical *instruments*, AORN recommends counting only at times 1, 3, and 5 above. AORN also recommends all counts be documented in the intraoperative record. If a discrepancy occurs between counts, surgical staff must search for the lost item (usually a sponge). If it is suspected in the OR that an item was left inside the patient, a radiograph may be necessary.

For comparison, the Surgical Safety Checklist of the World Health Organization requires a post-procedure count, but the checklist suggests neither pre-procedure counts nor intraoperative counts.⁵

What Supplementary Methods Have Been Used To Improve Counts of Surgical Items?

Three technologies can enhance the accuracy of the count, thereby further lowering (theoretically) the risk of leaving items inside patients: (1) bar coding, (2) radiofrequency tagging

without unique item ID numbers (abbreviated RF), and (3) radiofrequency tagging with unique item ID numbers (RFID). Bar coding is an established and low-cost technology, but a direct line of sight between the bar code scanner and the item's bar code label is needed in order to scan it, and blood-soaked items may be difficult to scan accurately. The RF technologies (a penny-sized or smaller chip implanted into the device) allow items to be detected by a specialized wand that is waved over the patient's body during and after the procedure. This scan can prevent the need for a radiograph, which itself can increase surgical risk because of the added time on the operating table and under anesthesia. RFID represent an advance from the simpler RF technologies because if each item is assigned a unique ID number, then the manual count can be checked against the RFID system's baseline count.

The FDA has cleared four products relevant to the above technologies for marketing in the United States (U.S.):

1. Safety-Sponge™ System, (SurgiCount Medical, Temecula, California).⁶ This system comprises bar-coded sponges.
2. RF Surgical Detection System™ (RF Surgical, Bellevue Washington). This technology permits detection of devices but does not provide a count, because items do not receive unique ID numbers. The detection wand is single use. The system can be used with sponges, laparotomic pads, gauze, and towels, but not surgical instruments or sharps.
3. SmartSponge™ System (Clear Count Medical, Pittsburgh Pennsylvania). This system assigns a unique ID for each device, so it is used for both detection and counting. As the procedure progresses and staff remove sponges or other items, they put the items into a specialized bucket fitted with an antenna that detects and counts the RFID items. If a discrepancy occurs between the baseline counts and the final counts, it notifies the OR team with auditory and visual warnings, thereby initiating a search for the lost item(s) using a detection wand. This system also can be used with sponges, laparotomic pads, gauze, and towels, but not surgical instruments or sharps.
4. ORLocate™ (Haldor, Boston, Massachusetts).⁷ This system also assigns a unique ID for each device, so it is used for both detection and counting. Unlike the two systems described above, it can be used for instruments and sharps as well as sponges and other non-metallic items

What Have We Learned About Methods To Improve Counts of Surgical Items?

Greenberg and colleagues (2008)⁸ randomized 298 patients to undergo operations involving either manual counting (148 patients) or bar-coded sponges (150 patients). Twice as many sponge count discrepancies were detected in the bar-coded group (24 operations) as in the manual counting group (12 operations). This difference was mostly explained by miscounted sponges (nine operations in the bar-code group vs. one operation in the manual counting group) rather than by misplaced or retained sponges (17 in the bar-code group vs. nine in the manual counting group). Interestingly, in these same operations, no difference was seen between the groups in count discrepancies for non-bar-coded surgical instruments (11 in the bar-code group vs. ten in the manual counting group).

A 2009 systematic review by Stawicki and colleagues⁹ on risks and measures to prevent retention of surgical items that considered a variety of case reports, case series, registry reports, and position papers concluded that “the most important preventive measure is to accurately count all the pieces of surgical gauze and surgical instruments used during an operation.” Authors also

listed additional factors that could help minimize this type of mistake: (1) Knowledge of risk factors, (2) Use of modern technology, (3) Improved perioperative patient processing systems.

Methods May Be Time Consuming and Present Technical Challenges

In the 2008 study by Greenberg and colleagues,⁸ 17 incidents of technological difficulties occurred because of the bar-code system (2.04 per 1000 sponges counted), issues that would not have arisen with manual counting. Further, of 150 operations with bar-coded sponges, the surgical team abandoned the bar-code system in five operations (3%) due to the extra time required. However, the authors concluded that the use of the bar-code technology was well tolerated by staff members. The amount of time needed to count items can potentially cause harm to patients if other key surgical steps are missed or rushed as a result of counting. Greenberg and colleagues⁸ found that the bar-code-sponge method required more than twice as much time to count sponges as the manual method (5.3 minutes vs. 2.4 minutes).

Other Implementation Issues May Arise

One consideration for hospitals regarding the use of RF and RFID technologies is that if only a portion of the hospital's surgical devices are RF-enabled, confusion might result. Staff may mistakenly assume that all devices are RF-enabled, and a post-procedural scan would miss any non-RF-enabled device inside the patient. Thus, it is recommended that RF-adoption be all or none.¹⁰ Also, wand technique can be important when using RF devices, because scanning too far away from the body, or too early—the surgeon may need to use additional tagged items—can fail to locate all items. Also, because adipose tissue can increase the distance between the wand and tagged items, some items may be missed when scanning obese patients.

In the 2008 study of bar-coded sponges by Greenberg and colleagues⁸, a post-study survey of 41 providers found moderately high ratings for ease of use (average rating 7.3 on a 0-10 scale) and confidence in the ability of the system to track sponges (average rating 7.5 on a 0-10 scale). Opinions on whether the bar-code system benefitted the counting protocol were mixed but slightly positive (on a scale from -5 to +5, the average was +1.6). Authors stated that “some providers felt that the system was especially useful in large operations with high blood loss and many sponges, whereas others felt that the system was difficult to use in these types of operations.”⁸

Questions About Cost-Effectiveness

The medical and liability costs of a surgical item left inside a patient can exceed \$200,000.¹¹ In 2009, Regenbogen and colleagues¹¹ performed a cost-effectiveness analysis of six strategies to prevent this type of incident. In their simulation, manual counting prevented 82 percent of the simulated incidents at a cost of \$1,500. In comparison, the other five strategies performed as follows:

- Bar-coding the sponges raised the effectiveness to 97.5 percent, and the cost-per-prevented-retained-sponge was \$95,000.
- RF-enabling the sponges (without a unique ID for each sponge) raised the effectiveness to between 97.5 percent and 100 percent, and the cost-per-prevented-retained-sponge was between \$620,000 and \$720,000.
- Three radiographic strategies were dominated by the two bar code strategies with respect to cost and effectiveness: 1. Do not count but always X-ray before closure; 2. Count, and

always X-ray before closure; 3. Count, and also X-ray before closure only for high-risk operations).

Conclusions and Comment

To prevent leaving items (typically sponges) inside patients during surgery, manually counting all items is widely recommended. Although several supplementary technologies exist, their use must remain limited to that of supplementing or aiding counting. These technologies include bar coding and radiofrequency tagging (with or without unique ID numbers). For each of these technologies, specific institutional hurdles (e.g., cost, confusion with older non-tagged devices, and wand technique with RF and RFID systems) must be overcome before their use can be considered both reliable and cost effective. A summary table is located below (Table 1).

Table 1, Chapter 15. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Rare/Low	Low	Negligible	Low if it simply involves more frequent manual counting; high if RFID is used	Little

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Chapter 16. Operating Room Integration and Display Systems: Brief Review (NEW)

Fang Sun, M.D., Ph.D.

Introduction

Patient monitoring is one of the central tasks in operating rooms (ORs). Because of the increasing use of advanced technologies in surgical procedures, today's ORs are commonly crowded with freestanding devices, support systems, and monitors. In addition to the traditional monitors that continuously present the patient's hemodynamic, respiratory, and electrophysiological signals, many innovative devices recently introduced into the OR feature their own platforms for data display. These devices may fall into one of four categories:¹

- Surgical machine-controlled applications (e.g., robotics, minimally invasive surgery, video-endoscopic surgery, master-slave systems)
- Designated diagnostic and real-time navigation devices (e.g., magnetic resonance imaging, computed tomography, three-dimensional ultrasound)
- Information technology (IT) applications generating a real-time connection between the OR and the hospital medical record archives (e.g., picture archiving and communication systems [PACS], videos, electronic medical records (EMRs), hospital information systems, and other laboratory data)
- Telecommunication and teleconferencing systems connecting the OR in real time with other medical centers

The increasing use of these devices leads to a congestion of data displays in the OR, compels OR staff members to increase the time devoted to monitoring the displays, and may divide their attention between monitoring and other tasks.¹ Meanwhile, the proliferation of freestanding devices and displays in the OR makes coordination difficult.² Surgeons, nurses, and anesthesiologists have their own perioperative devices or systems on which to focus. Human coordination of multiple electromechanical devices may lead to misunderstandings and delay action.

As some experts have commented, what is currently lacking in most ORs is a high-level overview of all the information that is already available in the room.³⁻⁵ The lack of integration of patient data makes ORs inefficient, overcrowded, and less safe. When patient data are not displayed to caregivers in an integrated fashion, OR staff have to frequently with multiple displays to obtain updates and exert control over the various devices at their disposal.^{4,5}

OR integration is an emerging technology that has the potential to address the long-standing problem of segregated data display in ORs. This technology organizes and consolidates patient data for clinicians during a surgical procedure. This chapter focuses on the latest form of the technology, which features a centralized data display platform.

What Are the Practices for Integrating Operating-Room Display Systems?

An OR is integrated if users can control the routing of audio/video (AV) signals from a central location.^{3,6} These AV signals can originate from within an OR (e.g., endoscopes, wall-mounted cameras) or outside an OR (e.g., PACS, AV feed from another OR). Depending on configuration, an OR integration system may also permit centralized control of certain clinical devices (e.g., insufflators and electrocautery units) and nonclinical equipment (e.g., lighting and room climate controls).^{6,7} Some OR integration systems may allow signals to be sent outside the room (e.g., to a conference room or to a central display used by the OR scheduling nurse) or exchange data with an EMR system.^{6,7}

Current-generation OR integration systems offer a range of capabilities. ECRI Institute has identified at least 10 vendors that offer products meeting the basic definition of OR integration (i.e., with centralized control of AV routing in the OR).^{3,7}

Centralized display of consolidated data. OR integration technology continues to evolve as new features are added. One of the latest developments in the field is the consolidation of real-time patient data from different devices and systems (e.g., physiologic monitors, anesthesia systems) for display on a “dashboard” format single screen that can be viewed simultaneously by all clinicians in the OR.^{3,7} We believe this new development represents the future of OR integration; thus, we focus this chapter exclusively on OR integration systems that can display consolidated data on a single screen. We exclude conventional OR integration systems that lack the capacity to present data in a centralized, single-screen format.

Two studies published by ECRI Institute in 2008 identified at least two vendors that offered OR integration systems featuring a centralized repository/display of consolidated data sent from a number of monitors and devices in real time.^{3,7} These two systems are the OR-Dashboard™ (LiveData, Inc., Cambridge, MA, U.S.) and the ICIS (integrated clinical information system) Dashboard (Global Care Quest, Inc., Aliso Viejo, CA, U.S.). Both systems have the capacity to interface with numerous medical devices, patient monitors, and information systems without encountering compatibility problems. Data may be collected from patient progress logs, OR scheduling software, real-time vital signs, anesthesiology systems, medical infusion pumps, radio frequency identification tracking systems, PACS, EMRs, clinical laboratory systems, in-room cameras, endoscopic systems, clinical notes and rounding lists, bidirectional video conferencing, and audio note recording. The data can be displayed on large, wall-mounted, flat-panel screens and on accessory monitors in the OR. Both systems allow clinicians to monitor time trends of various waveforms, such as respiration, blood pressure, and cardiac activity.^{3,7,8}

The central display of the OR-Dashboard changes to reflect one of four procedural stages: case setup, time out (safety pause), intraoperative, and closing. Case setup mode displays information such as surgical supplies and blood availability. The time out mode assists the surgical team in verifying patient and case information. Intraoperative mode displays information such as physiologic status, fluid status, and current readings from ventilators and infusion pumps. Closing mode includes information on equipment counts, postanesthesia care unit assignment, and family waiting status.^{3,7,8} This display arrangement is intended to improve situation awareness during the surgery.⁸

Used with other products provided by LiveData, the OR-Dashboard allows videoconferencing between the surgical team and other departments to monitor procedures remotely or consult specialists throughout the hospital in real time.^{7,8} The OR-Dashboard can

also securely archive all case data, including video, using various device and information protocols to permit case review after the surgery.^{7,8} With additional software provided by Global Care Quest, the ICIS Dashboard provides secure access to the collected patient data in real time through wireless mobile devices, including personal digital assistants and “smart” phones that clinicians can use where a wireless connection is available.⁷

Contribution to operative and perioperative safety. OR integration technology with centralized data display can potentially help improve operative and perioperative safety in several ways. First, the technology allows easy, just-in-time access to patient information from disparate devices or systems that is often unseen, unrealized, or unused.^{8,9} Increased access to this information may improve team situation awareness (TSA, i.e., the task- and team-oriented knowledge held by everyone in the team and the collective understanding of the unfolding situation).^{8,10} TSA is one of the critical factors in OR teamwork that can affect patient safety and quality of care. Augmented TSA can improve communication among clinical personnel and thus help reduce the number of medical errors.^{8,11,12}

Second, the integration of previously isolated information sources may open new opportunities for decision support and augment vigilance.⁸ For example, allergy information from the hospital information system may alert the team to not administer certain drugs to the patient and, thus, prevent harmful drug-related adverse events. Information from the laparoscopic insufflator can inform the team of impending asystole from insufflation. Information from the location tracking system may help the surgical team check the accuracy of patient identity. Integration with the order-entry system can help update the team on workflow and resource acquisition such as pathology, radiology, and the blood bank. The order information can be continuously displayed throughout the operative period to decrease uninformed or delayed decisions.

Additionally, the OR integration technology provides the ability to flexibly change the source or destination of an AV signal without requiring the cumbersome process of reconfiguring direct links between sources and destinations each time such a change is needed.⁶ This ability might decrease the risk of medical errors in the reconfiguration process. OR integration may also generate other opportunities for improving patient safety. For example, the technology might allow real-time, remote consultation from experts outside of the OR.⁶ The technology could enhance patient data collection during the surgery and decrease stale or duplicate data. These data can be analyzed later for the purpose of improving patient safety. The technology may also have a positive psychological effect on clinical personnel, making them feel more comfortable and more confident that things are going well.¹⁰

How Have Integrated Operating-Room Display Systems Been Implemented?

We identified several sources that described issues related to the design, planning, or installation of integrated OR systems (with or without centralized data display).^{5,6,14-17} In particular, two studies provided practical guidance on the implementation of integrated ORs. One of the studies offered step-by-step instruction for addressing the equipment and construction needs for OR integration.¹⁵ The study outlined the technical considerations for in-room integration, extended AV integration, and equipment control. The study also provided a detailed list of equipment and specifications required for OR integration.

The second study discussed the technical issues that must be addressed when installing integrated ORs.¹⁴ The issues included controlling the images, integrating team members, pre-construction planning, working with vendors, and managing the final project phases. It was not feasible to provide additional details about these studies in this brief review. Readers can refer to the original studies for detailed instructions on implementing integrated ORs.

Data about costs. According to an ECRI Institute study, as of October 3, 2007, a LiveData OR-Dashboard system costs about \$150,000.⁷ Total system costs can vary widely depending on the features that a hospital requests and the number of systems installed at a facility.^{6,18} Facilities could also face significant additional costs to integrate new systems into their existing IT infrastructure. Similar cost information for the ICIS Dashboard was not reported.⁷

Effect of context on effectiveness. We identified a survey of 17 surgeons and 9 scrub nurses from a single hospital that evaluated their satisfaction after 2 years of use of integrated ORs.¹³ The surgeons and scrub nurses agreed that a great degree of education and a cultural change were needed to use the system in a correct and complete way.¹³ However, we were not able to verify whether the integrated ORs described in the study had the centralized data display feature. We did not identify any other study that evaluated the effect of context on the effectiveness of an integrated OR and centralized display systems in improving patient safety.

What Have We Learned About Integrating Operating-Room Display Systems?

Despite all of the rationales supporting the adoption of OR integration and display systems, published evidence to validate the effect of this technology on patient safety is rare.⁷ Researchers face many practical obstacles in designing and conducting clinical trials that could deliver a hard-and-fast measurement of that effect.³ For example, surgical patients comprise a heterogeneous population, making it difficult to draw firm conclusions from any studies. Additionally, because the incidence of medical errors and other adverse events is rather low (from the statistical perspective), detecting a significant improvement in safety outcomes typically requires a very large number of patients. Recruiting enough patients to conduct a good study would be difficult.

Our search identified only one case report that described the experiences of a hospital in implementing an OR integration system with centralized display (called “wall of knowledge” in the review).⁹ The authors provided their opinion-based assessment of the system. The perceived benefits of the system included easy access to a patient’s vital signs for surgeons during the operation, improved staff handoffs, reduction of clutter in the OR, improved teaching function, and timely data reporting. No patient safety outcomes were reported in the study.

In the survey that evaluated the satisfaction of 17 surgeons and 9 scrub nurses from 1 hospital after 2 years of using integrated ORs,¹³ the clinicians agreed that integrated ORs—using a digitalized video acquisition system, boom-mounted devices, and multiple displays—can be very effective in increasing quality of care, reducing risk, and shortening surgery time. Scrub nurses were particularly confident that medical device control could reduce the confusion inside the OR and reduce the number of setting errors. However, as mentioned previously, based on the information reported in the study, we were not able to verify whether the integrated ORs had the centralized display feature.

In theory, if an OR integration system or its centralized display stop functioning appropriately or fail entirely, clinicians in the OR could receive delayed or misleading information about the patient. Clinical decisions based on such information could lead to patient harm; however, our search did not identify any study that reported data on harms caused by integrated OR centralized display systems.

Note that for this chapter, we reviewed only studies relevant to patient safety issues. We did not review studies that focused solely on management issues (e.g., the effects of a display system on OR efficiency or staff scheduling).

Conclusions and Comment

OR integration with centralized data repository/display represents the latest technology development in the OR setting. While the technology might help improve patient safety, evidence to demonstrate the technology’s benefits in improving safety outcomes is lacking. Given the many practical obstacles in designing and conducting empirical studies to test the benefits of this technology, decisions on its adoption will continue to be based on rationales rather than hard evidence in the near future. Patient safety is only one of the factors that are considered in the decisionmaking process. Other factors, such as the technology’s potential to improve OR efficiency and productivity, need to be considered as well. As this review has suggested, the implementation of integrated ORs with centralized data display is not inexpensive. Decisionmakers should carefully evaluate their facility’s needs and long-term goals to determine whether this technology is really needed and, if it is, which integration capabilities are appropriate.⁶ A summary table is located below (Table 1).

Table 1, Chapter 16. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low-to-high	Low	Negligible	Moderate	Moderate/Moderate

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Chapter 17. Use of Beta Blockers To Prevent Perioperative Cardiac Events: Brief Update Review

Sumant R. Ranji, M.D.; Paul G. Shekelle, M.D., Ph.D.

Introduction

Myocardial infarction and cardiovascular death are the most common complications of major non-cardiac surgery; thus, they have long been a focus of preoperative evaluations and a target of perioperative management strategies. Based on strong evidence linking myocardial ischemia with postoperative myocardial events and preliminary evidence that beta-blockade blunts electrocardiographic signs of ischemia, clinical researchers in the late 1990s began examining the effects of perioperative beta-blocker administration on patient outcomes. The 2001 report¹ reviewed the evidence up to that point regarding the effectiveness, safety, and cost-effectiveness of this intervention. Based on the results from several well-designed clinical trials, the authors concluded that use of beta-blockers in the perioperative period was associated with significant reductions in patient cardiac morbidity and mortality. However, as of publication of that report, many questions remained regarding the optimal type of beta-blocker, the patients most likely to benefit, and the safest and most effective dosing regimen.

What Have We Learned About the Use of Beta Blockers To Reduce the Risk of Perioperative Cardiac Events?

Since the publication of “Making Health Care Safer” in 2001, new studies have called for a re-examination of the initial enthusiasm for the use of beta blockers to reduce perioperative cardiac events. Two systematic reviews with meta-analysis and one large randomized controlled trial (RCT) have been influential. The first systematic review/meta-analysis was published in 2005 by Devereaux and colleagues.² This review, which scored 10 out of 11 relevant AMSTAR domains, included 22 trials encompassing 2,437 patients. The point estimates of effect favored patients treated with beta blockers for nearly all outcomes, but the 95% confidence intervals for these estimates were not statistically significant. The exception was the composite outcome of “major peri-operative cardiovascular events,” which included cardiovascular death, non-fatal myocardial infarction, and non-fatal cardiac arrest, where the results significantly favored treatment (pooled relative risk 0.44, 95% CI 0.20 to 0.97). Conversely, pooled estimates of the risk for three adverse effects (congestive heart failure, hypotension needing treatment, and bradycardia needing treatment), all indicated the potential for harm, with pooled relative risks of 1.27 to 2.27, the latter being for bradycardia needing treatment and being statistically significant (95% CI 1.53 to 3.36). This review concluded that the evidence supporting the use of beta blockers in this situation was “encouraging but too unreliable to allow definitive conclusions to be drawn.”

The large RCT was the POISE (perioperative ischemic evaluation) study, published in 2008.³ In this study, 8,351 patients 45 years of age or older who were undergoing non-cardiac surgery, and had either known vascular disease or strong risk factors were randomized to receive 100 mg of oral extended-release metoprolol 2 to 4 hours before surgery, followed by 200 mg every day for 30 days (patients unable to take oral medications received the comparable dose intravenously). The primary outcome was a composite of cardiovascular death, non-fatal

myocardial infarction, and non-fatal cardiac arrest (in other words, the exact composite outcome with the statistically significant effect in the earlier meta-analysis). Indeed, at 30 days, patients receiving metoprolol had a hazard ratio (HR) for the primary outcome of 0.84 (95% CI 0.70 to 0.99), due primarily to fewer myocardial infarctions. However, patients treated with metoprolol had a statistically significantly greater risk of stroke (HR 2.17, 95% CI 1.26 to 3.74), and, even more alarmingly, a greater risk of all-cause death (HR 1.33, 95% CI 1.03 to 1.74). The authors of POISE concluded that the perioperative use of beta-blockers has both benefits and risks. For example they calculated that for every 1,000 patients undergoing noncardiac surgery, the use of extended-release metoprolol would prevent 15 patients from having a myocardial infarction and three from undergoing cardiac revascularization, but that there would be eight extra deaths and five extra strokes. Based on these differences in benefits and harms, and on the potential for patients to place different values on these outcomes, the authors of POISE concluded that authors of current guidelines advocating the use of beta blockers “should reconsider their recommendations.”

The later systematic review/meta-analysis was published in 2008, and included the POISE results.⁴ This review, which scored 11 out of 11 relevant domains in AMSTAR, included 33 trials, now encompassing 12,306 patients. Recalling that POISE contributed more than 8,000 patients alone, in most of the pooled analyses the POISE results contribute 75 percent or greater weight to the pooled result. Unsurprisingly, the meta-analysis found statistically significant benefits for treatment for the outcomes of non-fatal myocardial infarction and myocardial ischemia, nonsignificant results for all other potential benefits, and statistically significant adverse effects for nonfatal stroke (pooled odds ratio[OR] of 2.16), perioperative bradycardia requiring treatment (pooled OR of 2.74), and perioperative hypotension requiring treatment (pooled OR 1.62). The effect on mortality was adverse, but did not reach statistical significance (pooled OR 1.20, 95% CI 0.95 to 1.51). The authors of this review concluded that “evidence does not support the use of beta blocker therapy for the prevention of perioperative clinical outcomes in patients having non-cardiac surgery.”

Conclusions and Comment

Evidence that has emerged since the 2001 publication of “Making Health Care Safer” indicates that perioperative beta blockers¹ have mixed benefits and harms and should not be considered a patient safety practice for all patients. An observational study of more than 600,000 patients suggests that perioperative beta blockers may have more benefit in high risk than in low risk patients.⁵ An observational study of more than 600,000 patients who underwent major noncardiac surgery, which did not find any evidence of benefit on in-hospital mortality for perioperative beta blockade (adjusted odds ratio = 0.99), did find a suggestion of possible benefit in the subgroup of patients at higher risk of death due to the presence of comorbidities (diabetes, renal insufficiency, ischemic heart disease, cerebrovascular disease) or receipt of high-risk surgery (ref 5). If these suggestive findings are confirmed in subsequent randomized clinical trials the use of perioperative beta blockers could yet be shown to have benefits exceeding risks for certain subgroups of patients, but this question remains a topic for clinical research. Moreover, randomized clinical trials may yet show this intervention to have benefits exceeding risks for some subgroups of patients undergoing noncardiac surgery, but this question remains a topic for clinical research. A summary table is below (Table 1).

Table 1, Chapter 17. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	High evidence we know harms may equal or exceed benefits	High (death, stroke, hypotension and bradycardia)	Low	N/A

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Chapter 18. Use of Real-Time Ultrasound Guidance During Central Line Insertion: Brief Update Review

Paul G. Shekelle, M.D., Ph.D.; Paul Dallas, M.D.

Introduction

Central venous catheters (CVCs) have multiple indications, including parenteral nutrition, treatment of intravascular depletion, access for vasoactive medications, hemodynamic monitoring, intravenous access during cardiopulmonary arrest, difficult peripheral intravenous (IV) access, and long-term IV access for medications, such as antibiotics.^{1,2} Although these catheters can be life saving, they are also associated with significant risk.³ This risk is heightened by a number of factors, including patient characteristics (e.g., morbid obesity, cachexia, or local scarring from surgery or radiation treatment), patient setting (e.g., patients receiving mechanical ventilation or during emergencies such as cardiac arrest), co-morbidities (e.g., bullous emphysema or coagulopathy), the variable training and experience of the clinicians who perform the procedure, and the method of insertion (e.g., percutaneous insertions are often performed “blind” and rely on anatomic landmarks).³⁻⁵ However, protocols have been developed that use portable ultrasound (US) devices to provide bedside imaging of the central veins during catheter placement. The advantages associated with US-guided CVC placement include detection of anatomic variations and exact vessel location (for example, the carotid artery is anterior to the internal jugular vein in 3% to 9% of patients⁶), avoidance of central veins with pre-existing thrombosis that may prevent successful CVC placement, and guidance of both guidewire and catheter placement after initial needle insertion.

The original report included a review of the efficacy, safety, and cost-effectiveness of real-time US guidance on the safety of CVC insertions. This review found that, in general, US improves the success rates and reduces the risks of CVC placement, particularly for inexperienced clinicians and for patients in high-risk situations. The purpose of the present report is to provide an update on the impact of US CVC insertion. We used the articles cited as evidence in the 2001 report to create a list of search terms and then used these terms to conduct an update search.

What Is the Practice of Using Ultrasound Guidance for Central Venous Catheter Insertion?

As a patient safety practice, utilizing portable two-dimensional ultrasonography to guide the insertion of CVCs (internal jugular, subclavian or femoral) can take one of two forms– the “static” approach, whereby a mark is placed on the skin to indicate where to insert the needle, or the “real time” approach, where the needle insertion is visualized during the procedure. The alternative to using US guidance is the “landmark” approach, whereby anatomic landmarks are used to determine, to the extent possible, where the underlying vein is located. A recent 18-minute video (and accompanying text⁷) demonstrates the use of US guidance for internal jugular vein catheterization (www.nejm.org/doi/full/10.1056/NEJMvcm0810156#figure=preview.jpg).

How Has the Use of Ultrasound To Guide Central Venous Catheter Insertion Been Implemented?

Our search identified two surveys of the use of US for CVC. In 2006, an Internet survey was sent to members of the Society of Cardiovascular Anesthesiology; 1,494 responses were received from 4,235 members (35%). Of these respondents, 37 percent stated they “never” used US for CVC insertion, and another 30 percent “almost never” used it. Only 15 percent “always” or “almost always” used US guidance.⁸ A survey from the United Kingdom (U.K.) asked 2000 senior members of the Association of Anesthetists of Great Britain and Ireland about their use of US guidance; 1,455 replied, for a response rate of 73%). Of the respondents, 93 percent regularly inserted internal jugular venous catheters as part of their practice, and 27 percent of respondents indicated that the use of US was their “first choice” as a technique (50% of respondents used “surface landmarks” and 30% used “palpation/balloting”; some respondents indicated more than one first choice).⁹

Educating clinicians on the use of US for central line placement has received relatively little attention. Studies have shown that clinical US guidance skills are improved by implementing simulator-based training (see Chapter 38). Although several medical schools offer training in portable ultrasonography, scant information exists on teaching US guided (USG) central line placement to medical students.¹⁰⁻¹² Particular specialties mandate portable US training for residents, including procedural skills like USG central line placement, whereas others have just begun to explore the benefits of portable US in their graduate medical education programs. In emergency medicine residency training for instance, the first US curriculum was published in 1994.¹³ While no clear consensus exists regarding the need for training in USG central line placement in emergency medicine residencies, a novel training program consisting of a brief web-based instructional module and a practical session was effective in enhancing emergency resident competency in USG central line placement.¹⁴ Carilion Clinic trains physicians in the use of US using a curriculum consisting of 16 hours of didactic and hands on experience during the first month of residency; this training covers physics, “knobology” (e.g., what all the knobs on the machine are for), echocardiography, abdominal US, vascular US, and includes 2.5 hours of procedural skills, of which USG central line placement is prominent. Physicians who are experienced in the procedure use special models to conduct the “hands-on” portion of this curriculum for groups of four to five trainees. Currently, skills assessment is done by observation, although a competency and performance checklist is being developed. With respect to continuing medical education, medical schools, clinics, and medical education companies sponsor a range of activities. These activities cover hands-on USG central line placement as part of multiday courses that concentrate on U.S. education.

What Have We Learned About the Use of Ultrasound Guidance for Central Venous Catheter Insertion?

The most relevant meta-analysis identified was published by Hind and colleagues in 2003, and was commissioned by the U.K. National Institute for Clinical Excellence.¹⁵ These authors identified 18 eligible randomized trials that compared either two-dimensional US or Doppler US with either the landmark method or the cut-down method (whereby an incision is made to directly visualize the vein) and that measured any one of five relevant outcomes. Data for adults and children were pooled separately, and data from 2D and from Doppler studies were also pooled separately. For all five relevant outcomes (failed catheter placement, complication with

placement, failure on the first attempt, mean number of attempts to successful catheterization, and seconds to successful catheterization), two-dimensional US had statistically significantly better outcomes than the landmark method for internal jugular vein catheterization in adults. More limited data in children and for subclavian and for femoral vein insertion favored the use of two-dimensional US. Pooled results from studies of Doppler US also favored its use. No studies directly compared two-dimensional and Doppler US. The authors made an indirect comparison by assessing the size of the pooled effects for each compared with the landmark method. This analysis favored the use of two-dimensional US. This review scored nine of 11 relevant AMSTAR criteria. A companion cost-effectiveness analysis estimated the marginal cost (in 2002) for use of US in CVC to be about 10 pounds sterling (approximately \$16) per procedure, assuming the machine was used for 15 procedures each week. The base case scenario estimated that for every 1000 patients, 90 complications would be avoided, with a net cost saving of about 2000 pounds sterling (approximately \$3200).¹⁶

Since that time, randomized trials in adults have consistently supported the conclusions about effectiveness, including patients treated in the Emergency Department,¹⁷ ventilated patients,¹⁸ critical care patients,^{19,20} and patients in other miscellaneous clinical settings.^{21,22} A new outcome—central venous catheter-associated bloodstream infection—has been assessed and found to be statistically significantly lower in one trial of US-guided catheter insertion compared with landmark methods.¹⁹

A more recent meta-analysis included five studies that focused only on children, most of whom were cardiac surgery patients. Although pooled point estimates favored the use of US, the 95% confidence intervals were wide and none of the results were statistically significant.²³ Two trials published since that meta-analysis, one of which compared real time to static US, both found that two-dimensional real-time US improved some outcomes.^{24,25}

Recent trials of US have focused less on its use in adult internal jugular vein catheterization and more on its use in other locations and refinements of the technique, including the insertion of hemodialysis catheters,²⁶ the radial artery,²⁷⁻²⁹ the femoral artery,³⁰ and even peripheral venous catheters in difficult patients.³¹⁻³⁶ In general, studies reported that US guidance improved outcomes compared with techniques without US guidance. Systematic reviews of the use of US guidance for hemodialysis catheter insertion³⁷ and radial artery catheters³⁸ each concluded that the use of real-time two-dimensional US improved outcomes.

Clearly, USG central line placement education varies in undergraduate, graduate, and continuing medical education. While educators at all levels are making inroads, greater consistency is needed in curricula, evaluation of outcomes, and guideline development.

Conclusions and Comment

In 2001, “Making Health Care Safer” concluded that the use of US guidance for the placement of CVCs is one of the patient safety practices with the strongest evidence. Since that time, new evidence continues to support and strengthen this conclusion. Simulator-based training can improve implementation of this patient safety practice. Emerging evidence suggests that two-dimensional real-time US guidance may also be beneficial for other kinds of catheter insertions. A summary table is located below (Table 1).

Table 1, Chapter 18. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low-to-moderate	High	Negligible	Low-to-moderate	A lot/Moderate

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Section D. Safety Practices Aimed Primarily at Hospitalized Elders

Chapter 19. Preventing In-Facility Falls

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How Important Is the Problem?

The rate of falls in acute-care hospitals is estimated to range from 1.3 to 8.9 per 1,000 bed-days,¹ which translates into well over 1000 falls per year in a large facility. Higher rates are reported in particular sites or wards, such as those specializing in neurology, geriatrics, and rehabilitation. Because falls are believed to be underreported, most estimates are assumed to be overly conservative.¹ However defining what is a “fall” is itself a challenge, as there is variability in the research literature and among older adults about what constitutes a fall.^{2,3} Authoritative bodies have definitions (e.g., the NQF defines a fall as “an unplanned descent to the floor without injury”⁴ and WHO defines a fall as “an event which results in a person coming to rest inadvertently on the ground or floor or some lower level”⁵) but even after accepting a conceptual definition of a fall, there is a difference between any fall, a fall with injury, the proportion of a population who has a fall, and the number of falls. Nevertheless, there is widespread agreement that falls, however defined, occur frequently and can have serious physical and psychological consequences. Between 30 percent and 50 percent of in-facility falls are associated with reports of injuries. Hip fractures occur in 1 percent to 2 percent of falls. Inpatient falls are also associated with increased health care utilization, including increased length of stay and higher rates of discharge from hospitals into institutional or long-term care facilities. In one recent analysis in three hospitals in Missouri, operational costs for patients who have fallen with serious injuries were \$13,000 higher than for control patients without falls, and patients who have fallen had an additional 6.3 days’ length of stay.⁶ Even falls that do not cause severe injuries can trigger a fear of falling, anxiety, distress, depression, and reduced physical activity. Family members, caregivers, and health care professionals are also susceptible to overly protective or emotional reactions to falls, which can also impact the patient’s independence and rehabilitation.

What is the Patient Safety Practice?

Most in-facility fall prevention programs are multicomponent interventions. Unfortunately, the individual components vary across each published evaluation, with the same combination of components never being evaluated in more than one application. Therefore, in terms of identifying and reviewing the evidence for fall prevention interventions, the best that can be done is to describe the components most commonly included in interventions that have been evaluated. The Prevention of Falls Network Europe (ProFaNE) proposed a detailed classification of fall risk assessment components (see Appendix C for the complete list),⁷ which map closely to the descriptions provided in this chapter. According to a review by Oliver and colleagues, the following were the most common components of successful interventions:

- Post fall review: to assess potential reasons for a specific instance of a fall and to remediate possible contributing factors
- Patient education
- Staff education
- Footwear advice
- Scheduled and supervised toileting
- Medication review: to assess for use of medication(s) that can affect mental alertness and balance (see ProFANE taxonomy for further details, Appendix C).

The most recent Cochrane review notes a “striking variability in type, targeting, intensity, and duration” within the fall prevention programs and does not attempt to draw conclusions about which components might be most effective.⁸ Table 1 lists all the studies in the reviews by Cochrane and by Oliver, as well as new studies from our update search, and the components included in the intervention.

All multicomponent interventions also included an assessment of falls risk. In about 60 percent of studies this was a formal falls risk assessment tool such as the Morse Fall Scale or STRATIFY, and the remainder used informal or idiosyncratic or unstated methods for assessing patients at increased risk of falls.

Other single intervention components include use or removal of bedrails, use of physical restraints, movement alarm devices, low-low beds (beds closer to the floor), exercise or additional physical therapy, increased observation or assistance, calcium or vitamin D, hip protectors, and prevention of delirium (this last topic is covered in Chapter 20). Since most reviews conclude that multi-component interventions are more effective than single components, in this chapter we will consider only multi-component interventions. Multicomponent interventions are also referred to in the literature as multifaceted or multifactorial interventions. Although some authors draw distinctions between these labels, we will not do so here, and refer to all of them as multicomponent.

Table 1, Chapter 19. Components of multi-factorial falls prevention trials in hospitals, 1999 to 2009^a

References	Environment Modified	Alert Wristband	Bedside Risk Sign	Hip Protectors	Staff Education	Patient Education	Bedrail Review	Vest/Belt/Cuff Restraint	Footwear	Toileting Schedules	Exercise	Movement Alarms	Medication Review	Urine Screening	Postfall Review	Other Interventions ^b
Ang et al, 2011 ^{9*}	√	√	√		√	√				√			√			Low beds; interventions specific to each risk factor in model used. Used Hendrich II Falls Risk Model
Barker et al, 2009 ¹⁰			√							√		√				Low beds; Introduction of a computerized falls reporting and analysis system ^c Used STRATIFY falls risk assessment tool
Barry et al, 2001 ¹¹	√			√	√								?		√	"Risk Factors assessed"
Brandis, 1999 ¹²	√	√	√	√												Falls history and continence assessment added to standard admission documentation / Unstated method of risk assessment
Cumming et al, 2008 ¹³					√	√	√				√	√				Modification of tool developed the Centre for Education and Research on Ageing in Sydney, Australia
Dykes et al, 2010 ^{14*}			√			√										Tailored plan of care; computerized Fall Prevention Tool Kit (FPTK) Used Morse Fall Scale
Fonda et al, 2006 ¹⁵	√	√						↓	√	√		√	?		√	Low beds, volunteer observers Used Falls Risk Assessment Scoring System
Grenier-Sennelier et al, 2002 ¹⁶						√		√	√			√			√	Improved assessment of mobility and self-efficacy Unspecified method for assessing risk
Haines et al, 2004 ¹⁷				22%		√					√					Used the Peter James Centre falls risk assessment tool
Healey et al, 2004 ¹⁸						√	√		√	√		√	√	√	√	Vision testing, lying and standing blood pressure Brief falls risk factor screen
Koh et al, 2009 ¹⁹		√	√		√											"Stand by me" notices to prompt staff to wait outside toilets ready to assist. Mobility level signs at bedside Unstated method of risk assessment
Krauss et al, 2008 ²⁰		√	√		√	√						√	(√)			Used Morse Falls Scale
Oliver et al, 2002 ²¹													?			Nursing and medical checklist for remediable risk factors, content not described and compliance poor Used STRATIFY falls risk assessment tool
Schwendimann et al, 2006 ²²			√	√		√	↓			√	√		√		√	"Briefly screened for falls risk" using 3 items
Stenvall et al, 2007 ²³					√									√	√	Additional therapy and nurse staffing Routine dietary protein supplementation Protocol driven delirium screening No clear risk assessment instrument, but population can be assumed to all be at elevated risk
Uden et al, 1999 ²⁴						√	↑		√			√				Career education A new formal risk assessment instrument created for the study
Van der Helm et al, 2006 ²⁵	(√)					↑	↑									Identification of high risk patients on the basis of a recent fall or 4 other criteria

Table 1, Chapter 19. Components of multi-factorial falls prevention trials in hospitals, 1999 to 2009^a (continued)

References	Environment Modified	Alert Wristband	Bedside Risk Sign	Hip Protectors	Staff Education	Patient Education	Bedrail Review	Vest/Belt/Cuff Restraint	Footwear	Toileting Schedules	Exercise	Movement Alarms	Medication Review	Urine Screening	Postfall Review	Other Interventions ^b
Vassallo et al, 2004 ²⁶		√				√	√		√				√			Medical Review/Used Downton fall risk assessment
Von Renteln-Kruse and Krause, 2007 ²⁷			√	0.5%	√	√			√	√						Bedside commodes Used STRATIFY falls risk assessment tool

Table adapted from Oliver¹

* New studies added from update search

“yes” = component included within the intervention; (yes) = component planned but not implemented; ? = component implied but not explicit; ↓ = intervention discouraged use of this component; ↑ = intervention encouraged use of this component.

^a (yes) indicates intervention in design but not applied in practice (e.g., environmental hazards identified but not addressed). ? indicates that the article implies, but does not specify, that an intervention was included. For bedrails and body restraints, ↓ indicates the intervention was to discourage their use, ↑ indicates the intervention aimed to encourage their use, while “yes” indicates either direction not described or a neutral risk versus benefit review was required.

^b Where interventions are described that would be considered very standard practice for control as well as intervention (e.g., call bell left in reach, walking aids provided as appropriate), these are not listed.

^c This potentially confounded the findings as this changed the method of collecting outcome data on falls at the same time as the intervention was introduced.

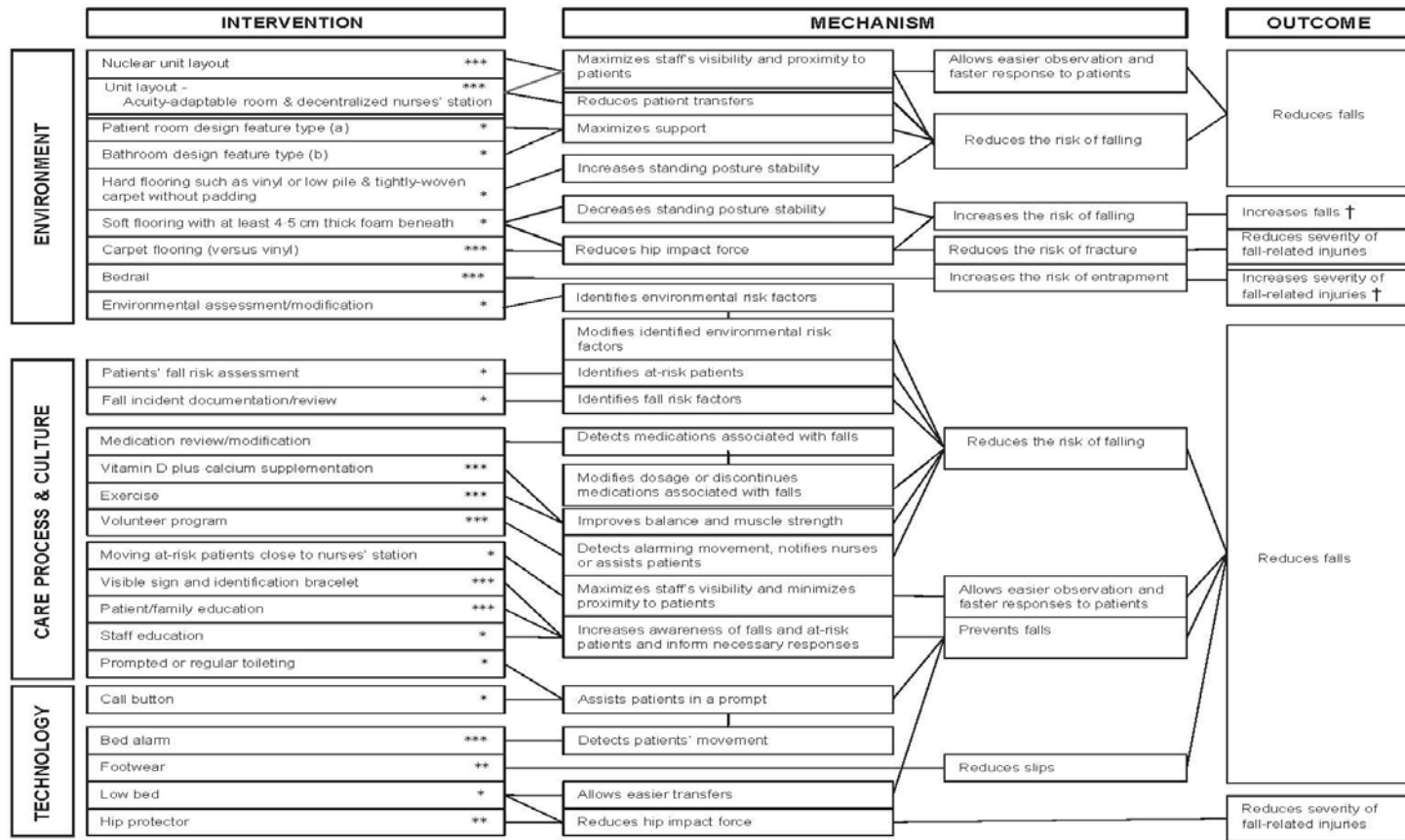
Reprinted from *Clin Geriatr Med.* 26(4), Oliver D, Healey F, Haines TP., Preventing falls and fall-related injuries in hospitals, 645-92, 2009 with permission from Elsevier

Why Should This Patient Safety Practice Work?

None of the controlled trials of fall prevention programs explicitly articulate the conceptual framework for their intervention. However, underlying each is the stated or implied understanding that falls have a multifactorial etiology and that attention to multiple risk factors will be more effective than an intervention that targets any single risk factor. A fall is usually the result of interactions between patient-specific risk factors and the physical environment. Patient-specific risk factors include patient age (particularly age over 85, sometimes called the “oldest old”), male sex, a history of a recent fall, muscle weakness, behavioral disturbance, urinary incontinence or frequency, certain medications, and postural hypotension or syncope. Environmental causes include poor lighting; ‘trip’ hazards (such as uneven flooring or small objects on floor); suboptimal chair heights; and staff availability, attitude, and skills. Given the multifactorial nature of falls, a patient safety practice designed to assess and remediate multiple factors is believed to be more likely to be effective. Indeed, the list of successful components in multi-component fall prevention interventions matches well with this list of patient and environmental contributors to falls. We identified one published logic model for why individual fall prevention components should work (Figure 1). For example, a bed alarm detects patient movements, which can allow a faster response to patients and reduce falls. Similarly, use of a visible sign or identification bracelet increases awareness of falls and at-risk patients and inform necessary responses, which in turn should reduce falls.

The second underlying assumption of most fall prevention programs in the published literature is that fall risk assessment is primarily a nursing function, but that insufficient attention is currently paid to this task due to other demands for nursing time, and that some method of reminder, checklist, or similar tool can be effective to ensure the assessment of fall risk.

Figure 1, Chapter 19. Multi-systemic fall prevention model



† Adverse outcomes

(a) Firm mattresses; low beds; appropriate chair heights and depths for easy transfer; chairs with arm rests; and secured handrails throughout the movement of a patient. (b) Non-slip surfaces in floors/bathtubs; shower seats; grab bars next to the toilet/bathtub; toilet seats that allow easy transfer; door magnets that hold doors in the open position; and arm rests next to the toilet.

*An intervention or a factor whose efficacy was NOT tested as a single factor in any healthcare setting. **An intervention or a factor whose efficacy was tested as a single factor in other healthcare settings but NOT specifically in a hospital setting. ***An intervention or factor whose efficacy was tested in a hospital setting.

Figure taken from Choi et al, 2011²⁸

Choi YS, Lawler E, Boenecke CA, et al. Developing a multi-systemic fall prevention model, incorporating the physical environment, the care process and technology: a systematic review. J Adv Nurs. 2011. Permission granted by John Wiley & Sons, Inc.

What Are the Beneficial Effects of the Patient Safety Practice?

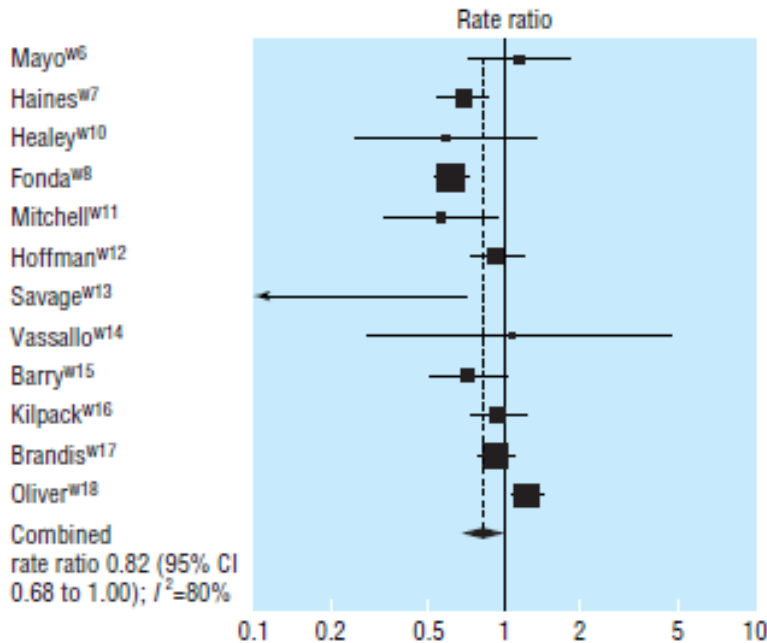
The primary sources of evidence about multi-component in-facility fall prevention programs are three systematic reviews: a 2008 review from the Cochrane Collaboration by Cameron and colleagues,⁸ a review by Coussement and colleagues also published in 2008,²⁹ and a review by Oliver and colleagues originally published in 2006,³⁰ which was updated in 2010 as a narrative review.¹ All three reviews scored well on the AMSTAR criteria for systematic reviews (11/11, 10/11, and 10/11 respectively).³¹ The Cochrane review searched a number of databases through November 2008 for randomized trials to assess the effectiveness of falls reduction interventions for older adults in nursing care facilities and hospitals.⁸ Of the 41 trials they included, 11 were conducted in hospital settings, of which four addressed multifactorial interventions. The review by Coussement identified four studies, three of which were included in the Cochrane review.²⁹ The Oliver and colleagues review also searched multiple databases for relevant literature through January 2005.³⁰ This review's objective was to evaluate the evidence for fall prevention strategies in care homes and hospitals, with an additional focus on the effect of dementia and cognitive impairment on fall risk. Broader inclusion standards than the Cochrane review led to the inclusion of 43 trials, case-control studies, and observational cohort studies. Thirteen of these studies addressed multicomponent inpatient interventions. The updated narrative review focused directly on inpatient fall prevention and discussed 17 multifactorial studies spanning 1999-2009, which include the four trials found by the Cochrane group.¹

The three reviews reached similar conclusions. The Oliver and Cochrane reviews found that multi-component in-facility fall prevention programs result in statistically and clinically significant reductions in rates of falls (see Table 2). The Cochrane pooled analysis of four fall prevention programs in 6,478 participants found a 31 percent decrease in the rate of falling (pooled rate ratio [RR] 0.69 (95% CI, 0.49 to 0.96) and a 27 percent decrease in the incidence of falls among three trials involving 4,824 participants (RR 0.73; 95% CI, 0.56 to 0.96).⁸ The Coussement review found a similar pooled rate ratio as the Oliver review; however, this effect was not quite statistically significant.²⁹ Principal results from the Oliver meta-analysis are reproduced below (see Figure 2).³⁰ The other systematic reviews and meta-analyses identified in the Oliver update review were “surprisingly consistent” (p. 679) and support the argument that multi-factorial interventions reduce fall rates more effectively than any single intervention in acute care settings.¹

Table 2, Chapter 19. Meta-analytic estimate of the effect of multicomponent fall intervention programs on inpatient fall rates

Meta-Analysis (First Author)	Number of Included Studies	Pooled Rate Ratio
Cameron, 2010 ⁸	4	0.69 (95% CI 0.49 – 0.96)
Coussement, 2008 ²⁹	4	0.82 (95% CI 0.65 - 1.03)
Oliver, 2007 ³⁰	12	0.82 (95% CI 0.68 – 1.00)

Figure 2, Chapter 19. Meta-analysis from Oliver et al. 2006 for multifaceted interventions in hospital falls (random effects model)³⁰



Reproduced from Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. Oliver D, Connelly JB, Victor CR, et al. 334(7584):82. 2007 with permission from BMJ Publishing Group Ltd.

The Cochrane and Oliver reviews were supplemented with an update search (described below) and an additional search by Hempel and colleagues (discussed in more detail later), which addressed the prevention of inpatient falls. After using 15 existing reviews and reports to identify pertinent sources, which included the two reviews in this chapter, Hempel then searched multiple databases for relevant literature. The search covered January 2005 to August 2011 and included randomized controlled trials, non-randomized trials, and before-after studies in English-language publications that addressed falls in the hospital setting. Details of the search strategy are in Appendix C.

In the update search, we focused on studies with large sample sizes (at least $N=1,000$), that assessed multi-component interventions in acute-care hospitals, in the general population or older adult population. We were looking for “pivotal studies,” as defined by Shojania and colleagues (see Methods, Chapter 2 p.ES-4) that could provide a signal when an existing systematic review is out of date.³² We identified two new relevant studies, both of which showed statistically significant improvements in intervention groups when compared with controls, and which we discuss briefly here. A third study is reviewed because of its unique design. Data for all studies included in the Oliver review, the Cochrane review, and our update search are in an evidence table in Appendix D. Table 3 provides an abbreviated description of each study.

Table 3, Chapter 19. Abridged evidence tables, adapted from Oliver and colleagues

Author, year	Study design	Setting	Participants	Quality Score**	Outcomes ⁺
Ang et al, 2011 ^{9*}	RCT	8 medical wards; acute care; Singapore	1822 patients.	25	SFF
Barker et al, 2009 ¹⁰	Before/After	Small; acute care; Australia	271,095 patients	16	SFI
Barry et al, 2001 ¹¹	Before/After	Small; long-stay and rehab; Ireland	All patients admitted to 95 beds for 3 years	15	SFI
Brandis, 1999 ¹²	Before/After	Acute, Australia	All patients admitted to 500 beds for 2 years	11	NFF
Cumming et al, 2008 ¹³	Cluster RCT	24 wards; acute and rehab; Australia	3999 patients	27	NFF
Dykes et al, 2010 ^{14*}	Cluster RCT	8 units; medical; urban U.S.	All patients admitted or transferred to units over 6 month study period	27	SFF
Fonda et al, 2006 ¹⁵	Before/After	4 wards; elderly acute and rehab; Australia	3961 patients	20	SFF
Grenier-Sennelier et al, 2002 ¹⁶	Before/After	400 bed; rehab; France	All admitted patients over 4 years	11	SFF
Haines et al, 2004 ¹⁷	RCT	3 wards; subacute rehab and elderly; Australia	626 patients	26	SFF
Healey et al, 2004 ¹⁸	Cluster RCT	8 wards; acute and rehab; 3 hospitals; UK	3386 patients	26	NFF
Koh et al, 2009 ¹⁹	Cluster RCT	2 hospitals; acute; Singapore	All admissions during 1.5 years	14	NFF
Krauss et al, 2008 ²⁰	Before/After	General medicine; acute academic hospital	All admissions over 18 months	18	NFF
Oliver et al, 2002 ²¹	Before/After	Elderly medical unit; acute hospital; UK	3200 patients admitted annually; data over 2 years	8	NGF
Schwendimann et al, 2006 ²²	Before/After	300 bed; internal medicine, geriatric and surgical; Switzerland	34,972 admissions	15	NFF
Stenvall et al, 2007 ²³	RCT	3 wards; orthogeriatric, geriatric, orthopedic; Sweden	199	25	SFF
Uden et al, 1999 ²⁴	Before/After	Geriatric dept; acute hospital; Sweden	379 patients	12	NGF
Van der Helm et al, 2006 ²⁵	Before/After	Internal med ward and neurology ward; acute hospital; Netherlands	2670 patients	11	NGF
Vassallo et al, 2004 ²⁶	Cohort Study	3 wards; rehab; UK	825 patients	25	NFF
Von Renteln-Kruse et al, 2007 ²⁷	Before/After	Elderly acute and rehab wards; Germany	7254 patients	17	SFF

*New studies added from update search

** Downs and Black Quality Score,³³ evaluated by the authors

⁺SFF= significantly fewer falls; SFI=significantly fewer injuries; NFF= nonsignificantly fewer falls; NGF= nonsignificantly greater falls

Reprinted from *Clin Geriatr Med.* 26(4), Oliver D, Healey F, Haines TP., Preventing falls and fall-related injuries in hospitals, 645-92, 2009 with permission from Elsevier.

Dykes and colleagues compared the fall rates of four intervention units to matched control units in four urban United States hospitals over a 6-month period.¹⁴ Control units received usual care, which included fall risk assessments, signage for high-risk patients, patient education as needed, and manual documentation in patient records. The intervention group tested the Fall Prevention Tool Kit (FPTK), which was developed by the study team. The FPTK is a health information technology application that includes a risk assessment and tailored signage, patient education, and plan of care components. The FPTK is integrated with, and seeks to enhance, existing workflow and communication patterns. Adjusted fall rates in the intervention units (3.15 per 1,000 patient days [95% CI, 2.54 to 3.90]) were significantly lower than in control units (4.18 per 1,000 patient days [95% CI, 3.45 to 5.06]), with a particularly strong impact among patients aged 65 or older (rate difference of 2.08 per 1,000 patient days [95% CI: 0.61 to 3.56]). This study was judged to have a low risk of bias using the criteria of the Effective Practice and Organizational Organisation of Care (EPOC) Cochrane Group (score of 8 of 9 components).³⁴

In the second study, Ang and colleagues⁹ randomized patients in eight medical wards of an acute-care hospital in Singapore over a 9-month interval. They used an assessment tool to match high-risk patients with appropriate interventions, in addition to a tailored educational session, in the intervention group. Both the intervention and control groups in this study received usual care, which included environmental modifications, review of medications and fall history, and educational sessions. The proportion of patients with at least one fall in the intervention group was 0.4 percent (95% CI, 0.2 to 1.1) while in the control group this was 1.5 percent (95% CI, 0.9 to 2.6) for a relative risk reduction of 0.29 (95% CI, 0.1 to 0.87). Using the EPOC criteria, this study was judged to be at low risk of bias (score of 8 of 9 components).³⁴

One additional study was identified and is noted here because of its unique design. The study by van Gaal and colleagues evaluated a program that targeted three patient safety practices (pressure ulcers, urinary tract infections, and falls prevention) simultaneously and found an overall positive effect on the development of any adverse event, a composite measure of pressure ulcers, urinary tract infections, and falls.^{35,36} The study was not powered to assess falls separately, yet it is worth noting that the point estimate for the relative risk reduction in falls was 0.69, which is within the range of results reported in other studies and meta-analyses. The value of this study is the demonstration of simultaneous improvements in several intervention targets.

Thus, new large controlled trials continue to support the conclusion of existing meta-analyses that multifactorial falls prevention programs are effective in reducing inpatient fall rates.

What Are the Harms of the Patient Safety Practice?

Most trials of fall prevention programs have not reported any harms. The Cochrane review reported none.⁸ It is not clear whether the possibility of harms was explicitly assessed in these trials. However, concern exists that some falls prevention interventions may lead to harms. The review by Oliver and colleagues detailed a number of potential harms, including an increased use of restraints or sedating medications. However, Oliver and colleagues also note “so little empiric evidence on adverse effects of fall prevention activities on other clinical activities has been incorporated into clinical trials that one has very little with which to substantiate or refute these concerns.”¹

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

The ways in which falls prevention programs have been implemented and a description of contexts are lacking in most reports. The limited evidence available is summarized below.

Structural Organizational Characteristics

Fall prevention programs have been implemented in both acute-care hospitals and nursing homes. For this report, we focused on inpatient interventions, with a mix of acute-care, rehabilitation, long-term care, and geriatric wards and facilities represented. All but two of the studies came from outside the United States: five from Australia, three from the United Kingdom, two each from Sweden and Singapore, and one each from France, Switzerland, the Netherlands, and Germany. Six studies mentioned having an academic affiliation or being a teaching hospital. Of the 15 studies that reported the size of the setting, three were under 100 beds, five were between 100 and 500 beds, and two were over 500 beds. Three other studies described size using alternative measures: 24 wards in 12 hospitals, a staff of 641, and 2300 inpatients annually. Thus, falls prevention programs have been successfully implemented in hospitals of varying size, location, and academic/teaching status.

No studies reported on financial concerns (e.g., how patients' care or the interventions were financed), although one U.S. study mentioned the potential impact of reimbursement on the emphasis on falls prevention.¹⁴ Since some countries where these studies have been conducted have national health insurance, this context may be less applicable, and therefore not reported.

Existing Infrastructure

Five studies reported on the existing quality and safety infrastructure. Here we describe this infrastructure in terms of factors that may affect implementation of a patient safety practice, which could include presence of electronic health records or prior experience with quality improvement or patient safety practices. The five studies included text that captured this concept; of these, four described their usual fall prevention care. The fifth study provided a more explicit statement, namely, "prior to this study none of the wards carried out specific fall assessments or interventions, and investigations such as lying and standing blood pressure or ophthalmology referral occurred on an 'ad hoc' basis. There was no specialist falls clinic or other falls service available at this hospital."¹⁸ Another explanation was less explicit, and was embedded in the authors' explanation of the intervention, which noted that the two control wards "continued with the regular fall prevention policy used at the hospital (i.e., daily assessment of fall risk, review of fall prevention with the patient and/or their family, use of fall prevention signage, and implementation of other prevention strategies as needed)."²⁰ Two other reports of randomized controlled trials discussed usual care in a similar fashion when contrasting it with the intervention.^{9,14} These descriptions illustrate the potential diversity that may exist in the "control" sites in terms of "usual care."

In addition to a description of the current fall prevention care, a second type of infrastructure description addressed an inadequate information system, reporting that "the existing information system was not useful for producing data that we could use to analyze the causes of falls."¹⁶ A further example of this type of explanation is presented by Dykes and colleagues, who suggest that "including hospitals with diverse clinical information and documentation systems enhanced the [intervention] generalizability."¹⁴ The remaining studies do not mention existing quality and safety infrastructure.

Consequently, a dearth of data exists regarding the infrastructure needed to support fall prevention programs or how the effectiveness of implementation may vary as a result of infrastructure differences.

External Factors

Although a few studies briefly mentioned patient safety culture, teamwork, or leadership, only four studies presented expanded explanations that merited mention. Grenier-Sennelier¹⁶ use a framework from Shortell and colleagues^{37,38} to analyze safety on the unit level, teamwork at both the organizational and unit level, and leadership on the organizational and unit level. Stenvall discusses teamwork at the unit level in Table 2 of their article (See Appendix D).²³ Koh discusses leadership on the organizational and unit level: “Successful implementation is mediated by strong leadership and environmental support, which are integral to building positive attitudes among nurses, ensuring that the sociocultural environment is conducive to the process of change. In our study, the multifaceted strategy targeting barriers to change exemplified the commitment of the leadership and environmental support.”¹⁹ (p. 429) Van der Helm made multiple observations addressing leadership on both the organizational and unit level:

- “Although the clinical ward management underlined the importance of implementing the guideline at the outset of the project, the actual support given was too weak to be effective. Some managers expressed doubt about the project’s chances for success to the project leader, stating that implementation “had already failed before.” Ward staff often regarded improvement activities as unwanted additional work that hindered daily operations. The two senior nurses often displayed a delegating rather than a directive management style, for example, in terms of ensuring that the risk assessment tool was completed or all incidents reported.” (p.157)
- “nurses told us that the medical center did not take the falls problem seriously, which therefore undermined their own motivation to contribute to the project’s success.” (p.158)
- A measure in the Questionnaire Regarding Knowledge of the Guideline and Attitude Toward Implementation, “There is enough support from the management for guideline implementation” scored 44% to 53%.²⁵

Implementation

The most commonly reported implementation details were patient characteristics (17 studies) and an initial plan, or what was going to be done in the intervention (17 studies). Slightly less often (14 studies), studies reported the intended roles of project staff, or by whom the intended plan components were to be completed. The majority of studies reported the recipients of any training component (15 studies), with slightly fewer reporting the type of training or giving a description of the training (12 studies), and even fewer studies reporting the length of training (5 studies).

Another characteristic that distinguished studies was who conducted the risk assessments and performed the interventions. In the reviews by Oliver and colleagues and the Cochrane group, among the 17 studies of inpatient fall prevention programs, the risk assessments were performed by the existing ward staff in 15 and by research staff in two. In 15 studies, the intervention was performed by the ward staff: seven involved the nursing staff only, seven were multiprofessional, and two involved physical therapy. In both of the new studies, clinicians or nurses from the wards performed the risk assessments. The study with nurse risk assessments had research team

nurses provide the intervention, whereas the other study relied mainly on ward nurses, although reference was made to clinicians more generally.

Thirteen studies provided the tools or materials used in the program implementation. Whereas eight reported on adherence or fidelity to the designed initiative, only five described how and why the plan evolved. Adherence or fidelity was most often characterized in a qualitative statement, as with Brandis: “The strategies implemented... had high acceptance by staff... it is suggested that the higher reductions occurred in areas where the multidisciplinary team enthusiastically embraced the project.”¹² An example from a less positive characterization comes from Cumming: “The lack of effect was evident in both... wards and occurred despite the planned nursing and physiotherapy interventions being successfully implemented.”¹³ Dykes and colleagues provided a strong example of adherence reporting, where protocol adherence was measured by the completion of components in both control (81%) and intervention wards (94%). Measures of adoption and reach were usually provided in the form of a flow chart: Six studies presented these data for providers, and eight presented the data for patients.

For additional information on implementation, we used our update search and sought suggestions of additional studies from experts. All of these studies had pre-post designs or were a time series. Six were post-study evaluations of falls implementations that reported a great deal of detail about the potential reasons for effectiveness or lack thereof. Nine of the eleven studies assessed implementation at only one or two facilities. Four of the studies did not report beneficial effects of the fall prevention program and the article highlighted potential implementation factors that might account for the lack of success. One study explicitly assessed the effect of some contextual factors on intervention success across 34 facilities.³⁹ One study explicitly assessed sustainability. Details of these studies are presented in Appendix D.

We used five of the implementation articles to develop themes regarding effective implementation and then reviewed all articles for these themes. The following are the most consistently supported themes:

- **Leadership support** is critical, both at the facility level and at the unit level (e.g. “clinical champions”).
- **Engagement of front line clinical staff** in the design of the intervention helps ensure that it will mesh with existing clinical procedures.
- **Multidisciplinary committees** guided or oversaw most interventions developed/guided/overseen by
- **Pilot testing** the intervention helps identify potential problems with implementation
- **Informational technology systems** capable of providing data about falls can facilitate evaluations of the causes, compliance with the intervention components, and (in one case) be a crucial facilitator of the intervention.
- **Changing the prevailing attitude** that “falls are inevitable” and “nothing can be done about them” is required to get buy-in to the goals of the intervention
- **Education and training** of clinical staff is necessary to help ensure compliance does not diminish.

Table 4, below, presents textual support from the implementation articles for five of the seven themes (pilot testing and information technology systems are not presented due to space limitations).

Table 4, Chapter 19. Implementation themes highlighted in implementation studies

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
Browne et al., 2004 ⁴⁰	--	--	Falls Committee; quarterly meetings	Once the tool was developed, it was piloted and validated. The results were presented to the MHS Falls Committee, who gave permission for automated implementation system-wide.	"the redesign of an adult inpatient falls program using a computerized information system...the tool provides an accurate assessment of the fall risk of each patient. Indicators are embedded into routine assessment documentation, eliminating added charging time. The program allows tailored interventions for specific patient risks."	--	"Nurses were taught about the redesigned falls program by 'fall and restraint fairs' that coincided with its implementation.	Successful

Table 4, Chapter 19. Implementation themes highlighted in implementation studies (continued)

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
Capan et al., 2007 ⁴¹	A unit champion was selected to “act as a staff resource... who was respected as a mentor and passionate about patient safety”	Staff involved in choosing equipment	“the hospital quality council chartered a multidisciplinary falls prevention task force. The team included nurses, nursing management, a physician/geriatrician, nursing educators, a psychiatric clinical specialist, risk management staff, performance improvement/measure staff, and representatives from physical therapy and pharmacy.”	A pilot test of the new tool was conducted in “a medical/neurology unit with a high fall incidence rate.” The original plan to roll the tool out one unit at a time was modified to “an immediate hospital-wide implementation” after the success of the pilot program.	--	“Nurses were reluctant to impose the interventions... [but] they came to recognize the importance of each step” “As the staff began using the interventions... falls began to decline”	The research team “educated the staff about falls and the importance of fall prevention,” including background information on falls and how the new tool was to be used. “95% of staff completed the education prior to the implementation of the tool.”	Successful
Dempsey, 2004 ⁴²	--	Raised concern over nurses’ power to induce change	--	A tool was developed and “tested for inter-rater reliability in a pilot study when five nurses of different experience levels assessed the same patient.” “On the basis of the results of the research project, the Falls Prevention Programme became standard practice for medical patients...”	--	“In the pilot study...a number of nurses expressed the belief that falls were inevitable and that there was nothing that could be done to change this. Although the study demonstrated that it was possible to reduce the rate of patient falls, the remarks of the nurses support the suggestion...that the successful reduction of patient falls lay in the attitude of the nurses themselves. “	“The Falls Prevention programme consisted of an assessment tool, an alert graphic, and education (patient and staff)” “ Staff education commenced at the introduction of the study and continued intermittently though formal and informal means.”	Mixed results, initial success followed by deterioration over five years.

Table 4, Chapter 19. Implementation themes highlighted in implementation studies (continued)

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
Gutierrez, 2008 ⁴³	Identify clinical champions; leadership on unit agreed to send a nurse to the Evidence-Based Practice Institute	“project design included soliciting staff and physician feedback”	--	--	--	--	Yes, one key component was a brief “elevator speech” for engaging and educating staff	Successful
Kolin et al., 2010 ⁴⁴	Leadership formed a team to address falls issue, team was led by a senior vice president, information was presented to leadership throughout project	--	“The fall team meets regularly, with in-depth analysis... at regular intervals...”	Multiple tools were tested before the redesign team developed their own, which was also tested.	Currently, the team is are “working on an interface to connect the system electronic medical record with the event reporting system.” The system had a combination of paper documentation and electronic record sites, which had separate program roll out.	“Implementation means changing the way nurses think about falls... accepting that ‘all’ patients are at risk.”	“Comprehensive nursing education was conducted”	Successful

Table 4, Chapter 19. Implementation themes highlighted in implementation studies (continued)

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
McCollam, 1995 ⁴⁵	Nursing Administration involved in full implementation	--	"Research in Practice Committee" oversaw the project	Problems identified during the pilot included inconsistent and incomplete reassessment, identification of secondary diagnoses, and score consistencies between shifts. Adjustments were made for full implementation.	--	Compliance for care plans and interventions lagged behind risk assessment, which could be due to skepticism about the program. "Some nurses may question the instrument's findings or not believe the problem serious enough to address."	Training sessions were conducted for nursing; video tape was shown about tool; understanding checked using evaluation	Successful
Neily, 2005 ³⁹	"Senior leadership support helps remove organizational barriers to change and provides resources needed to implement change" "The four sites that reported spreading changes to other facilities also indicated that leadership was a major success factor."	--	"...teamwork skills are an important component of sustained success" Interdisciplinary or multidisciplinary falls team was a core component of all four high performing sites.	--	--	--	--	Successful

Table 4, Chapter 19. Implementation themes highlighted in implementation studies (continued)

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
O'Connell, 2001 ⁴⁶	--	--	Team of researchers and clinicians	No pilot test was conducted.	--	Risk assessment tool difficulties may have undermined staff confidence and the program "may have lost some of its significance." Staff felt that they were already doing everything they could, and this program did not add anything	--	Unsuccessful
Rauch et al., 2009 ⁴⁷	Leadership hired a consulting team. All levels of leadership were engaged and accepted ownership of the project. A champion was identified in each unit.	"It is imperative to obtain frontline staff input and feedback to ensure that successful change management occurs in the clinical arena" "If there are any words of advice here, they would be: never change a program without directly involving and getting buy-in from those it immediately affects."	"The Fall Team, multidisciplinary in nature and inclusive of managers and frontline staff [were involved in all phases of the project]" Weekly teleconferences during implementation; monthly fall team meetings after implementation	During the 30 day pilot, "staff were routinely questioned and encouraged to provide feedback on elements working well and elements that were failing... Changes were made as needed...the pilot was extended...to ensure a solid process before total hospital roll-out."	--	--	"...educational needs were identified and sessions were scheduled... [including] an introduction of the assessment tool and proper utilization"	Successful

Table 4, Chapter 19. Implementation themes highlighted in implementation studies (continued)

Author/Year	Leadership Support	Frontline Engagement	Multidisciplinary Committees	Pilot Testing	Information Technology Systems	Attitude Change	Education and Training	Results of Intervention and Implementation
Semin-Goossens, 2003 ⁴⁸	Attempt to involve medical chiefs and nurse managers could have promoted implementation "In our case, efforts to reach and involve the people higher in the hierarchy such as the Medical Chiefs and nursing managers were not successful."	"We did not believe in a top-down strategy and so we involved the nurses in rewriting and implementing the guideline." Authors would have tried to get more buy-in from floor nurses if given another try, but they did receive feedback and modify the intervention accordingly.	A project team was formed consisting of 9 nurses in various positions, a clinical epidemiologist, and a consultant for quality improvement projects.	After a 3 month pilot, the guidelines were finalized.	--	"Nurses...frequently stated that it was simply impossible to prevent patients from falling. Falling was recurrently considered to be an inevitable part of aging, hospitalization, and illness, and therefore seen as an unavoidable accident, rather than something predictable and often preventable."	Dissemination of the guideline, including large posters.	Unsuccessful
Weinberg et al., 2011 ⁴⁹	Hospital leadership initiated effort and prioritized fall prevention	--	Committee was formed by leadership and attendance was mandated; monthly fall reviews were attended by unit managers, staff involved in patient care, and fall prevention initiative co-chairs	The Fall Prevention Initiative was rolled out incrementally, using continuous quality improvement methods	--	Transforming the culture was integral to implementation; emphasis placed on building a "just culture" and having a "constructive, nonpunitive forum" for discussion	Yes	Successful

Are There Any Data About Costs?

The Cochrane review found no economic evaluations of the falls prevention programs that met inclusion criteria.⁸ The review by Oliver and colleagues estimated the cost for specific combinations of components in terms of environment and equipment and in terms of staff. Fourteen of 17 trials were considered “low” cost in terms of equipment and environment (meaning some equipment costs like slippers, hip protectors, or alarms for a limited proportion of patients), and 14 of 17 were considered as “nil,” meaning none or inconsequential, for extra staff FTE.

Are There Any Data About the Effect of Context on Effectiveness?

The study by Neily and colleagues was the only one identified that explicitly assessed the effect of context on effectiveness. Across 34 Veterans Affairs health centers, a mix of acute care and long-term care facilities, leadership support was cited as one of the strongest factors for success. At 1-year followup, high-performing sites reported greater agreement with questions assessing leadership support, teamwork skills, and useful information systems than low-performing sites.³⁹

Conclusions and Comment

Inpatient multicomponent programs have been shown to be effective at reducing falls. The strength of evidence is high.

The effects of context have not been as well studied; however multicomponent interventions have been effective in hospitals that vary in size, location, and teaching status.

An assessment for themes in eleven implementation studies found the following to be most consistently supported:

- Leadership support is critical, both at the facility level and at the unit level (e.g. “clinical champions”).
- Engagement of front line clinical staff in the design of the intervention helps ensure that it will mesh with existing clinical procedures.
- Most interventions were developed/guided/overseen by multidisciplinary committees
- A pilot test of the intervention helps identify potential problems with implementation
- An informational technology system capable of providing data about falls can facilitate evaluations of the causes and compliance with the intervention components, and (in one case) can be a crucial facilitator of the intervention.
- Changing the prevailing attitude that “falls are inevitable” and “nothing can be done about them” is required to get buy-in to the goals of the intervention
- Adequate time for education and training of clinical staff is necessary to help ensure compliance does not diminish.

By January 2013, AHRQ intends to make available a list of tool kits for inpatient fall prevention programs. A summary table is located below (Table 5).

Table 5, Chapter 19. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence For Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	High	Moderate (increased use of restraints and/or sedation)	Moderate	Moderate/Moderate

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Chapter 20. Preventing In-Facility Delirium

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How Important Is the Problem?

Delirium (also known as acute confusional state) refers to an acute decline in attention and cognition that constitutes a serious problem for older hospitalized patients and long-term care residents. Estimated hospital occurrence rates have ranged from 14% to 56% and vary depending upon reason for hospitalization (e.g., urgent surgery, intensive care, general medical admission) and the patient's risk of developing delirium.¹ Development of delirium is associated with an increased risk of mortality, postoperative complications, longer hospital and intensive care unit stays, and functional decline.^{1,2} In addition, delirium presents a significant burden in terms of short and long-term health care costs. A study of 841 patients (age ≥ 70 years) admitted to non-intensive care general medical units over a three year period at Yale-New Haven hospital found that costs per day were more than 2.5 times higher for patients with delirium compared with those without delirium. The total cost estimates associated with delirium ranged from \$16,303 to \$64,421 per patient, which the authors extrapolated to national costs ranging from \$38 billion to \$152 billion each year.¹ As these cost estimates were based on data from 1995-1998, the costs of delirium today would be even higher. Accordingly, prevention of delirium is extremely important both for improving patient outcomes and for lowering health care costs.

What Is the Patient Safety Practice?

Several delirium prevention programs are multifactorial bundles of interventions. In general, the components in the bundle vary across each published evaluation, and the same bundle is rarely evaluated in more than one application (see Appendix D, Table 2). Therefore, the best that can be done is to describe the components most commonly included in bundles that have been found to reduce incident delirium. Based on our review (described later), we identified the following as the most common components of successful bundles:

- Anesthetic protocols
- Assessment of bowel/bladder functions
- Early mobilization
- Extra nutrition
- Geriatric consultation
- Hydration
- Medication review
- Pain management
- Prevention and treatment of medical complications
- Sleep enhancement
- Staff education
- Supplemental oxygen
- Therapeutic cognitive activities/orientation
- Vision and hearing protocols

Additional components have been reported in successful multifactorial bundles. An intervention used in a Swedish university hospital for patients with hip fracture included increased physiological monitoring, avoidance of delays in transfer through different areas of the hospital, daily delirium screening, and avoidance of polypharmacy (as well as several components from the bolded list, including extra nutrition, IV fluid supplementation, pain management, and perioperative/anesthetic period protocols).³ A multifactorial intervention used at another Swedish university hospital for patients with hip fracture included treatment of sleep apnea, prevention and treatment of decubitus ulcers, and measurement of blood pressure along with components from the bolded list, although it is not clear that all of these components were specifically designed to prevent delirium.⁴

The Hospital Elder Life Program (HELP) or a modified version of HELP was the most frequently-evaluated multifactorial intervention, appearing in three studies.⁵⁻⁷ This program typically consists of six components, including orientation, therapeutic activities, vision and hearing protocols, sleep enhancement, and early mobilization. Two studies (one U.S., one Australian) used proactive geriatric consultation with targeted recommendations (several from the bolded list) based on a structured protocol.^{8,9}

Components that have been used as single interventions include: medical therapy (anesthetics or other drugs believed to lower the risk of delirium), hydration, and music therapy (see Table 3). The overwhelming majority of single interventions consisted of some type of medication; this included Dexmedetomidine for post-operative anesthesia (two studies), Rivastigmine (two studies), Propofol (two studies), Olanzapine (one study), Ketamine (one study), Melatonin (one study), Risperidone (one study), Haloperidol (one study), Donepezil (one study), and Diazepam plus Flunitrazepam plus Pethidine drip infusion (one study).

Why Should This Patient Safety Practice Work?

Evidence from risk-factor studies suggests that delirium has a multifactorial etiology. Our literature review identified 55 studies of factors associated with delirium occurrence that met inclusion criteria (see Appendix D, Table 1 for individual study data). Collectively, these studies found significant associations between several factors and occurrence of delirium. However, no two studies evaluated the exact same set of factors or found the same combination of significant factors associated with delirium. The risk of bias was moderate in 31 studies and high in 24 studies.

Age was the most commonly evaluated factor, assessed in 34 studies. Twenty studies (58.8%) found a significant association between older age and delirium occurrence, including the two largest studies that evaluated data from more than a million patients recorded in large databases (most of the other studies included between 40-500 patients). These large studies had a high risk of bias due to retrospective design, identification of delirium from ICD-9 codes, and inclusion of prevalent as well as incident cases of delirium in the same analysis, but smaller studies with a moderate risk of bias supported the findings. Since many studies exclusively enrolled older patients (age >65 or >70 years), it may have been more difficult to demonstrate an association in some of these studies (due to restriction of range), which may partially explain the inconsistent findings in the evidence base. Another potential explanation is that some studies may have lacked adequate power to find statistical significance, although this was clearly not the case in all studies that did not have a significant finding. Cognitive impairment or dementia was evaluated in 26 studies; 22 studies (84.6%) found a significant association between this factor

and incidence of delirium. Depression was evaluated in 10 studies, but only four (40%) found a significant association with delirium occurrence.

Other patient-specific risk factors that showed a significant association with delirium in more than one study include male gender, multiple medications, comorbidities (e.g., diabetes), pneumonia, various anesthetics, neuropsychiatric drugs (e.g., benzodiazepines), anticholinergics, blood transfusions, abnormal serum chemistry (e.g., urea levels, creatinine levels), apolipoprotein E4 (APOE4), atrial fibrillation, heavy alcohol intake, volume depletion (dehydration), oxygen levels, complications, restraints (rendering patients immobile) and visual impairment. Several studies evaluated patients undergoing specific surgical procedures (e.g., hip repair or replacement, cardiac surgery); some of these studies focused on surgery-specific risk factors (e.g., blood transfusions, intraoperative anesthesia) and evaluated few non-surgical factors.

Given the multifactorial nature of delirium, a patient safety practice designed to assess and remediate multiple factors is believed to be more likely to be effective. Indeed, the list of components in successful delirium prevention bundles targets several factors identified in this list of patient and environmental contributors to delirium. For example, the Hospital Elder Life Program (HELP) specifically targets six risk factors for delirium: cognitive impairment, visual impairment, hearing impairment, sleep deprivation, immobility, and dehydration.⁷ Of this list, only hearing impairment was not identified as a risk factor by the studies in our evidence base, but this may be because only one of those studies even evaluated it as a possible risk factor.

What Are the Beneficial Effects of the Patient Safety Practice?

To assess the effects of delirium prevention interventions, we performed a systematic review of six databases (including Medline and CINAHL) from 1999 to 2011 from which we got 587 titles of which 85 were reviewed in detail. From this we identified 31 studies that met inclusion criteria for addressing this question. Fifteen studies evaluated the efficacy of multicomponent interventions (see Appendix D, Table 2), and the remaining 16 studies evaluated single interventions (see Appendix D, Table 3). Most of these studies reported the incidence of delirium following intervention compared with a control arm of usual care treated concurrently or during a period immediately prior to adoption of the new intervention. Some studies of medical therapy used an alternative medical therapy as the comparative arm. Since very few studies used the same intervention, comparison group, study design and/or patient population, meta-analyses were not performed for the majority of interventions.

Multicomponent Interventions

Hospital Inpatient Care

Of the multicomponent intervention studies, two used HELP and a third used a modification of HELP. One was a controlled before-and-after study with a concurrent control group consisting of patients from usual care units^{7,10}; this study had a moderate risk of bias. The remaining two studies were before-and-after studies where the usual care group consisted of patients treated prior to implementation of HELP (historical control)^{5,6}; these studies had a high risk of bias. All three of these studies found a significant reduction in incident delirium after implementation of HELP compared with usual care. Although the findings of the studies were consistent, the average risk of bias was high mainly due to lack of randomization and blinding.

Two studies used proactive geriatric consultation with targeted recommendations based on a structured protocol for patients with hip fracture. One was a single-blind RCT with usual care control,⁸ while the other was a before-after study with a historical usual care control.⁹ Both studies reported a significant reduction of incident delirium for the geriatric consult group compared with the usual care group; however, the RCT findings were no longer statistically significant after adjustment for baseline imbalances. The risk of bias was high and moderate for the respective studies.

Of the remaining multicomponent studies, all but one reported a significant reduction in delirium by at least one measure in the intervention group versus the control group. The exception was a study of a system-wide quality improvement project.¹¹ A study of nurse-facilitated family participation reported significantly fewer patients with a diagnosis of delirium (defined by a score ≥ 4 on the Intensive Care Delirium Screening Checklist [ICDSC]) in the intervention group, but also reported no significant between-group difference in mean scores; this study placed more emphasis on the latter measure.¹² Overall, the findings are consistent with the findings from studies of the HELP intervention, although the risk of bias was high again due to lack of randomization and blinding.

Long-Term Care

The single study set in a nursing home setting reported that homes randomized to use pharmacist-led geriatric risk assessment medguide (GRAM) reports and automated medication monitoring plans had a significant reduction in potential delirium onset among newly-admitted residents compared with homes randomized to usual care.¹³ However, it is unclear how much of this is due to delirium prevention or resolution of new-onset delirium.

The majority of the evidence suggests that multicomponent interventions are effective in preventing onset of delirium in at-risk patients. However, these studies do not address the question of which particular components within a program provide the most benefit.

Single Interventions

The majority of the single-intervention studies also found a significant reduction in delirium incidence for the study interventions, but roughly one-third (five studies) did not find a significant reduction. Unlike the multicomponent evidence base, almost all of the single-intervention studies were RCTs. However, few studies used the same medication or comparison treatment in the same patient population, making it difficult to determine consistency of findings for most of these interventions.

Hospital Inpatient Care

Sedatives/anesthetics. The sedative Dexmedetomidine was compared with other post-operative anesthetics in two studies of patients who underwent cardiac surgery. One found a significant reduction in post-operative delirium for the Dexmedetomidine group compared with patients receiving Propofol or Midazolam.¹⁴ This study had a high risk of bias. The other study did not find a significant reduction in post-operative delirium for Dexmedetomidine compared with Morphine, although the study was underpowered to detect a small difference between groups.¹⁵ This study did find a significant reduction in duration of delirium for those receiving Dexmedetomidine; the risk of bias was moderate. Because these two studies used different comparison groups, the consistency of the findings cannot be determined.

A study of light versus deep Propofol sedation during spinal anesthesia for hip repair found that patients receiving light Propofol sedation (measured by the bispectral index [BIS]) had a significantly lower rate of postoperative delirium.¹⁶ The risk of bias was moderate. It is unclear how this compares to the amount of Propofol used in the study comparing Dexmedetomidine and Propofol, which reported the amount in $\mu\text{g}/\text{kg}/\text{minute}$.¹⁴

Patients undergoing cardiac surgery had significantly lower rates of postoperative delirium after receiving Ketamine (an NMDA receptor antagonist) during anesthetic induction compared with placebo.¹⁷ The risk of bias was moderate, and the findings should be confirmed by other studies.

Patients undergoing joint surgery had significantly lower incidence of delirium after receiving fascia iliac block prophylaxis via Bupivacaine (a local anesthetic) compared with placebo.¹⁸ The risk of bias was moderate, and the findings should be confirmed by other studies.

Acetylcholinesterase inhibitors. One study of patients undergoing cardiac surgery did not find a significant between-group difference for those receiving Rivastigmine compared with those receiving placebo.¹⁹ This study was judged to have a low risk of bias. Patients undergoing joint surgery who received a different acetylcholinesterase inhibitor (Donepezil) did not show a significant reduction in postoperative delirium compared with those receiving placebo.²⁰ This study had a moderate risk of bias. Pooling of these two studies' findings resulted in a relative risk of 1.11 (95% CI 0.69 to 1.79); the confidence interval was too imprecise to rule out the competing possibilities that acetylcholinesterase inhibitors are ineffective or might confer a benefit.

Atypical antipsychotics. Patients undergoing cardiac surgery had significantly lower rates of postoperative delirium after receiving Risperidone compared with placebo in one RCT with a moderate risk of bias.²¹ Patients undergoing joint surgery who received Olanzapine had a significant reduction in postoperative delirium compared with placebo in another RCT with low risk of bias.²² Both studies showed a substantial reduction with almost identical risk ratios; the combined summary relative risk is 0.35 (95% CI 0.25 to 0.50, $P < 0.0001$). The findings are therefore consistent and precise for this drug class.

Typical antipsychotics. Patients undergoing joint surgery who received Haloperidol did not show a significant reduction in postoperative delirium compared with those receiving placebo.²³ The risk of bias was moderate and the findings were imprecise, therefore requiring confirmation from additional studies.

Melatonin. Patients undergoing joint surgery had significantly lower incidence of delirium after receiving Melatonin compared with placebo.^{18,22,24} The risk of bias was moderate, and the findings should be confirmed by other studies.

Benzodiazepines. One RCT found that postoperative delirium was significantly lower in gastrointestinal surgery patients who received the benzodiazepines Diazepam + flunitrazepam as a drip infusion in addition to a pethidine drip infusion for the first 3 days compared with those who did not receive these infusions.²⁵ The risk of bias was high.

Music therapy. In two RCTs conducted by the same authors at the same hospital, patients undergoing hip or knee surgery had significantly lower rates of acute confusion after receiving music therapy compared with those receiving usual care.^{26,27} Both studies had a high risk of bias, in part because they employed an unvalidated delirium assessment method, and should be repeated at other hospitals for confirmation of the results.

Long-Term Care

Hydration therapy. A quasi-randomized study comparing 8 weeks of hydration therapy to usual care for delirium prevention among residents of four nursing homes (hydration or control was randomized by nursing home) did not find a significant difference between intervention or control homes in episodes of acute confusion.²⁸ The risk of bias was high.

Acetylcholinesterase inhibitors. A study using Rivastigmine daily for two years in patients with vascular dementia found that the Rivastigmine group had significantly fewer episodes of delirium than those taking cardioaspirin (the control group).²⁹ This was the only study in the entire evidence base that exclusively enrolled patients with dementia, and it was judged to have a high risk of bias. Although these were ambulatory outpatients, they were judged to be similar to patient populations in long-term care settings.

What Are the Harms of the Patient Safety Practice?

Most trials of delirium prevention programs have not reported any harms. However, it is not clear whether or not the possibility of harms was explicitly assessed in all of these trials. One study of a multicomponent intervention based on a structured quality improvement model reported four unexpected minor events (rectal or feeding tube removal) but no significant complications (and no significant difference compared with usual care).³⁰ Two other multicomponent studies reported no significant differences in complications between intervention and usual care groups.^{3,13} Seven out of 16 studies on single interventions reported information on adverse events; all seven studies evaluated a variety of medical therapies (medications or anesthesia). Three of these studies reported no significant between-group difference in adverse event rates.^{16,19,21} One study of Dexmedetomidine versus Morphine for patients after cardiac surgery found that bradycardia occurred significantly more often in the Dexmedetomidine group, while systolic hypotension occurred significantly more often in the Morphine group.¹⁵ Another study reported that patients who received Olanzapine had significantly more severe and longer-lasting delirium than patients who received placebo, although incidence of delirium was significantly lower in the Olanzapine group.²² One study of melatonin reported that 2/61 patients had side effects of nightmares or hallucinations, while no patients who received placebo had side effects.²⁴ The remaining study reported no complications associated with fascia iliac block prophylaxis other than local hematomas at the injection site, which resolved spontaneously.¹⁸

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Literature searches identified 15 studies of multicomponent delirium prevention programs that met inclusion criteria (see Table 2). The limited information on how these programs have been implemented and in what contexts is summarized below.

Structural Organizational Characteristics

Multicomponent delirium prevention programs have been successfully implemented in both acute care hospitals (14 studies) and in nursing homes (1 study). Five of the acute care hospital studies were conducted in the United States, three in the United Kingdom, three in Sweden, and one each in Australia, Spain, and Taiwan. Ten studies were from academically-affiliated urban hospitals, two studies were conducted in urban hospitals that were not described as teaching hospitals, and the remaining two studies were set in community hospitals (in one study the participating community hospitals were part of a larger Health System). No studies have been reported from rural hospitals. The single study of nursing homes was conducted in the U.S..

Existing infrastructure. Only one study reported minimal information on patient safety culture at the organizational level; the authors stated merely that “SHS [Summa Health System] maintains a strong commitment to patient safety and quality.”¹¹

External factors. External factors or motivators were not mentioned in any delirium study.

Implementation. All multicomponent intervention studies provided at least minimal information concerning teamwork and/or leadership at the level of the unit where the intervention was implemented. Eleven of 15 studies specifically identified the study leaders, while 14/15 studies identified the team members by job status (e.g., nurses, geriatricians) or at least stated that all staff in the intervention ward or unit were part of the team. All of these studies reported multidisciplinary teamwork that included clinical experts, nurses, and other staff (e.g., physical therapists, volunteers). One study reported minimal information on teamwork or leadership at the hospital level.¹¹

Seven studies described multi-professional implementation, one had the intervention performed by the ward staff, one involved ward staff plus physical therapists (at home visits), one involved ward staff plus ambulance workers, one involved unit staff plus volunteers, one involved the nursing staff only, one involved nursing staff plus consultant pharmacists, one involved nurses assisting family members with the intervention, and one involved elder life specialists plus volunteers.

Twelve studies reported on staff education/training if this was part of the intervention, and seven studies reported the individual(s) responsible for implementation. Most of these studies reported that all staff involved in the implementation underwent some type of education or training. Ten studies reported the type of training, and only four studies reported the length of training.

Four studies reported a change in the implementation process due to local tailoring or an iterative process. Only one study (Rubin et al. 2011) reported that internal incentives were used to promote implementation.⁵ Allen et al. (2011) published the only study that provided a table summarizing an actual implementation instrument (a scorecard used to track process and outcome variables).¹¹

Fourteen studies outlined the intended intervention and the general sequence in which the components were implemented; only 11 studies included enough detail to determine the roles of the various team members. However, this was generally a description of how the intervention was supposed to be implemented; most studies did not describe any modifications or failures of adherence that might have occurred during the actual implementation. Only one study actually measured adherence to targeted recommendations, reporting an adherence rate of 77% regarding implementation of a geriatric consultant's recommendations for patients after hip fracture repair.⁸ Twelve studies reported patient characteristics.

Although implementation of multicomponent delirium prevention programs has not been well-described in most studies, a few themes seem sufficiently constant to report here:

- Engagement of front line clinical staff in the design of the intervention helps ensure that it will mesh with existing clinical procedures.
- A multidisciplinary team comprising clinical experts, nurses and additional staff is helpful for implementation of a complex intervention
- Education and training of clinical staff is necessary to help ensure compliance does not fall.

Are There Any Data About Costs?

Two studies in the evidence base reported information on costs or cost savings associated with multicomponent delirium prevention programs. Rizzo et al. calculated the total intervention costs of HELP over a three year period (1995-1998) at Yale-New Haven hospital as \$257,385 (personnel plus equipment costs). In a cost-effectiveness analysis, they found that the intervention was cost-effective for patients at intermediate risk of delirium but not for patients at high risk of delirium (lack of effectiveness and higher overall costs). However, these findings may be due to inadequate power based on their sample size of higher risk patients.³¹ Rubin et al. calculated that implementation of HELP at their hospital led to estimated cost savings of over \$2 million per year from prevention of delirium cases. In addition, there was over \$2.2 million per year of estimated revenue generated by shorter hospital stays for patients without delirium.⁵

What Is Known About the Effect of Context on Outcomes?

Only two studies reported on the effect of context on outcomes. One study of an educational package for medical and nursing staff reported that it was effective at preventing delirium in hospitalized men but not in women.^{32,33} A study of proactive geriatric consultation with target recommendations based on a structured protocol for patients with hip fracture reported a "trend" toward more effectiveness among patients without pre-fracture dementia or activities of daily living (ADL) impairment, but the differences were not statistically significant.⁸

One study assessed the somewhat related concept of patient adherence and its effect on outcomes of a multifactorial intervention (HELP). Based on a composite adherence score for the three components assigned to all patients (orientation, mobility, and therapeutic activities), increased adherence scores were associated with a reduction in delirium incidence rates (OR 0.69, 95% CI 0.56 to 0.87).⁷

Conclusions and Comment

Evidence from multiple studies suggests that a variety of factors may contribute to a hospital patient's risk for developing delirium; cognitive deficit was most consistently shown to be a risk

factor in these studies. All but two studies were judged to have high risk of bias, and these exceptions were judged to have a moderate risk of bias. The majority of the evidence suggests that most multicomponent interventions are effective in preventing onset of delirium in at-risk patients in a hospital setting (Strength of Evidence: Moderate). In general, successful delirium prevention programs involved a multidisciplinary team of clinical experts, nurses, and other staff (e.g., physical therapists, volunteers) and included protocols for early mobilization of patients, volume repletion (for hydration and electrolyte balance), and addressing visual or hearing deficits; a few programs included elimination of unnecessary medications.

Other components reported in more than one study included staff education, geriatric consultation, therapeutic cognitive activities/orientation, extra nutrition, sleep enhancement, pain management, anesthetic protocols, supplemental oxygen, assessment of bowel/bladder functions, and prevention and treatment of medical complications. However, these studies do not address the question of which particular components within a program provide the most benefit.

There was not enough evidence to evaluate the benefit of delirium prevention programs in long-term care settings.

Although implementation of multicomponent delirium prevention programs has not been well-described in most studies, a few themes seem sufficiently constant to report here:

- Engagement of front line clinical staff in the design of the intervention helps ensure that it will mesh with existing clinical procedures.
- A multidisciplinary team comprising clinical experts, nurses and additional staff is helpful for implementation of a complex intervention
- Education and training of clinical staff is necessary to help ensure compliance does not fall.

Although several of the single-intervention studies also found a significant reduction in delirium incidence for the study interventions, few studies used the same medication or comparison treatment in the same patient population; this makes it difficult to determine consistency of findings for most of these interventions. For atypical antipsychotics, two RCTs with a low to moderate risk of bias evaluating different drugs within this class showed consistent and precise findings of reduction in postoperative delirium among surgical patients (Strength of Evidence: Moderate). Although two RCTs reported a significant reduction in acute confusion for patients receiving music therapy, these studies were conducted at the same institution by the same authors and used an unvalidated delirium assessment method. Therefore, the evidence is insufficient for a conclusion regarding music therapy. Two RCTs had inconclusive findings (even when pooled) regarding the efficacy of acetylcholinesterase inhibitors, rendering the strength of evidence insufficient.

Most of the remaining treatments (or treatment comparisons) were represented by only one study with a moderate or high risk of bias; we judged the evidence about these treatments to be insufficient.

Future comparative effectiveness studies with standardized protocols are needed, particularly to identify which components in multicomponent interventions are most effective for delirium prevention. Identification of the most effective bundle of components might encourage hospitals to adopt a more standardized approach to delirium prevention. Additional RCTs are also needed to determine which single-component medical therapies or drug classes are truly beneficial for patients at risk of delirium. A summary table is located below (Table 1).

Table 1, Chapter 20. Summary table

Scope of the Problem targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Moderate	Low	Moderate	Moderate/Moderate

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Section E. General Clinical Topics

Chapter 21. Preventing In-Facility Pressure Ulcers

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How Important Is the Problem?

Pressure ulcers (PUs) are preventable, but PU rates continue to escalate alarmingly fast. In fact, between 1995 and 2008, the incidence of PUs increased by as much as 80%.¹ Estimates of incidence are high for both acute and long-term care patients. Current estimates indicate that 2.5 million patients will develop a PU, and 60,000 U.S. patients will die from complications related to hospital-acquired PUs.² A 2009 National Center for Health Statistics (NCHS) Data Brief reported about 11% of nursing home residents had PUs (in 2004), stage 2 being the most common.³

Preventing PUs is important not only to protect patients from harm, but also to reduce costs of care. Estimates suggest that PU treatment costs could be as high as \$11 billion annually.⁴ Patients with PU-related morbidity need more care and resources and have longer inpatient stays. In some cases, late-stage PUs lead to life-threatening infections. Because of the ever-increasing number of obese, diabetic, and elderly patients, PU rates are predicted to continue to rise. To gather available information about the effectiveness of PU prevention programs, we searched CINAHL, the Cochrane Library, EMBASE, MEDLINE, and PreMEDLINE from 1981 to 2011, in addition to searching gray literature. We identified 454 abstracts from which 87 full-text articles were reviewed in more detail, yielding 47 articles contributing data to this review.

What Is the Patient Safety Practice?

Sources for patient safety practices to prevent pressure ulcers included evidence- and consensus-based guidelines, how-to guides from national organizations, and comprehensive frameworks from well-recognized wound organizations.

A national campaign by Advancing Excellence in America's Nursing Homes provides an implementation guide that includes "efficient, consistent, evidence-based approaches to address the prevention and minimization of pressure ulcers."⁵ The coalition recommends that nursing homes seeking to identify areas for improvement in processes and practices should verify whether the homes' current policies and protocols are consistent with current evidence-based approaches, (i.e., new National Pressure Ulcer Advisory Panel [NPUAP] guidelines). In 2008, the Joint Commission included healthcare-associated PU prevention as a National Patient Safety Goal (NPSG) for long-term care. "Elements of performance" for this NPSG include using a validated risk assessment tool, reassessing PU risk at intervals defined within the organization, and educating staff on how to identify risk for and prevent PUs.⁶ The Institute for Healthcare Improvement describes six key evidence-based care components in its How-to Guide: Prevent Pressure Ulcers. Essential elements include making risk and skin assessments (upon admission and daily), managing moisture, optimizing nutrition and hydration, and minimizing pressure.⁷

A search of the National Guideline Clearinghouse™ identified recommendations to prevent and manage PUs by many well-respected organizations including the Wound, Ostomy and Continence Nurses Society (WOCN).⁸ Preventive interventions based on Level B evidence

include scheduling regular repositioning and turning for bed- and chair-bound individuals and using pressure redistribution surfaces in the operating room for high-risk individuals.

We identified two frameworks for Patient Safety Practices that appear to thoroughly embody components used in PU prevention initiatives today (see Table 1 and Table 2 following). A recent systematic review⁹ describes the Indiana State Department of Health's classification of PU initiative components, as follows:

- Organization components include team makeup, policies and procedures, ongoing quality evaluation processes, educating staff, utilizing "skin champions," and the development and system-wide communication of the written care plan
- PU prevention components include risk and skin assessment, moisture management, nutrition and hydration optimization and pressure management
- Care coordination components include the establishment of regular meetings to facilitate communication, collegiality, and learning

The ABCDE of Pressure Ulcer Incidence Reduction Initiatives was outlined at the 12th NPUAP Biennial Conference held on February 2011. The initiatives were described as: **administrative** support backed by support at the patient care level; **bundling** care practices and having an identifiable theme; **creating** a culture of change, commitment, and communication; **d**ocumentation of PU prevention practices must be visible; and **education** is essential.¹⁰

Table 1, Chapter 21. Components of pressure ulcer prevention trials in U.S. hospitals, 2000 to 2011

Study	Implement Protocol	Review Wound Care Products	Upgrade Automated Systems	Integrate New Reporting	Education/ Training	Risk Assessment Tool	Skin Champion	Multi-disciplinary Team	Audit and Feedback
Lynch and Vickery 2010 ¹¹	X	X		X	X			X	X
Young et al. 2010 ¹²	X	X	X	X	X	X	X	X	X
Bales et al. 2009 ^{b,d13}	X		X		X			X	X
Chicano and Droishagen 2009 ^{b14}	X	X		X	X	X		X	X
Walsh et al. 2009 ¹⁵	X	X			X	X		X	
Dibsie L. 2008 ¹⁶	X	X		X	X		X		X
McInerney J. 2008 ¹⁷	X	X	X	X	X	X		X	X
Ballard et al. 2007 ¹⁸	X	X	X	X	X		X		X
Catania et al. 2007 ¹⁹	X				X	X		X	X ^a
LeMaster K. 2007 ^{b,c20}	X		X	X	X	X			X
Courtney et al. 2006 ²¹	X	X		X	X	X	X		X
Gibbons et al. 2006 ^{d22}	X				X			X	X
Hiser et al. 2006 ²³	X				X	X			X
Lyder et al. 2004 ²⁴			X		X			X	X ^a
Stier et al. 2004 ²⁵	X	X			X	X		X	X

Shading = reported a significant reduction in pressure ulcer rates

^a Audit only.

^b Reduced prevalence/incidence to zero.

^c Describes role of CNS as a direct consultant.

^d Describes use of incentives.

Table 2, Chapter 21. Components of pressure ulcer prevention trials in long term care, 2000 to 2011

Study	Implement Protocol	Upgrade Automated Systems	Integrate New Reporting	Education/ Training	New Assessment Tool	Use of Outside Consultants *	Skin Champion	Multi-disciplinary Team	Audit and Feedback
Horn et al. 2010 ^{b26}	X	X	X	X	X	X	X	X	X
Rantz et al. 2010 ^{b27}	X	X				X			
Milne et al. 2009 ^{d28}	X	X	X	X	X	X	X	X	X
Tippet A. 2009 ^{c,d29}	X		X	X	X	X	X	X	X
Rosen et al. 2006 ^{c30}	X			X		X		X	X
Abel et al. 2005 ³¹	X			X	X	X	X		
Ryden et al. 2000 ³²	X			X			X		
Rantz et al. 2001 ^{a33}	X		X	X		X			X

Shading = reported a significant reduction in pressure ulcer rates

*Examples include advanced practice nurses,²⁸ physician wound consultant,²⁹ and state quality improvement program staff.^{27,31} Services included identifying team leaders/multidisciplinary teams,²⁶ streamlining documentation,²⁶ educating staff,²⁹ providing evidence-based tools (i.e., assessment cards),³¹ team leadership and technical assistance²⁹

^a Randomized controlled trials.

^b Nonrandomized controlled trial.

^c Describes use of incentives.

^d Reviewed wound care products.

Why Should This Patient Safety Practice Work?

Age, immobility, incontinence, inadequate nutrition, sensory deficiency, multiple comorbidities, circulatory abnormalities, and dehydration are a handful of the more than 100 factors that have been identified as placing adults at risk for developing PUs.^{2,34} In addition to having many risk factors, PUs can develop very quickly. PUs have been documented as developing in just 1 hour.¹²

However, despite the many risk factors and the quick development of PUs, they can be successfully prevented with several strategies. Improvements in care processes (e.g., skin assessments) and patient outcomes (e.g., incidence, length of stay) have resulted from single-component PU prevention initiatives such as a turn-team nursing program,³⁵ an educational intervention,³⁶ and a tracking system.³⁷ A recent systematic review concluded that using support surfaces, repositioning the patient, optimizing nutritional status, and moisturizing sacral skin are appropriate strategies for preventing PUs.⁴

Use of intervention bundles has also been effective in eliminating PUs.³⁸ The concept of bundling care practices is credited to the Institute for Healthcare Improvement. Defined as a structured way of improving processes of care and patient outcomes, a bundle typically includes three to five evidence-based practices that “when performed collectively and reliably, have been proven to improve patient outcomes.”³⁹ Although successful in and of themselves, bundling care practices is only one of several important components listed in the ABCDE of Pressure Ulcer Incidence Reduction Initiatives.

During the NPUAP keynote address, former president Elizabeth Ayello mentions the importance of a partnership between administration and bedside caregivers. She describes the administration’s role in making PU prevention a priority by providing adequate resources and infrastructure and listening to staff about how to implement best practices.¹⁰ Jankowski and Nadzam (2011) concur on the importance of facilities’ administration in their quest to identify gaps, barriers, and solutions in implementing PU prevention programs.⁹ Additionally, NPUAP lists “creating a culture of change, commitment and communication” as paramount to reduction initiatives. “Training and communication among turn-team members, the enterostomal staff, and clinical nursing directors was critical for the success” of one initiative.³⁵

Both single and multicomponent programs described the importance of adding documentation and education into PU prevention initiatives. Challenges encountered during the implementation of a tracking system included manpower resources and documentation.³⁷ Jankowski and Nadzam (2011) reported that major barriers to protocol implementation were related to documentation. They indicated that although “every hospital had a written PU protocol and used the Braden Scale for Predicting Pressure Sore Risk, none of the hospitals routinely included the risk scores or PU prevention care plans in shift-to-shift reports, RNs-NA reports, RN-physician communications, or other handoffs between hospital staff (e.g., staff nurse to transporter).”⁹ A 2009 ECRI Institute risk analysis on PUs⁴⁰ recommends that “to establish mechanisms of effective communication between facilities, include the following for all transfer documentation: (1) standardized location of information; (2) current risk assessment; (3) skin and observed wound assessment; and (4) current interventions (if applicable).”

What Are the Beneficial Effects of the Patient Safety Practice?

We limited our research to studies implementing multicomponent initiatives in acute (k = 15) and long-term care settings (k = 8) in the U.S. from 2000 to the present (see evidence tables in

appendix). Study designs were mostly time series assessments of changes before, during, and after implementation of the intervention. Other study designs included randomized controlled (k=2)^{27,33} and controlled before-and-after (k=1).³² A majority of the studies focused on universal prevention (all risk levels); one focused on high-risk patients.²⁶ Pressure ulcers were the primary focus of 20 studies and part of a comprehensive approach in three.^{27,32,33}

The review group agreed not to assess risk of bias or rate the strength of evidence for those reviews primarily focused on implementation. Therefore, in this section, we briefly summarize the primary results; subsequently, we provide detailed assessments of the implementation efforts.

Acute Care

Evidence presented below on PU prevention programs implemented in the acute care setting is based primarily on one systematic review (Soban 2011) of nurse-focused quality improvement (QI) initiatives.⁴¹ Of the 39 studies included in the review, 12 met our inclusion criteria. Additionally, we discuss three other studies that were published since the Soban review was completed.

The Soban review⁴¹ had three objectives: describe the intervention strategies used, describe the process and outcome measures reported, and examine the interventions' effects on outcomes. Study findings were categorized as processes of care (e.g., staging of acquired stage 2 PUs) and/or patient outcomes (e.g., PU incidence). Eleven studies reported patient outcomes; only one study²⁴ reported both. Because the review included limited data, we accessed information directly from the studies.

First, we examine intervention effects on several processes of care reported in one multihospital QI collaboration overseen by the Connecticut Quality Improvement Organization, Qualidigm. In 2004, Lyder et al.²⁴ reported a 2-year follow-up on 14 measures, seven of which were process of care measures. Four plan-do-study-act (PDSA) improvement cycles implemented at 17 hospitals resulted in significant increases in identifying high-risk patients (20.3% vs. 35.3%, $p < 0.001$); repositioning of bed-bound patients every 2 hours or every hour in chair-bound patients (50.9 vs. 56.9, $p = 0.01$); use of nutritional consults in malnourished patients (34.3% vs. 48.6%, $p < 0.001$); and staging of acquired stage 2 or greater PUs (22.4% vs. 44.2%, $p < 0.01$). No statistically significant findings were reported for the remaining processes of care (including staging of acquired stage 1 PUs) or hospital-acquired incidence rate (baseline vs. follow-up; 20.6 vs. 20.8, $p = 0.90$).

Five of the 11 remaining studies reported in the Soban review conducted nurse-focused initiatives facility- or system-wide. A majority of studies reported on prevalence or incidence measures; both types of measures have been described as useful in assessing and improving patient care. Catania indicates that a declining *incidence* of PUs would indicate that a prevention program is working to decrease new PU cases, while a declining *prevalence* indicates that the treatment strategy was also having an impact on the duration of PUs.¹⁹ Several studies reported that initiatives reduced prevalence or incidence to zero.

After a 10-month implementation of the SKIN (Surfaces, Keep the Patient Turning, Incontinence Management, Nutrition) bundle, Gibbons et al.²² reported a 90% reduction (5.7% to 0.448%) in prevalence at the Nation's largest Catholic and nonprofit health system.²² Similar reductions were reported at a 548-bed, two-hospital system in Southwest Florida:¹⁷ a 5-year trend analysis indicated a significant reduction in PU prevalence (overall [-81%] and ulcers located on the heel [-90%]) after "proactive assessment and management of at-risk patients." One study reported zero PU prevalence and incidence after 1 year of a nurse-focused initiative at a 300-bed

community hospital.¹³ Other benefits listed were optimal patient care and avoiding the cost of treating stage 3 or 4 ulcers.

In 2006, Courtney (SOS program/Six Sigma methodology) reported that one 710-licensed bed, multisite, not-for-profit hospital reduced the PU incident rate from 9.4% to 1.8% over 3 years. Incidence was reduced by 6.3% after only 1 quarter.²¹ Two years earlier, Stier et al.²⁵ reported reducing incidence by more than 50% at a 5,600 bed nonprofit health care system.

Significant improvements were also reported from initiatives implemented in patient care units, with two studies reporting zero prevalence postimplementation. In 2006, a two-unit intensive care unit (ICU) significantly reduced PU prevalence (34% to 8%), noting that National Database of Nursing Quality Indicators (NDNQI) benchmark data were “instrumental in helping our unit focus on PU prevention, ultimately leading to improved patient outcomes.”¹⁸ Catania et al.¹⁹ reported reducing PU prevalence by more than 50% due to implementing the Pressure Ulcer Prevention Protocol Interventions in five in-patient units at one cancer hospital. From September 2004 (baseline) to June 2006 (postimplementation), the percentage of patients with all types of PUs and with hospital-acquired pressure ulcers (HAPUs) was reduced to 4% and 2%, respectively. NDNQI benchmarks at the time were 12.65% for all ulcers and 6.84% for HAPUs.

In a 2007 study, preimplementation PU prevalence rates for a pulmonary and oncology unit were 9% and 12%, respectively. LeMaster²⁰ reported that nurse-focused QI initiatives reduced prevalence in these two hospital units to zero. Rates were reduced from 9.2% to 6.6% in five units in one Florida hospital.²³ One medical ICU, which reportedly had the highest HAPU prevalence (average of 29.6%) among the participating units, reduced prevalence to zero.

Dibsie et al.¹⁶ reported a facility-wide reduction in percentage of patients with stage 2 or greater HAPUs (4.2% vs. 3.2%) in four adult critical care units (54 beds) at two U.S. hospitals. Rates for the surgical intensive care unit, however, did not improve over time (6.1% pre- and postimplementation). A 23-month initiative (Chicano 2007) at a 25-bed intermediate care unit reduced incidence.¹⁴

Benefits described in three separate studies (Walsh et al., Young et al., and Lynch and Vickery) included a reduction in prevalence and incidence and improvements in processes of care. In 2009, Walsh et al. reported a reduced PU prevalence from 12.8% to 0.6% from an 18-month initiative. Walsh also reported increased focused communication among patient caregivers; once improvements were noticed, clinician’s behavior and clinical processes improved.¹⁵ Young et al. reported several successes, including streamlining online policies (from 7 to 1) and reduction in time spent documenting skin care. Young also reported “clinically relevant reductions” in development of nosocomial PUs.¹²

In one year, PU rates were reduced by 82.8% (2.8% to 0.48%) at one rehabilitation hospital. Lynch and Vickery reported that streamlining documentation increased timely and accurate completion of documentation from 60% to 90% in 90 days. This facility also increased patient/family involvement in patients care by providing an educational brochure and reviewing interventions on admission.¹¹

Long-Term Care

A total of eight studies met our inclusion criteria in their evaluation of multicomponent programs to prevent PUs in long-term care facilities. Study duration ranged from 6 months to 6 years. Among these eight programs, four reported significant reduction in PU incidence or prevalence rates.

In 2010, Horn et al. reported on three main outcome measures.²⁶ First, they considered prevalence of PUs using Centers for Medicare & Medicaid Services (CMS) quality measures (QMs). Based on data from seven facilities, they report that the CMS high-risk PU QM decreased from 13.0% (baseline) to 8.7% (12 months postimplementation). A second outcome of interest was the number of in-house acquired PUs. The average number of in-house PUs (all stages) per facility was reduced by 62% (12.1 [baseline] to 4.6 [postimplementation]). Lastly, Horn et al. reported a 53.2% reduction in the average number of certified nursing assistant (CNA) documentation forms and a mid-90% completeness rate of CNA documentation.

Tippet et al. reported that nosocomial PU ulcers were eliminated after 6 months.²⁹ They also reported an 86% reduction in average incidence: 5.19% (preinitiative) vs. 0.73% (postinitiative); $p < 0.0001$. By the end of the fourth year, both incidence and prevalence were reduced by 99%.

In 2006, Rosen et al. reported a significant reduction in PU incidence.³⁰ The percentages of patients identified as “high-risk” were 22.3% and 28.0% at the baseline and intervention periods, respectively. Significant reductions in PU incidence were reported for stage 1 and beyond ($P < 0.001$) and stage 2 and beyond ($p < 0.05$). However, these improvements were not sustained during the postintervention periods when no weekly reports (indicating completion of training) were provided; no targets or goals were established; and no financial incentives were offered to staff.

One RCT was conducted in three privately owned facilities in the midwestern United States.³² This 6-month study evaluated the effectiveness of advanced practice nurses (APNs) to successfully implement scientifically based protocols for PUs and other clinical problems. The APNs delivered treatment in two facilities; in the third facility, patients received usual care. At 6 months, the percent of APN-treated patients with PUs was significantly reduced (19.8% vs. 3.5%; $p = 0.04$). The percentage of patients with PUs for the usual care group was also reduced, although not significantly.

Four studies conducted in long-term care facilities reported no significant findings from primary analysis. At 12 months, Rantz et al.²⁷ reported relative improvements in high-risk PU scores (negative indicating improvement) were -53%, -12%, -5%, and +435% for Group 1, 2, 3, 4, respectively. At 24 months, relative improvement was -3%, -8%, +59%, and +105% for these same groups, respectively.

Abel et al. describe results from a 2-year study conducted in 20 sites.³¹ They report a significant improvement for 8 of 12 PU-related quality indicators; however, only a trend toward a lower incidence of facility-acquired PUs ($\chi^2_{MH} = 3.66$, $p = 0.06$) was observed. Facilities also fell short in two other key measurements: proportion of high-risk residents with facility-acquired PUs whose care plan intervention reflects treatment orders and proportion of skilled nursing facilities that have a wound protocol.

Milne et al.²⁸ reported several successes. The facility-acquired PU prevalence rate at baseline was 41%. PUs were reduced to <3% on two units due to increased monitoring of modified nasal cannula (pulmonary unit) and increased attentiveness to heel offloading, support surfaces, and proper positioning (SCI/trauma unit). Of the 396 charts reviewed, fewer than 1% had missing data. A review of 45 patient charts showed that wound teams consistently determined staging and wound etiology in more than 90% of cases. The facility-acquired PU rate was reduced by 37% within 1 year postimplementation.

In 2001, Rantz et al.³³ randomly assigned 87 facilities to receive workshop plus feedback reports (Group 1); workshop, feedback reports, and clinical consult (Group 2); and control

(Group 3). Primary analysis indicated no statistically significant findings for prevalence of stage 1-4 PUs or prevalence of stage 1-4 PUs (low-risk residents).

What Are the Harms of the Patient Safety Practice?

There have been no reported harms of the PSP.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

We examined studies of multicomponent PU prevention programs for information on contexts. The description of contexts is limited: most reports contain information on certain contextual factors but lack information on other factors. The limited evidence available is summarized below.

Use of a Model or Theory

Of the 15 studies conducted in acute care facilities, only four programs described a model or theory as the basis of their implementation strategy. The PDSA framework was a methodology used in 17 hospitals in Connecticut.²⁴ The four PDSA improvement cycles involve identifying the problem and designing an intervention (Plan), implementing change (Do), evaluating the collected data (Study), and implementing what was learned (Act). Lyder et al. indicated that these processes should be developed rapidly to “sustain momentum in changing behaviors, procedures, and policies as quickly as possible.” Although described as being used on a “hospital-wide scale,” this framework may also be applied on a smaller scale such as a hospital unit.

Courtney et al. integrated Six Sigma methodologies into treatment processes developed for a multisite, not-for-profit facility. Described as a data-driven quality strategy for improving processes, DMAIC consists of five interconnected steps: (1) **defining** the problem, (2) **measuring** the performance; (3) **analyzing** the data, (4) **improving** the process, and (5) **controlling** change.⁴² Young¹² stressed the importance of empowering staff at point of care, which “suggests a model of shared governance where decisions are made at the point of service.” A shared governance model was also employed at an Illinois-based intermediate care unit.¹⁴ Use of quality council members or a self-managing work team has been described as a second-generation shared governance model. According to Nursingworld.com, a self-managing work team such as the quality council members are “jointly responsible for achieving goals, lead themselves, and thus have authority and control over the work and access to information.”⁴³

Of the eight long-term care studies, one study²⁷ referenced effectiveness of similar components in a previous study;³³ another described using the failure mode and effects analysis (FMEA) developed by the U.S. military.²⁸ FMEA is defined as a systematic process for identifying potential design process failures before they occur to eliminate them or minimize risk. The basis for one program was Havelock’s (1974) model of effective research utilization. This model is described as integrating knowledgeable resource individuals as links between relevant sources of scientific knowledge and the user (e.g., staff).³²

External Factors Motivating Attention to Pressure Ulcer Prevention

Most studies in acute care facilities reported feeling pressure from impending changes in CMS reimbursement. Specifically, subsequent to passage of the Deficit Reduction Act of 2005,

CMS will no longer allow higher DRG (diagnosis-related group) payments for patients with stage 3 and 4 HAPUs. Catania reported that one dedicated cancer hospital was responding to the identification of two stage-4 PUs and evidence from the NDNQI survey that the prevalence of PUs in the hospital exceeded the national benchmark by close to 50%.¹⁹ A 25-bed intermediate-care unit indicated that identification of high prevalence rates, nursing peer reviews, chart audits, and unit observations played an important role in the hospital's response.¹⁴ Lynch mentioned that the facility experienced an upward trend in PUs on two units.¹¹

One 528-bed nonprofit facility, at which prevalence of HAPUs was lower than national norms, set out to eliminate HAPUs completely.²² In 2006, Courtney et al.²¹ described the emergence of new guidelines from the American Nurses Association and the Agency for Healthcare Research and Quality as showing a "revitalized interest" in preventing and treating PUs. Additionally, studies using the Nursing Care Quality Initiative guidelines revealed high prevalence of PUs (13%) and lack of documentation and management. Two critical incidents (not specified), concerns within individual units, and inconsistent documentation were listed as external motivators by Dibsie et al.¹⁶ Additionally, "the frequency with which concerns and incidents were discussed, but went unreported within the internal reporting system" were of concern. Young reports stakeholder commitment to improve patient outcomes and a goal "to be recognized as a quality provider of patient services."¹²

External factors influencing the staff at one 151-bed Midwest skilled facility were a G-level citation (a deficiency judged to cause actual harm to residents) and State survey deficiencies.²⁹ This facility recorded PU prevalence and average incidence rates as high as 25% and 23.9%, respectively. One facility reported receiving multiple citations from the Department of Health.³⁰ Abel et al.³¹ indicated that the 20 participating facilities were identified from 143 Medicare-certified skilled nursing facilities with high rates of PUs despite a high volume of residents receiving preventive care.

Structural Organizational Characteristics

Organizational characteristics described in all studies included financial and academic status, location, and size. Bed range for acute care studies ranged from 18 to 800. Settings included a community hospital, a multisite academic medical center, and a cancer hospital. Implementation studies included as few as two units and as many as 17 hospitals.^{18,24}

Long-term care programs were conducted in not-for-profit facilities;^{26,30} a privately owned facility,³² a Midwest-skilled nursing facility,²⁹ and a mix of for-profit, not-for-profit, and governmental facilities.^{27,33} Other studies were conducted in Medicare-certified skilled nursing facilities³¹ and in a 108-bed long-term acute care facility.²⁸

Two studies published in 2010^{26,27} were conducted in seven and three states, respectively; 20 studies were conducted in one state. The number of facilities included in each study ranged from 1 to 87. Bed size ranged from 1 to 60 in one study³³ and from 44 to 432 in another.²⁶ Only the highest-risk units (three maximum) participated in one program.²⁶ Five studies indicated prior experience with QI or presence of electronic medical record (EMR).^{26-28,30,33} Two studies reported on organizational complexity.^{30,32} Of the 23 included studies, only two studies described patient characteristics.^{29,32}

Teamwork/Leadership

Although a majority of studies utilized a multidisciplinary team, skin champions were described as key team members. Studies set in acute care settings described use of certified

wound ostomy continence nurses (CWOCNs),^{13,18,23} staff registered nurses or patient care technicians,²¹ clinical nurse specialists (CNSs),¹⁹ and a collaboration between CNSs and wound ostomy nurses²⁰ in this role. Of eight studies set in long-term care settings, skin champions were designated in five studies;^{26,28,29,31,32} in two studies, advanced practice nurses served in this role.^{28,32}

Three studies included lengthy descriptions of leadership within their facilities. Stier et al. described leadership support to multidisciplinary teams at a 5,600-bed nonprofit New York-based health care system.²⁵ Teams consisting of clinical experts from 18 facilities convened to openly discuss the various risk assessment tools and facility protocols in place. Multidisciplinary teams agreed to develop a uniform policy, skin care formulary, and specialty bed contract. “System leadership (e.g., nurse executives, quality management directors, and senior physicians) provided support to the team at both the system and facility level” vis-a-vis “resources, ensured staff orientation and education, maintained quality control programs, and continually assessed actions to improve performance through system-wide care committee meetings.”

Dibsie¹⁶ described the importance of teamwork and leadership at a multisite academic medical center. Discussions on serious skin-related issues were held with unit nursing management, immediate senior nursing management, and selected peers. Discussions later involved a larger group of managers and clinical specialists after “it became evident that the issues crossed many areas and could be better handled by the group together.” When necessary, senior management stepped in to stress “the importance of resolving issues related to prevention...throughout the organization.”

Young et al. described a change in leadership at a 540-bed acute care facility in Indiana. “Clinicians were initially wary of management’s intent for clinician involvement. Their hesitation was attributed to past experiences when some clinicians joined the task force to attain required activities relating to clinical advancement or in response to a manager’s request.” As a result of mandates that the new skin team be clinician-led, “the majority of the original task force members left...The few remaining committee members were charged with selecting new task force members who could serve as unit champions.”¹²

Patient Safety Culture

Several studies provided a glimpse of the patient safety culture that existed before programs were implemented. Staff at a 528-bed nonprofit hospital believed “that PUs were unavoidable in complex, critically ill patients.” At this facility, chart reviews of 30 patients who developed PUs indicated that 87% of the time a nutritional consult had been ordered, but nutritional recommendations were only followed 35% of the time.²² McInerney¹⁷ reported a high prevalence of PUs at a two hospital system; greater than 50% of ulcers were located on the heel. Further review revealed that physician and nurse reluctance to use a rigid boot was the root of the problem.

Lyder et al. reported that most hospitals participating in a multihospital QI collaboration did not believe that PU prevention was a huge priority.²⁴ In 2010, Lynch¹¹ discussed several process issues at a 166-bed acute rehabilitation facility. A review of 2007 data indicated many misidentified PUs at admission, incomplete and inconclusive skin assessments, incorrect staging, and inconsistent documentation of interventions.

At the unit level, staff at one medical ICU also believed that PUs were inevitable among seriously ill patients.²³ Staff at a two-unit ICU did not believe the prevalence data, stating the higher acuity patients “were more likely to develop skin breakdown.”¹⁸ Accountability,

knowledge deficit, and communication deficits were identified as root causes of reported high incidence/prevalence at one teaching hospital. Incomplete initial and ongoing skin assessments, inconsistent implementation of prevention interventions, and lack of coordination among staff were cited as examples of preimplementation safety culture.²¹ Lastly, analysis of survey results at one 25-bed intermediate care unit revealed that admission documentation did not identify patients with an increased risk for developing PUs.¹⁴

In the long-term care setting, five studies reported minimal information on patient safety culture at the organizational level.^{26,28-31} One study included information at the unit level.²⁸ Abel³¹ reported that facilities were plagued by inadequate assessments and data omissions associated with risk. Milne indicated that one facility had above-average PU prevalence, used a faulty EMR that was inconsistently used by clinicians, and had deficient documentation of risk assessment.²⁸

Implementation Tools

Below, we describe examples of unique tools that were used for audit and feedback, education and training, monitoring progress, identifying specific groups of patients at risk, and streamlining products and processes in more than 20 PU prevention initiatives. For a complete listing of implementation tools, see evidence tables in the appendix.

Audit and Feedback

Audit and feedback were mentioned as key elements in initiatives implemented in long-term care studies. In one study, facilitators provided direct feedback to CNAs regarding data inconsistencies by unit and by shift to help track progress.²⁶ Real-time management feedback in Rosen et al.³⁰ consisted of a prominently displayed graphic thermometer tracking weekly PU incidence, and positive (\$10 reward) or negative reinforcement (termination). Weekly informal feedback by nursing supervisors,²⁹ formal weekly walk-rounds¹¹ and frequent patient positioning audits were also used during implementation.²⁹ See below for more detailed descriptions included in acute care studies:

- “Identification of skin breakdown must be reported within the electronic system, and weekly surveillance summaries need to be shared with administration.”¹⁴
- Feedback was provided during weekly SKIN operations meeting where unit leadership reported compliance with the SKIN bundles and related issues.²²
- “The team provided clinical staff with consistent and frequent feedback about the results of prevalence studies for their specific units so they could benchmark their results over time. This immediate and ongoing feedback helped engage staff members in their program and allowed them to take credit for the improved clinical outcomes. To reinforce the positive changes, medical ICU staff members were given a certificate for the Most Improved Unit.”²³
- While providing feedback to nursing staff, the CNSs “attempted to balance compliments for a job well done with recommendations for improvement.”²⁰

Education and Training

The majority off the 23 studies reported including some form of education or training. Training was reported as mandatory in four studies.^{12,13,29,30} Only one study reported on duration of training (40 minutes).³⁰ Unique tools used in education and training sessions are described as follows:

- Guest speakers discussed new concepts and educated physicians about the CWOCN's role, level of clinical expertise, and best-practice wound care interventions.²³
- During 30-minute mandatory continuing education sessions, participants sit on bedpans that act as a reminder that PUs can occur within as brief a time as 1 hour.¹² Compensation was provided to staff participating on their own time. Educational content was tailored for RNs, LPNs, secretaries, and CNAs. A post-test survey measured effectiveness of presentation.
- Staff education included critical thinking using case studies and role-playing exercises.¹⁹
- Staff participated in skin-care training using an interactive video.³⁰

Identifying Specific Groups of Patients at Risk

- McInerney et al.¹⁷ reported that using computerized charting and order entry helped identify specific groups of patients at risk for developing PUs. A consult with a specially trained nurse is automatically generated when patients are identified as high/very high risk. Consults are also generated for two other patient groups considered high risk (e.g., patients placed on a ventilator and patients receiving hemodialysis).

Monitoring Progress

- To monitor progress at a large 528-bed hospital, a SKIN Bundle Compliance Tool was developed. Nutrition-related items include noting completion of a nutrition consult, orders written, and orders carried out.²²
- One rehabilitation hospital posted report cards on every unit allowing staff to track progress against other units and unit goals.¹¹

Streamlining Products and Processes

- A large nonprofit health care system streamlined a skin product line, trimming it from 100 products to 24. Standardizing products controlled costs and reduced training.²⁵
- Four critical care units conducted extensive in-service education on a new wound care product line and made vendor support available. Vendor clinical experts were available to educate staff on new products. Dibsie recommends informing clinicians when modifications are made to the skin protocol or product line.¹⁶
- Nursing leadership, nursing staff and those from other disciplines (e.g., nutritionists, respiratory therapists) compared current policies and procedures to clinical practice guidelines. The Director of Informatics facilitated revisions¹² of seven existing policies into one.

Barriers

Reported barriers to implementing PU prevention programs included expansion of the initiative to a larger scale,¹⁶ unmotivated staff,^{13,14,19} staff turnover,^{26,31-33} staff resistance,^{24,31} limited resources,¹² inconsistent documentation,^{13,20,31} difficulties in exporting data,²⁶ and miscommunication between electronic systems.²⁰ One facility also faced increased PU rates.²⁸ Examples of barriers described and ultimate solutions are as follows:

Acute Care

- Dibsie¹⁶ reported that expanding initiatives from a 20-bed critical care unit to all nursing units in two sites provided an extra challenge. Obstacles included the coordination of a skin committee, difficulty in coordinating schedules, and keeping abreast of new equipment that can contribute to PU development.
- Chicano¹⁴ reported a challenge motivating staff who were relatively uninvolved in planning and implementing initiatives. Perseverance of council members encouraged the staff to finally “accept the concept of shared governance and acknowledge that it can positively influence patient care.”
- During the early stages of one initiative, staff members were not sufficiently committed. Although a QI analysis indicated that two stage 4 PUs were the result of “inconsistencies in or lack of documentation, staff awareness and assessment,” staff members denied that the PUs were due to poor nursing care. Catania indicated that “overcoming it took additional education, mentoring, and support at the unit level.”¹⁹
- As reported by Lyder et al.,²⁴ hospitals identified as a major barrier the view that PU prevention was a nursing issue. The medical staff was reportedly the most resistive when asked to play a role in PU prevention. Due to this mindset, considerable time was spent “re-educating various disciplines about their roles in PU prevention.”
- Young et al. reported that clinicians complained of time constraints, insufficient computer resources, and competing goals. To address these concerns, clinicians were allocated 4 paid hours to carry out responsibilities related to PU prevention, and web access to library resources was added to the organization’s intranet.¹²
- Bales et al.¹³ reported unmotivated staff and lack of proper reporting and documentation. Monthly to quarterly campaigns were launched to maintain staff motivation. Nursing units that had zero HAPUs were recognized and awarded during campaigns.
- LeMaster²⁰ reported Braden scores (a scale for predicting PU risk) were not documented at 100% according to policy. Patients were missed because of a communication failure between two different electronic documentation systems. To address this, the facility transitioned to a single, universal electronic record system.

Long-Term Care

- Horn et al. reported difficulties at one of 11 facilities in exporting data elements.²⁶ As a result, the facility could create only one of four possible clinical decision-making reports. Additional issues concerned the preparation of documents—specifically forms needing the resident’s study ID number and faxing forms for report generation. Staff turnover, especially for director of nursing, also seemed to slow program momentum. To overcome these barriers, suggestions included adding new CNA documentation processes into orientation programs, phasing in use of documentation, and developing a strong multidisciplinary team to lead improvement efforts. Ryden et al.³² reported barriers to their implementation program included high turnover (range of 11% to 45%) of unlicensed staff.
- Barriers faced by 20 facilities in Texas included incomplete admission assessments, staff reverting to previously unsuccessful practices, and inappropriate use of monitoring systems. Staff resistance, staff turnover, and variations in new staff orientation also affected program implementation. Monthly visits by a State Quality Improvement

Organization (TMF Health Quality Institute) and improving performance may have helped resolve these issues.³¹

- Barriers reported by Milne et al.²⁸ included a climb in PU rates once strict monitoring of processes was leveled off from weekly to monthly for 1 month. To overcome this barrier, the wound team increased presence on the units, monitored charts more closely, provided feedback to staff, and scheduled biweekly prevalence rounds.
- Rantz 2001³³ indicated that staff turnover, especially the nurse coordinator, cancellations of site visits at the last minute, and teams “mired in the MDS [minimum data set] assessment process and coding issues” impeded initiatives. To address some of these issues, multiple nurses were assigned responsibility for processes, accomplishments were posted, and a quality manager was placed on staff to support care delivery.

Sustainability

Several acute and long-term care facilities reported sustainability of PU prevention programs. Conducting quarterly prevalence studies and continually monitoring all HAPUs were key to sustaining improvements at a large nonprofit health system. A focus on skin pigmentation and the development of a skin fragility assessment tool were the most recent strategies introduced.²² McInerney¹⁷ indicated that publicizing improvements in PU rates will keep staff focused on prevention efforts.

One 710-bed multisite facility reported that the “overall culture change at the medical center remains a work in progress. Therefore, PU incidence continues to be a measurement used in organization-wide scorecards and staff bonus programs.” Measuring performance routinely has since become a priority facility-wide and at sister facilities.²¹ LeMaster²⁰ reported a request by staff members for items to provide both visual and auditory clues to sustain improvements at their facility. Dibsie et al.¹⁶ reported “staff members continued to meet on a monthly basis to discuss skin issues, participate in quarterly prevalence data collection, and learn from the medical center’s expert WOCNs as well as from one another.”

Walsh indicates the importance of maintaining gains, including keeping current regarding “initiatives for improved patient safety, changes in regulatory mandates, and changes in EBP [evidence-based practices].” At a 540-bed acute care facility, RNs and LPNs must demonstrate competency annually; monthly updates provided via intranet to staff include product changes.¹²

One rehabilitation hospital printed quarterly newsletters and attached them to paychecks. The newsletters described findings, results, and new initiatives in PU management.¹¹ According to Bales et al.,¹³ sustainability requires awareness of key management skills and priorities, such as strong leadership, involvement of staff in decision-making, and a desire to foster interdisciplinary relationships.

Eleven long-term care facilities across seven states stated that “managing the manual data collection, faxing forms to the project office and creating clinical reports for distribution back to the facilities on a weekly basis” could not be maintained over the long term. By date of study publication, more than 70 additional facilities were participating in the On-Time program.²⁶ A wound care coordinator position²⁹ and a wound care committee³² were established to help sustain program gains in two long-term care programs. Lastly, one 108-bed LTC facility noted that two wound coordinators provided additional education. Monthly review of documentation and the presence of multiple PU prevention interventions on units also helped to sustain improvements.²⁸

Lessons Learned

Several programs implemented facility-wide reported key lessons learned. Recommendations from one large nonprofit health system include the following: (1) use current leadership to support staff; (2) disregard a spike in reported skin breakdown, which is probably due to staff's increased awareness, education and reporting; (3) make staff accountable for success of initiatives; (4) do not assume that the knowledge base between disciplines is equal; (5) stay on task and celebrate successes.²²

Seventeen hospitals reportedly liked the idea that PDSA cycles could be completed using a small number of cases to identify improvement areas and implement potential interventions at a reduced scale before implementing programs at full scale, saving time and human resources.²⁴

Lessons learned in Courtney et al. include the following: (1) identify and involve the process owner (unit manager) and S.O.S. (Safe our Skin) unit champion early in the project; (2) develop a detailed training plan to include delegation and team work; (3) communicate the changes to everyone; (4) streamline the process to make it as easy as possible; (5) celebrate success, give recognition, spread the success; (6) define roles and responsibilities; (7) realize that you cannot fix everything at one time; (8) support and commitment from senior leadership are critical to the success and help to sustain the gains.²¹

Abel et al. reported lessons learned by 20 Medicare-certified skilled nursing homes while working collaboratively with TMF, a State quality improvement organization.³¹ A TMF representative provided the following recommendations:

- Strive to transition from quality assurance to QI, moving from defect detection to defect prevention, while making continuous improvement in the process of care delivery.
- Incorporate interventions designed to address barriers to preventive care while sustaining existing processes that have proven effective.
- Publicly recognize front line staff successes.
- Share data often.
- Implement change on one unit/hall at a time to ensure staff buy-in.
- Accept failure in the systems as an opportunity to improve.
- Operationalize systems that use continued measurement to monitor and improve performance that is reported to be below a designated threshold.
- Allow staff to maintain a level of autonomy during design of the intervention.
- Ensure accountability in following agreed-upon process changes.
- Ensure consistency in a formalized staff training/orientation related to documentation requirements.
- Include staff that directly affect the process in the intervention design.⁴⁴

Are There Any Data About Costs of Pressure Ulcer Prevention Programs?

Five studies included information on costs of PU prevention programs: two in acute care facilities and three in long-term care facilities. In 2008, McInerney¹⁷ indicated millions of dollars in cost savings due to the significant reductions (-81%) in PU prevalence at a two-hospital system in Naples, Florida. A conservative analysis (assuming savings of \$3,000 per case) found that this 548-bed system saved “approximately \$11.5 million annually as a result of the program.”

A Midwest 710-bed teaching hospital estimated additional cost per case (in 2001) was \$3,037, and the additional overall cost related to PU development was \$4,877,000. Based on these figures, “a reduction in the number of HAPUs by 50% to 5% would reduce overall costs by \$2,438,000.00.” This amount would not preclude the “anticipated significant improvements in patient satisfaction, length of stay/quality, staff awareness of skin integrity issues, and risk management issues.”²¹

The most recently reported costs in a long-term care setting were from 2010 in a four-group comparison study that assessed the value of a bedside electronic health record PU initiative.²⁷ “Total costs for the 3-year evaluation for the groups of facilities implementing technology increased \$15.11 (12.5%) for Group 1 and \$16.89 (9.6%) for Group 2, while those for the comparison groups did not.” Rantz et al. attributed cost increases to the cost of technology, including maintenance and support and ongoing staff training to use the EMR system.²⁷

In 2009, a 151-bed Midwest skilled facility described cost savings 4 years after program implementation. The authors estimated cost savings per PU/per month was \$1,617; monthly savings, \$10,187; and yearly savings greater than \$122,000.²⁹ Lastly, in 2006, Rosen et al. stated “based on a mean cost of \$2700 to treat a single stage II PU,⁴⁵ reducing the incidence of ulcers by approximately 15 over 12 weeks would yield savings of approximately \$40,000. Less than \$10,000 was distributed as financial incentives.”

What Is Known About the Effect of Context on Outcomes?

Several studies directly commented on the effect of context on outcomes, and all studies specifically mentioned the influence of staff on implementation. Dibsie¹⁶ reported that “the changes in the climate and practice related to skin care and prevention of breakdown are the direct result of nursing taking ownership of their practice with the support of nursing leaders at all levels.”

Lyder indicated that “focusing pressure ulcer prediction and prevention programs on the nursing staff is limited. Effective pressure ulcer prevention requires a multidisciplinary effort. The PDSA model assists hospitals in working in multidisciplinary teams and places the onus for improvement on the team rather than on a particular discipline.”²⁴ According to Lyder, hospitals found that the most sustainable interventions were those that were institutionalized. For example, two hospitals changed their hospital mattresses to pressure-relieving mattresses. However, interventions that are most dependent on sufficient staffing were more difficult to sustain (for example, ensuring that every resident is turned every 2 hours).²⁴

Bales et al.¹³ reported that the hospital’s managerial style encouraged staff involvement in decision-making about developing a program, and leadership gave strong support to the program and promoted it to both other leaders and hospital staff. Chicano¹⁴ reported that “commitment and diligence from the QI team and from the members of the staff’s self-governance councils played a significant factor in achieving our goal of reducing HAPU prevalence in our intermediate care unit.”

Contextual factors that Horn et al.²⁶ identified as key to their success were resident participation, use of a multidisciplinary team, and integration of all clinical reports. The facility with the highest reduction in PUs (-82.4%) had 100% involvement of residents. In addition, this facility incorporated all 4 weekly clinical reports into care planning. Two facilities with the lowest reduction in PUs did not involve a multidisciplinary team. This study included only the highest risk units at each facility.

Abel et al. reported that higher QI scoring and greater improvement in scores equaled lower PU incidence rates. He indicated that 10 facilities with the highest quality indicator scores at re-measurement showed a trend toward lower PU incidence rates than the 10 facilities with the lowest QI scores at re-measurement (-4.6% vs. -2.6%) ($S = 125.5$, $p = 0.07$). In addition, the 10 facilities with the greatest improvement in QI scores had significantly lower PU incidence rates than the 10 facilities with the least improvement in QI scores (-6% vs. -1.2%) ($S = 131.0$, $P = 0.03$). Later, Abel noted that study results demonstrated a relationship between PU incidence rates and improvement in QI scores, suggesting a relationship between the process of care measures and patient outcome (i.e., PU incidence). He adds that “improved performance was primarily noted in measures that were less dependent on staffing, i.e., use of support surfaces and risk assessment tools rather than patient turning.”

Milne et al.²⁸ reported on revisions of care in two units with greatly improved PUs. On a pulmonary focused unit, PUs were observed at the ear/scalp junction of 25% of patients. With the adaptation of the nasal cannula, PU rates on the ear/scalp junction were reduced within 2 months to less than 3%. On a separate unit, 33.8% of SCI and trauma patients were suffering from sacral and heel sores due to immobility and sensory deficit. Due to several focused initiatives, including pressure redistribution support surfaces, PU rates dropped to 2.9%, a 30.9% reduction.

Rantz 2001³³ observed that intensive consultation contributed to a greater improvement in MDS QI measures for several outcome measures, including two focused on PUs.

Conclusions and Comment

A review of the evidence indicates that a variety of multicomponent initiatives have been implemented in U.S. acute and long-term care settings to prevent PUs. Improvements (many significant) were reported both from comprehensive initiatives (targeting several patient safety concerns) and from those primarily focused on reducing PUs. Successful prevention initiatives were reported regardless of setting (system-, facility-, or unit-wide) or number of components integrated in the initiative. However, evidence indicated that the majority of successful initiatives integrated several core components. Key to improving these measures were the simplification and standardization of pressure-ulcer-specific interventions and documentation, involvement of multidisciplinary teams and leadership, designated skin champions, ongoing education, and sustained audit and feedback for promoting both accountability and recognizing successes.

Several studies commented on the influence of context on outcomes. Useful information was also included on topics such as barriers, solutions to barriers, and issues surrounding sustainability. Key lessons learned include keeping both leadership and staff accountable for the initiative's success, streamlining processes, learning from front-line staff, implementing change one unit at a time, providing feedback, and celebrating successes.

Of the 23 studies included in this review, eight studies (evenly split between acute and long-term care settings) reported on both processes of care and patient outcomes. A majority of these studies reported improvements in processes of care and corresponding improvements in patient outcomes. We did, however, identify two studies that reported significant improvement in several processes of care with little or no improvement in patient outcomes. Future research should focus on the specific preventive measures or processes of care undertaken to better understand their influence on patient outcomes. We also encourage clinicians to report findings regardless of success level and to report strategies to sustain momentum of preventive programs. A summary table is located below (Table 3).

Table 3, Chapter 21. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate	Negligible	Moderate	Moderate/Moderate

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Chapter 22. Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection (NEW)

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How Important Is the Problem?

Hyperglycemia is a common finding among medical and surgical inpatients with and without known diabetes.^{1,2} Moreover, several observational studies have found an association between inpatient hyperglycemia and poor outcomes in patients undergoing general and cardiac surgery,^{3,4} and in patients with a variety of conditions including myocardial infarction, stroke, and trauma.⁵⁻⁷ Hyperglycemia could contribute to these poor health outcomes by causing inflammation, oxidative stress, poor immune function, endothelial dysfunction, and tissue ischemia.⁸ Given the mechanistic and observed association between hyperglycemia and poor outcomes in hospitalized patients, significant interest has developed in using intensive insulin therapy (IIT) to control blood glucose in a variety of inpatient subpopulations. However, over-aggressive use of insulin can result in dangerously *low* levels of blood glucose, which also can be harmful to patients. This chapter reports the results of a systematic review conducted in 2010-2011 on the use of IIT to control blood glucose among inpatients as well as the findings of studies released subsequent to the searches we conducted for that review.

What Is the Patient Safety Practice?

The evidence evaluating the balance of benefits and harms from the use of IIT to control blood glucose in hospitalized patients is detailed in the following sections. Overall, trials have not consistently found that use of IIT to lower blood glucose to normal levels (i.e., 80-110 mg/dL) improves health outcomes, whereas aggressive IIT approaches are clearly associated with high rates of hypoglycemia. Nevertheless, many organizations continue to recommend moderate blood glucose control (e.g., 140–200 mg/dL) because of the association of high blood glucose with infection, poor wound healing, dehydration, and other complications. Given the uncertainty about the benefits of IIT, the remaining concerns that untreated hyperglycemia is harmful, and the hypoglycemia risks associated with IIT, the patient safety practice of interest is the implementation of inpatient glycemic control strategies that minimize the risk of hypoglycemia.

What Are the Beneficial Effects of the Patient Safety Practice?

Initially encouraging trial data in critically ill patients spurred some organizations to recommend tight glycemic control strategies be implemented in hospitals across a variety of settings.^{8,9} In one of the key trials fueling these recommendations, 1,548 patients in a single surgical intensive care unit (SICU) were randomized to either an intensive insulin regimen, with a goal glucose range of 80-110 mg/dl, or a conventional insulin regimen with a goal glucose range of 180-200 mg/dl.¹⁰ The trial was terminated early after finding all-cause ICU mortality was significantly lower in the IIT group (4.6% vs. 8%, relative risk [RR] 0.58, 95% CI, 0.38 to 0.78) (Table 1). The short-term mortality benefit was limited to the subgroup of patients who required 5 or more days of ICU care (10.6% vs. 20.2%, $p = 0.005$); long-term mortality did not differ between the two groups.¹¹

Table 1, Chapter 22. Large trials (n > 500) evaluating the health outcome effects of intensive insulin therapy

Patient Population; Diabetes Mellitus (%); Single or Multicenter; Country; Study Quality	Implementation Context	Glucose Target, T v C (mg/dL)	Inpatient BG Achieved, T v C (mg/dL)	Mortality T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate, T v C, RR (95%CI)	Other Reported Outcomes* T v C
SICU 13 Single center Belgium ¹⁰ Fair	Insulin protocol was developed and use overseen by study investigators.	80-110 v 180-200	103 v 153† (p<0.001)	ICU mortality 4.6 v 8% (p=0.005 unadjusted) RR 0.42 (95% CI 0.22-0.62); Hospital mortality: 7.2 v 10.9% (p=0.01) RR 0.66; 95% CI 0.48-0.92	<40, 5 v 0.76%, RR 6.65 (2.83-15.62)	Renal replacement 4.8 v 8.2% (p=0.007) Sepsis 4.2 v 7.8% (p=0.0003)
Neurosurgical ICU NR Single center Italy ⁵⁸ Fair	Efforts made to limit nursing turnover. New nursing staff worked with experienced staff.	80-110 v 180-200	92 v 143‡ (p<0.001)	6-month mortality: 74.0 v 72.0% (p=0.82)	<50, 93.8 v 62.8%, p<0.001	Sepsis 2.9 v 3.3% (p=NS) Long-term disability: 40.2 v 41.1% (p=0.98)
MICU 16 Single center Belgium ⁵⁹ Fair	Study conducted in a hospital that had already conducted similar IIT study in SICU patients. Authors note the nurse:bed ratio of 2.5 was not changed for study.	80-110 v 180-200	111 v 153† (p<0.001)	ICU mortality: 24.2 v 26.8% (p=0.31) Hospital mortality: 37.3 v 40.0% (p=0.33) RR 0.93; 95% CI 0.81-1.08 90d mortality: 35.9 v 37.7% (p=0.53)	<40, 18.7 v 3.1%	Infection 0.7 vs 0.8% (p=NS) Renal replacement 20.8 v 22.7% (p=0.50)
MICU 30 Multicenter Germany ²¹ Fair	No details provided	80-110 v 180-200	112 v 151† (p<0.001)	28d mortality: 24.7 v 26% (p=0.74) RR 0.95, 95% CI 0.70-1.28 90d mortality: 39.7 v 35.4% (p=0.31)	<40, 17 v 4.1% RR 4.11 (95% CI 2.21-7.63)	Renal replacement 27.5 v 22.5% (p=0.001)
MICU/SICU 17 T, 22 C (p=0.031) Multicenter Europe ⁶⁰ Fair	Characteristics from each study site were reported. Median nurse:bed ratio was 2. ICUs ranged widely in size, patient volume, and number of glucometers per ICU.	80-110 v 140-180	117 v 144‡ (p<0.001)	ICU mortality: 17.2 v 15.3% (p=0.41) Hospital mortality: 23.3 v 19.4% (p=0.11) 28d mortality: 18.7 v 15.3% (p=0.14)	< 40, 8.7 v 2.7%	Renal replacement (patient days) 519 v 523 (p=0.75)

Table 1, Chapter 22. Large trials (n > 500) evaluating the health outcome effects of intensive insulin therapy (continued)

Patient Population; Diabetes Mellitus (%); Single or Multicenter; Country; Study Quality	Implementation Context	Glucose Target, T v C (mg/dL)	Inpatient BG Achieved, T v C (mg/dL)	Mortality T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate ,T v C, RR (95%CI)	Other Reported Outcomes* T v C
MICU/SICU 32 T, 48 C (p<0.001) Single center Saudi Arabia ¹⁹ Fair	24/7 ICU coverage by intensivists. Protocol designed by multidisciplinary team at study site. Physicians and nurses attended training sessions before and during study.	80-110 v 180-200	115 v 171‡ (p<0.001)	ICU mortality: 13.5 v 17.1% (p=0.70) RR 1.09 (0.70 -1.72) Hospital mortality: 27.1 v 32.3% (p=0.19) RR 0.84 (0.64 -1.09)	< 40, 28.6 v 3.1%, p < 0.001	Renal replacement 11.7 v 12.1% (p=0.89) Sepsis 36.9 v 40.9% (p=0.35)
MICU/SICU 13 T, 12 C (p=NS) Single center Colombia ⁵⁴ Fair	Three month staff training period before study.	80-110 v 180-200	120 v 149‡ (p,0.001)	ICU mortality: 33.1 v 31.2%; RR 1.06 (0.82-1.37) 28d mortality: 36.6 v 32.4%; RR 1.1 (0.85-1.42)	<40, 8.3 v 0.8%	Infection 27.2 v 33.2% (p=NS) Renal replacement 10.8 v 13% (p=0.45)
MICU/SICU 20 Multicenter International ¹³ Fair	Pre-trial pilot studies carried out to test/improve insulin protocol. Final computerized insulin protocol algorithm accessible to study sites through a central Web site. No clear explicit training prior to study.	80-108 v <180	115 v 144§ (p<0.001)	28d mortality: 22.3 v 20.8% (p=0.17) RR 1.07 (0.97-1.18) 90d mortality: 27.5 v 24.9% (p=0.02) RR 1.14 (1.02-1.28)	<40, 6.8 v 0.5% OR 14.7 (9.0-25.9)	Renal replacement 15.4 v 14.5% (p=0.34) Sepsis 12.8 v 12.4% (p=0.57)
Acute MI 39 Multicenter CCU Sweden ⁶¹ Fair	No details provided	126-198 v NR	24 hours: T: 172.8 (59.4) C: 210.6 (73.8) p < .001	3 month mortality: 12.4% v 15.6%, p = NS 1 year mortality: 18.6% v 26.1 %, RR 0.69; 95% CI 0.49-0.96	<54, 15.0 v 0% (p < .001)	
Acute MI 77 established DM; 23 new DM of < 1y Multicenter Europe ⁶² Poor	No details provided	group 1 and 2: 126-180 group 3: NR	24 hours: group 1: 163.8 (54.0), group 2: 163.8 (50.4), group 3: 180.0 (64.8) p = .0001	Adjusted 2-year mortality: Group 1 v 3 = 1.19 (0.86 - 1.64) Group 2 v 3 = 1.23 (0.89 - 1.69)	< 54, Gr 1 v Gr2 v Gr3: 12.7 v 9.6 v 1.0	

Table 1, Chapter 22. Large trials (n > 500) evaluating the health outcome effects of intensive insulin therapy (continued)

Patient Population; Diabetes Mellitus (%); Single or Multicenter; Country; Study Quality	Implementation Context	Glucose Target, T v C (mg/dL)	Inpatient BG Achieved, T v C (mg/dL)	Mortality T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate, T v C, RR (95%CI)	Other Reported Outcomes* T v C
Stroke 17 Mutlicenter Britain ⁶³ Poor	Conducted as a "pragmatic" trial as part of routine clinical care. No clear explicit training prior to study.	72-126 v <306	24 hour mean difference I v C (95% CI): 10.3 (4.9 - 15.5), p < .0001†	90-day mortality: 30.0% v 27.3%, OR (95% CI) = 1.14 (0.86-1.51) 90-day severe disability: 35.1% v 36.0%, OR (95% CI) = 0.96 (0.70-1.32)	< 72 for > 30 mins, 15.7, control group rate NR	

Notes: Abbreviations: BG = Blood glucose; d = day; CCU = coronary care unit ; ICU = intensive care unit; MICU = medical intensive care unit; SICU = surgical intensive care unit; C = comparator; DM = diabetes mellitus; NR = not reported; NS = not statistically significant; RR = relative risk; T = treatment
Other reported outcomes include renal replacement, infection, cardiovascular events, and long-term disability.

Quality was assessed using criteria from the U.S. Preventive Services Task Force.

SI unit conversion for glucose: 1 mg/dL x 0.0555 = 1 mmol/L.

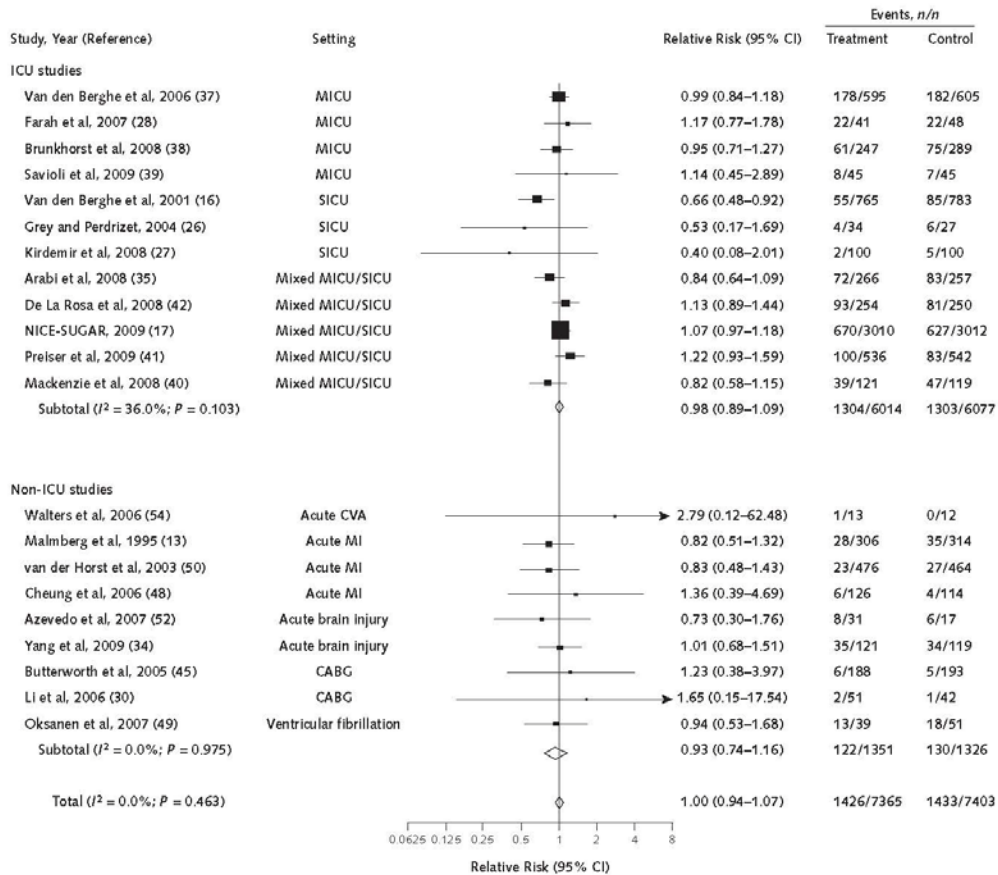
* Infection includes wound infection, urinary tract infection, or pneumonia; or a combination of these.

† Morning blood glucose.

‡ Average of blood glucose measurements, not otherwise specified.

However, over the last decade, IIT trials have failed to replicate these results consistently. Our recent meta-analysis of 21 randomized controlled trials (RCTs), including a total of 14,768 inpatients, found no effect of IIT on short-term mortality (RR 1.00, 95% CI 0.94 to 1.07) (see Figure 1), with remarkably little heterogeneity among studies ($I^2 = 0.0\%$, $p=0.463$).¹² The body of evidence is strongest in ICU settings.

Figure 1, Chapter 22. Short-term mortality in studies of intensive insulin therapy, by inpatient setting and condition



Short-term mortality includes death occurring within 28 d of or during the ICU or hospital stay; we used 28-d mortality in the meta-analysis when a study reported >1 outcome. *Events* is the number of deaths among participants in the treatment and control groups. CABG = coronary artery bypass graft; CVA = cerebrovascular accident; ICU = intensive care unit; MI = myocardial infarction; MICU = medical intensive care unit; NICE-SUGAR = Normoglycemia in Intensive Care Evaluation–Survival Using Glucose Algorithm Regulation study; SICU = surgical intensive care unit.

Figure taken from Kansagara et al., 2011¹²

Kansagara D, Fu R, Freeman M, Wolf F, Helfand M. Intensive insulin therapy in hospitalized patients: a systematic review. *Ann Intern Med.* Feb 15 2011; 154. Permission granted from the American College of Physicians (Annals of Internal Medicine is the original source of the material).

Table 2 summarizes the main characteristics and results from the largest trials ($n > 500$ patients). The NICE-SUGAR trial, with 6,104 medical intensive care unit (MICU) and SICU patients, was by far the largest and likely provides the most generalizable results, given its size, multicenter design, and the broad ICU population included.¹³ Patients randomized to a lower blood glucose target (80-110 mg/dL) had higher 90-day mortality than those assigned a higher blood glucose target (140-180 mg/dL), with approximately one excess death for every 39 patients treated with the more intensive protocol ($n = 6,022$ with 90-day outcomes reported; RR 1.14; 95% CI 1.02 to 1.28).

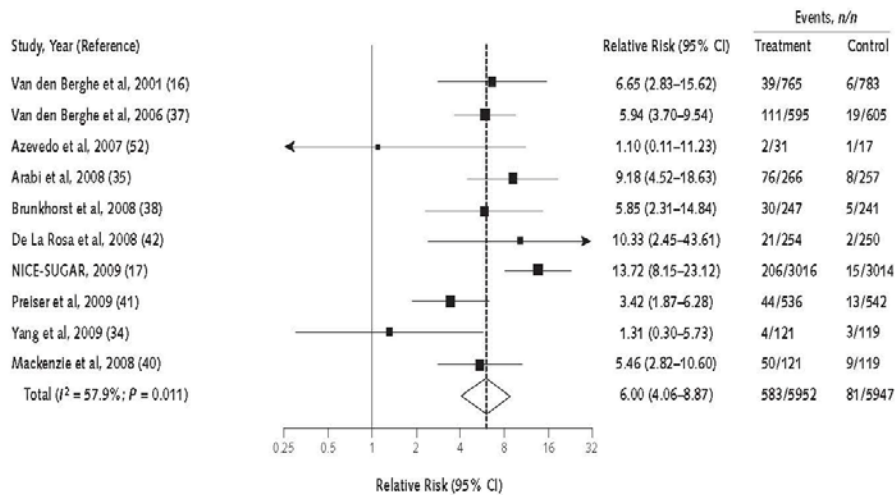
Morbidity outcomes have also been assessed. Trials of IIT failed to demonstrate consistent benefits in reducing renal failure or length of stay. The effects of IIT on infection are mixed. The 2001 Van den Berghe SICU trial did find IIT reduced the incidence of sepsis,¹⁰ whereas the NICE-SUGAR trial did not.¹³ Trials also reported a variety of other infection-related outcomes, including wound infections, pneumonia, and urinary tract infection. A pooled analysis of these trials found a nonsignificant reduction in infection, though the results were quite heterogeneous (RR 0.68; 95% CI 0.36 to 1.30, $I^2 = 56.3\%$, $P=0.033$).¹²

Several trials have reported results since January 2010 (the end of the search period of our systematic review). Two trials found no benefit of IIT on neurologic or mortality outcomes in patients with traumatic brain injury or stroke.^{14,15} One trial did find postoperative IIT reduced wound infections in diabetic patients who had undergone partial gastrectomy (7.6% v 18.4%, $p = 0.03$), but the trial had several methodologic flaws.¹⁶ Finally, the recent RABBIT 2 trial was among the first to compare the effects of a subcutaneous basal-bolus insulin regimen with sliding-scale insulin on health outcomes.¹⁷ In this trial, 211 noncritically ill general surgery patients were randomized to either a basal-bolus insulin regimen using insulin glargine and meal-time glulisine or a sliding-scale insulin regimen (whereby fixed doses of insulin are given in response to specific glucose readings), with a goal glucose target in both groups of 100-140 mg/dL. The basal-bolus group achieved significantly better glycemic control and a lower incidence of wound infections (2.9% vs. 10.3%, $p = 0.05$), but several methodologic issues, including poor outcome ascertainment methods and no blinding of outcome assessors, threaten the validity of results.

What Are the Harms of the Patient Safety Practice?

The main harm of IIT is hypoglycemia. Insulin has a narrow therapeutic window: Underuse may fail to resolve potentially risky hyperglycemia, whereas overly aggressive insulin use can lead to severe hypoglycemia. Nearly all 31 trials in our recent systematic review reported that IIT was associated with excess risk of hypoglycemia.¹² Our meta-analysis of 10 trials found that IIT was associated with a six-fold increased risk of severe hypoglycemia, defined as glucose <40 mg/dL (RR 6.00; 95% CI 4.06 to 8.87; $I^2 = 57.9\%$; $p<0.001$) (Figure 2).¹² The few trials published since we did the searches for our review corroborated these findings.¹⁴⁻¹⁶

Figure 2, Chapter 22. Risk for hypoglycemia in studies of intensive insulin therapy in various inpatient settings



We included inpatients in the MICU, SICU, and perioperative settings as well as patients with traumatic brain injury. We defined hypoglycemia as a blood glucose level less than 2.2 mmol/L (<40 mg/dL). Events is the number of participants with 1 or more hypoglycemic episodes in the treatment and control groups. MICU = medical intensive care unit; NICE-SUGAR = Normoglycemia in Intensive Care Evaluation-Survival Using Glucose Algorithm Regulation study; SICU = surgical intensive care unit.

Figure taken from Kansagara, 2011¹²

Kansagara D, Fu R, Freeman M, Wolf F, Helfand M. Intensive insulin therapy in hospitalized patients: a systematic review. *Ann Intern Med.* Feb 15 2011; 154. Permission granted from the American College of Physicians (Annals of Internal Medicine is the original source of the material).

The consequences of hypoglycemia in hospitalized patients may be severe. Several MICU studies found excess risk-adjusted mortality and/or extended length of stay among patients experiencing one or more episodes of severe hypoglycemia.¹⁸⁻²² However, these studies reported few in-hospital adverse effects of hypoglycemia during IIT, though many critically ill patients in these studies were sedated, which limits the completeness of neurologic assessment.

How Has the Patient Safety Practice Been implemented, and in What Contexts?

The safety of IIT may depend on intervention and implementation characteristics of the IIT protocols. In addition to the IIT trials reviewed above, we reviewed an additional 40 insulin protocol studies that did not report health outcomes in order to better understand how intervention and implementation characteristics of protocols impact safety. These protocol studies differed in terms of patient characteristics, target glucose ranges, the time required to achieve the target glucose levels, the definition and incidence of hypoglycemia, the rationale or algorithm used for adjusting the insulin rates, the methods used to assess effectiveness, and the methods of glucose monitoring.¹² Nevertheless, some themes emerge from a review of these protocol studies.

The vast majority of studies evaluated intravenous insulin infusions; fewer examined the effects of subcutaneous insulin protocols. Protocols were most widely tested in ICU populations (both surgical and medical); few studies occurred in general medical or surgical ward settings. Most of the studies were single-center studies of insulin infusion protocols iteratively developed by a local group of providers. The rate of hypoglycemia in these studies was, in general, lower than that seen in IIT trials evaluating health outcomes.

Glucose Targets

Not surprisingly, we found that protocols targeting higher blood glucose ranges were generally associated with lower rates of hypoglycemia. This observation echoes findings from the trial literature in which insulin infusions were used to target strict (80-110 mg/dL) or moderate (140-200 mg/dL) glucose goals. The rates of severe hypoglycemia were substantially higher in the strict glucose target groups.

We also found protocols that achieved mean blood glucose <120 mg/dL were not consistently safe, even when clinicians used relatively sophisticated computerized algorithms.^{23,24} Two observational studies evaluated the safety of phasing in progressively stricter glucose targets over time.^{25,26} One of these was a large single-center retrospective study evaluating the effects of an increasingly aggressive IIT policy in the ICU.²⁵ The authors found a nearly four-fold increase in the incidence of hypoglycemia as the institution moved from no insulin protocol to IIT with a target of 80-130 mg/dL and finally to a target of 80-110 mg/dL.²⁵ The infusion protocol details were not available. A second study of a relatively simple infusion protocol reported a doubling of the rate of severe hypoglycemia as the glucose target moved from 120-150 mg/dL to 80-110 mg/dL, although the overall rate of severe hypoglycemia remained less than 5 percent.²⁶

Insulin Dosing Factors

The factors used to guide insulin dosing may also be important. Some protocols use only current blood glucose levels to guide dosing, whereas others attempt to anticipate insulin needs based on measures of insulin sensitivity. For example, one recent observational study examined an insulin-resistance-guided protocol in which cardiac surgery patients were assigned to one of six insulin resistance categories.²⁷ The insulin dosing adjustments depended on the category to which each patient was assigned. Hourly arterial blood glucose monitoring was used along with changes in medications and patient condition to determine subsequent changes to insulin resistance category. The authors found that such an approach reduced the rates of both hypoglycemia and hyperglycemia. The SPRINT protocol used a similarly complex approach and also found reductions in hyperglycemia and hypoglycemia in critically ill patients.²⁸

Other reviews speculate that better protocols incorporate bolus insulin doses, account for the direction and rate of glucose change, and make allowances for “off-protocol” adjustments. However, these conclusions are not based on direct comparisons of protocols.^{29,30}

Computerized Protocols

Most protocols studied have used a paper-based algorithm to guide nurses in making insulin dose adjustments and timing glucose measurements. In recent years, computer-based algorithms have become available and, in 2010, the first RCT comparing these algorithms to a paper-based algorithm was reported.³¹ This multicenter trial of 153 MICU patients compared a paper-based algorithm to the computerized Glucommander system, which directed insulin dosing and glucose monitoring timing using glucose measurements at the patients’ bedside. The glucose target was 80-120 mg/dL. Patients in the computer-algorithm group had fewer instances of marked hyperglycemia (glucose > 200 mg/dL, 11.7% vs. 25%, $p = 0.05$), but a similar rate of severe hypoglycemia (< 40 mg/dL, 3.9% vs. 5.6%, $p = \text{NS}$). An older observational study of the same computerized system had reported similar results.³² However, a recent small observational study found only minor improvements in glucose control using a computerized protocol and no change in hypoglycemia rates.³³ This study also found that using the computerized protocol led to more

frequent glucose testing and insulin dose adjustments. Finally, another recent observational study found that fewer dosing errors occurred with a computer-based protocol than with a paper-based protocol.³⁴

Continuous Glucose Monitoring

Recently, studies have also examined the use of continuous glucose monitoring devices, although none have tested their use outside of small, single-center populations. In a single-center RCT of 124 MICU patients, a subcutaneous continuous glucose monitoring strategy did not improve glycemic control but did reduce the rate of severe hypoglycemia (1.6% vs. 11.5%, $p = 0.03$).³⁵ One observational study evaluated a closed-loop glycemic control device, which continuously monitors glucose and automatically delivers insulin and glucose, and found no hypoglycemic events.³⁶

Glucose Monitoring Site

Capillary blood glucose is the most common source for glucose monitoring. However, it has several notable limitations to its accuracy, which, in turn, affect the safety of IIT. Capillary blood sampling is less dependable than arterial sampling in critically ill patients for several possible reasons, including low perfusion pressure, use of vasopressors, and low pH.³⁷⁻⁴⁰ The rate of agreement between capillary and whole blood samples is particularly low in the hypoglycemic range.^{41,42} Capillary blood testing also tends to overestimate glucose levels in anemic patients, which could lead to overaggressive use of insulin to achieve tight glucose control. One recent study found high rates of measurement error in patients with hematocrit less than 34 percent; the investigators suggested a mathematical correction factor, but it has yet to be tested on a wide scale.⁴³

Nutrition

Most insulin protocols neither coordinate insulin dosing with patient nutrition nor provide detailed nutritional guidance. In one RCT, 337 critically ill patients were randomized to either a carbohydrate-restrictive strategy or an insulin infusion regimen targeted to blood glucose levels of 80-120 mg/dL.⁴⁴ Although the glucose level achieved in the carbohydrate-restrictive group was higher than in the infusion group (144 vs. 134 mg/dL, $p = 0.03$), the difference was modest and the rate of hypoglycemia was substantially lower in the carbohydrate-restrictive group (3.5% vs. 16%, $p < 0.01$). The results suggest that more-intensive nutritional strategies may be a promising adjunct, or alternative to, IIT. An observational study of the SPRINT protocol, which directly prescribes both insulin dosing and dietary intake, found that it improved glycemic control and reduced the risk of severe hypoglycemia.²⁸

Sliding Scale Insulin

Although most trials evaluating health outcomes of IIT have used insulin infusions to achieve blood glucose control, subcutaneous insulin is more often used in real-world settings, especially in general ward patients. Subcutaneous sliding scale insulin (SSI) regimens have several theoretical disadvantages when used as the sole method for inpatient glycemic control. For that reason, various researchers have called for a reduction in the widespread use of SSI approaches.^{45,46}

Very few controlled trials have compared SSI with basal-bolus subcutaneous insulin regimens in which both long-acting and meal-time insulin are provided. The multicenter

RABBIT 2 surgery trial¹⁷ and several small, single-center trials in general medical⁴⁷⁻⁴⁹ and gastric bypass populations⁵⁰ found that basal-bolus regimens were more effective in lowering blood glucose than SSI, although both strategies had similar rates of hypoglycemia. The RABBIT 2 surgery trial is the only one to have reported the effects of basal-bolus insulin on health outcomes.¹⁷

Are There Any Data About Costs?

No studies evaluating the cost-effectiveness of IIT incorporate findings from trials reported within the past few years. Several earlier studies suggest that IIT is cost-effective, but these studies relied on findings from older studies that had found cost reductions from shorter length of stay and lower risk of costly complications such as infections. However, as noted above, such benefits have not been replicated consistently in more recent trials.

The incremental impact of IIT on resource utilization is unclear. Some studies have suggested that costs are relatively low. For instance, the cost attributable to IIT in cardiac surgery patients in one center were estimated to be \$138 per patient.⁵¹ Because nurses are typically responsible for glucose monitoring and insulin adjustments, implementing IIT protocols might require more nursing time and effort. One large ICU cohort study found that IIT implementation did not change either nurse:patient ratios or nursing hours.⁵² By contrast, a multi-center ICU study using more detailed time-in-motion observations found that the nurse-led intensive glucose monitoring and insulin dosing adjustments were burdensome and costly. The authors estimated that nursing personnel could spend up to 2 hours on IIT-related activities for a given patient per 24-hour period; this level of effort totaled \$182,488 for nurses' salaries and about \$58,500 for supplies in cost over 1 year.⁵³

Are There Any Data About the Effect of Context on Effectiveness?

All IIT strategies involve frequent insulin dose adjustments and glucose monitoring; these tasks are usually performed by nursing staff and guided by a protocol. Above, we detailed the protocol characteristics that may affect safety, but, because of the frequent human input required, careful implementation strategies and training may also be important to execute IIT safely. Most large IIT trials (see Table 1) did not provide much detail about the clinical context within which they had implemented their IIT interventions. Only two trials specified explicit nursing training before the start of the study.^{19,54}

The high rates of hypoglycemia in recent multicenter IIT trials, such as NICE-SUGAR, may provide some information about implementation of IIT protocols.¹³ Some have argued that, in general, the protocols used in IIT trials are difficult to implement safely across multiple centers because of the lack of specific instructions, the simplicity of inputs used to guide insulin dosing, and the relative lack of clinical expertise that nurses would gain with IIT in each study site.⁵⁵ Van den Berghe and colleagues used a simple infusion protocol in their 2001 SICU study, but theirs was a single-center study in which the investigators were practicing clinicians and the nursing staff had more opportunity to develop clinical expertise with the protocol because all patients were treated in one setting.¹⁰

In our review of observational studies and smaller IIT trials, we could indirectly glean similar lessons about implementation. Furnary and colleagues acknowledged the importance of local physician champions, an iterative process, and nursing buy-in to the successful implementation of their IIT protocol in cardiac surgery patients.⁵⁶ They gradually lowered glucose targets from 200 mg/dL to 100-150 mg/dL over 15 years. The rate of deep sternal wound infections dropped

with use of IIT, although theirs was an uncontrolled study, and they did not report overall hypoglycemia rates. In contrast, another institution went from no glycemic control policy to a normal glucose target over 5 years in a large population of critically ill patients (n = 10,456); these investigators reported markedly increased rates of hypoglycemia and a trend to increased mortality.²⁵ These results may well reflect the difficulty with broad, rapid implementation of aggressive glucose control practices.

Conclusions and Comment

The use of IIT to achieve very tight blood glucose control does not reduce short-term mortality in MICU patients (high strength of evidence) or SICU patients (moderate strength of evidence). It increases the risk of severe hypoglycemia in all settings (high strength of evidence). The lack of consistent benefit from very tight blood glucose control and the increased risk of hypoglycemia has led to recommendations for a moderate blood glucose target of 140-200 mg/dL in ICU populations.⁵⁷ However, it is unknown whether implementation of IIT protocols targeted to moderate blood glucose levels (140-200 mg/dL) with low rates of hypoglycemia improves health outcomes. Despite the lack of evidence to support a specific blood glucose target, many organizations continue to recommend moderate blood glucose control in inpatients because of the association of high blood glucose with infection, poor wound healing, dehydration, and other complications. Although glycemic control protocols remain an important part of quality inpatient care, the lack of clear and consistent evidence of benefit underscores that minimization of hypoglycemia is of paramount importance in the implementation of any glycemic control protocol.

Based on data from a review of insulin protocols and of trials evaluating the health outcome effects of IIT, the following emerge as important issues to consider when implementing IIT protocols:

- The glucose target is important. Glucose targets in the normal range (80-110 mg/dL) markedly increase the risk of severe hypoglycemia and do not improve health outcomes. Higher glucose targets (e.g., 140-200 mg/dL) can be safely achieved with careful IIT implementation.
- The clinical factors used to guide insulin dosing are important. Very simple protocols based only on current and past glucose levels may be difficult to replicate safely across institutions. Protocols incorporating some estimate of a patient's insulin sensitivity may be safer and more effective than those that ignore these factors.
- Newer technologies such as continuous glucose monitoring and computerized protocols may improve glycemic control. However, the evidence base is limited. Whether these technologies reduce hypoglycemia rates remains unclear. The cost of such technology has not been adequately assessed.
- In critically ill patients, capillary blood glucose can be markedly inaccurate, particularly in the hypoglycemic range. Clinicians should exercise caution using capillary blood glucose measurements in these patients and in patients with anemia.
- IIT protocols should be coupled to patient nutrition whenever possible because failure to modify IIT dosing in response to discontinuities in nutritional intake can increase the risk of hypoglycemia. Additionally, some nutritional interventions may, themselves, be effective in reducing the risk of hypoglycemia.
- In surgical patients, weight-based subcutaneous insulin protocols using both basal and bolus insulin may reduce infection rates more than sliding-scale-only insulin. The

comparative effects of different subcutaneous insulin regimens has not been well studied in non-surgical populations.

- IIT is a complex endeavor requiring buy-in from nurses and physicians. Implementation of IIT in a given setting is likely best done iteratively, with multidisciplinary involvement and training, and using real-time data to inform continuous quality improvement of the process.

Table 2, Chapter 22. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate-to-high evidence it doesn't help	High (hypoglycemia)	Low-to-moderate	N/A

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Chapter 23. Interventions To Prevent Contrast-Induced Acute Kidney Injury

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How Important Is the Problem?

Over 70 million computed tomography (CT) scans are performed yearly in the United States,¹ approximately half of which use iodinated radiocontrast media, and over 2 million patients undergo other studies using radiocontrast media such as coronary angiograms.² Contrast-induced acute kidney injury (CI-AKI) is one of the major risks of procedures using radiocontrast media. CI-AKI is generally defined by laboratory criteria: biochemical CI-AKI is usually defined as an increase in serum creatinine of 25%, or an absolute increase of 0.5 mg/dl, within 2-5 days after receiving contrast.³ A prospective study⁴ found that the incidence of CI-AKI by this definition was 7.7% in patients with impaired baseline kidney function (defined as an estimated glomerular filtration rate of less than 60 mL/min/ 1.73 m²), ranging from 6.5% in patients undergoing CT scans to 13.2% in patients undergoing non-coronary angiography.

Risk factors for CI-AKI include chronic kidney disease (CKD) of any cause, especially in diabetic patients. Other risk factors include intravascular volume depletion and disease states associated with decreased effective circulating volume and renal perfusion, such as congestive heart failure (CHF) and liver failure, and concomitant use of nephrotoxic medications, particularly non-steroidal anti-inflammatory drugs (NSAIDs).⁵ Procedural risk factors also play a role, with larger volumes of contrast media, intra-arterial contrast administration (such as in coronary angiography), and use of high-osmolality contrast media all independently associated with elevated risk for CI-AKI. Patients with normal baseline kidney function have minimal risk of CI-AKI.

Although biochemical CI-AKI is commonly documented, the link between laboratory abnormalities and clinical outcomes is controversial. Several studies have shown an independent link between CI-AKI diagnosis in hospitalized patients and subsequent increases in length of stay,⁶ progression to end-stage renal disease,⁷ and short- and long-term mortality.⁸ However, causality is difficult to determine despite the presence of this association, because many factors that predispose to CI-AKI (especially CHF and CKD) also are associated with adverse clinical outcomes independent of CI-AKI development. In addition, AKI of any cause is associated with worsened short- and long-term outcomes in hospitalized patients.⁹ In prospective studies, CI-AKI has been found as an asymptomatic laboratory abnormality in the vast majority of patients. Only 1 of 660 patients in a 2008 study by Weisbord et al.⁴ required kidney dialysis after receiving contrast.

What Is the Patient Safety Practice?

The standard of care to prevent CI-AKI includes several widely accepted, evidence-based interventions:

- Intravascular volume expansion with intravenous normal saline¹⁰
- Limiting the volume of contrast administered

- Avoidance of high-osmolar contrast media in patients with impaired baseline renal function¹¹
- Stopping nephrotoxic medications, especially NSAIDs

Published guidelines from the American College of Radiology, the European Society of Radiology,¹² and the Canadian Association of Radiology¹³ all recommend the above measures. The original review of this topic for Making Health Care Safer (2001) also recommended volume expansion with normal saline and avoidance of high-osmolar contrast. The 2009 American College of Cardiology/American Heart Association guidelines for percutaneous coronary interventions also recommend avoidance of high-osmolar contrast media.²

In addition to standard care, several interventions have been widely studied to prevent CI-AKI. These practices are the focus of this review:

- Volume expansion with intravenous sodium bicarbonate
- Administration of n-acetylcysteine
- Use of iso-osmolar (instead of low- or high-osmolar) contrast media
- Prophylactic renal replacement therapy (dialysis)
- Administration of HMG CoA-reductase inhibitors (“statins”)

Why Should This Patient Safety Practice Work?

The pathophysiology of CI-AKI is complex and incompletely understood.³ Intravascular contrast administration is thought to induce renal vasoconstriction, which may lead to medullary ischemia, particularly in the presence of intravascular volume depletion or other medications that may cause afferent renal artery vasoconstriction such as NSAIDs. Contrast media, particularly older high-osmolar media, may be directly toxic to the renal tubules. Finally, some component of renal damage is thought to be mediated by generation of reactive oxygen species (“free radicals”). Because patients suspected of suffering CI-AKI rarely undergo kidney biopsy for definitive diagnosis, the relative contribution of these mechanisms is unclear. As a result, the mechanisms by which the proposed PSPs prevent CI-AKI are also somewhat speculative.

Opportunities for improving CI-AKI prevention definitely exist, as studies show that appropriate and proven prophylactic interventions are not universally applied. Studies have found that volume expansion is used in only 40% of at-risk patients undergoing coronary angiography⁴ and 60% of patients undergoing computed tomography.¹⁴ In the latter study, only 7% of patients had nephrotoxic medications discontinued.

What Are the Beneficial Effects of the Patient Safety Practice?

We designed a structured literature search with the assistance of a medical librarian to identify studies of interventions to prevent CI-AKI. Searching PubMed identified 193 randomized controlled trials and 53 meta-analyses of various interventions to prevent CI-AKI published in the past 10 years. (Searching of the Cochrane Controlled Trials Registry and the Cochrane Database of Systematic Reviews did not identify any additional trials.) In contrast, the original Making Health Care Safer report published in 2001 identified only 10 RCTs and 1 meta-analysis.

Based on the expansion in this literature, we opted to conduct a systematic meta-review of the meta-analyses of CI-AKI prevention published since January 1, 2007. We chose this inclusion date based on prior literature demonstrating that the results of systematic reviews are

generally not stable by 5 years after publication.¹⁵ The revised search identified 32 studies, of which 20 were confirmed to be meta-analyses after full-text review (the others were largely narrative reviews). These 20 meta-analyses evaluated the effectiveness of 5 distinct interventions for preventing CI-AKI:

- Hydration with intravenous sodium bicarbonate (N=11)¹⁶⁻²⁶
- Administration of oral N-acetylcysteine (NAC, N=3)²⁷⁻²⁹
- Use of iso-osmolar radiocontrast media (N=3)³⁰⁻³²
- Prophylactic renal replacement therapy (RRT, N=1)³³
- Administration of HMG CoA-reductase inhibitors (statins, N=1)³⁴

In addition, one study³⁵ evaluated the combination of NAC and bicarbonate in preventing CI-AKI compared with NAC alone.

We followed the methodology previously outlined by Whitlock³⁶ for incorporating previously published systematic reviews into a new review. Each identified review was evaluated for quality using the AMSTAR checklist³⁷, and information was extracted on the interventions and outcomes assessed, the study populations (including the types of radiologic studies for which contrast media was used) and sample size, the definition of CI-AKI used, and the overall conclusions of the review (Table 1).

Hydration With Intravenous Sodium Bicarbonate

We identified a total of 11 meta-analyses published since 2007¹⁶⁻²⁶ comparing sodium bicarbonate hydration to volume expansion with normal saline. These meta-analyses all used the same definition of CI-AKI (a 25% increase in the serum creatinine level, or an absolute increase of ≥ 0.5 mg/dl, within 2-5 days of the procedure).

The review with the most recent inclusion date¹⁹ completed its search through February 2009, and identified a total of 18 published and unpublished trials. This meta-analysis was methodologically sound, scoring 11 (of a possible 11) on the AMSTAR scale, and overall found a slight benefit for bicarbonate compared with saline volume expansion in preventing CI-AKI by the laboratory definition (pooled OR 0.66, 95% CI 0.45-0.95). There was no reported improvement in the need for renal replacement therapy or mortality. This seemingly positive result was tempered by numerous caveats. The authors noted significant heterogeneity across included trials, found evidence for publication bias, and considered the quality of included trials to be low. Therefore, the authors concluded “only a limited recommendation can be made in favour of sodium bicarbonate.”

Another meta-analysis with a slightly earlier study inclusion date of December 2008²⁵ actually included more trials (N=23, including 14 unpublished trials). This meta-analysis also scored 11 on the AMSTAR scale. The pooled trial results found evidence for a slight benefit for bicarbonate compared with saline volume expansion in preventing laboratory-defined CI-AKI (pooled relative risk 0.62, 95% CI 0.45 to 0.86). However, the authors performed a meta-regression analysis and found that bicarbonate was effective only in smaller, poor-quality trials. Larger, higher-quality trials generally found neutral results. This meta-analysis, which appears to be the most comprehensive study of bicarbonate prophylaxis for CI-AKI, concludes that “the effectiveness of sodium bicarbonate treatment to prevent contrast-induced nephropathy remains unclear.”

The other 9 meta-analyses identified in our search did not include any other trials (published or unpublished) that were not included in the 2 meta-analyses discussed above. Significant

heterogeneity was found in all 11 meta-analyses, and all of the meta-analyses that included unpublished studies found evidence of publication bias.

Therefore, we conclude that sodium bicarbonate therapy appears to offer only marginal benefit at best over routine saline volume expansion, and the primary literature suffers from significant limitations. Routine bicarbonate administration cannot be recommended to prevent CI-AKI.

Administration of Oral N-Acetylcysteine

The role of N-acetylcysteine in CI-AKI prevention has been quite thoroughly studied. We identified 3 meta-analyses published since 2007²⁷⁻²⁹, but prior to 2007 an additional 12 meta-analyses and 2 meta-reviews had already been published. Limitations in the prior literature—and the meta-analyses of this literature—have been well documented; in fact, a 2006 meta-review³⁸ described the plethora of NAC trials and meta-analyses as “a case study in the pitfalls of the evolution of evidence”. No consensus on the effectiveness of NAC existed as of 2007, as the existing meta-analyses produced differing results.

The most recent meta-analysis of interventions included randomized controlled trials published through February 2008²⁹ and evaluated only studies of high-dose NAC protocols (defined as administration of $\geq 1,200$ mg/day of oral NAC or a single periprocedural dose of ≥ 600 mg) compared with saline volume expansion. This high-quality meta-analysis (AMSTAR score of 11) found that high-dose NAC protocols were effective in preventing biochemically defined CI-AKI (random effect odds ratio 0.52; 95% CI, 0.34 to 0.78) in a trial population predominantly composed of patients undergoing coronary angiography. This meta-analysis did not extract or report information on clinical outcomes. However, a large RCT³⁹ that was published after this review and also used a high-dose NAC protocol did not find any reduction in biochemical CI-AKI, need for hemodialysis, or mortality in patients undergoing coronary angiography. This study enrolled 2,308 patients, whereas the 16 RCTs included in the meta-analysis in total enrolled only 1,677 patients.

Another earlier meta-analysis that included trials published through March 2006²⁸ identified 26 trials of NAC, using different dosing regimens ranging from 400 mg/day to 1,200 mg/day. This meta-analysis did find evidence for a significant reduction in biochemically defined CI-AKI. However, there was significant unresolved heterogeneity in this study. The meta-analysis published by Gonzales et al.²⁷, which included all but 6 of the same studies, noted that evidence of benefit was confined to a small group of relatively low-quality studies which showed very large relative benefits from NAC. These studies were also performed and published earlier than subsequent larger, higher-quality trials that reported negative results.

Based on these findings, we conclude that routine use of NAC at any dose does not appear to convincingly reduce the incidence of CI-AKI. As with bicarbonate infusion, there is no evidence that NAC administration decreases the incidence of clinically meaningful outcomes such as the need for renal replacement therapy.

Use of Iso-Osmolar Contrast Media

There are three types of iodinated radiocontrast media: high-osmolar, low-osmolar, and iso-osmolar. High-osmolar contrast is little used due to its nephrotoxic effects, and low-osmolar contrast media has become the standard of care. So-called iso-osmolar contrast has an even lower osmolality than “low-osmolar” contrast, and 3 meta-analyses³⁰⁻³² have evaluated the renoprotective effect of the iso-osmolar contrast medium iodixanol compared with low-osmolar

contrast media (LOCM, of which there are several agents). The most recent and largest meta-analysis³² identified 36 randomized controlled trials published before December 2009. This meta-analysis was high quality, scoring 11 on the AMSTAR scale. It did not find a statistically significant reduction in biochemical CI-AKI for iso-osmolar contrast compared with all LOCM agents (pooled OR 0.77, 95% CI 0.56 to 1.06). However, a subgroup analysis did find that iso-osmolar contrast was associated with a reduction in CI-AKI in studies comparing iodixanol to one specific low-osmolar agent, iohexol (pooled OR 0.25, 95% CI 0.11-0.55, N=10 trials). This finding was also noted in the other two meta-analyses of this question.^{30,31} None of the meta-analyses evaluated the effect of iso-osmolar contrast media on clinical outcomes.

Other than this advantage of iodixanol over the specific agent iohexol, there is therefore no convincing evidence supporting the routine use of iso-osmolar contrast. The 2009 ACC/AHA guidelines for percutaneous coronary intervention² recommend use of iso-osmolar contrast or use of LOCM other than iohexol. This is a change from the 2007 guidelines, which specifically recommended use of iso-osmolar agents.

Prophylactic Renal Replacement Therapy

One meta-analysis³³ analyzed 9 RCTs evaluating the effectiveness of prophylactic renal replacement therapy (RRT) on prevention of biochemically defined CI-AKI, need for long-term RRT, and mortality. The patients included in the individual studies uniformly had baseline kidney dysfunction (at least stage 3 chronic kidney dysfunction, with baseline serum creatinines ranging from 1.5 to 4.2 across the studies). Overall, prophylactic RRT was not associated with decreased biochemical CI-AKI or the need for long-term hemodialysis. The authors did find a statistically significant reduction in mortality associated with prophylactic RRT (RR 0.33, 95% CI 0.11 to 0.77), but the significance of this finding is quite questionable given the lack of effect on the primary outcome. The authors speculated that the mortality benefit might instead represent a general benefit of RRT in critically ill patients with AKI.

Administration of Statins

One recent meta-analysis³⁴ identified 6 small RCT's evaluating the effect of statins on biochemical CI-AKI. There was no overall beneficial effect of statins on prevention of CI-AKI.

Coadministration of Bicarbonate and N-Acetylcysteine

One meta-analysis³⁵ identified 10 RCT's that studied the effectiveness of combination of bicarbonate and NAC compared with NAC alone. The authors reported a reduction in biochemical CI-AKI with combination therapy, but the result did not reach statistical significance (pooled RR 0.65, 95% CI 0.40 to 1.05), nor did combination therapy reduce the incidence of renal failure requiring dialysis.

What Are the Harms of the Patient Safety Practice?

The individual interventions that have been evaluated to prevent CI-AKI are generally considered low risk. Bicarbonate and NAC are not associated with a significant risk of clinically relevant adverse effects, and likewise, iso-osmolar contrast media do not have a unique side effect profile compared with other routinely used radiocontrast agents. The exception is renal replacement therapy, which requires placement of large bore central venous access, exposing patients to complications of this procedure including hemorrhage, pneumothorax, or central line-associated bloodstream infections.

One potential harm is that administration of intravenous fluids may increase the risk of clinically significant congestive heart failure (CHF) in patients with a known diagnosis of CHF. However, the largest meta-analysis of intravenous bicarbonate administration did not find an increased incidence of symptomatic CHF.²⁵

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Interventions to prevent CI-AKI have been studied in patients with a range of risk factors for CI-AKI, and have included patients with no preexisting renal dysfunction as well as those with chronic kidney disease. Studies have also assessed patients undergoing a variety of radiologic procedures, including those associated with a higher risk of CI-AKI such as coronary angiography. Within specific interventions, there are a range of specific protocols used for administering prophylactic medications. However, across all the meta-analyses of this subject, no unique subgroup of patients has been identified that benefits from any specific intervention.

At the health care system level, some steps have been taken to implement protocols to minimize the risk of CI-AKI. Brown et al.⁴⁰ conducted a mixed-methods study of CI-AKI prevention practices at 10 centers enrolled in the Northern New England Cardiovascular Disease Study Group PCI Registry. The incidence of biochemically defined CI-AKI varied widely across sites, ranging from 1.9% to 10% even after adjustment for covariates. The two centers with the lowest CI-AKI rates both had strong clinical leadership that prioritized CI-AKI prevention and utilized standardized protocols for volume administration, NAC administration, and minimizing the time that patients were NPO prior to procedures. Interestingly, one of these centers used normal saline and the other bicarbonate for volume administration, indicating that the choice of fluid likely matters less than ensuring that patients receive adequate volume prior to the procedure.

Are There Any Data About Costs of the Patient Safety Practice?

We did not identify any formal cost-effectiveness analyses of the various modalities proposed to prevent CI-AKI published since 2007. Interventions such as bicarbonate and NAC are low cost, whereas iso-osmolar contrast media (IOCM) is more costly than standard LOCM. One cost-effectiveness analysis demonstrated that IOCM is cost-effective compared with LOCM,⁴¹ but this analysis was based on earlier, more favorable estimates of the benefits of IOCM that have not been borne out in subsequent trials or meta-analyses. We also identified one cost-effectiveness analysis of prophylactic RRT published in 2006,⁴² which found that prophylactic RRT might be cost-effective only in a subset of patients with stage 4 chronic kidney disease. This analysis was also based on favorable treatment estimates that have not been confirmed in formal systematic reviews.

Are There Any Data About the Effect of Context on Effectiveness?

There is no definitive evidence that any single intervention to prevent CI-AKI is more effective in specific patient populations (e.g., patients with more advanced chronic kidney disease) or undergoing specific radiologic procedures (e.g., patients undergoing intra-arterial contrast procedures such as coronary angiography versus patients undergoing procedures requiring intravenous contrast). Health care system factors have not been studied as an effect modifier for specific CI-AKI preventive interventions.

Conclusions and Comment

We identified 20 meta-analyses testing various interventions to prevent CI-AKI. However, despite this intensive research, we were unable to identify any unique interventions that clearly are effective at preventing either biochemical CI-AKI or clinically relevant outcomes such as renal failure requiring hemodialysis. Moreover, even the significance of biochemical evidence of kidney injury after contrast is debated, and some experts question the importance of this as a proxy measure or target for intervention. At this point, it appears that standard therapy, most importantly volume administration with intravenous normal saline prior to procedures, is the most efficacious method of preventing CI-AKI. Use of standardized CI-AKI prevention protocols that emphasize volume administration may be associated with a lower risk of CI-AKI in patients undergoing coronary angiography. A summary table is located below (Table 1).

Table 1, Chapter 23. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low	Low	Negligible	Low	Little/Not difficult

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Chapter 24. Rapid-Response Systems (NEW)

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How Important Is the Problem?

General ward patients often experience unrecognized deterioration in their clinical status that may progress to cardio-respiratory arrest. Such cardio-respiratory arrests are known to carry a poor prognosis for hospitalized patients. Mortality for in-hospital arrest is as high as 80%. One study, examining patient data prior to an arrest event, found that clear signs and symptoms heralding arrest often exist in these patients for many hours prior to the arrest (median time \cong 6 hours) yet are unrecognized and/or unappreciated. In addition, an average of two visits by health care staff occurred during those median 6 hours of developing instability without apparent recognition of the patient's condition or any intervention.¹

Rapid response systems (RRSs) were developed by clinicians as a way to improve recognition of deterioration (this portion is called the Afferent Limb) and provide a critical care team to respond to those deteriorations (the Efferent Limb), in order to improve outcomes such as reducing the incidence of cardio-respiratory arrest and hospital mortality. RRSs have been implemented in many hospitals to remedy the failure of our current system model (intermittent vital signs) to monitor general ward patients adequately, to recognize the signs and symptoms of deterioration, to rescue such patients, to deliver optimal care rapidly in patients who develop signs or symptoms of clinical deterioration; and to escalate care and triage appropriately.²

What Is the Patient Safety Practice?

At the 3rd International Medical Emergency Team (MET) conference, the disparate nomenclature for this intervention was codified to bring all the terms under one umbrella term: the Rapid Response System or RRS. An RRS includes a multidisciplinary team, most frequently consisting of intensive care unit (ICU)-trained personnel who are available 24 hours per day, 7 days per week to evaluate patients not in the ICU who develop signs or symptoms of clinical deterioration. RRSs include Medical Emergency Teams (METs, which includes a physician), Rapid Response Teams (RRTs, which do not include a physician), and Critical Care Outreach Teams (CCOT, which provide specific follow-up care for patients discharged from an intensive care unit to a general ward, and may also include as part of the intervention, the ability to respond to deteriorating ward patients that may or may not have been in the ICU previously). The response team is referred to as the Efferent Limb and the system of tracking and recognizing deterioration and activating the Efferent Limb is referred to as the Afferent Limb.

“Rapid Response Systems aim to improve the safety of hospital-ward patients whose condition is deteriorating. These systems are based on identification of patients at risk, early notification of an identified set of responders, rapid intervention by the response team, and ongoing evaluation of the system's performance and hospital-wide processes of care.”² Similar types of systems exist for acute myocardial infarction (AMI)/cardiac stenting emergencies (Heart Attack Teams or HATs), cerebrovascular accident (CVA) (Brain Attack Teams or BATS), and other specialty issues such as hyperkalemia. However, these are different programs, with different structures and effectiveness, designed to address very specific disease states. In

contrast, RRSs are non-specific and address a panoply of conditions. Therefore, we do not include the disease-specific systems (BATs and HATs etc.) in this review.

A Rapid Response System generally has four components:

- Criteria for notifying the response team and a system for activating it (the Afferent Limb). The criteria usually include vital signs (single trigger criteria or more complicated algorithms including aggregate and weighted early warning scores). However, in some cases a clinician or family member might initiate activation, based on clinical judgment and concern even though specific activation criteria are not met (e.g., heart rate >130).
- The response team – the Efferent Limb. Refers to personnel and equipment (can be led by a critical-care physician, other physician, or by an nurse or respiratory therapist). Team composition varies based on local needs and human resources.
- Feedback loop to collect and analyze event data and quality improvement.
- Administrative component, coordinating resources, staff, equipment, and education.

Jones et al² also cites importance of support of leadership and administration, use of criteria that are not too complicated (argues for simple vital signs triggers as opposed to complicated early warning scores), education of the personnel on the team regarding the criteria (including possibly simulation training), and involvement of physicians who can facilitate ICU transfers and end-of-life planning. In a narrative review of data from the MERIT trial (the only multi-center cluster randomized trial of RRS) and subsequent data, Jones et al. also note that RRSs exhibit a dose response curve, where utilization rates (number of RRS activations) positively correlate with reduction in the incidence of cardiac arrest. The authors found that a utilization rate of approximately 17 RRS calls/1000 patient admissions is required to reduce the incidence of cardio-respiratory arrest by 1/1000 admissions. Given this relationship, many hospitals have sought to increase utilization of their RRSs to realize improvements in outcome.

Why Should This Patient Safety Practice Work?

That RRSs should be able to improve patient outcomes has strong face validity. These outcomes include the incidence of cardio-respiratory arrests and unexpected mortality. All but a small number of cardio-respiratory arrests have clear antecedents indicating that the patient is deteriorating, yet these signs and symptoms of deterioration are not recognized or recognition is delayed. In usual care, even when recognition of deterioration occurs, the process of responding to that patient runs into a range of barriers, including a culture of medicine that is not patient-centered (i.e., concepts of “patient ownership”, autonomy, respect for authority and the “chain of command”) and imbalances in the need (patient) to resource (available physicians, nurses, respiratory therapy, monitoring etc.) ratio. These combined problems of poor recognition and/or poor response create the opportunity for intervention. RRSs have been the primary intervention of choice for the last decade to address the problems of poor recognition (afferent limb) and poor response (efferent limb).

The afferent limb defines the parameters that indicate deterioration and democratizes that knowledge to all clinicians. It also often allows for bedside clinicians (primarily nurses) to trigger the Efferent Limb, even in cases where individual thresholds are not met but the bedside clinician has a “sense” that something is not right. Since these signs often exist for hours before a crisis actually occurs, improving the recognition process through defined criteria and democratization of knowledge should lead to earlier recognition and hopefully intervention before the patient becomes too unstable to be rescued. Providing a critical care response team

that can be directly triggered should also help to circumvent the delays that typically occur in summoning a physician or higher level expertise. Together, these two elements (afferent and efferent limbs) should catch treatable problems early before they are life-threatening. Finally, the feedback component should help make clinicians aware of the need and benefits of using the RRS, the quality improvement component should ensure improvement or maintenance over time, and the administrative component should ensure that adequate resources are available to respond to patient rescue needs.

What Are the Beneficial Effects of the Patient Safety Practice?

RRSs were not addressed as a topic in “Making Health Care Safer.” RRS have mostly been implemented and evaluated since 2000, although a small number of hospitals such as Dandenong Hospital in Australia and University of Pittsburgh in the U.S established them in the mid-1990s.^{1,3}

For this review, a total of 2177 unique abstracts were captured by the search strategy. Of these, 1,982 were excluded during the abstract screening phase. A total of 174 additional articles were excluded at the article screening phase. Twenty one articles in total met the inclusion criteria for this systematic review. Twenty articles met the inclusion criteria for intervention studies evaluating the effectiveness of rapid response systems and 15 articles met the inclusion criteria for intervention studies evaluating the implementation of rapid response systems.

We identified seven systematic reviews of RRSs: The one high-quality review is described below. A second review addressed implementation, and we discuss it in that section. We excluded two reviews from 2007 that contained many fewer publications than reviews published in 2009 or later.^{4,5} We also excluded three additional reviews with low AMSTAR criteria scores (5-6/11); they generally cover the same literature and time period, and report similar findings.⁶

The highest-quality systematic review and only meta-analysis⁷ (AMSTAR criteria score 10/11) identified 18 studies from 17 publications through November 2008, involving nearly 1.3 million hospital admissions. The meta-analysis concluded that, among adults, implementation of an RRS was associated with a statistically significant reduction in cardiopulmonary arrest outside the intensive care unit (ICU) (relative risk [RR], 0.66; 95% confidence interval [CI], 0.54 to 0.80) but not with lower hospital mortality (RR, 0.96). In children, implementation of an RRT was associated with statistically significant reductions in both cardiopulmonary arrest outside the ICU (RR, 0.62; 95% CI, 0.46 to 0.84) and hospital mortality (RR, 0.79; 95% CI, 0.63 to 0.98). The review assessed studies as high quality if they adjusted for confounding and for time trends by using either concurrent control groups or an interrupted time series design. Studies were rated as fair quality if they adjusted only for confounding. Five studies were rated high quality, two as fair quality, and the rest were rated as low quality.

This review identified two cluster-randomized, controlled trials (RCTs) but treated one in their meta-analysis as a concurrent cohort controlled study (the MERIT Study) and the other as a before-after historically controlled trial (Priestley, 2004 which used 3 different methodologies in their analysis one of which was a before-after control). A key finding was that the major multicenter RCT (the MERIT study) did not show an effect in the main analysis. However, in further analysis, the change in arrest rate was exactly as expected given the utilization rates, and exposure to the intervention was well below that which is necessary to realize a significant change. The implication was that the implementation of RRSs may be critical to their success. Additionally, in the MERIT trial, the intervention hospitals did see a statistically significant improvement compared with their baseline period (before/after historical control), but the control

hospitals demonstrated essentially the same before/after improvement as the intervention hospitals. The end result was no difference between intervention and control hospitals. Reasons for the lack of difference may include other systems changes that improved care or decreased mortality, or the Hawthorne effect since the intervention could not be blinded. Post-hoc analysis did show that control hospitals increased their code team calls for non-code events, suggesting that they engaged in “RRS-like” activities using their existing cardiac arrest teams.⁸

We identified 20 additional effectiveness studies that met our inclusion criteria published since this systematic review. None were randomized trials or had a concurrent control group, and only one study included multiple centers. Three studies were in pediatric hospitals. Most occurred in the United States, Australia, or Canada, with only a few in Europe or Asia; most studies were conducted in teaching hospitals. Almost no studies included any information on context, and no studies reported a theoretical or logic model. The number of included hospital admissions or discharges during the study periods ranged from 2426 to 277,717.

Most studies reported the main outcomes of total hospital or non-ICU cardiac arrests and total hospital mortality; some studies also reported variations on these outcomes, such as unexpected or non-DNR cardiac arrests or mortality. Of those studies that reported results and statistics on total hospital (or non-intensive care unit) mortality, 8/14 (57%) reported statistically significantly decreased mortality in the period after the RRS was implemented; one study reported decreased mortality only on the medical (not the surgical) service (the study had separate RRSs for the two services). Two studies that also reported non-DNR or unexpected death rates in addition to in-hospital mortality also found a significant decrease in those outcomes.

Of the studies that reported the outcome of cardiac arrest, 9/14 (64%) reported a significant decrease after implementation of the RRS. One study reported unexpected cardiac arrest and found no significant change; one study reported unplanned intubations and found no significant change. Finally, of the 13 studies that reported outcomes and statistical testing for both cardiac arrest and for mortality, 4 (31%) found different results for these 2 outcomes: 2 found significant results for mortality but not for cardiac arrest, and 2 found significant results for cardiac arrest but not mortality.

The overall strength of evidence for this topic was low. Risk of bias was high for all studies due to study design issues—there were no studies using any type of randomization since the multi-institution MERIT study published in 2005; almost all studies were pre-post, with no interrupted time series or concurrent controls. Few studies reported or accounted for differences in patient populations over time or reported characteristics of providers in the two time periods. Few studies reported or attempted to control for secular trends over time that could have impacted mortality or cardiac arrest rates. The one study that did account for secular trends over time in these outcomes found that, after adjusting for them, the changes in mortality and cardiac arrest rate were no longer statistically significant. No studies reported on or accounted for other safety initiatives in the hospital that might have also contributed to trends in decreasing mortality or cardiac arrests.

No studies conducted blinded outcome assessment; although mortality is an objective outcome, the other key outcome measured, incidence of cardiac arrest, can be defined in a number of different ways (e.g., calling the code team vs. documented use of cardiac compressions, stopped breathing, etc.) and is subject to bias, as are some of the other variations in outcomes reported in some studies (e.g., unexpected mortality vs. total mortality, which required retrospective, implicit assessment of medical records). Ideally, studies should report

cardio-respiratory arrest (codes) rates outside of the ICU and Emergency Departments since these patient populations are not part of the exposure group (RRSs do not respond to these locations), yet often hospital-wide rates were reported. One study⁹ included ICU arrests in their analysis, concluding there was no effect, though data presented on their non-ICU code rate showed a statistically significant difference. Cardiac arrest rates are also affected by changes in patient casemix over time and the frequency of do-not-resuscitate orders and terminal illness, which most studies did not account for.

Most studies reported in-hospital mortality. Only one reported longer-term mortality (such as 180-day mortality) reflecting patient survival more accurately. Most other outcomes reported, such as the cardiac arrest rate, unanticipated intensive care unit admissions, or other health care utilization measures are also indirect outcomes. In terms of precision, we did not identify any additional studies that would have been assessed as high-quality in the 2009 meta-analysis⁷ – all would have been fair or poor quality. Evidence for association of RRSs with lower in-hospital mortality was not strong. A summary table is located below (Table 1).

Table 1, Chapter 24. RRS summary table: effectiveness

Author, Year	Description of PSP	Study Design	Outcomes: Benefits*
Anwar ul, 2010 ¹⁰	PICU physicians (Pediatric MET)	Pre-post	Cardiac arrest: Y
Bader, 2009 ¹¹	Nurse led, with Critical care outreach component (proactive rounding on ICU-discharged patients)	Pre-post	Mortality (non ICU): NR Cardiac arrest: Y
Benson, 2008 ¹²	Advanced practice nurses (APN) with intensivists and other disciplines involved as needed	Pre-post	Mortality: Y Cardiac arrest: NR
Campello, 2009 ¹³	ICU physician and ICU nurse	Pre-post	Mortality: Y Cardiac arrest: Y
Chan, 2008 ⁹	Respiratory therapist and 2 ICU nurses (RRT model)	Pre-post	Mortality: N Cardiac arrest (hospital-wide): N Cardiac arrest (non-ICU): Y
Gerdik, 2010 ¹⁴	RRT (specifics not described) including option for patient and family activation	Pre-post	Mortality: N Cardiac arrest: NR
Hanson, 2009 ¹⁵	PICU fellow, resident, nurse and respiratory therapy	Pre-post	Mortality: N Cardiac arrest (ward): N
Hatler, 2009 ¹⁶	ICU nurse and respiratory therapy (RRT model)	Pre-post	Cardiac arrest: NR
Konrad, 2010 ¹⁷	ICU nurse and ICU physician	Pre-post	Mortality (adjusted total): Y Cardiac arrest: Y
Kotsakis, 2011 ¹⁸	Peds ICU attending and/or fellow, respiratory therapists and ICU nurse, family activation	Pre-post	Mortality (hospital): N Cardiac arrest: N
Laurens, 2011 ¹⁹	MET: anesthesiologist, medical house officer and ICU/ED nurse	Pre-post	Mortality: Y Cardiac arrest: Y
Lighthall, 2010 ²⁰	MET: ICU fellow, anesthesiologist nurse, pharmacist, respiratory therapist	Pre-post	Mortality (all): Y Mortality (non-DNR): Y Cardiac arrest: Y
Medina-Rivera, 2011 ²¹	MET (no specifics given)	Pre-post	Mortality: N Cardiac arrest: N
Rothberg, 2011 ²²	Hospitalist-led MET -critical care nurse, respiratory therapist, intravenous therapist, physician	Pre-post	Mortality (overall hospital): N Cardiac arrest: Y
Santamaria, 2010 ²³	MET: ICU registrar, general medical registrar and the ICU nurse	Pre-post	Mortality (unexpected): Y Cardiac arrest: Y
Sarani, 2011 ²⁴	2 METs – surgery, medicine; critical care nurse, pharmacy, respiratory therapy, resident, ICU attending /fellow	Pre-post	Mortality: Y (Medical service only) Cardiac arrest: Y
Scott, 2009 ²⁵	ICU nurse and respiratory therapy (RRT model)	Pre-post	Cardiac arrest: NR
Shah, 2011 ²⁶	Critical care nurse and respiratory therapist (RRT model)	Pre-post	Mortality (In-hospital): Y** Cardiac arrests: N

Table 1, Chapter 24. RRS summary table: effectiveness (continued)

Author, Year	Description of PSP	Study Design	Outcomes: Benefits*
Snyder, 2009 ²⁷	MET: critical care physician and nurses	Pre-post	Mortality: N Unplanned intubations: N
Tibballs, 2009 ²⁸	MET: hospital's resuscitation officer, RN coordinating position, ICU physician and RN, ED physician and RN	Pre-post	Mortality (in-hospital): Y Mortality (unexpected): Y Cardiac arrest (unexpected): N

*Overall results statistically significant – Yes, No, or NR (Not reported – no statistics reported)

** Significant in early time period but not later

What Are the Harms of the Patient Safety Practice?

Potential harms include decrease in the skills of ward staff due to dependence on the RRS, inappropriate patient care for other patients (decreased responsibility or responsiveness of the usual team), staff conflict, and diversion of critical care staff from usual care in the ICU.² Unexpected beneficial consequences include improvements in the frequency and quality of end-of-life discussions with patients and their families.

Despite several papers discussing these potential harms and unexpected consequences, neither the high-quality systematic review⁷ nor any of the additional studies we identified reported any harms or unexpected consequences.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

External factors. The need for programs such as RRSs is part of the Joint Commission's National Patient Safety Goals (Goal #16): organizations should select “a suitable method that enables health care staff members to directly request additional assistance from a specially trained individual(s) when the patient's condition appears to be worsening.” While this goal does not specifically state RRSs as the correct strategy for meeting the goal, RRS have been the near exclusive response to this requirement. RRSs are also included as one of several interventions in the Institute for Healthcare Improvement's 100K and 5 Million Lives Campaigns (www.ihl.org/ihl/programs/campaign).

Structural organizational characteristics. In the high-quality review, of the 12 studies that reported academic status, 10 were in academic centers and 1 multicenter study included academic and community hospitals. Studies were mainly from Australia and the United States; 2 were in England and 1 was in Canada.⁷

Teamwork/leadership/patient safety, management tools. While the systematic reviews of RRSs we identified and reviewed did not address issues such as teamwork and leadership several papers did so individually.

Jones et al²⁹ analyzed the literature for the implementation issues of factors impacting nurses' use of Medical Emergency Teams. Five major themes emerged: education on the MET, expertise, support by medical and nursing staff, nurses' familiarity with and advocacy for the patient, and nurses' workload.

Rapid response systems have been implemented in a variety of contexts (different countries, and hospital and patient characteristics) and have varied in their composition, activation criteria, and implementation process. In term of composition, the RRS studies reviewed might include physicians, nurses, respiratory therapists, and other staff with different training or based in

different settings (intensive care unit, emergency room), as well as different management, administrative staff, or quality oversight involvement. The majority of studies utilized interdisciplinary teams comprised of at least one physician and one nurse. However, several studies examined alternative RRS configurations. For example, two studies examined systems that leveraged nurse leaders or nurse liaisons as primary first responders.^{12,30} Implementation processes varied widely, often guided by the Institute on Healthcare Improvement (IHI) suggestions or using IHI materials. Education and promotion of the new service was often a factor, although actual staff training (such as simulation training) was uncommon. A variety of different objective criteria were used for calling the team, and some interventions depended on nurses' clinical judgment; a few studies also developed and promoted a system for family or patient initiation of the team.

Fifteen studies met our inclusion criteria for studies of the implementation processes surrounding Rapid Response Systems. Eleven of these studies used quantitative methods, primarily for evaluating the impact of a change in the implementation process for an RRS program, and four used primarily qualitative methods such as interviews or focus groups of staff regarding RRS implementation issues.³¹⁻³³ The majority of implementation studies were conducted in academic hospitals; however two studies specifically detailed implementation efforts within community hospitals.^{31,34} Another study also examined the effects of separating the overall emergency response system into two teams with different activation criteria and processes in order to increase utilization.³⁵ Results indicated significant increases in utilization (15.7calls/1000 admissions vs. 24.7 admissions/1000admissions, $p < .0001$) after changes were implemented.

Activation criteria and reasons for activation were focal study topics related to RRS implementation. Several studies included subjective activation criteria (e.g., staff were worried that a patient was at risk for an adverse event) in addition to traditional activation triggers based on vital sign abnormalities.^{8,35} For example, one study that examined data from the MERIT trial found that MET hospitals were 35 times more likely to activate their emergency response team based upon this "worried" criteria compared with control hospitals (14.1% of activations vs. 0.4% of activations, $p < .001$).⁸

Descriptions of themes in the implementation processes included the categories of technology and tools, staff and training, and barriers and facilitators. In terms of technology and tools, no studies reported use of technology (such as computerized alerts) in RRS implementation. Tools mentioned included changing activation criteria, triggers, or activation methods, including one study changing to mandatory activation based on alert criteria; and review of events, feedback, and rewards. In terms of staff and education, several implementation studies brought on new staff, such as a nurse educator or liaison. Most studies indicated that implementation processes explicitly included educational activities; however, these varied in the degree to which they were strictly information-based (e.g., emails, meetings) or included dedicated training and practice opportunities for either RRS members or staff. The majority of studies also explicitly noted that on-the-job cognitive aids such as posters with activation criteria or badge cards listing activation criteria were included. Finally, barriers and facilitators mentioned included knowledge of activation criteria and other knowledge and attitudes about the RRS; communication, teamwork, and lack of criticism for calling the team; perceptions about the team's helpfulness to nurses and patients; and the importance and role of RRS champions.

One study specifically examined MET processes over time with the maturation of the MET (and therefore potentially higher team skill level and more acceptance from ward staff). The

study found that the proportion of patients with delayed MET activation was significantly lower (40.3% vs. 22%, $p < .001$) and that the proportion of patients with unplanned ICU admissions was lower in a later cohort (31.3% vs. 17.5%, $p < .001$). A summary table is located below (Table 2).

Table 2, Chapter 24. RRS summary table: implementation studies

Author, year	Main Study objective	Implementation Themes
Adelstein, 2011 ³⁶	To assess if new strategies could improve the time to delivery of MET	Tools: centralized activation system, review of all events, automatic escalation to code team if MET did not respond within 30 min Staff/training: nurse educator for training and compliance
Buist, 2007 ³⁰	To assess impact of change programs (education for nurses and housestaff)	Staff/training: nurse liaison, development and education
Calzavacca, 2010 ³⁷	To assess impact of maturation of an RRS on the failure to rescue rate (recognition of deterioration) and associated outcomes	Barriers/facilitators: Maturation of system over time
Chen, 2010 ⁸	To compare reasons for calling emergency help between hospitals with a MET and those without	Barriers/facilitators: worry about the patient, effect of teaching hospital, metropolitan hospital, patient location and time of activation
Cretikos, 2007 ³⁸	To assess process components of MET implementation correlated with utilization	Barriers/facilitators: knowledge of activation criteria, understanding of MET purpose, perceptions of readiness for change, overall attitude to MET program
Donaldson, 2009 ³³	To identify factors associated with successful implementation across hospitals- qualitative	Barriers/facilitators: Extra resources, rapid transfer, communication enhancement, "one stop shopping" (single team assessment), strength of adoption
Forajda, 2003 ³⁹ , DeVita, 2004 ³	To determine if specific educational and feedback interventions would increase MET utilization	Tools: immediate review of all stat sequential paging events, feedback to those involved in delaying MET activation, creating better objective alert criteria, dissemination and education for those new criteria.
Genardi, 2008 ³⁴	To revitalize existing RRT and improve code reductions	Tools: rewards program (recognition of effort), improved documentation, alter alert criteria, increase access to RRT, change to centralized paging Staff/education: education, support for nurses, critical thinking skills, ensure competencies
Jones, 2006 ³⁵	To assess whether systems changes in existing MET would increase utilization rate	Tools: Method of activation (changing activation methods to separate the teams), triggers (changing alert criteria for calling MET) Staff/training: team composition (separation of unified code/MET into separate teams with separate activations), re-education on purpose of MET, criteria, and the changes
Jones, 2006 ⁴⁰	To assess education program to increase utilization of existing MET	Staff/training: education, improved communication, on-the-job aids (e.g., posters, observational charts)
Jones, 2010 ⁴¹	To determine if mandatory MET activation improves outcomes compared with elective	Tools: conversion from elective MET activation to mandatory based on alert criteria
Shapiro, 2010 ³²	To determine nurses' perceptions of RRS impact on practice and what constitutes a successful RRS – qualitative	Barriers/facilitators: Nurse enthusiasm about teams; clarity about when to call team; concerns about being reprimanded for calling team; institutional and individual inertia; concerns about who would care for other patients during a call

Table 2, Chapter 24. RRS summary table: implementation studies (continued)

Author, year	Main Study objective	Implementation Themes
Soo, 2009 ⁴²	To evaluate major features of the patient safety practice champion role	Barriers/facilitators: Both executive and managerial champions were important; were skilled communicators, well-respected and familiar with institutional culture. Champions were educators, advocated for RRT, built relationships, and navigated boundaries between professions/units.
Williams, 2011 ³¹	To clarify nurse perceptions of RRS – qualitative	Barriers/facilitators: advantages of RRT to nurses (develops skills, autonomy, resource and way to circumvent unit problems), perceived benefits for patients; degree of teamwork with RRT; RRT skills; concerns about activating an RRT

Are There Any Data About Costs?

This was not evaluated in the high-quality systematic review by Chan in 2010⁷ or in any of the additional effectiveness or implementation articles that we reviewed.

Are There Any Data About the Effect of Context on Effectiveness?

The high-quality meta-analysis concluded that RRSs were associated with significantly reduced hospital mortality in pediatric but not in adult populations.⁷ Effectiveness appeared high in earlier studies, but less in later studies. In our update, however, we found the opposite to be true. We found that the most recent studies are more likely to demonstrate positive results for mortality. In fact, there were 7 studies in a row, starting with Kenward in 2004 and continuing to Chan in 2008, where the point estimate of effect doesn't go below 0.95. After Chan 2008, all point estimates are < 0.95. Potential explanations for this include maturation of the intervention and improved implementation strategies that may have led to improved results within and across institutions.

We did not find any studies evaluating the impact of context on effectiveness. One study that had two separate MET teams for the two groups showed an impact in a medical, but not a surgical population.²⁴

Conclusions and Comment

In summary, a previous high-quality meta-analysis of 18 studies published from 1990 through November 2008 found that although RRSs were associated with a significant reduction in rates of cardiopulmonary arrest outside the intensive care unit, there was a significant reduction in mortality only in pediatric studies (not in studies in adults). Our update identified an additional 20 studies, none of which was high quality, and the strength of evidence in those studies for the impact of RRSs on in-hospital mortality in both adult and pediatric populations was low.

Tools mentioned in qualitative and quantitative implementation studies included changing activation criteria, triggers, or activation methods, but technology was not mentioned. In terms of staff and education, themes included bringing on new staff or educational activities, but efforts were mainly focused on information rather than training. Finally, barriers and facilitators mentioned included knowledge and attitudes about the RRS; communication, teamwork, and lack of criticism for calling the team; and perceptions about the helpfulness of the team for nurses and patients. Studies included little information about context, and we found no evidence about how context impacted effectiveness or implementation.

Despite their strong face validity, RRSs have exhibited mixed results in the literature. There are several potential explanations for this--none mutually exclusive. The afferent limb can provide clear definitions to identify which patients are likely deteriorating and can educate staff on those definitions. However, activation triggers were originally developed through clinical chart review of patients who had arrested or been transferred to the ICU, and subsequent attempts to improve upon this model have not generated a better approach. Studies of aggregate scores, weighted scores, and single parameter triggers have not demonstrated clear superiority of one over another.² Confounding this approach is the way that vital signs, which constitute most of the data for afferent limb systems, are collected. On general wards, vital signs are, at best, collected every 4 hours and more typically every 6 or 8 hours, leaving ample time for deterioration to develop unrecognized. The fidelity with which vital signs are collected and recorded is also known to be poor,¹ amplifying the problem. Finally, vital signs are not the only variable predicting risk of deterioration. Weighted and aggregated scores try to address this issue, but the interconnectedness of these changes is complex and varies with specific populations.

There are also a number of issues with the implementation of the efferent limb (the RRS team). Optimal team composition is unknown, including the structure (including a physician or not, level or training, and overall team composition), and whether the RRS should be unified with the code team or be separate not only in function but in personnel. Hospitals are reluctant to fund free standing RRSs whose only responsibility is to attend to deteriorating patients and/or arrests. As a result, RRS team members need to leave other duties (often caring for critically ill patients in the ICU) to respond. This may limit the available resources they can bring to the ward patient and risks harm to the patients they have stepped away from. Restricted financial resources may also impact the RRS's ability to self-audit and evaluate code events and unanticipated ICU transfers that occur outside an RRS intervention. As a consequence, the RRS cannot make appropriate assessments in order to improve systematically. Efforts to improve utilization may likewise suffer, especially given evidence that utilization (dose) matters, that utilization can be improved with changes in implementation strategies, and that many programs have low utilization rates. Utilization of RRSs is reported to be low often because of issues with the culture of safety, including reluctance on the part of the ward staff to activate the team.

Finally, there are a number of issues regarding how outcomes in RRS studies are measured. Cardiac arrests and hospital mortality can be affected by many other factors such as patient characteristics and other aspects of care, including trends over time in reducing hospital mortality and length of stay and in caring for more terminally ill patients outside the hospital setting. Additionally, several metrics commonly used to evaluate RRSs count patients who are not exposed to the intervention (i.e., total hospital mortality), potentially affecting the results. Unfortunately, using metrics such as "preventable general ward-only mortality" is more difficult and potentially introduces bias (chart review to determine preventability of a death).

In summary, RRSs are clearly associated with decreased rates of cardiopulmonary arrest, but the question of whether RRSs as currently defined and implemented affects mortality is unclear. Insufficient evidence exists on the impact of context, different implementation strategies, or RRS structure. RRSs are not likely to realize their full potential for improving outcomes without accurate, more frequent (possibly even continuous) and integrated patient specific data to inform the afferent limb, an understanding of what team structure and training works best, greater commitment to fully support RRSs so they can carry out all necessary functions unencumbered,

a greater focus on patient-centered care and patient safety, and improved measurement and reporting. A summary table is located below (Table 3).

Table 3, Chapter 24. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Moderate	Low	Moderate	Moderate/Moderate

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Chapter 25. Medication Reconciliation Supported by Clinical Pharmacists (NEW)

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We have specified support by clinical pharmacists in the title for this review, because the evidence for the clinical impact of medication reconciliation exclusively involves interventions in which pharmacists play a key role. We regarded this specification as important since accreditation standards to implement medication reconciliation do not require involvement by pharmacists. Thus, medication reconciliation as implemented in many hospitals may not achieve the same impacts reported in the literature that led to this required practice.

How Important Is the Problem?

Transitions in care, such as admission and discharge from an acute care hospital or changes in setting within a hospital, place patients at risk for errors due to poor communication and inadvertent information loss. Unintended medication discrepancies represent one well-studied category of such patient safety problems related to information loss at transitions of care.

When patients are admitted to or discharged from a hospital, treating physicians may intentionally make changes to patients' preadmission medication regimens. However, they may also make changes unintentionally (e.g., as the result of not being aware of the full list of preadmission medications or having inaccurate information on the most recent doses). Published studies suggest that 40–54% of patients experience unintentional medication discrepancies upon admission to acute care hospitals.¹ Slightly higher rates of unintentional discrepancies may occur during internal hospital transfers (e.g., intensive care unit to ward), and at least 40% of patients experience discrepancies at hospital discharge.^{2–5} A recent large observational study using population data from Ontario, Canada showed that 187,912 patients admitted to a hospital were at significantly increased risk for unintentional discontinuation of chronic, evidence-based therapies as compared with control patients not admitted to a hospital ($n = 208,468$).⁶ Admission to an intensive care unit carried an even greater risk of unintentional discontinuation of these medications.

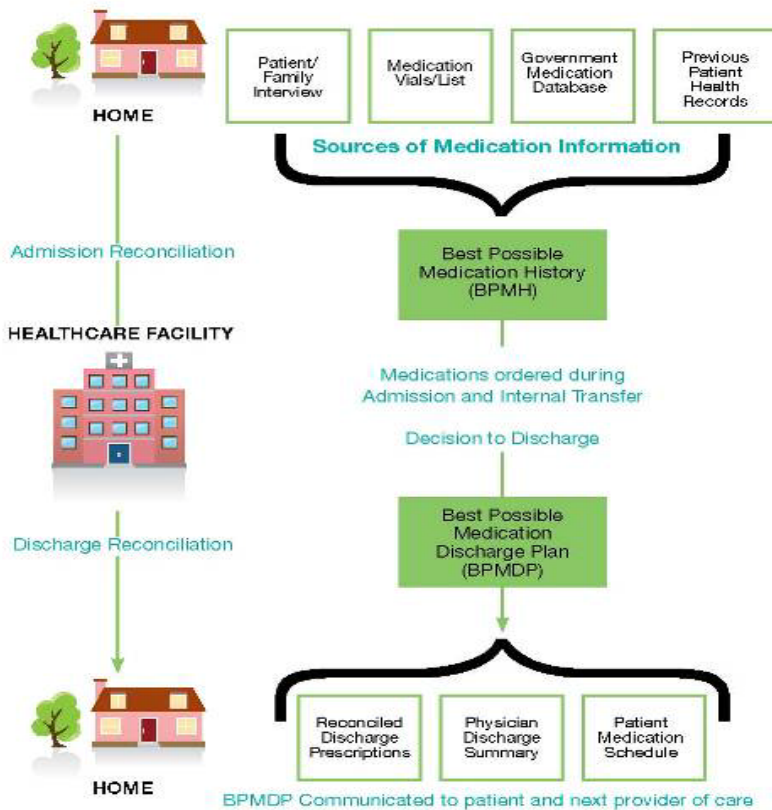
Not all unintended discrepancies carry substantial risks for harm. In a systematic review of unintended discrepancies at hospital admission, only five of 22 studies estimated the clinical importance of errors in the medication history. The proportion of all discrepancies likely to cause clinical problems, as estimated by these five studies, ranged widely from 11% to 59%.¹ The two common categories of unintended discrepancies that contribute to clinical risk are 'omissions'—key prescription and non-prescription medications are inappropriately not started or continued (range: 46–56% of all discrepancies)—and 'commissions'—medications that patients have discontinued are inadvertently re-started.^{1,2,5}

What Is the Patient Safety Practice?

Medication reconciliation is the proposed formal, systematic strategy to overcome medication information communication challenges and reduce unintended medication discrepancies that occur at transitions in care (Figure 1). Ideally, health care providers from

different professions (physicians, nurses, pharmacists) work together and with patients (and their families) to ensure the accurate and consistent communication of medication information across transitions in care.

Figure 1, Chapter 25. Overview of medication reconciliation



Adapted from Pharmacy Practice 2009;25(6):26 with permission

The World Health Organization (WHO) has prioritized medication reconciliation as one of five top patient safety strategies, within the *Action on Patient Safety: High 5s*.⁷ National campaigns targeting the reduction of preventable patient adverse events such as the Institute for Healthcare Improvement’s “100,000 Lives Campaign” in the United States (U.S.) as well as the Canadian Patient Safety Institute’s “Safer Healthcare Now!” have championed medication reconciliation as one of a few core interventions. Furthermore, accreditation authorities such as The Joint Commission in the U.S. and Accreditation Canada made medication reconciliation best practices a mandatory requirement for various health care settings. However, of note, The Joint Commission no longer formally scores medication reconciliation during accreditation surveys, although the latter loosely remains part of the National Patient Safety Goal to “Maintain and communicate accurate patient medication information.”⁸

The ‘Best Possible Medication History’ (BPMH) constitutes the cornerstone for medication reconciliation. The BPMH is more comprehensive than a routine primary medication history, as it involves “(1) a systematic process for interviewing the patient/family; and (2) a review of at least one other reliable source of information (e.g., review of a central medication database, inspection of medication vials, or contact with the community pharmacy) to obtain and verify patient medications (prescribed and non-prescribed).”⁹

Some may argue that ambulatory patients face greater risks from medication problems than do patients in a protected hospital setting. Studies of ambulatory reconciliation have begun to appear.^{10,11} However, most studies of medication reconciliation still focus on the hospital setting, which remains the focus of this review.

What Are the Beneficial Effects of the Patient Safety Practice?

One previous systematic review¹² has summarized the evidence on inpatient medication reconciliation, but this review did not include quantitative synthesis. We sought to quantify the impact of medication reconciliation on unintentional discrepancies with the potential for harm (“clinically significant discrepancies”) and hospital utilization following discharge, as assessed by unplanned emergency visits and readmission to hospital.

To evaluate these impacts of medication reconciliation, we searched major bibliographic databases (MEDLINE, Embase, Cochrane CENTRAL) and scanned article reference lists. Appendix C, Section A and B, present the search strategy, article flow, and methods. Eligible studies reported emergency department visits and hospitalizations within 30 days of discharge or evaluated the severity of clinical significance of unintentional discrepancies. We included randomized controlled trials, before-after evaluations, and post-intervention studies.

All included 18 studies reporting 20 medication reconciliation interventions came from hospitals in the United States or Canada (Table 1). We identified studies with interventions related to medication reconciliation from other countries, but all met pre-specified reasons for exclusion, such as not clearly distinguishing intended from unintended medication discrepancies¹³⁻¹⁵ and assessment of clinical severity performed solely by personnel conducting medication reconciliation.^{16,17}

It is notable that all but three interventions involved pharmacists playing a major role, which does not reflect routine practice, nor is it a requirement in the accreditation standard in either the U.S. or Canada. Some of the studies also involved additional enhancements beyond medication reconciliation itself (Table 2), such as the creation of a single place in the electronic medical record (EMR) to enter and update the preadmission medication history, or functionality in the EMR to facilitate creation of the pre-admission medication history. These characteristics probably also differentiate medication reconciliation as reported in the literature from routine practice.

Table 1, Chapter 25. Studies of medication reconciliation that include assessment of clinically significant unintended discrepancies and emergency department visits and hospitalizations within 30 days of discharge

Study	Setting	Study Design	Transition Targeted	Additional Interventions Beyond Medication Reconciliation	Outcome
Coffey, 2009 ¹⁸	Pediatric ward in academic medical center in Canada	Prospective post-intervention study (272 patients)	Admission to hospital	None	Clinically significant unintentional discrepancies
Cornish, 2005 ²	Medical ward in academic medical center in Canada	Prospective post-intervention study (151 patients)	Admission to hospital	None	Clinically significant unintentional discrepancies

Table 1, Chapter 25. Studies of medication reconciliation that include assessment of clinically significant unintended discrepancies and emergency department visits and hospitalizations within 30 days of discharge (continued)

Study	Setting	Study Design	Transition Targeted	Additional Interventions Beyond Medication Reconciliation	Outcome
Gleason, 2004 ¹⁹	Surgical and medical wards in U.S. academic medical center	Post-intervention study (204 patients, 12 adult medical-surgical units)	Admission to hospital	None	Clinically significant unintentional discrepancies
Gleason, 2010 ²⁰	Medical ward in U.S. academic medical center	Prospective post-intervention study (651 patients)	Admission to hospital	None	Clinically significant unintentional discrepancies
Kripalani, 2012 ²¹	Medical and cardiology wards in two U.S. academic medical centers	RCT (428 patients)	At time of enrollment in study, discharge home, and in-hospital transfer	Discharge counseling	Clinically significant unintentional discrepancies
Kripalani, 2012 ²¹	Medical and cardiology wards in two U.S. academic medical centers	RCT (423 patients)	At time of enrollment in study, discharge home, and in-hospital transfer	Pharmacist intervention including in-patient pharmacist counseling, low-literacy adherence aids, and post-discharge phone call	Clinically significant unintentional discrepancies
Lee, 2010 ⁵	Inpatient wards and critical care units in two academic medical centers in Canada	Prospective post-intervention study (129 patients, 10 patient care units)	In-hospital transfer	None	Clinically significant unintentional discrepancies
Pippins, 2008 ²²	Medical wards in two U.S. academic medical centers	Prospective post-intervention study (180 patients, 7 medical teams)	Discharge home	None	Clinically significant unintentional discrepancies
Stone, 2010 ²³	Pediatric ward in U.S. academic medical center	Prospective post-intervention study (23 patients on 2 medical teams)	Admission to hospital	None	Clinically significant unintentional discrepancies
Vira, 2006 ²⁴	Acute care units in urban community hospital in Canada	Retrospective post-intervention study (60 patients)	Admission to hospital; discharge home	None	Clinically significant unintentional discrepancies
Wong, 2008 ⁴	Medical ward in academic medical center in Canada	Prospective post-intervention study (150 patients)	Discharge home	None	Clinically significant unintentional discrepancies

Table 1, Chapter 25. Studies of medication reconciliation that include assessment of clinically significant unintended discrepancies and emergency department visits and hospitalizations within 30 days of discharge (continued)

Study	Setting	Study Design	Transition Targeted	Additional Interventions Beyond Medication Reconciliation	Outcome
Schnipper, 2009 ²⁵	Medical wards in two U.S. academic medical centers	RCT (162 patients, 7 medical teams)	Admission to hospital; discharge home	None	Clinically significant unintentional discrepancies Emergency department visits and hospitalizations within 30 days of discharge
Dedhia, 2009 ²⁶	Medical wards in U.S. academic medical center, community teaching hospital, and urban community hospital	Prospective before-after study (185 patients)	Discharge home	Safe STEPS intervention including admission assessment, communication with PCP, multidisciplinary discharge meeting	Emergency department visits and hospitalizations within 30 days of discharge
Jack, 2009 ²⁷	Medical ward in U.S. academic medical center	RCT (373 patients)	Discharge home	Nurse discharge advocates created after-hospital care plan, and post-discharge phone call	Emergency department visits and hospitalizations within 30 days of discharge
Koehler, 2009 ²⁸	Medical ward in U.S. academic medical center	RCT (21 patients, 2 hospital-medicine groups)	Admission to hospital, discharge home	Counseling by registered nurse	Emergency department visits and hospitalizations within 30 days of discharge
Koehler, 2009 ²⁸	Medical ward in U.S. academic medical center	RCT (20 patients, 2 hospital-medicine groups)	Admission to hospital, discharge home	Supplemental elderly care bundle: counseling by pharmacist, post-discharge phone call, discharge letter to PCP	Emergency department visits and hospitalizations within 30 days of discharge
Kramer, 2007 ²⁹	Medical ward in U.S. community teaching hospital	Prospective before-after study (136 patients)	Admission to hospital; discharge home	None	Emergency department visits and hospitalizations within 30 days of discharge
Schnipper, 2006 ³⁰	Medical ward in U.S. academic medical center	RCT (92 patients, 4 medical teams)	Discharge home	None	Emergency department visits and hospitalizations within 30 days of discharge

Table 1, Chapter 25. Studies of medication reconciliation that include assessment of clinically significant unintended discrepancies and emergency department visits and hospitalizations within 30 days of discharge (continued)

Study	Setting	Study Design	Transition Targeted	Additional Interventions Beyond Medication Reconciliation	Outcome
Showalter, 2011 ³¹	All admitted patients through emergency department in U.S. academic medical center	Retrospective before-after study (17,516 patients)	Discharge home	Standardized mandatory electronic discharge instructions document with embedded computerized medication reconciliation	Emergency department visits and hospitalizations within 30 days of discharge
Walker, 2009 ³²	Medical ward in U.S. academic center	Prospective quasi-experimental study (358 patients, 2 medical teams and 1 hospitalist service)	Discharge home	Pharmacist-facilitated discharge program including counseling, provision of medication reconciliation list to PCP, and post-discharge phone call	Emergency department visits and hospitalizations within 30 days of discharge

Abbreviations: RCT, randomized control trial; PCP, primary care physician; Safe STEPS, Safe and Successful Transition of Elderly Patients Study.

Table 2, Chapter 25. Key features of the 12 included medication reconciliation interventions

Study	Intervention	Selection for More Complex Patients	Medication History	Electronic- or Paper-Based Medication Reconciliation	Institutional Informatics Functionality	Medication Reconciliation Became Order Process
Coffey, 2009 ¹⁸	Medication reconciliation by pharmacy student	No	BPMH performed by pharmacy student	Paper*	CPOE*	No*
Cornish, 2005 ²	Medication reconciliation by pharmacist, pharmacy student, or medical student	≥ 4 medications	BPMH performed by pharmacist, pharmacy student, or medical student	Paper*	Limited*	No*
Gleason, 2004 ¹⁹	Medication reconciliation by pharmacist	No	Structured history performed by pharmacist or PharmD student	Paper*	Limited*	No*
Gleason, 2010 ²⁰	Medication reconciliation by pharmacist	No	Structured history performed by pharmacist	Electronic*	EMR, CPOE*	No*
Kripalani, 2012 ²¹	Medication reconciliation by physician and nurse	No	History performed by pharmacist	Electronic (at one site)	EMR, CPOE, Preadmission Medication List Builder (embedded at one site)	Yes (at one site)
Kripalani, 2012 ²¹	Medication reconciliation by pharmacist with pharmacist intervention	No	History performed by pharmacist	Electronic (at one site)	EMR, CPOE, Preadmission Medication List Builder (embedded at one site)	Yes (at one site)
Lee, 2010 ⁵	Medication reconciliation by pharmacist	No	BPMH performed by pharmacist	Both*	EMR, CPOE (partial)*	Not reported
Pippins, 2008 ²²	Medication reconciliation by pharmacist	No	BPMH performed by pharmacist	Not reported	Not reported	Not reported
Stone, 2010 ²³	Medication reconciliation by pharmacist	Identification of medically complex conditions based on published guidelines	BPMH performed by pharmacist	Paper*	EMR*	No*
Vira, 2006 ²⁴	Medication reconciliation by pharmacist	No	BPMH performed by pharmacist	Paper*	Limited*	No*
Wong, 2008 ⁴	Medication reconciliation by pharmacist or pharmacy resident	No	BPMH performed by pharmacist	Paper*	EMR, CPOE*	No*

Table 2, Chapter 25. Key features of the 12 included medication reconciliation interventions (continued)

Study	Intervention	Selection for More Complex Patients	Medication History	Electronic- or Paper-Based Medication Reconciliation	Institutional Informatics Functionality	Medication Reconciliation Became Order Process
Schnipper, 2009 ²⁵	Medication reconciliation by physician and confirmed by pharmacist or nurse	No	BPMH performed by physician and verified by nurse and pharmacist	Electronic*	EMR, CPOE, linkage to Preadmission Medication List Builder*	Partial (not at time of study)*
Dedhia, 2009 ²⁶	Medication reconciliation by physician and reviewed by pharmacist	Age ≥ 65	History performed by physician and reviewed by pharmacist	Paper*	EMR, CPOE*	No*
Jack, 2009 ²⁷	Medication reconciliation by nurse	None	Not reported	Electronic*	EMR, CPOE*	No*
Koehler, 2009 ²⁸	Medication reconciliation by nurse and reviewed by pharmacist	Age ≥ 70, ≥ 5 medications, ≥ 3 chronic comorbid conditions, requirement for assistance with ≥ 1 ADL	Not reported	Paper*	Limited*	No*
Koehler, 2009 ²⁸	Medication reconciliation by pharmacist with supplementary elderly care bundle	Age ≥ 70, ≥ 5 medications, ≥ 3 chronic comorbid conditions, requirement for assistance with ≥ 1 ADL	Not reported	Paper*	Limited*	No*
Kramer, 2007 ²⁹	Medication reconciliation by pharmacist and physician	One or more of: ≥ 7 medications, significant comorbid condition, previous admission for ADR, ≥ 4 drug allergies	Structured history performed by pharmacist	Electronic*	Limited (pharmacist electronic order entry)*	Yes*
Schnipper, 2006 ³⁰	Medication reconciliation by pharmacist	None	History performed by pharmacist	Paper*	EMR, CPOE*	No*
Showalter, 2011 ³¹	Medication reconciliation by physician	None	Not reported	Electronic*	EMR, CPOE, electronic discharge program (embedded as force function)*	Not reported

Table 2, Chapter 25. Key features of the 12 included medication reconciliation interventions (continued)

Study	Intervention	Selection for More Complex Patients	Medication History	Electronic- or Paper-Based Medication Reconciliation	Institutional Informatics Functionality	Medication Reconciliation Became Order Process
Walker, 2009 ³²	Medication reconciliation by pharmacist	One or more of: ≥ 5 medications, ≥ 1 targeted medications**, medication requiring monitoring, ≥ 2 changes to regimen, dementia or confusion, or inability to manage medications	History performed by pharmacist	Electronic*	EMR, CPOE, internal electronic pharmacy database*	No*

Abbreviations: BPMH, best possible medication history; CPOE, computerized physician order entry; EMR, electronic medical record; ADL, activity of daily living; ADR, adverse drug reaction

*Information obtained by communication with authors.

**Targeted medications included digoxin, diuretics, anticoagulants, sedatives, opioids, asthma and/or chronic obstructive pulmonary disease medications, angiotensin converting enzyme inhibitor and/or angiotensin receptor blocker.

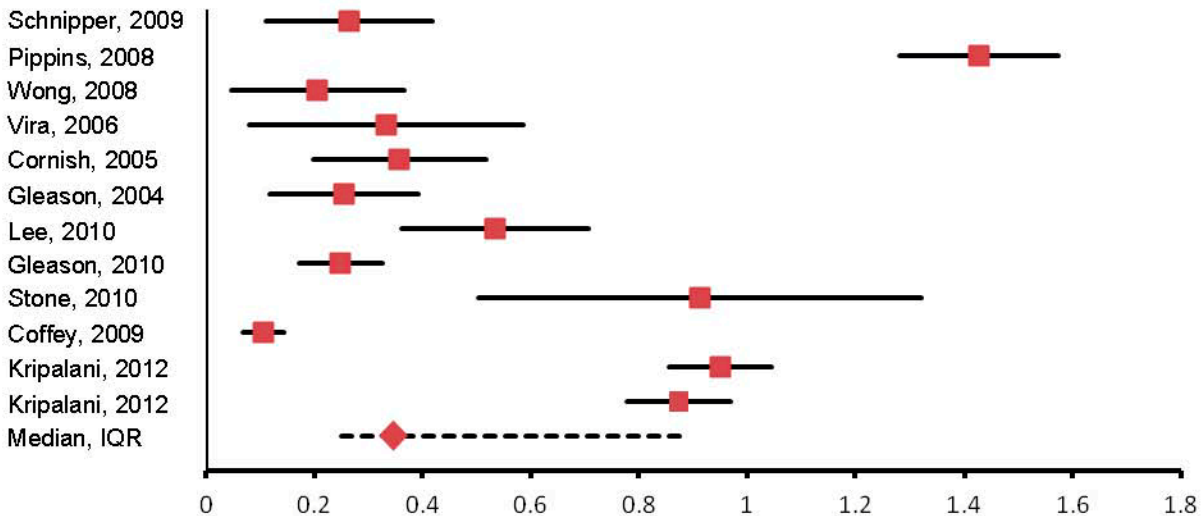
Clinically Significant Unintended Medication Discrepancies

Studies varied in their definitions of clinical importance and categories of severity applied to each medication discrepancy. However, all included studies reported a category that amounted to “trivial,” “minor,” or “unlikely to cause harm,” with all other unintentional discrepancies deemed to be “clinically significant.” This definition corresponds to the term, potential adverse drug events (ADEs), though only three included studies explicitly used this term.^{21,25} We required that assessments of clinical severity be performed by at least one clinician independent from the medication reconciliation process. We also required an explicit statement that unintentional discrepancies were distinguished from intentional medication changes, as well as a clear description of the method for doing so.

As shown in Figure 2, rates for clinically significant discrepancies ranged from a low of 0.11 per patient to a high of 1.43. The only randomized controlled trial of medication reconciliation vs. usual care yielded an estimate of 0.27 per patient, but this result included potential ADEs, not just unintended discrepancies. This study is discussed in more detail below.

Across 13 medication reconciliation interventions, the median value for the number of clinically significant unintentional discrepancies per patient was 0.35 (interquartile range [IQR] 0.25-0.88). Four interventions (2 from the same study²¹) reported notably higher values (Figure 2). No features of the intervention (Table 2), such as selection for high risk patients, inclusion of additional interventions beyond medication reconciliation, or integration with clinical informatics applications explained these outlying results.

Figure 2, Chapter 25. Median and interquartile range for the number of clinically significant unintentional discrepancies per patient for the 13 included interventions



Only a minority of unintended discrepancies had clinical significance. The meta-analytic mean for the proportion of unintended discrepancies that were clinically significant was 35.1% (95% CI: 27.5%-43.6%). This result exhibited significant heterogeneity ($I^2 = 92\%$) as the results ranged from 15% to 54% (median: 34%, IQR 28%-49%). The meta-analytic average for the proportion of patients with at least one clinically significant unintended discrepancy was 39.3% (95% CI: 21.4%-60.5%). This result also exhibited significant heterogeneity ($I^2 = 95\%$), due to a wide range in values, from 15% to 60% (median 45%, IQR 31%-56%).

Only two randomized controlled trials^{25,30} evaluated the impact of medication reconciliation in comparison with usual care using the established concept of adverse drug event (ADE). One trial³⁰ involved randomizing 178 patients being discharged from the medical service at a teaching hospital in Boston to an intervention that included medication reconciliation and counseling by a pharmacist, as well as a follow-up phone call within 5 days. For patients in the control arm, nurses provided discharge counseling and pharmacists reviewed medication orders, but did not perform a formal reconciliation process. Significantly fewer patients in the intervention arm experienced preventable ADEs (1% vs. 11%; $p=0.01$), though total ADEs did not differ between the two groups.

A subsequent, cluster randomized trial from the same research group involved 14 medical teams at two teaching hospitals in Boston.²⁵ The intervention included a web-based application using the hospital's electronic medical record (which included ambulatory visits) to create a preadmission medication list in order to facilitate the medication reconciliation process. Of note, the intervention's effect achieved statistical significance at one of the hospitals, with a relative reduction of potential ADEs (equivalent to clinically significant unintended medication discrepancies) of 0.72 (95% CI, 0.52-0.99), but not at the other (0.87, 95% CI, 0.57-1.32). The authors attributed this difference to variation in the degree to which the two hospitals integrated the medication reconciliation tool into the computerized order entry applications at discharge.

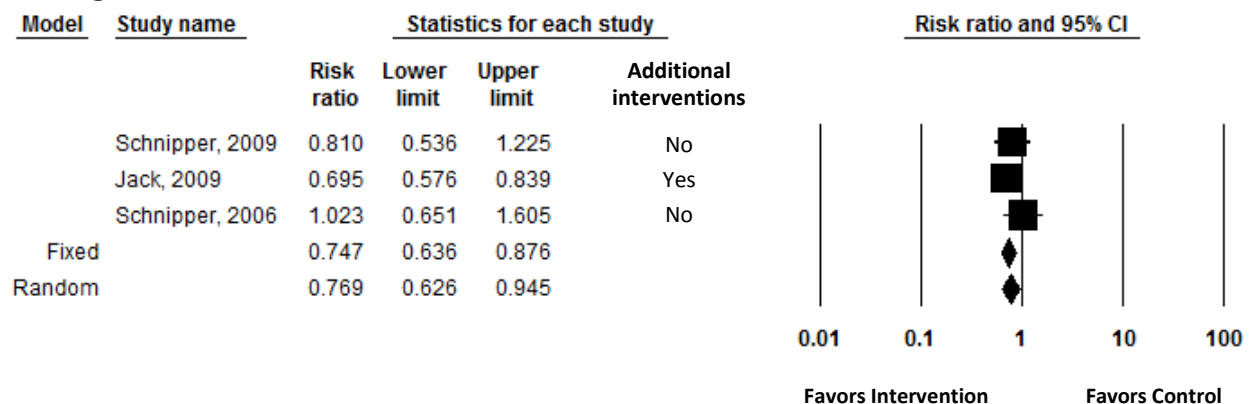
Emergency Department Visits and Readmission Within 30 Days

Across nine medication reconciliation interventions, the median proportion of patients with emergency department visits or hospitalizations within 30 days of discharge was 28% (IQR,

20%-32%). The median rate of hospitalization or emergency department visits across seven studies with control data was 30% (IQR, 22%-31%), a difference that was not statistically significant.

Across three randomized controlled trials, readmissions and emergency department visits were significantly reduced by 23% (95% CI, 5%-37%; I^2 24%) (Figure 3). However, this pooled result was driven by the statistically significant reduction achieved by an intensive intervention³³ that included several interventions beyond medication reconciliation that were specifically aimed at reducing readmissions.

Figure 3, Chapter 25. Emergency department visits and hospitalizations within 30 days of discharge in three randomized controlled trials



With respect to the appropriate time period for observing an impact on post-discharge utilization, it is particularly noteworthy that the two randomized controlled trials^{25,30} that included no additional interventions beyond medication reconciliation did not reduce hospital utilization within 30 days. However, one additional randomized controlled trial³⁴ met all of our inclusion criteria but was excluded because it measured hospital utilization at 12 months, rather than 30 days, following discharge. This trial reported a statistically significant 16% reduction in all visits to the hospital. The intervention consisted of intensive medication reconciliation in which pharmacists identified drug related problems beyond unintended discrepancies, delivered counseling to patients at admission and discharge, and telephoned patients 2 months after discharge to ensure adequate home management of medications.

The lack of impact of medication reconciliation by itself on hospitalization utilization within 30 days of discharge may reflect the need to consider a longer window of observation to demonstrate benefits from resolving unintended medication discrepancies. For instance, inadvertent discontinuation of cholesterol lowering medications, antiplatelet or anticoagulant agents, thyroid hormone replacement, anti-resorptive therapy for osteoporosis, and gastric acid suppression agents all may produce adverse clinical effects requiring hospital utilization in the long term, but not necessarily within 30 days of discharge.

Limitations of the Evidence

As emphasized at the outset, all but three of the 20 interventions that include any assessment of the impacts of medication reconciliation involved clinical pharmacists as a key part of the intervention. Thus, the literature provides evidence only for medication reconciliation supported

by pharmacists, which is not the intervention implemented in routine practice and required by accreditation bodies in the U.S. and Canada.

In two RCTs that evaluated medication reconciliation using ADEs as the outcome, one³⁰ reported a reduction in preventable ADEs, but the other²¹ (a comparably rigorous RCT from the same research group) found only a reduction in potential ADEs at one of the two sites. The remaining included studies evaluated the outcomes that have been judgments about the potential clinical importance of detected medication discrepancies. These judgments are far from straightforward. First, there is the usual problem with inter-rater reliability seen in studies of adverse events and ADEs. Second, assessing the impact of unintended medication discrepancies involves speculation about a number of factors, including not just the potential risk to a given patient associated with the discrepancy, but also the likelihood that the discrepancy will persist and for how long before it is eventually detected by the patient, an outpatient physician, or some later health care encounter.

In the studies that reported particularly serious (e.g., potentially life-threatening) discrepancies, few events were judged to be serious. Moreover, in the widely quoted study of post-discharge adverse events,³⁵ even though one of the examples of post-discharge adverse events involved a medication discrepancy, the subsequent analysis of ADEs highlighted problems with drug monitoring as the most common cause, not problems with medication reconciliation.³⁶

What Are the Harms of the Patient Safety Practice?

Mistakes in the medication reconciliation process have the potential to become “hardwired” into the patient record. Once medication reconciliation has occurred, personnel caring for a given patient may rely exclusively on the documented medication history and be less likely to confirm the accuracy with the patient or other sources.

The larger issue with medication reconciliation concerns the opportunity costs. Clinical pharmacists have proven roles in the prevention of adverse drug events,³⁷⁻³⁹ but they are in short supply in most hospitals. Thus, involving pharmacists in medication reconciliation, the method for which all the evidence of efficacy exists, risks taking these personnel away from other important activities related to patient safety.

How Has the Patient Safety Practice Been Implemented, and in What Context?

The number and intensity of medication reconciliation activities in the literature varies substantially. Table 3 outlines a continuum of varying levels of medication reconciliation intensity ranging from “Bronze” (simply a “best possible medical history” and admission reconciliation) to “Silver, Gold, Platinum and Diamond.” The more advanced levels of medication reconciliation involve progressions in interprofessional collaboration and patient participation, integration of reconciled information into discharge summaries and prescriptions, as well as the delivery of more comprehensive medication education and counseling to patients.

Table 3, Chapter 25. Medication reconciliation in varying levels of intensity as seen in published studies

Level	Key Components	Published Examples
“Bronze”	BPMH with admission reconciliation	Cornish et al. 2005 ² ; Kwan et al. 2007 ³
“Silver”	Bronze + reconciliation at discharge by prescribing physician	Schnipper et al. 2009 ²⁵ ; Wong et al. 2008 ⁴
“Gold”	Silver + discharge reconciliation is interprofessional (e.g., prescribing physician and pharmacist) + Electronically generated discharge prescription	Cesta et al. 2006 ⁴⁰ ; Dedhia et al. 2009 ²⁶ ; Schnipper et al. 2009 ²⁵
“Platinum”	Gold + attention to broader medication issues, such as appropriateness of medication choices (e.g., safe prescribing in the elderly)	Dedhia et al. 2009 ²⁶ ; Murphy et al. 2009 ⁴¹ ; Nazareth et al. 2001 ⁴² ; Al-Rashed et al. 2002 ⁴³
“Diamond”	Platinum + additional elements, such as <ul style="list-style-type: none"> • pharmacist-led medication counseling prior to discharge (including discussion of medication changes) • communicating medication changes directly to community pharmacy • post-discharge follow-up phone call to patient by hospital clinician (e.g., nurse or pharmacist) 	Gillespie et al. 2009 ³⁴ ; Jack et al 2009 ²⁷ ; Karapinar-Çarkit et al. 2009 ⁴⁴ ; Schnipper et al. 2006 ³⁰ ; Walker et al. 2009 ³²

Are There Any Data About the Effect of Context On Effectiveness?

We did not identify any studies that explicitly assessed the differential effect of various contexts on the effectiveness of medication reconciliation. However, we note that our review is limited to interventions within hospitals, so that effectiveness in the outpatient setting is not assessed, and further that the intervention needed to include a clinical pharmacist. Hence, to the extent that “context matters”, these interventions have only been assessed in academically-affiliated hospitals using clinical pharmacists, and effectiveness in other contexts is not established.

Are There Any Data About Costs?

Some studies provided informal data on costs, loosely estimating the amount of time spent by pharmacists performing medication reconciliation and equating that to a dollar value.¹⁹ One model-based study⁴⁵ considered the cost effectiveness of five pharmacist-led strategies for reducing adverse drug events. In this analysis, pharmacist-led medication reconciliation carried a reasonable probability of cost effectiveness (compared with no reconciliation) at £10,000 (\$16,272) per quality adjusted life year. The main limitation of this analysis is the uncertainty surrounding assumptions about reductions in actual ADEs from reducing potential ADEs.

Conclusions and Comment

Medication reconciliation addresses the conceptually plausible and well-documented problem of unintended medication discrepancies introduced at the time of transitions in care. The frequency of non-trivial discrepancies varies across studies—those studies that characterized extremely severe discrepancies reported few such events. One well-designed randomized controlled trial reported a significant reduction in potential ADEs at one of the two study hospitals. The only study that reported a reduction on preventable ADEs (within 30 days of discharge) found no difference in total ADEs. By itself, medication reconciliation probably does

not reduce hospital utilization within 30-days of discharge, but may do so when bundled with other interventions aimed at improving transitions in care. It may by itself reduce hospital utilization over timelines longer than 30 days.

Given limited resources, the paramount issue becomes how to target medication reconciliation in order to direct resources most efficiently. This is especially important given that all but three of the included interventions involved the use of pharmacists to conduct medication reconciliation. Disappointingly, the studies that selected high-risk patients did not consistently report higher rates of clinically significant unintentional discrepancies or show larger effects on readmissions.

This null result could reflect the limited number of studies. But, the high risk criteria used also have plausible limitations. For instance, elderly patients and patients with multiple chronic conditions may take large numbers of medications. However, their medication regimens may remain stable for some time and/or are well known to the patient or their caregivers. These risk factors for unintended medication discrepancies do not account for such nuances. A more direct risk factor is probably frequent or recent changes to medication regimens. Unfortunately, this risk factor cannot be ascertained reliably without conducting a thorough medication history, not unlike the BPMH required for medication reconciliation. A summary table is located below (Table 4).

Table 4, Chapter 25. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues How Much do We Know?/How Hard Is it?
Common/Low	Moderate	Low	Moderate	Moderate/Moderate

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Chapter 26. Identifying Patients at Risk for Suicide: Brief Review (NEW)

Steven C. Bagley, M.D.

Introduction

Patients are often hospitalized after suicide attempts or because of suicidal ideation. However, hospitalization is not fully protective and the inpatient population remains at risk. Many risk factors are associated with inpatient suicide, but – as detailed below – reported rates vary widely, and the importance of this topic derives from the fatality of the outcome in close proximity to care, not primarily from its frequency. Suicide has been frequently associated with certain mental health diagnoses, especially depression and schizophrenia, but the risk of suicide is not limited to patients psychiatrically hospitalized: medical and surgical patients have profound risk factors, including severe pain, altered mental status, and progressive or terminal diagnoses. For all patients, these risks persist, even if patients are placed on special observation status with nursing personnel directly monitoring them.¹

Assessing and reducing the suicide risk for inpatients has become a component of national patient safety efforts. In 1998, The Joint Commission released a Sentinel Event Alert about inpatient suicides based on a review of 65 cases, making brief recommendations about suicide risk assessment, policy and procedures, staff training, and modification of the hospital to reduce environmental risks.² Although the 1998 Alert was not specific to behavioral health units, in 2010 the Joint Commission added a Sentinel Event Alert for inpatient suicide on medical/surgical units and in emergency departments.³ The current Joint Commission (2011) National Hospital Safety Goals include the goal of identifying patients at risk for suicide (NPSG.15.01.0), with three elements of performance (perform risk assessment, identify appropriate treatment environment and safety needs, and provide patient and their family with suicide prevention information at discharge).⁴ National Quality Forum's Serious Reportable Events (2011) lists suicide, suicide attempts, and "self-harm that results in serious injury."⁵ Medicare has placed inpatient suicide on the "never events" list. The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered Never Events. Since then, many states and private insurers have adopted similar policies.⁶

The Agency for Healthcare Research and Quality's evidence report, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices" (2001)⁷, focuses on general safety practices that would extend to psychiatry and other areas of medical practice, and on the relative lack of evidence for behavioral health interventions within the patient safety remit. Consequently, the authors did not specifically address inpatient suicide. The purpose of this narrative literature review is to identify new developments and trends starting from the date of the AHRQ report up to the present.

This review addresses three important questions related to the safety of medical, surgical, and psychiatric inpatients at risk for suicide.

- What is the evidence that clinical, organizational, or environmental programs work to reduce attempts or completions for hospitalized patients?
- What is the state of programs in use at this time?

- What has been learned from their implementation?

To conduct the review, we searched PubMed in October 2011 using major heading search terms Suicide, and Hospital or Inpatient or Safety Management, for English language articles published starting in the year 2000. We expanded the search using the PubMed “related citations” feature, and Google Scholar to search for citing articles of those retained for review; we identified additional relevant articles by reference mining. Clinical trials, large observational studies, reviews, and reports on implementations were given priority. Systematic reviews were scored for methodologic quality using the 11-point AMSTAR scale,⁸ items rated Not Applicable were not counted towards either the score or the total.

What Are the Practices for Reducing Inpatient Suicide?

Systematic reviews by Links⁹ (AMSTAR score 2/10) and Tishler¹⁰ (AMSTAR score 1/10), and informal reviews and expert opinions¹¹⁻¹⁴ have reached generally similar conclusions about programs to reduce suicide risk for inpatients, including: (1) Suicide risk assessment at admission, repeated especially during times of risk elevation such as personal crises, along with careful and consistent chart documentation of these assessments. (2) Treating psychiatric disorders that placed patients at risk, and addressing continuity and followup issues to maintain the patient in treatment after discharge. (3) Removing risk factors in the physical environment. (4) Staff training in risk assessment and communication. (5) Use of staff to observe high-risk patients, and (6) Defining hospital policies in these areas, including those for collecting statistics about suicide attempts and completions.

How Have These Practices Been Implemented?

Identifying Patients at Risk

Bowers et al¹⁵ (AMSTAR score 5/11) conducted a systematic review of 98 articles published in English, German, or Dutch since 1960 covering almost 15,000 inpatient suicides. Given the breadth of articles surveyed, they found a great diversity in suicide rates, trends, risk factors, and timing that reflected the national, cultural, social, and temporal variation. A personal history of suicidal behavior was very consistently associated with suicide completions. Schizophrenia and mood disorders (especially depression) were the leading psychiatric diagnoses. Mechanisms varied with availability; hanging was consistently reported. The mechanisms and rates were associated with location, because patients off-ward on a pass, or having eloped, are typically considered to still have inpatient status, regardless of the actual site of their suicide. Similar results were reported in articles by Kapur,¹⁶ Meehan,¹⁷ Hunt,¹⁸ Combs,¹⁹ (AMSTAR score 4/10). Hunt²⁰ reported an UK survey on suicides after absconding from the ward. Stewart²¹ reported on a retrospective analysis of medical records from hospitals in London and surrounding areas, finding that 10% of psychiatric inpatients made self-harm attempts, and 4% made suicide attempts. Pompili²² (AMSTAR score 3/10) reported a literature review on suicide in patients diagnosed with schizophrenia. Most of the reported deaths occurred while the patient was on leave, or having eloped from the hospital. Specific risk factors for suicides on hospital wards were not reported.

Ballard²³ reviewed 12 case series comprising 335 general hospital suicides (including patients off-ward on a pass), and found slightly different risk factors from those from inpatient psychiatry. The most common medical diagnoses were cancer, cardiovascular and pulmonary

disease. The mental status of patients was infrequently and inconsistently reported. Jumping from a building was the leading mechanism, unlike the pattern seen in psychiatric inpatients and in the general population. Bostwick²⁴ in an informal review of the same area based on a case series of 50 psychiatric consultations from general medical/surgical wards concluded that medical and surgical patients have different risk factors, and a different profile from psychiatric patients, typically by lacking a strong personal history of suicide attempts, psychiatric diagnoses, and substance abuse.

Risk factors, and the difficulties of risk prediction. Suicide is relatively rare, making it difficult to predict even in populations with multiple risk factors and high relative risk. This conclusion, long established for outpatients and the general population, holds true for inpatients as well. Large²⁵ (AMSTAR score 9/11) in a systematic review and meta-analysis of 29 studies concluded that some specific risk factors are associated with inpatient suicide, but using the presence of multiple risk factors to identify high-risk patients produces many false positives, and misses some who will go on to commit suicide in the hospital. They concluded that reducing environmental risks and improving systems of clinical care are likely to have greater effects on suicide reduction than reliance on suicide prediction methods. The difficulties of accurate prediction for inpatients are consistent with conclusions reached by others, including Busch,²⁶ Cassells,²⁷ Paterson,²⁸ Bisconer,²⁹ and the American Psychiatric Association Practice Guideline for the Assessment and Treatment of Patients With Suicidal Behaviors.³⁰

Environmental risk reduction factors. The removal of physical or structural risk factors from the hospital environment has been frequently proposed. Lieberman³¹ and Cardell³² both report expert opinions of this topic, and make specific suggestions for environmental modifications. The modifications follow from the frequency with which hanging is used in inpatient suicide by removing both materials that could form a noose and anchor points for the noose. Most of these recommendations target inpatient psychiatric wards. Bostwick²⁴ notes the difficulties of applying these same recommendations to typically open general medical wards, which are more difficult to secure; they recommended use of nursing observation for those areas.

Experiences of Specific Hospital Programs

A number of reports described implemented program or program components, mostly guided by expert opinion or slight modifications of current practice. Few outcomes data were reported, and the quality of the studies was poor in those that did.

Sullivan³³ described a multi-component suicide reduction program implemented at Elmhurst Hospital Center in Queens, NY, a teaching hospital affiliated with Mount Sinai School of Medicine, with 117 inpatient psychiatric beds, including specialty units for Asians and Latinos. The hospital's psychiatry service implemented a suicide reduction program that included a formal assessment of suicide risk, encouraged accurate diagnosis (taking into consideration the multicultural nature of the patients treated), replaced some use of one-to-one nursing observation with "close" observation (visual observation at any distance, sometimes with a ratio of one nurse for two patients), encouraged careful use of medications, used group sessions for inpatients (on coping in the community, identifying triggers for suicidal thoughts, and listing information about resources available in a crisis), added environmental rounds to remove safety hazards, along with discharge planning and post-discharge followup. They reported a reduction in self-injurious behaviors from 1.4 per 1000 before the intervention to 0.5 per 1000 afterwards. The reported

decrease was described as associated with the component involving the formal assessment of suicide risk; unfortunately, the timing of the other components was not clearly described making it difficult to assess their role in any reduction in suicides or attempts, and in the assignment of causality to their intervention.

Other program experiences are described here more briefly. Temkin³⁴ proposed a “precaution monitoring sheet” to improve the consistency of documentation and communication within treatment team, but did not report of evaluation of it. McAuliffe³⁵ described the implementation of a program at Trillium Health Centre, Ontario, Canada, reporting on their experiences with risk assessment, staff surveys and focus groups, and training workshops; no outcomes data of inpatient suicides were reported. Ellis³⁶ reported on a program, called the Collaborative Assessment and Management of Suicidality, underway at the Menninger Clinic in Houston. The program began with the elaboration of suicide risk assessment into a comprehensive collaborative framework for patient treatment and risk reduction. The framework does not appear to be limited to inpatients. They noted the need for rigorous evaluation and planned to conduct a randomized controlled trial of their program. Ballard³⁷ proposed a framework for organizing the response of a hospital to an inpatient suicide. No evaluation of this framework was reported.

Root Cause Analyses and Related Techniques

Root cause analysis (RCA) is a structured analysis technique originally developed for human factors and systems engineering to retrospectively determine the interrelationship of component elements in causing an observed malfunction or accident. It has been adapted for use in medical and health care systems.

Dlugacz³⁸ reported on the use of the results of RCAs of 17 suicides or suicide attempts at North Shore–Long Island Jewish Health System, Great Neck, NY to design safety strategies. They developed an “inpatient suicide risk assessment and evaluation tool” (apparently for use by RNs), and an “environmental suicide risk assessment tool” used by a multidisciplinary hazard surveillance team to identify environmental risks for all facilities with some specific additional items for behavioral health units. They also developed an alcohol withdrawal protocol, as alcohol problems had been relatively common in their RCA data. They reported “no suicide attempts in the acute care setting” after implementing the alcohol withdrawal assessment protocol. Overall, there had been 6 completed suicides and 11 attempts in the interval from April 1998 to December 2001 represented in the RCAs; after making the implementations, there were no suicides and one attempt from December 2001 to December 2002. No data were reported that would allow assessment of the causal role of the other program components.

Mills³⁹⁻⁴¹ reports on the Department of Veterans Affairs (VA) experience in using RCAs to guide the development of policies and procedures. Their first study³⁹ used information from RCAs from completed suicides and parasuicidal behavior to identify the most common root causes: communication issues (including documentation of risk), policies about suicide risk assessment and treatment, patient stressors, and training or education for both staff and patients. In the second study,⁴⁰ they used VA RCA reports (presumably a superset of those in their previous article) to identify the common locations (inpatient psychiatry) and means of suicide (hanging). They also reported specific details on the anchor points and the material used as a noose, by frequency. Outside of inpatient psychiatric units, drug overdoses were also common. They made recommendations for reducing access to means through engineering interventions to remove common anchor points, and for making regular environmental rounds using a comprehensive checklist. Their environmental rounds checklist was described in detail in their

next report.⁴¹ No outcomes measures were reported. They also noted there was no evidence that the checklist was being used correctly. The target location was inpatient psychiatric units; they recommended using one-to-one observation for general medical units.

Janofsky⁴² reported on the use of Failure Mode Effects Analysis (FMEA), a structured, systematic, prospective methodology from systems engineering, to identify possible system failures, and used this analysis to redesign the communication flow related to observation of psychiatric patients. No outcome results were reported.

Wu⁴³ examined the use of RCAs in medicine generally, and noted a very wide range of skill in performing RCAs accurately, a lack of best practices in reporting and followup, and the absence of peer-reviewed evidence of the effectiveness of RCAs or their cost-benefits tradeoffs.

Observation of At-Risk Patients by Nursing Staff

One important area not frequently mentioned in some reviews is the use of nursing observation. Nursing observation is regularly invoked for patients at risk of suicide (as well as those with risks for violence, elopement, or falls). The practice varies considerably on multiple dimensions. The intensity of the observation can range from intermittent through continuous, and at specified distances from the at-risk patient. Observation also varies in who can initiate it, whether by psychiatrists, psychologists, or nursing staff. There are also differences in the degree of professional training needed to work as an observer, ranging from experienced psychiatric nurses, thorough lower levels of nursing training, other staff, volunteers, or security personnel. The terminology for the practice itself varies, being referred to constant observation, continuous observation, enhanced observation, special observation, constant special observation, and suicide precautions; all of these will be referred to here as observation status. Not considered are the effects of nursing observation on staff morale, patients' perceptions of caring, or the relationship between staff and patients, although it would be expected that these could have second-order effects on patient engagement in treatment and patient safety.

A 2006 Cochrane Systematic Review of non-pharmacological methods for the containment of unsafe behavior found no evidence supported by any randomized controlled trials⁴⁴ (AMSTAR score 7/7). A similar conclusion were reached by Manna⁴⁵ (AMSTAR score 5/10).

Dodds⁴⁶ reported an observational study with a before/after design at an inpatient psychiatric ward in the UK, in which control-oriented formal observation of at-risk patients was replaced by a care-oriented interventions on both an individual and group basis. They reported a two-thirds decline in self-harm episodes in the following year, compared with the year before the intervention. There was one inpatient suicide in the year before, and two the year after, both of the latter while the patients were off the ward on leave. There were staffing changes and changes in the size and demographics of the inpatients during the implementation of the program.

Bowers⁴⁷ reported a survey of 128 psychiatric wards in the UK, finding no relationship between the use of constant special observation and self-harm incidents, but an inverse relationship for intermittent observation: greater use of intermittent observation was associated with lower self-harm rates. This was an observational study, and causality cannot be inferred.

Stewart⁴⁸ reported a longitudinal analysis of 16 wards at three London hospitals. Regression modeling showed no statistical relation between the use of constant special observation (CSO), when the staff person was either within reach of or in sight of the patient, and self-harm incidents. No suicides were recorded. This was also an observational study and subject to the same weaknesses in inference of causality. They noted a wide variation in the profiles of CSO

usage across time, wards, and hospitals, perhaps driven by idiosyncratic differences in staff preferences for or against the use of CSO.

Bowers et al. in their literature review¹⁵ noted that suicide rates showed a mixed association with the presence of nursing observation (at different levels of intensity) in force at the time of the suicide. The cautions about inference from observational studies apply here.

Because the observer cannot be simultaneously engaged in other activities, use of nursing observation can be expensive. More details about cost and the implementation of observation programs at one Massachusetts hospital are reported by Harding.⁴⁹

Most other articles note the lack of evidence that constant observation is efficacious. Issues such as the quality or therapeutic effect of the observer-patient relationship have not been addressed here, but common sense suggests they might vary widely, and have therapeutic or counter-therapeutic effects, depending on the kind of interpersonal relationship between the observer and the patient. Cutcliffe¹ noted that suicides have occurred while the patient was on observation status.

Alternatives to constant observation were explored by Cox,⁵⁰ who proposed an alternative nurse-team framework, with greater nurse autonomy and greater engagement with the patient, along with the use of intermittent observation. These proposals have not been formally empirically tested.

Jayaram⁵¹ reported an informal survey of the use of “15-minute checks” (observation of the patient at least once every 15 minutes), which showed considerable variation in the use of this practice. No outcomes data were reported.

What Have We Learned About Practices for Reducing Inpatient Suicide?

Patients at-risk for suicide are frequently hospitalized, but suicides can be completed by inpatients on psychiatric, general medical, and surgical wards. Risk factors vary across these groups, as do the available mechanisms, typically by hanging in behavioral health units, by jumping or overdose in medical/surgical units. Risk factors are likely to be higher and involve other means in patients for predicting risk suffer from unacceptably high error rates, falsely predicting suicide in those who do not go on to commit it, and not predicting suicide in some who do.

Most existing suicide reduction programs have not been formally or carefully evaluated. Means reduction through careful periodic inspection and reengineering of the hospital ward’s physical structure has been implemented, often based on results of root cause analyses of suicides and suicide attempts. These programs have clear face validity, and are unlikely to elevate risk. However, no controlled trials or high quality observational studies have been performed so the magnitude of any risk-moderating effects is not known, limiting the ability to make strong policy recommendations, or to develop cost-benefit analyses that could guide the deployment of staff and capital resources.

Using staff to observe at-risk patients is a frequently used suicide prevention practice, but there is no evidence from controlled trials showing the magnitude or even the direction of its effect. Several observational studies have shown that the intensity of nursing observation is not associated with reduction in self-harm episodes, but these did not control for the confounding effect of the severity of the patients’ suicidality, which would be expected to both increase their risk of suicide and increase the frequency with which nursing observation would be invoked for their protection. Without controlled experiments, true causality cannot be inferred, and it remains

uncertain if nursing observation raises, lowers, or has no effect on the rates of suicide and self-harm for any given level of suicide risk. The psychological effects of nursing observation on both staff and patients are not the focus of this review; however, these might be expected to have second-order effects, including forging risk-lowering relationships between the at-risk patient and a staff person or, conversely, raising risk by interfering with patient privacy and autonomy, and increasing patient confinement and alienation.

What Methods Have Been Used To Improve Practices for Reducing Inpatient Suicide?

Because there is little empirical evidence to support the suicide prevention practices in current use, recommendations for improving practice have focused on the need for high quality research⁴⁴ including some specifics for making the results useful to both clinicians and policymakers. Although data on completed suicides might seem to be the most valid outcome measure, their use has been questioned because of problems in tracking and sampling, and the statistical noise in the low rates, leading to instability in the measurements.⁵² Future work will likely refer to structure or process measures of quality,⁵³ in addition to, or in lieu of, hard outcomes data. It is expected that continued efforts will necessitate periodic reassessment of this topic area for consideration of review.

Conclusions and Comment

Current practice for the reduction of inpatient suicides is supported by tradition, expert opinion, very limited observational studies of low quality, and the face validity of some of the interventions.

The use of staff to observe at-risk patients is frequently employed, but there is no evidence from controlled trials showing the magnitude or even the direction of its effect.

Recommendations for high quality research in this area, including some specifics for making the results useful to both clinicians and policymakers, have been proposed.⁴⁴ Although data on completed suicides might seem to be the most valid outcome measure, their use has been questioned because of problems in tracking and sampling, and the statistical noise in the low rates, leading to instability in the measurements.⁵² Future work will likely refer to structure or process measures of quality,⁵³ in addition to or in lieu of hard outcomes data. It is expected that continued efforts will necessitate a periodic reassessment of this topic area for consideration of review. A summary table is located below (Table 1).

Table 1, Chapter 26. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Rare/High	Low	Low	Moderate	Little/Moderate

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Chapter 27. Strategies To Prevent Stress-Related Gastrointestinal Bleeding (Stress Ulcer Prophylaxis): Brief Update Review

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Introduction

Stress-related gastrointestinal ulceration is a known complication of critical illness. Disruption of mucosal barriers and gastric acid hypersecretion lead to diffuse shallow mucosal injury and discrete ulcerations in the proximal stomach and duodenum, which in turn can lead to gastrointestinal (GI) bleeding and perforation.¹⁻³ The prevalence of clinically significant bleeding in patients with documented stress ulcers varies from 0.6-15%, and mortality associated with the complication of GI bleeding can be nearly 50%.⁴⁻⁷

Independent risk factors for bleeding include respiratory failure requiring mechanical ventilation for longer than 48 hours and coagulopathy.^{4,8} Other associated risk factors for mechanically ventilated patients include shock of any cause, renal failure, and burns.⁸

Several pharmacologic therapies have been studied for the prevention of stress-induced gastrointestinal bleeding, including proton pump inhibitors (PPIs), histamine-2 receptor (H-2) antagonists, sucralfate, and enteral nutrition. Despite decades of research, significant controversy continues to surround standardization of prophylactic therapy, particularly because of evidence that prophylaxis is associated with pneumonia, inappropriate use, and cost. Independent of prophylactic therapy, rates of clinically significant bleeding have actually declined, likely related to other patient safety practices around management of sepsis and enteral nutrition.⁹

Multicomponent or “bundled” interventions are becoming increasingly common as a method of improving outcomes by preventing complications in ICU patients. Examples of these approaches include the Surviving Sepsis Campaign,¹⁰ which includes stress ulcer prophylaxis and deep venous thrombosis prophylaxis along with evidence-based clinical strategies to improve sepsis outcomes, and the Institute for Healthcare Improvement’s “Ventilator Bundle,” one of the key components of the “100,000 Lives” campaign¹¹ and the Keystone ICU project.¹² Given the wide implementation of these bundles, the key issues around stress ulcer prophylaxis involve not only standardization of therapy with the most efficacious agents but also appropriateness of therapy based on risk assessment, and discontinuation of therapy when appropriate.

The 2001 Making Health Care Safer report reviewed evidence on the epidemiology of stress-related GI bleeding, and included an evaluation of two meta-analyses and one large randomized controlled trial (RCT) on the effectiveness of pharmacologic therapies, including H2-antagonists and sucralfate.¹³⁻¹⁵ Both H2-antagonists and sucralfate were found to be effective at preventing clinically significant GI bleeding in ICU patients, but the overall magnitude of benefit was small. The review found a relatively low incidence of clinically significant stress ulcer-related GI bleeding and a higher cost-to-benefit ratio for low-risk patients. Concern was also raised regarding a possible associated risk of hospital-acquired pneumonia with acid suppression. Therefore, the review concluded that no evidence supported the institution of universal stress ulcer prophylaxis in the ICU. The report recommended considering stress ulcer prophylaxis with either an H2-antagonist or sucralfate for the prevention of GI bleeding in certain high risk ICU

patient populations, including patients with respiratory failure, coagulopathy, renal failure, and/or burns, and considering enteral nutrition for other populations.

What Is Stress Ulcer Prophylaxis?

Pharmacologic acid suppressive therapy has been used to prevent stress-induced GI bleeding in the critical care setting. Previous studies have reported decreased rates of bleeding with agents such as H₂-antagonists, PPIs, sucralfate, and prostaglandin inhibitors. The practice is to treat at-risk patients prophylactically with appropriate therapy to prevent stress-related gastrointestinal ulceration and bleeding.

What Is the Context for the Use of Stress Ulcer Prophylaxis?

Guidelines from the American Society of Health Pharmacists recommend the use of stress ulcer prophylaxis for high risk patients with any of the following conditions: mechanical ventilation >48 hours, coagulopathy (platelet count <50,000 mm³, International Normalized Ratio (INR) >1.5, or Prothrombin Time (PTT) >2× control value), or GI bleeding within the last year; or ≥2 minor risk factors including >1 week ICU stay, sepsis, glucocorticoid therapy, or occult GI bleeding ≥6 days.¹⁶

What Have We Learned About Stress Ulcer Prophylaxis?

In the past decade, several systematic reviews have been conducted on stress ulcer prophylaxis. PPIs have increasingly replaced the use of H₂-receptor antagonists and sucralfate, despite a limited number of studies evaluating effectiveness in comparison to other agents. Thus, the remainder of this chapter will present a recent review of the literature including specific recommendations based on the evaluation of the evidence.

Recent Reviews and Systematic Evaluations

From 2010 to 2011, three systematic reviews compared the effectiveness of acid suppressive therapies,¹³⁻¹⁵ including one systematic review that assessed studies on PPIs.¹⁷

Huang et al.¹⁷ conducted a meta-analysis of 10 RCTs, including 2092 patients, that directly compared H₂-antagonists and sucralfate in mechanically ventilated patients. The main outcome measures were rates of clinically important gastrointestinal bleeding, ventilator-associated pneumonia, gastric colonization, and ICU mortality. While there was a trend towards decreased overt bleeding with H₂-antagonists compared with sucralfate (OR = 0.87, 95% CI: 0.49 to 1.53), sucralfate was associated with a decreased incidence of ventilator-associated pneumonia (OR = 1.32, 95% CI: 1.07 to 1.64). No difference between the agents was found for mortality (OR = 1.08, 95% CI: 0.86 to 1.34). The authors concluded that H₂-antagonists were not more effective in the prevention of overt GI bleeding than sucralfate, but were associated with higher rates of ventilator-associated pneumonia.

Lin et al.¹⁸ evaluated 7 RCTs involving 936 patients that compared H₂-antagonists with PPIs. The meta-analysis reported on the incidence of stress-related upper gastrointestinal bleeding, pneumonia, and ICU mortality. The review found no strong evidence that PPIs were significantly different from H₂-antagonists in the prevention of overt or clinically important upper GI bleeding (pooled risk difference -0.04, 95% CI: -0.09-0.01), pneumonia, or ICU mortality.

Marik et al.¹⁹ evaluated the effect of H₂-antagonists compared with placebo, with specific attention to the role of enteral nutrition as an effect modifier. The review found H₂-antagonists

reduced the incidence of clinically significant GI bleeding, but only in patients not receiving enteral nutrition. In patients receiving enteral nutrition, H₂-antagonists did not affect the risk of GI bleeding; however, this finding is based on only three trials enrolling a total of 262 patients. The possibility that enteral nutrition may have a protective effect on patients' baseline risk of stress ulceration implies that routine acid suppressive therapy may not be necessary even in patients with traditional risk factors. This finding, while exploratory, is certainly worthy of further study.

These systematic reviews suggest that acid suppressive therapy, while effective in preventing stress-related mucosal bleeding, is also associated with significant risks, including pneumonia. PPIs, though widely used, do not appear to be superior to H₂-antagonists in preventing clinically significant GI bleeding.

No New Studies for Effectiveness of Acid Suppressive Therapy for Stress Ulcer Prophylaxis

To date, no additional RCTs or large scale observational or cohort studies of adequate quality have evaluated the effectiveness of pharmacologic acid-suppressive therapy for stress ulcer prophylaxis, apart from those included in the recent systematic reviews discussed above.

PPI Use and Misuse Have the Potential for Harm

The only PPI that is FDA-approved for stress ulcer prophylaxis is omeprazole immediate-release suspension. Overall, data demonstrate that PPIs are becoming the preferred agents of choice for prophylaxis, despite no clear evidence that these agents are superior to H₂-receptor antagonists or placebo.²⁰ Widespread use of PPIs, and inappropriate use, is common in hospitalized patients and is associated with significant cost.²¹⁻²⁵ A survey of trauma ICUs found that the majority of patients continued stress ulcer prophylaxis after leaving the ICU.²⁶ In a retrospective chart review over a 3 month period, Wohlt found 357 patients received stress ulcer prophylaxis in the ICU and 80% continued therapy following transfer out of the ICU. In 60% of these cases, the authors judged that the therapy was continued inappropriately. Approximately 25% of patients were discharged from the hospital with inappropriate therapy, at a total cost of \$13,973.²⁷

Several RCTs and systematic reviews have noted the association between acid suppressive agents, specifically proton pump inhibitors and H₂-receptor antagonists, and risk of nosocomial pneumonia, community-acquired pneumonia and enteric infections, specifically *Clostridium difficile*.^{13,15,17,18,28-31} The risk of hospital-acquired pneumonia extends to patients taking PPIs outside of the ICU. A cohort study of 63,878 non-ICU patients demonstrated that PPI use was associated with development of hospital-acquired pneumonia.²⁹ Inappropriate continuation of acid suppressive therapy, particularly PPIs, after discharge from the ICU therefore can have adverse short-term effects for patients.

Costs and Implementation

Effective prevention of stress ulcer-related bleeding involves implementing methods to both increase rates of appropriate prophylaxis and decrease inappropriate prophylaxis. Much of the literature on increasing prophylaxis rates derives from studies of bundled approaches to ICU preventive practices. The Keystone ICU Project, which ranks as one of the most successful patient safety interventions of the past decade, used a “ventilator bundle” of five practices to

improve safety of mechanically ventilated patients, including stress ulcer prophylaxis.³² This project was remarkably successful at preventing hospital-acquired infections and improving other safety outcomes in the ICU, and also successfully increased stress ulcer prophylaxis rates. Another successful approach to increasing prophylaxis was described by Krinsky et al, who implemented a similar bundle approach incorporating several ICU prophylactic measures, including stress ulcer prophylaxis. The implementation method emphasized team communication, used prompts to providers to address the evidence-based measures on a daily basis, and used a “data wall” to provide real-time feedback.³³ This approach resulted in nearly 100% adherence to bundle use.

Evidence on efforts to control inappropriate prophylaxis use is limited. Coursol and Sanzari described the implementation of an ICU algorithm with specific indications according to guidelines on appropriate use, length of therapy, and cost.³⁴ The algorithm was associated with a reduction in inappropriate use of prophylaxis and costs.

Evidence on the cost of prophylaxis as it relates to implementation is also lacking. The cost of acid suppressive therapy varies, with H2-receptor antagonists being less expensive than PPIs. Decreasing inappropriate PPI use could likely be cost-saving for hospitals.

Conclusions and Comment

Acid suppressive therapy (H2-receptor antagonists and PPIs) and sucralfate are effective in the prevention of bleeding from stress-related gastric ulceration in ICU patients. PPIs are widely used, but are more expensive and no more effective than H2 receptor antagonists. Both types of acid suppressive therapy appear to be used inappropriately, often being continued after patients are discharged from the ICU. This practice raises safety concerns given the association between acid suppressive therapy and pneumonia. While relatively strong evidence indicates that rates of appropriate prophylaxis can be improved through the use of bundled approaches to ICU prophylaxis, evidence on how to limit inappropriate prophylaxis is lacking. Further research in this area is required in order to determine how to target prophylaxis most effectively to patients who will receive the most benefit, while avoiding prophylaxis when it is not required. A summary table is located below (Table 1).

Table 1, Chapter 27. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues How Much do We Know?/How Hard Is it?
Rare/Moderate	Moderate	Moderate (pneumonia)	Moderate	Little/Not difficult

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Chapter 28. Prevention of Venous Thromboembolism: Brief Update Review

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Introduction

Deep venous thrombosis (DVT) refers to occlusion within the venous system, most commonly of the lower extremities, which can lead to pulmonary embolism (PE), or embolism to the pulmonary vasculature. Venous thromboembolism (VTE), comprising PE and DVT, is estimated to account for 5 to 10 percent of all deaths among hospitalized patients,^{1,2} and also is associated with significant morbidities. In 2008, the United States Surgeon General issued a Call to Action to Prevent DVT and PE. The report brings to light the huge numbers of patients afflicted by DVT (350,000-600,000) and killed by PE (>100,000) every year in the United States.³ Even though high quality evidence exists for safe and effective strategies to reduce the risk of VTE, studies continue to show that many hospitalized patients are not given risk-appropriate VTE prophylaxis. One recent study across 32 countries found that only 59 percent of at-risk surgical and 40 percent of at-risk medical patients received guideline-recommended VTE prophylaxis⁴ and a United States registry study found that only 42 percent of patients diagnosed with DVT during a hospitalization had received prophylaxis.⁵

The Agency for Healthcare Research and Quality (AHRQ) has indicated that delivery of appropriate VTE prophylaxis is an essential patient safety practice and one that can prevent in-hospital death.⁶ As of 2011, the National Quality Forum (NQF) has 10 VTE-related standards and endorsed outcomes measures.⁷ Evidence-based best practice prophylaxis varies by primary service (e.g. medicine, surgery, trauma, orthopedics) and patient risk factors. Risk of VTE among hospitalized patients varies based on several risk factors including medical condition, type of surgery, trauma, cancer, age, immobility, hypercoagulable state, and previous history of VTE. Most hospitalized patients have one or more VTE risk factors, and well-developed guidelines are available that specify which types of patients should receive prophylaxis measures, and which specific measures are most appropriate.¹

The original report, *Making Health Care Safer*, reviewed the effectiveness, safety, cost-effectiveness, and indications for VTE prophylaxis. This review concluded that whereas VTE prophylaxis shows clear benefits for a number of conditions and minimal concerns regarding adverse events, the practice remains underused. A small number of interventions aimed at improving use of prophylaxis were reviewed. The current review provides an update on the most effective VTE prophylaxis regimens as well as on interventions aimed at improving adherence to guidelines on the use of these preventive strategies. A MEDLINE search was conducted from 2001 to 2011 to identify studies that assessed the effectiveness and safety of VTE preventive measures as well as those aimed at improving their use.

What Are the Practices for Preventing Venous Thromboembolism?

Both pharmacologic and mechanical prophylactic interventions have been demonstrated to be effective in preventing many VTE events and have been evaluated for their appropriateness for certain types of patients (medical vs. surgical) with certain risk factors.^{1,8} Pharmacologic prophylaxis includes low dose unfractionated heparin; low-molecular weight heparins, including

enoxaparin, dalteparin, and fondaparinux; warfarin; and aspirin, along with newer classes of anti-thrombotic agents. Mechanical prophylaxis includes anti-embolic stockings and intermittent pneumatic compression devices. Because the underlying approach of all prophylaxis medications is to decrease clotting, they may increase the risk of bleeding. The balance between bleeding and clotting must be considered in every patient, and the benefits and harms must be weighed before administering these drugs. For this reason, patient risk stratification is paramount to ensure that only at-risk patients are treated and that they receive the right prophylaxis. Ongoing clinical research and evidence-based medicine reviews suggest that blanket approaches that give the same medication to all patients without risk stratification may not be beneficial and may even cause more harm than benefit.⁹⁻¹¹

New Medications for VTE prophylaxis

New versions of low molecular weight heparins (LMWH) are being brought to market, with additional newly approved indications by the U.S. Food and Drug Administration (FDA). In addition, other medications with different pathways of action are being researched and approved. Most recently in July 2011, rivaroxaban, an oral direct Factor Xa inhibitor, was approved by the FDA for prophylaxis of DVT/PE in adults undergoing hip and knee replacement surgery. Dabigatran, an oral direct thrombin inhibitor, is FDA approved for prevention of stroke in patients with non-valvular atrial fibrillation. Although it is not currently approved for VTE prophylaxis in the United States, it is being used in this capacity in some European countries and Canada. A recent systematic review and meta-analysis of three novel oral agents, dabigatran, apixaban and rivaroxaban, for VTE prophylaxis after total hip and total knee replacement surgery found no difference in net clinical benefit. In fact, this review reported that success in prevention of VTE was inversely associated with clinically relevant bleeding.¹² These findings are indicative of the diminishing returns associated existing medications developed to prevent VTE and highlight the need to improve prescription of the best-practice medications currently available.¹³

Inferior Vena Cava Filters

New technologic advances in devices to prevent DVT from becoming PE via mechanically trapping the clot in the inferior vena cava before they can reach the heart and lungs may be beneficial in some patient populations. Although originally designed for permanent use, multiple approved devices can now be placed for temporary (also known as “optional” or “retrievable”) prophylaxis and then removed at a later date. However, the evidence to support the use of this technology is unclear.

For example, the placement of inferior vena cava filters (IVCFs) is rapidly increasing among trauma patients¹⁴ for primary prophylaxis against PE even in patients without proven DVT. Clinical uncertainty remains about whether prophylactic IVCFs should be used in trauma. Current guidelines from the American College of Chest Physicians (ACCP)¹ and the Eastern Association for the Surgery of Trauma (EAST)¹⁵ have diametrically opposed opinions on the use of IVCFs for primary PE prophylaxis. An ongoing AHRQ sponsored Evidence-based Practice Center Systematic Review Protocol entitled “Comparative Effectiveness of Pharmacologic and Mechanical Prophylaxis of Venous Thromboembolism among Special Populations” will assess the role of IVCFs in the prevention of pulmonary embolism in trauma and other special populations (including those patients undergoing bariatric surgery).

What Approaches Have Been Used To Improve Appropriate VTE Prophylaxis?

Evolution of information technology is enabling development of more sophisticated clinical decision support systems to improve compliance with guidelines. Several recent examples are described below.

Lesselroth et al,¹⁶ developed a clinical decision support-enabled order menu in their computerized patient record system (CPRS) to recommend appropriate VTE prophylaxis at the time medication orders are written at the Portland Oregon VA Medical Center. After identifying and addressing some key initial limitations (providers could unintentionally or intentionally bypass the order menu and recommended guidelines), use of the order menu increased from 20 percent to 80 percent. This study underscores the need for interventions to integrate well into provider workflow and ideally be mandatory without any possibility of ignoring or bypassing the VTE algorithm. Alerts and systems are only effective if they consistently reach their intended target.

In the study by Beeler et al,¹⁷ an electronic alert was displayed in the medical chart of every hospitalized medical patient who did not have pharmacological or mechanical VTE prophylaxis ordered within 6 hours after admission and had documented VTE risk. Rates of thromboprophylaxis orders among medical patients significantly increased from pre-implementation rates of 43.4 percent to 66.7 percent ($p < 0.0001$) during the 4 months after implementation. The following year, thromboprophylaxis orders increased further to 73.6 percent ($p = 0.011$).

Kucher et al,¹⁸ proactively searched for hospitalized patients at risk for developing VTE who were not prescribed prophylaxis (pharmacological or mechanical). Electronic alerts were sent to providers of patients randomized to the intervention group that their patient was at risk for VTE. Patients in the intervention group were significantly more likely to receive mechanical prophylaxis ($p < 0.001$) and significantly more likely to receive prophylactic doses of unfractionated heparin ($p < 0.001$). There were no significant changes to orders of enoxaparin ($p = 0.18$) or warfarin ($p = 0.11$) between intervention and control groups. In addition, patients in the intervention group were significantly more likely to be free from DVT or PE after 90 days ($p < 0.001$). This approach is reactive – it identifies patients who were not initially ordered prophylaxis and then attempts to correct the patient safety problem, rather than suggesting and improving rates of prophylaxis at the appropriate time of initial treatment.

In 2008, a mandatory, computerized decision support-enabled VTE risk stratification order set was implemented in the computerized provider order entry system at the Johns Hopkins Hospital to recommend ACCP guideline-appropriate, service-specific (e.g. medicine, general surgery, trauma, etc.) prophylaxis for an individual patient's risk stratum.^{19,20} Within the first year, adherence to guideline-appropriate VTE prophylaxis increased significantly hospital-wide and rates of VTE have been on a decreasing trend. This system overcomes the downsides of the Kucher approach since it requires proactive risk stratification during the completion of the admission order set for all admitted patients and therefore is nearly 100 percent effective at forcing providers to assign an appropriate risk stratum to all patients within 24 hours of hospital arrival.²¹ However, this system remains fallible since the guideline-suggested VTE prophylaxis is merely a recommendation; it is not mandatory and may be ignored.

What Have We Learned About These Practices?

What Are the Beneficial Effects of VTE Prophylaxis?

The original “Making Health Care Safer” report focused on the evidence for effectiveness of specific clinical interventions (i.e. medications and mechanical prophylaxis) for specific clinical situations, and concluded that there was extensive evidence supporting their effectiveness and low cost, particularly after certain types of surgical procedures, trauma, and medical conditions such as cerebrovascular accidents.²² Quality improvement-related interventions such as practice guidelines, clinical decision support systems, and educational interventions to change provider behavior were addressed in separate chapters in the original support. A few studies found beneficial effects of clinical decision support systems and educational interventions, both separately and combined.

The updated evidence for VTE prophylaxis in selected patients has been well-described in a variety of recent evidence-based clinical guidelines and systematic reviews.^{1,10,15} The evidence for clinical interventions for VTE prophylaxis remains strong in specified populations, and prophylaxis is recommended by practice guidelines for those patients, although it should not be applied universally. Since the availability of medications and condition-specific evidence is rapidly evolving and these guidelines are regularly updated, this evidence is not summarized here, and the remainder of this section focuses on interventions intended to improve compliance with risk-appropriate VTE prophylaxis among different patient populations.

Interventions To Improve Prophylaxis Adherence

A systematic review of interventions to improve VTE prophylaxis use in hospitals, based on literature searches from 1996-2003, found 30 eligible studies; only one was an RCT and only three had concurrent controls. Strategies included passive dissemination, which had little effect (50% compliance), single-strategy studies (12 studies—audit and feedback, documentation aids, and quality assurance activities all produced about 80% compliance), and clinical decision support systems approached 100 percent compliance. Twelve studies incorporated two or more strategies, usually including an educational component, and all demonstrated improvements in use of VTE prophylaxis. In addition to the types of strategies used in the single-strategy studies, these studies also included strategies such as advertising, appointment of specific implementation staff, and recruitment of local change agents or opinion leaders. Most studies evaluated change in provider behavior, not patient outcomes, and no study that evaluated outcomes demonstrated a reduction in DVT or PE rates, often due to lack of adequate power.²³

Interventions to improve adherence to prophylaxis include implementation of clinical decision support tools, financial disincentives, and outcomes reporting. Clinical decision support tools have the potential to improve adherence to guideline-appropriate prophylaxis ordering^{24,25} which may then have a sustained impact on clinical outcomes. While this method has classically taken the form of paper-based order-sets, as computerized provider order entry systems are adopted in hospitals across the country, an opportunity exists to build electronic clinical decision support into these systems to evaluate, risk stratify patients based on individual patient risk factors and recommend the appropriate VTE prophylaxis strategies.

Outcomes reporting is another approach to improve VTE prophylaxis, through feedback and public reporting or the financial incentive of nonpayment for VTE events. The Centers of Medicare and Medicaid Services (CMS) placed VTE after orthopedic hip/knee replacement on their list of “never events” for which providers will not be reimbursed. However, even with best

practice, not all VTE events can be prevented;^{26,27} it has been estimated that best practice prophylaxis may reduce incidence of DVT by up to 70 percent.¹ Another potential limitation to the use of DVT/PE rates alone to measure quality is the significant issue of surveillance bias—because many DVTs are clinically silent and therefore go undetected without routine screening.²⁸ For example, in the field of trauma surgery, clinical ambiguity persists regarding the clinical and cost effectiveness of the screening of high-risk asymptomatic trauma patients for DVT with duplex ultrasound.²⁸ As a result, certain providers and hospitals report higher DVT rates due entirely to higher rates of diagnostic testing— a classic example of surveillance bias.²⁹⁻³¹

Because of these issues—and variation in patient risk—unadjusted VTE rates are likely not appropriate for public reporting. A better definition of preventable harm may be obtained by combining an outcome and process measure rather than relying on an outcome alone. For example, it has been suggested that only VTE events occurring in patients who did not receive adequate prophylaxis should be labeled a “preventable VTE.”²⁸ This approach and specific definition has been incorporated as one of the six Meaningful Use Quality Measures related to VTE,²² although this measure has not yet been evaluated for its impact on VTE prophylaxis compliance.

Conclusions and Comment

Strong evidence from numerous high-quality trials supports the effectiveness of VTE prophylaxis for specific populations, although there are significant risks and risk stratification is necessary to ensure that prophylaxis is targeted to appropriate patients. However, rates of VTE prophylaxis are suboptimal, and VTE remains a difficult and elusive crisis in patient safety. Less evidence exists on which interventions are effective for increasing rates of VTE prophylaxis in appropriate populations. As with other patient safety interventions, educating providers on the benefits of appropriate VTE prophylaxis alone is not an effective strategy to improve appropriate use of VTE prophylaxis. Evidence, although mostly low-quality, non-randomized studies without concurrent controls, supports that education combined with other quality improvement strategies, and information technology approaches such as mandatory computerized clinical decision support, appear to offer the most effective approaches to promote best practice prophylaxis use and prevent patient harm resulting from VTE. A summary table is located below (Table 1).

Table 1, Chapter 28. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	High	Moderate (bleeding)	Low	Little/Moderate

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Chapter 29. Preventing Patient Death or Serious Injury Associated With Radiation Exposure From Fluoroscopy and Computed Tomography: Brief Review (NEW)

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Introduction

Fluoroscopically- and computed tomography (CT)-guided diagnostic and interventional procedures are being performed with increasing frequency worldwide. From 1980 to 2007, annual performance of CT in the U.S. increased from 3 million¹ to 80 million.² With this rapid increase in the use of imaging techniques, there has been a concurrent increase in patient exposure to ionizing radiation.¹

Effects associated with radiation can be categorized as either deterministic or stochastic. Deterministic effects manifest themselves in a relatively short time after a high-intensity exposure to radiation (e.g., 1 or more sieverts).³ In 1994, approximately 50 radiation-induced burns were reported to the U.S. Food and Drug Administration (FDA). In 2000, a review of 73 reports of radiation-induced skin injuries⁴ identified fluoroscopically-guided procedures as the cause of 38 severe skin injuries (e.g., chronic ulceration); 18 requiring skin grafts.^{5,6} Radiation-induced burns have also been reported after extended radiation exposure during CT brain perfusion scans.⁷

Stochastic effects are increased risks of various conditions (e.g., cancer, heart disease) that manifest themselves over a longer time period. Recent estimates indicate that CT scans performed in the U.S. in 2007 will be related to approximately 29,000 future cancers; killing nearly 15,000. Almost one half of the projected cancers will be due to scans of the abdomen and pelvis.⁸ Experts indicate that more than 400 patients (across eight U.S. hospitals) who recently received “higher-than-expected” radiation doses while undergoing CT brain perfusion scans may now face long-term risks of cancer and brain damage.⁹

What Are the Practices for Reducing Ionizing Radiation Exposure?

The core principle governing the use of ionizing radiation is ALARA (As Low As Reasonably Achievable). The goal of ALARA is to reduce both patient and technician exposure to ionizing radiation without compromising diagnostic or therapeutic efficacy. Several measures recommended by national organizations to reduce patient’s exposure to ionizing radiation are discussed below.

Technical measures. The American College of Radiology (ACR), the Radiological Society of North America (RSNA), the American Association of Physicists in Medicine (AAPM), and the American Society of Radiologic Technologists (ASRT) are primary participating members in the Image Wisely campaign.¹⁰ On its Web site (imagewisely.org), a list of technical mechanisms for dose reduction during CT include x-ray beam filtration, x-ray beam collimation, tube current modulation, peak kilovoltage optimization, improved detector efficiency, and noise-reduction algorithms.^{11,12} In 2010, task force members of the U.S.-based Conference of Radiation Control Program Directors (CRCPD)¹³ recommended technical methods during fluoroscopy:

- Minimize x-ray beam time
- Vary the site of the entrance port on the patient as clinically possible
- Optimize collimation
- Use the least amount of machine magnification possible
- Position the x-ray source and image receptor optimally
- Apply machine dose reduction features (e.g., last image hold feature, pulsed fluoroscopy)
- Maintain equipment in good repair and calibration

Appropriate utilization. Steps to improve use of diagnostic imaging by referring physicians include reexamining the need for more dose-intensive diagnostic imaging, which may affect the number of self-referrals.¹¹ As one of several U.S. physician groups participating in the Choosing Wisely Campaign, the ACR recently identified imaging exams that, although commonly used, might be unnecessary.¹⁴ To reduce unnecessary imaging, ACR recommended further physician-patient discussion before scheduling five specific imaging exams. The list includes imaging for uncomplicated headache absent specific risk factors for structural disease or injury and imaging for suspected pulmonary embolism without moderate or high pre-test probability of pulmonary embolism.¹⁵ The ACR recommendations were based on a review of professional guidelines and published evidence.

The ACR also suggests that regularly posting individual physician ordering patterns, whether appropriate or inappropriate, may positively influence physician ordering behavior through peer pressure. This practice may be especially helpful for non-physicians (e.g., physician assistants, nurse practitioners) who may be ordering imaging studies, and whose ordering patterns are likely to reflect the behavior of their supervising physicians.¹⁶ The ACR also sponsors registries (e.g., Dose Index Registry), which provide participating facilities with feedback on their radiation-exposure levels in comparison with nationwide levels and those from other institutions.¹⁷ Prior and recent successes have been reported in providing physician feedback and the psychology underlying it.¹⁸⁻²⁰

Education and training. Referring physicians must be thoroughly educated on radiation safety in order to routinely consider this factor when ordering imaging examinations. Technologists should be trained to ensure that proper procedures and techniques are followed to prevent the need for repeated imaging due to suboptimal image quality. Technologists can also notify a radiologist when a duplicate questionable examination is ordered. Substituting less dose-intensive modalities (e.g., MRI, ultrasound and radiography in lieu of CT) should also be considered.¹⁶ According to the CRCPD, training of fluoroscopist and staff on the biological effects of ionizing radiation is one of three components of a comprehensive radiation dose management program. Two remaining components are monitoring and tracking of fluoroscopic dose and patient follow-up.

Algorithms and protocols. CT-related strategies targeted to Imaging Physicians by the Image Wisely campaign include use of adaptive iterative reconstruction and development of protocols that maximize diagnostic yield while minimizing dose. A few preliminary studies have suggested for example that more limited CT of the lower abdomen and pelvis (versus standard practice to perform CT of the entire abdomen and pelvis) should be performed to evaluate conditions such as suspected appendicitis.²¹⁻²³ Adjustment of CT protocols to reduce radiation exposure according to factors such as body mass is also a recommended strategy.²⁴

How Have These Practices Been Implemented?

Studies focusing on radiation exposure reduction measures during fluoroscopy and CT were mostly conducted at single institutions at a university hospital setting. The largest study examined efforts among 15 imaging centers involved in a Mid-west consortium.

Fluoroscopy. Lee et al. evaluated the effectiveness of a quality assurance (QA) protocol to reduce radiation exposure during fluoro urodynamics.²⁵ Prior to implementation, this institution identified many unnecessary images that did not contribute to the diagnostic value of a patient's study. In this study, fluoroscopic imaging helped to visualize the anatomy of the lower urinary tract in 97 patients diagnosed with urinary incontinence, urinary retention, and other conditions. The QA protocol, limiting fluoroscopy to 4-5 static images, was distributed to all physicians, nurses, and radiology technicians involved in the procedure. The importance of radiation safety was emphasized to all staff involved in the procedure. This QA protocol was limited to anteroposterior views in the sitting position so generalizability of this protocol may be limited.

Ngo et al.²⁰ evaluated cases of unilateral ureteroscopy for stone disease. First steps to implementation included working with operating room (OR) personnel to track fluoroscopy time as an additional step in their post-procedural documentation. This process was not widely publicized and "required minimal changes to existing OR staff workflow."

The multicomponent QA protocol evaluated in Greene et al.²⁶ started with a detailed review of prior imaging, which was later placed in front of the scrubbed surgeon on a high-definition monitor during the entire case. In addition, while previous radiation-reducing measures were performed without regard for respiratory motion, the fluoroscopy-reducing protocol included C-arm activation timed with the patient's respiration. Key to implementation was participation of a designated fluoroscopy technician "acquainted with the protocol goals and completely familiarized with the fluoroscopy machine usage and relevant urological anatomy."

Lakkireddy²⁷ reported use of four high-dose lithium fluoride thermoluminescent dosimeters, a direct method to measure patient exposure. As a relatively new technique, atrial fibrillation (AF) catheter ablation involves a steep learning curve. Staff physicians, the primary operators during the procedure, were described as having experience performing more than 400 AF ablations. Three of the four studies described above stated adherence to the ALARA principle as an external influencer.

Computed tomography. Implementation tools used in one study²⁸ included the use of "real" and "distractor" stickers to blind study radiologists to the location of the region of tenderness. Staff participating in the study was also blinded to clinical information, including the patient's original radiology reports. Broder et al. indicated that targeted CT strategies that focus on scan length optimization may be inappropriate under certain conditions such as the need to visualize an entire structure (e.g., aorta) or "when diffuse abdominal processes are strongly considered" (e.g., bowel obstruction). Changes in clinical practice in one study¹ included the integration of computed tomography angiography (CTA) as part of routine imaging in monitoring patients for development of vasospasm.

The first step in implementing an imaging algorithm in another study was providing an imaging protocol to the ED staff.²⁹ A collaborative approach between imaging services (including radiology and nuclear medicine) and the ED staff followed soon after. If ED staff requested a CTPA [computed tomographic pulmonary angiography] for a patient with a normal chest radiograph, an action that violated the protocol, a radiologist would followup with the ED

by phone or email to discuss the request. Implementing this patient safety practice has encouraged the ED at this institution to implement additional radiation reduction measures for other diagnoses (e.g., renal colic).

Use of prospective gating was a core element of radiation reduction measures in two studies.^{30,31} Other measures used in one study³⁰ included limiting scan length, minimizing tube current or voltage according to body physique, use of small bowtie filters, and tube current modulation during cardiac cycle. A collaborative effort amongst three sites was involved in protocol development in one study.³¹ LaBounty states that two measures (prospective ECG gating and 100-kV tube voltage imaging) were only used in 92% and 67% of patients, suggesting that additional radiation reductions would have been possible if protocol compliance had been higher. Lack of awareness, uncertainty regarding appropriate implementation, and concern about the quality of studies that assessed reduction techniques were also described as barriers to implementing multiple radiation reduction techniques in everyday practice. The generalizability of implementing a similar initiative at less experienced sites may be limited because the patient population involved in this study underwent cardiac computed tomography angiography (CCTA) at three large-volume, experienced centers.

One large urban medical center benefitted from adding a decision support (DS) system to its existing radiology order entry (ROE) system.³² Before DS integration, referring physicians completed a ROE form to initiate a CT exam. After introduction of the DS component, a second form was populated providing physician feedback on appropriateness of the exam (1-9 appropriateness score), alternate procedures to consider, and options to proceed or cancel the request. Appropriateness scores, based on ACR Appropriateness Criteria scores and “locally developed indication and procedure pairs,” are continuously reviewed and modified.

Locally derived evidence-based imaging guidelines were the basis for a DS tool at another multispecialty integrated health care network.³³ Rapid implementation of the DS tool was attributed to pressure from local commercial payers and an institutional culture already vested in evidence-based medicine (including evidence-based imaging protocols) and lean health care management methodology.³⁴ An audit of imaging requests to determine outcome for orders initially denied by the DS system was described as a potential screening method to determine whether providers had “gamed” (developed ways to order inappropriate studies) the system.

Lastly, Raff et al. described implementation efforts at 15 hospital imaging centers participating in the Advanced Cardiovascular Imaging Consortium in Michigan. Hospital imaging centers were located in both small community hospitals and large academic medical centers (1,000+ beds). Best practice recommendations were developed based on data (including radiation dose and image quality metrics) from CCTA scanning of 620 patients acquired during a 13-month control period. During an 8-month intervention period, recommendations created by a team consisting of a physician program director, a consulting radiologic technician, and a licensed medical physicist were distributed to participating sites at scheduled consortium meetings, during on-site visits by coordinating center staff and through personal communication.

This Best-Practice Model for Scan Acquisition includes directives on topics such as medical history, administration of beta blockers and nitroglycerin, and protocol parameters (e.g., field of view, tube current modulation). Scanner manufacturers were involved in training on scanner-specific techniques. Responsibility for on-site implementation was designated to a physician and radiology technologist. Raff et al. reported that the greatest reduction in dose occurred at low-volume sites (≤ 30 scans per month).

What Have We Learned About These Practices?

We limited our research to studies implementing initiatives to reduce patient's radiation exposure from fluoroscopy and computed tomography in the United States from 2005 to the present. Study designs of the 12 included studies were randomized controlled, non-randomized comparison, prospective double-blind observational, retrospective cohort, pre-post observational, and a time-series analysis.

Fluoroscopy. Two studies evaluated the effectiveness of single component initiatives to reduce radiation exposure during diagnosis of urologic conditions. Several benefits were reported from implementation of a QA protocol to limit fluoroscopy to 4-5 static images (unless clinically warranted).²⁵ Significant decreases at the 0.001 level were reported post-implementation for mean fluoroscopy time (40.9 to 11.7 seconds per procedure), mean dose area product (energy absorbed across the entire x-ray beam)(518.90 to 150.28 mGy), and mean air kerma (the energy absorbed by ionizing radiation in a unit mass of air)(15.48 to 4.25 mGy). Increased physician and staff awareness of radiation safety were also listed as benefits. Lee (2011) indicated that significant reductions in outcomes did not change the treatment or diagnosis in 100% of the fluoro urodynamics.

Ngo et al. reported a statistically significant reduction in mean fluoroscopy time (2.74-2.08, $p = 0.002$) for unilateral ureteroscopy after physician feedback.²⁰ Baseline data were collected over a 9-month period. A continuous downward trend in mean fluoroscopy time was reported over three consecutive years (263 cases) after surgeons received quarterly reports that showed their mean fluoroscopy time and mean times of their peers. Multivariate analysis indicated that a surgeon's receiving feedback was an independent factor predicting decreased fluoroscopy time ($p = 0.0004$).

Two studies evaluated the effectiveness of comprehensive radiation safety programs. In 2010, Greene et al. compared 30 ureteroscopy cases pre- and post-implementation of a QA protocol. This multicomponent protocol consisted of use of a laser-guided C-arm, use of a designated fluoroscopy technician, and substitution of visual for fluoroscopic cues during ureteroscopy. Results included a significant reduction in mean fluoroscopy exposure from 86.1 seconds to 15.5 seconds ($p < 0.001$).²⁶ Greene et al. stated "this represents an 82% reduction in fluoroscopy time and consequently a proportional reduction in radiation exposure."

A comprehensive radiation-reducing program examined by Lakkireddy et al. included (1) verbal reinforcement of previous fluoroscopy times; (2) effective collimation; (3) minimizing source-intensifier distance; and (4) effective lead shield use.²⁷ These techniques were implemented during catheter ablation of atrial fibrillation, a procedure that requires extensive fluoroscopy time with 15-20% of patients needing a second procedure. Patients were randomized to either Group I (unexposed to program) or Group II (exposed to program). Significant improvements were reported in Group II for lower dose area product (234 ± 120 vs. 548 ± 363 Gy cm², $p = 0.03$) and mean patient peak skin dose (0.40 ± 0.08 vs. 0.12 ± 0.03 Gy, $p < 0.001$). Using five cancer deaths/mSv [millisievert] for assessing excess cancer risk, additional lifetime cancer risk was reported as significantly lower in Group II patients (0.08 vs. 0.2%, $p < 0.001$).

Computed tomography. Broder et al. examined 93 emergency department (ED) patients who had abdominal tenderness; 51 (55%) patients had abnormal CT results. Implementation of two hypothetical z-axis restricted CT-reduced strategies, based on the region of tenderness, resulted

in reductions in mean radiation exposure by 70% (Strategy 1; 95% confidence interval [CI] 60% to 78%) and 38% (Strategy 2: 95% CI 29% to 48%). The primary endpoint was the frequency of complete inclusion of the acute pathologic region (detected on the complete CT scan) within the scope of the two hypothetical z axis-restricted CT scans. Current standard practice indicates a CT scan of the entire abdomen and pelvis. Abdominal pathology was completely included in limited CTs in 17% to 36% of patients; completely or partially included in 84% to 92% of patients. However, in 12 cases (eight from Strategy 1), the pathology detected at CT lay completely outside the marked region of tenderness (see harms below).

Two studies examined use of algorithms to reduce radiation exposure from CT. Loftus et al. examined use of an imaging algorithm to reduce radiation exposure in 60 patients with aneurysmal subarachnoid hemorrhage (435 CT examinations).¹ This imaging algorithm describes the most appropriate time points at which to detect vasospasm with CTA and CT perfusion imaging. Post-implementation results included a 12.1% decrease in cumulative radiation exposure ($p>0.05$), a 25.6% reduction in mean number of CT examinations performed per patient, and a 32.1% decrease in the number of CT perfusion examinations per patient. Stein et al.²⁹ implemented an imaging algorithm in which stable ED patients with a clinical suspicion of pulmonary embolism underwent chest radiography followed by V/Q scanning (negative chest radiograph) or CTPA (positive). Data indicates that when comparing CTPA to V/Q scanning, the total effective dose from CTPA is almost five times greater; the dose to the female breast 20 to 40 times greater.^{35,36} After one year, results included a statistically significant 20% reduction in mean effective dose (8.0 mSv to 6.4 mSv; $p<0.0001$); a 32% reduction in mean effective dose in women younger than 40 years. From 2006 to 2007, no significant difference in the false-negative rate (range, 0.8-1.2%) between CTPA and V/Q scanning occurred and CTPA usage in ED patients with suspected PE declined from 64.6% to 39.4%.

Two studies evaluated the effectiveness of clinical DS systems to reduce unnecessary CT imaging.^{32,33} Siström et al.³² reported results after integrating a new DS component to a computerized ROE system at a large, integrated, multispecialty group practice. Significant decreases were demonstrated in absolute growth (311 vs. 37; $p<0.001$) and growth rate (3% vs. 0.25%; $p<0.001$) of CT exams per quarter from 2004 to 2007. The authors reported that the number of CT exams was “essentially flat” despite an increase in outpatient visits by almost 70,000 over the same period. One retrospective cohort study evaluated use of an evidence-based clinical DS tool to reduce outpatient imaging use rates for several high-volume imaging procedures.³³ Two years after implementation, Blackmore et al. reported data from a single commercial payer indicating a clinically and statistically significant decrease (-26%) in use of sinus CT for suspected sinusitis (relative risk [RR], 0.73; 95% CI 0.65 to 0.82; $p<0.001$). Secondary analysis indicated that use of the DS tool was also associated with a decrease in overall volume of sinus CT studies, regardless of diagnosis.

The three remaining studies implemented several radiation reduction measures in cardiac computed tomography angiography (CCTA);^{30,31,37} prospective gating was implemented in two studies. Prospective gating was a core element in initiatives implemented in one study ($n = 623$) by Choi et al.³⁰ Results included a statistically significant difference in radiation dose between the prospective ($n = 384$) and retrospective ($n = 239$) gating groups (2.0 vs. 9.6 mSv; $p<0.0001$). In addition, median radiation doses per month decreased from 6.2 to 2.1 mSv over time due to increased usage of prospective gating. One multisite study ($n = 449$) examined effectiveness of a standardized BMI [body mass index]-based and heart rate-based protocol. Post-implementation, LaBounty (2010) reported median radiation dose had decreased from 2.6 mSv (interquartile

range 2.0 to 4.2) to 1.3 mSv (interquartile range 0.8 to 1.9) due to use of the standardized protocol ($p < 0.001$). Statistically significant reductions ($p < 0.001$ level) were also reported for prospective (versus retrospective) electrocardiographic gating (-82%), reducing tube voltage (-41% for 100 vs. 120 kV [kilovolts]), lowering tube current (-25% per -100 mA), and reducing overall scan length (-6% per -1 cm). LaBounty also reported no differences between groups in the frequency of interpretable studies on a per patient (96.4% vs. 95.5%; $p = 0.66$) or per artery (99.1% vs. 98.5%; $p = 0.26$) basis.³¹

Lastly, Raff et al. (2009)³⁸ reported improvements from dose reduction strategies from a consortium of 15 imaging centers ($n = 4,862$). Radiation reduction measures involved implementation of a best-practice model including techniques to minimize scan range, heart rate reduction, electrocardiographic-gated tube current modulation, and reducing tube voltage in suitable patients. Compared with the control period, patients' estimated median radiation dose in the follow-up period was reduced by 53.3% (dose-length product decreased from 1493 mGy x cm [IQR 855-1823 mGy x cm] to 697 mGy x cm [IQR, 407-1163 mGy x cm]; $p < 0.001$). A statistically significant reduction in effective dose was also reported (21 mSv (IQR, 12-26 mSv) to 10 mSv (IQR, 6-16 mSv) ($P < 0.001$)). No significant changes were reported in median image quality assessment (control vs. follow-up period) or proportion of diagnostic-quality scans.

Harms. Harms from a PSP were reported in one study when implementation of CT-reduced strategies resulted in erroneous findings of no pathology in 12 patients.²⁸ Three patients required emergency treatment resulting in a laparoscopic appendectomy, stent placement, and admittance for pyelonephritis.

Conclusions and Comment

A range of radiation-reduction measures have been successfully implemented by U.S. institutions to lower risk of deterministic and stochastic injuries. Significant improvements were reported for imaging time, number of images, and radiation dose (mostly measured by indirect methods)—measures that hypothetically correspond to reduction in patient exposure. Benefits also included increased physician and staff awareness of radiation safety and no impact on diagnostic interpretability.

Several studies provided moderately detailed descriptions of implementation but minimal information on the influence of context on outcomes. Two studies included a discussion of generalizability. One study described the expansion of radiation reduction measures for other diagnoses. Two studies described reliance on national and local evidence-based guidelines to assist in developing decision support systems.

Direct costs were not reported in these studies. However, initiatives were described as inexpensive, easy to implement, and requiring minimal changes to current workflow. One study described implementation of a comprehensive QA protocol with simple radiation-reducing techniques as adding no technical difficulty. A summary table is following (Table 1).

Table 1, Chapter 29. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Rare/High	Moderate	Negligible	Low	Moderate/Not difficult

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Chapter 30. Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment: Brief Update Review

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Introduction

Numerous studies have documented that the care patients receive at the end of life is often not consistent with their preferences. In addition, communication about end-of-life issues is suboptimal, and advance directive completion and documentation of health care proxies and preferences for life-sustaining treatment often does not occur. For example, a study of advanced cancer patients who died in one hospital and cancer center¹ found that only 19 percent of patients had documentation of an advance directive or a surrogate decisionmaker in the medical record. Furthermore, only one of the 17 patients who received mechanical ventilation had documentation of preferences regarding mechanical ventilation or documentation of why this information was unavailable. Other research has found that a majority of physicians whose patients had advance directives were not aware of them, that having an advance directive did not increase medical record documentation of patient preferences, and that advance directives were often not used in medical care.²

These gaps in quality can have several consequences. They can lead to patients receiving care that is not consistent with their preferences: lack of appropriate documentation or other miscommunication about the appropriate application of Do Not Resuscitate (DNR) orders or a patient's desire to not receive aggressive care at the end of life can lead to errors of providing invasive treatments, such as intubation and resuscitation, that are inconsistent with patient preferences and can lead to significant patient and family suffering. Poor documentation or communication about these preferences can also lead to confusion among staff, miscommunication with families, and errors in code situations. Significant harm may result if a patient's health care proxy is not documented or not followed, or if end-of-life decisions are made with a surrogate who was not the patient's surrogate of choice.

The original "Making Health Care Safer" report reviewed interventions aimed at increasing individuals' communication of their preferences for end-of-life care, through completion of either advance directives or health care powers of attorney. This review found that although policies to facilitate and increase rates of completion of such instruments completed are widespread, evidence was lacking that these instruments actually improve compliance with patients' end-of-life care wishes. Based on a recent systematic review that we conducted on the impact of quality improvement interventions on end-of-life care, this chapter updates the review of interventions aimed at improving completion of advance directives, as well as interventions to increase general communication about preferences and care at the end of life, and examines evidence that communication or advance directives increase the likelihood that patients' end-of-life care preferences are followed.³

What Is the Practice of Ensuring Documentation of Life-Sustaining Treatment?

Ensuring documentation of preferences regarding life-sustaining treatment is included as one element of the 2010 Update of the National Quality Forum's 34 "Safe Practices for Better Healthcare." This patient safety practice (PSP) is described as follows⁴:

Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart...Organization policies, consistent with applicable law and regulation, should be in place and address patient preferences for life-sustaining treatment and withholding resuscitation.... The definition of life-sustaining treatment may include, but is not limited to, mechanical ventilation, renal dialysis, chemotherapy, antibiotics, and artificial nutrition and hydration.

As conceptualized by the National Quality Forum and Joint Commission, this PSP focuses on encouraging advance directive completion and documentation in patients' medical records. Advance directives can document patients' wishes about life-sustaining treatment (the living will), choice of a surrogate decisionmaker (the durable power of attorney), or both. Advance directives have many drawbacks, including frequent lack of applicability to decisions about life-sustaining treatment until patients are incapacitated and close to death, imprecise language, and lack of translation into medical care, such as DNR orders. Therefore, this practice has become more broadly conceptualized as advance care planning, defined as a **process of communication** between a patient, family/health care proxy, and health care providers for the purpose of identifying a surrogate decision-maker, clarifying treatment preferences, and developing individualized goals of care about life-sustaining and other aggressive treatments. It can also include ensuring appropriate communication about and completion of Do Not Resuscitate orders when consistent with patients' preferences; documentation practices to ensure that these orders are followed when present; and newer forms of documentation to ensure that preferences are honored across settings, such as POLST (Physician Orders for Life-Sustaining Treatment) and similar programs (described below).

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

A variety of interventions intended to improve end-of-life care of include improving care planning as part of the intervention, such as palliative care services in hospitals and case management. Descriptions of implementation and effectiveness of key policy initiatives are described below.

In the United States, the Patient Self-Determination Act, passed by Congress in 1990, requires that patients are given written notice upon admission to a variety of health care institutions of their decision-making rights and policies regarding advance health care directives. Although it is unclear if implementation of this legislation improved rates of advance directive completion or elicitation of patient preferences, several expanding programs are improving implementation of advance care planning at the community or state level. A program to promote and implement advance care planning processes across an entire community, The Respecting Choices program in Lacrosse, Wisconsin, (<http://respectingchoices.org/>),⁵ has achieved nearly

universal advance directive completion in the community, although no rigorous research to document the impact of this initiative on end-of-life care in the community was identified in our systematic review.³

POLST (Physician Orders for Life-Sustaining Treatment) (www.ohsu.edu/polst/)⁶ is an initiative to document patients' preferences on an order form that is accepted across all settings of care. Similar initiatives have been endorsed in at least 10 U.S. States. In our systematic review, we did not find any evaluations of POLST or similar initiatives on the hospital or community level that met our inclusion criteria of enrolling a comparison group.³

The Gold Standards Framework (www.goldstandardsframework.org.uk/)⁷ is a systematic approach for improving care at the end of life that has been widely implemented in primary care practices, nursing homes, hospitals, and other settings throughout the United Kingdom. This approach includes goals of increasing the percentage of patients with advance care planning discussions and increasing concordance between patient preferences and care at the end of life. In our systematic review,³ we identified one evaluation with patient-centered outcomes, a 2009 non-randomized trial⁸ addressing symptoms, needs, and coordination in 49 nursing homes, that found statistically significant reductions in nursing home deaths and in crisis hospitalizations.

The Liverpool Care Pathway (www.liv.ac.uk/mcpcil/liverpool-care-pathway/)⁹ is a template for structuring care at the end of life, including communication and documentation about which treatments are appropriate. Programs based on this template have been implemented in a variety of settings and countries, including the United Kingdom, Australia, and the Netherlands. In our systematic review,³ we identified one evaluation, a 2010 non-randomized trial, which evaluated the Liverpool Care Pathway in a variety of settings, including hospitals, nursing homes, residential facilities, and home care in the Netherlands. The intervention did not statistically significantly increase use of do-not resuscitate orders at the end of life, possibly because sample sizes were small.¹⁰

What Have We Learned About Documenting Life-Sustaining Treatments?

The issue of documentation of life-sustaining treatment was addressed in the 2001 Making Health Care Safer report, as Advance Planning for End-of-Life Care. That review discussed early studies on the POLST and Respecting Choices initiatives (described above) as well as several studies of improving rates of advance directive completion.

More recent systematic reviews have found that interventions can significantly increase rates of advance directive completion. However, these reviews have found few studies on the actual impact of documentation of preferences for life-sustaining treatment such as advance directives on patient outcomes, and have concluded that the few studies that have been conducted have not generally found a significant impact.^{11,12}

In a systematic review of the literature from 2000 through March 2011, we addressed quality improvement interventions for end-of-life care, including the target of communication.³ We included prospective studies with a comparison group, enrolling patients with serious or advanced illness who were unlikely to recover or be cured, and assessing patient-centered outcomes, including quality of care and health care utilization.

For the target of communication, we did not identify any studies addressing this practice specifically (i.e., the impact of increasing or improving documentation of life-sustaining treatment preferences on improved outcomes or decreased errors). However, we did identify a number of studies focusing on increasing and improving end-of-life communication more

generally, primarily in the intensive care unit setting. These studies included quality improvement interventions to increase the frequency and/or structure of family meetings to address these issues, and the use of palliative care and ethics consultants. Fifteen studies (6 RCTs, 9 non-RCTs) evaluated health care utilization, such as intensive care unit length of stay, as an outcome. We found moderate strength of evidence to support the impact of interventions on this outcome: 73% of studies found a statistically significant improvement in the intervention compared with the control group.

Observational studies have shown that patients with advance directives or related documents are more likely to receive care consistent with their preferences. A retrospective evaluation of the care provided for residents with POLST orders found that care provided was consistent with residents' preferences 98% of the time for resuscitation and 94% overall.¹³ Another retrospective analysis of survey data found that patients who died with advance directives received care strongly aligned with their preferences (97% of those who requested comfort care received it). Subjects with living wills or who had a health care proxy were statistically significantly less likely to receive aggressive care than those without advance directives.¹⁴ Patients who had discussions about prognosis and end-of-life care with their providers also had care at the end of life that was less invasive and more consistent with their preferences.

Conclusions and Comment

Achieving concordance between patients' end-of-life care preferences and the care that they receive is an accepted goal in health care, and improving communication about and documentation of patients' preferences is important. Errors such as resuscitation in a patient who wanted comfort care because the correct documentation had not been completed can cause significant harm and suffering for patients and families.

Recent systematic reviews have found moderate strength of evidence that interventions can improve rates of advance directive completion and that interventions to improve end-of-life communication can reduce health care utilization, which may be a marker for overly aggressive care, at the end of life. However, insufficient evidence exists to support whether advance directives or current policy initiatives to improve documentation of care preferences across settings, such as POLST in the United States, improve the likelihood that patients receive care consistent with their preferences at the end of life. Interventions to improve communication about end-of-life care issues should be implemented in hospitals, particularly in the intensive care unit settings. Emerging types of interventions, such as initiatives present in some hospitals for requirements for code status or health care proxy documentation for all patients upon admission or other initiatives to improve documentation of care preferences, deserve further evaluation. A summary table is following (Table 1).

Table 1, Chapter 30. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate	Low	Low	Moderate/Moderate

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Part 2b. Practices Designed To Improve Overall System/Multiple Targets

Chapter 31. Human Factors and Ergonomics

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How Important Is the Problem?

Many patient safety incidents are related to lack of attention to human factors and ergonomics (HFE) in the design and implementation of technologies, processes, workflows, jobs, teams and sociotechnical systems. For instance, a systems analysis of medication errors¹ identified a range of proximal causes of medication errors, such as rule violations, memory slips and lapses, poor communication with other services, and incorrect pump programming caused by poor design of the pump interface. Lack of attention to HFE in areas such as technology design can contribute to medication errors and preventable adverse drug events.

The Institute of Medicine (IOM) report on Medication Errors² emphasizes the need for addressing HFE issues, such as the design of medication labels and packages, and the design of medication administration technologies (e.g., infusion pump). A study by Han et al.³ in a pediatric hospital showed an increase in mortality rates after the implementation of Computerized Provider Order Entry (CPOE); many factors that contributed to the increase were related to HFE. For instance, the design of the CPOE interface required about 10 clicks per order, thus significantly increasing time needed to enter orders. The poor usability of the CPOE system and its lack of integration with clinician workflow contributed to delays in patient care that were a major factor in the increased mortality rate after CPOE implementation.

The recent IOM report on Health IT and Patient Safety⁴ clearly indicates the need for HFE in the design, implementation and use of health IT. The report proposes a sociotechnical approach that emphasizes the need for health IT to support clinical workflows. Increased cognitive workload associated with the implementation and use of health IT and lack of usability of health IT are two HFE issues associated with patient safety incidents highlighted in the report.

A systematic review showed how environmental hazards can contribute to patient safety incidents such as patient falls.⁵ For instance, the use of bedrails can contribute to patient falls by contributing to entrapment injuries.

These studies provide evidence for the importance of HFE in patient safety; they highlight the range of physical, cognitive and organizational HFE issues that can contribute to patient safety incidents. There are many other examples of how lack of attention to HFE contributes to patient safety incidents. For instance, a fatal medication error occurred on July 5, 2006 at St. Mary's hospital in Madison, WI: An epidural penicillin solution instead of an intravenous (IV) penicillin retain was administered to a 16-year old pregnant patient's IV line, causing her immediate death. A root cause analysis identified several HFE issues that contributed to the fatal error⁶. The IV and epidural bags had similar designs, and both medication bags could be connected to IV and epidural tubing. A barcoded medication administration (BCMA) technology had been recently introduced in the hospital, but the nurse did not use it. Because of the technology's poor usability and lack of training (i.e., HFE issues), many nurses did not use the technology and thus could not take advantage of its safety features.

Vincent et al.⁷ describe three groups of factors for explaining adverse surgical outcomes:

1. patient risk factors (e.g., increased body mass index, presence of comorbidity)
2. surgical skills (e.g., technical skills), and
3. operation profile (or system factors).

The operation profile includes a range of HFE-related system factors, such as operative environment, team performance and communication, and decisionmaking processes. System characteristics are factors that, in addition to patient characteristics and the skills of the surgery team, can contribute to complications and adverse events⁷. A range of system factors can influence the safety of surgery and can be addressed by using concepts, models, theories and methods from HFE. Vincent's approach can be extended to patient safety incidents in other care settings besides surgery.⁸ Patient characteristics and clinician skills and knowledge are important for patient safety; but poor system design can also contribute to patient safety incidents. HFE helps to identify system design deficiencies and hazards that affect patient safety and provides the concepts and methods to improve system design and, therefore, patient safety.

What Is the Patient Safety Practice?

According to the International Ergonomics Association (IEA),⁹ “Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize human well-being and overall system performance.”

Key Characteristics of Human Factors and Ergonomics

“Human Factors” and “Ergonomics” are synonymous names for the discipline; the discipline is often referred to as Human Factors and Ergonomics or HFE. HFE covers a wide range of physical, cognitive, and organizational issues involved in system design. Physical HFE issues include physical dimensions of tools that do not fit physical characteristics of users (e.g., too small font size on computer screen), inappropriately designed physical environments (e.g., lighting too bright and creating glare, noisy and distracting environment) and physical layout that does not support clinician work (e.g., monitoring patients from the central nursing station). Cognitive HFE issues include interactions between people and the rest of the system such as perception, memory, attention, mental workload, and support for decisionmaking. At the organizational level, HFE focuses on communication and coordination, teamwork, job design, sociotechnical system, and system design, and change (e.g., participatory ergonomics). Other examples of physical, cognitive and organizational (macroergonomic or sociotechnical) HFE issues of relevance to patient safety can be found in textbooks and papers.¹⁰⁻¹²

Rather than attempting to fit the person to the system, HFE works to fit the system to the person.¹³ Systems should be designed to accommodate the range of characteristics, needs, and limitations of people. In this context, people means single individuals, teams, or larger organizational units. According to the IEA definition, the objective of HFE-based system design is to improve both human well-being and overall system performance. Patient safety can be considered one aspect of ‘overall system performance.’ From an HFE viewpoint, patient safety activities should not only reduce medical errors and improve patient safety, but also improve human well-being, such as job satisfaction, motivation and acceptance of technology. For instance, patient safety programs that increase the workload of already busy clinicians would not

be considered well designed from the HFE perspective. See Table 1 for a summary of the key characteristics of HFE.

Table 1, Chapter 31. Key characteristics of HFE and its application to patient safety

Definition of HFE by the International Ergonomics Association (www.iea.cc)	“Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize human well-being and overall system performance.”
Name of the discipline	“Human Factors” and “Ergonomics” are two different names for the same discipline.
Range of HFE issues	Physical, cognitive and organizational (macroergonomic or sociotechnical) issues of HFE are all relevant to patient safety.
Goal of HFE	The goal of HFE is to fit the system to the people instead of fitting people to the system.
Objectives of HFE	The objective of HFE-based system design is to improve both well-being and system performance. Patient safety is one component of system performance.

Human Factors and Ergonomics Applications to Patient Safety

HFE contributes to five domains of patient safety: (1) usability of medical devices and health information technology, (2) focus on human error and its role in patient safety, (3) role of health care worker performance in patient safety, (4) system resilience and its role in patient safety, and (5) HFE systems approaches to patient safety.

Usability of Medical Devices and Health IT

A significant focus of HFE in health care and patient safety has been the design of usable medical devices and health IT.^{14,15} For instance, to improve medication management in medical emergencies, HFE principles were used to redesign the code cart medication drawer¹⁶. User testing was conducted to compare the medication retrieval time and number of wasteful actions associated with the existing and prototype drawers. Compared with the existing drawer, the prototype drawer resulted in shorter medication retrieval time and fewer wasteful actions. The prototype drawer also received higher ratings for visibility, organization, and general usability. A detailed example of the application of usability methods for improving safety of radiotherapy treatment delivery is provided in the section on “What are the beneficial effects of the Patient Safety Practice?”

Health IT can contribute to patient safety by eliminating hazards.^{17,18} However, it may also create new hazards.¹⁹⁻²¹ Usability is one HFE design characteristic that can influence health IT’s patient safety benefits, or lack thereof.⁴ HFE methods have been used to improve the usability of CPOE order sets,²² to design the user interface of a software application that was developed to extract and present data relevant to the treatment of critically ill patients to providers,^{23,24} and to improve the design of medication alerts.^{25,26} The second example in the section on “What are the beneficial effects of the Patient Safety Practice?” provides information on the usability evaluation of CPOE technology.

Human Error and Patient Safety

Another major focus of HFE in patient safety has been understanding the nature of human error and identifying the mechanism of human error involved in patient safety.^{8,27} This probably represents the largest contribution of HFE to patient safety.²⁸ The Swiss Cheese model of Reason^{29,30} describes the alignment of hazards (or ‘holes’) that can lead to an accident—(e.g., a patient safety event) and distinguishes between latent failures and active failures. Latent failures

result from decisions made by system designers and organizational decision-makers that lead to unsafe conditions. Active failures are errors made by the operators of the system.

Vincent and colleagues⁸ have adapted Reason's Swiss Cheese model to patient safety. They describe management decisions and latent failures that can influence error and create conditions that produce safety violations. In turn, these conditions create problems for care delivery and may lead to unsafe acts (i.e., errors and violations), which may then produce an incident if the defenses and barriers are not appropriate. Reason's Swiss Cheese model and its patient safety version by Vincent and colleagues include both errors and violations as active failures. Recent HFE research has broadened the focus on human error and developed knowledge about the contribution of violations to patient safety.^{31,32}

Bogner³³ has proposed another HFE model of human error and patient safety: the Artichoke model defines layers of system factors that influence provider-patient interactions, such as legal-regulatory-reimbursement, national culture, organization, physical environment, social environment, and ambient environment. The frameworks proposed by Vincent and colleagues⁸ and Bogner³³ can be used by health care organizations to investigate specific patient safety incidents.

Health Care Worker Performance

Performance obstacles may endanger patients by making it difficult for clinicians to perform tasks and procedures safely.³⁴ A range of physical (e.g., lifting, injecting, charting), cognitive (e.g., perceiving, attention, communicating, awareness) and social/behavioral (e.g., motivation, decision-making) performance processes can influence patient safety.³⁵ When obstacles are present in the work environment, physical, cognitive and social/behavioral performance of clinicians may be challenged and accidents may occur. Performance obstacles have been identified for ICU nurses,³⁶⁻³⁸ staff in outpatient surgery centers,³⁴ and hospital nurses.³⁹ Information on performance obstacles can be used to improve working conditions of health care professionals; these changes may produce patient safety benefits.⁴⁰ When faced with performance obstacles, clinicians have to improvise ways of getting their work done. HFE research has characterized such work-arounds and their patient safety implications in nursing medication administration,³² especially in the context of BCMA use.^{41,42} HFE has proposed a range of approaches, including work teams and team training, to enhance health care worker performance, and improve communication, coordination, and information flow.

System Resilience

Recently, HFE research in patient safety has focused on system resilience.⁴⁶ Resilience has been defined as "the ability of systems to anticipate and adapt to the potential for surprise and failure."⁴⁷ Because not all errors may be prevented, HFE researchers have developed models to understand how errors can be detected, corrected, mitigated, and dealt with by operators.^{48,49} The WHO model of patient safety incorporates the concepts of error detection and mitigation.^{50,51} Strategies for error detection and recovery have been explored among nurses,⁵² in particular critical care nurses,^{53,54} and among pharmacists.^{49,55} This line of HFE research can produce information about mechanisms for achieving resilience, such as cross-checking.^{56,57} Resilience engineering builds on and extends the work done by High Reliability Organization (HRO) researchers. A key characteristic of HROs is mindfulness, i.e., the ability to prepare for the unexpected and to be vigilant about hazards, and one aspect of mindfulness is organizational commitment to resilience.⁵⁸

Four factors contribute to resilience⁵⁹:

1. knowing how to respond to disruptions and disturbances
2. monitoring events, in particular those likely to lead to an accident
3. anticipating developments, threats and opportunities
4. learning from patient safety incidents.

Further research is necessary to understand how these factors contribute to resilient performance; this research should focus on understanding the role of distributed cognition (i.e., the distribution of knowledge across the social and physical environments as well as across time) and situation awareness in demanding situations and the ways that clinicians react and deal with surprising, demanding situations and other vulnerabilities or hazards.⁶⁰

Human Factors and Ergonomics Systems Approaches to Patient Safety

The first four HFE approaches focus on specific aspects of HFE and patient safety--usability of technology, human error, clinician performance, and resilience. A number of HFE approaches have been proposed to describe more comprehensive systems of patient care. These systems approaches address the following: (1) a broad range of system variables that can affect patient safety, (2) interactions between system elements, and (3) interacting system levels.^{28,61} These approaches include the systems approach proposed by Vincent and colleagues^{8,62} and the SEIPS (Systems Engineering Initiative for Patient Safety) model of work system and patient safety proposed by Carayon and colleagues.⁶³

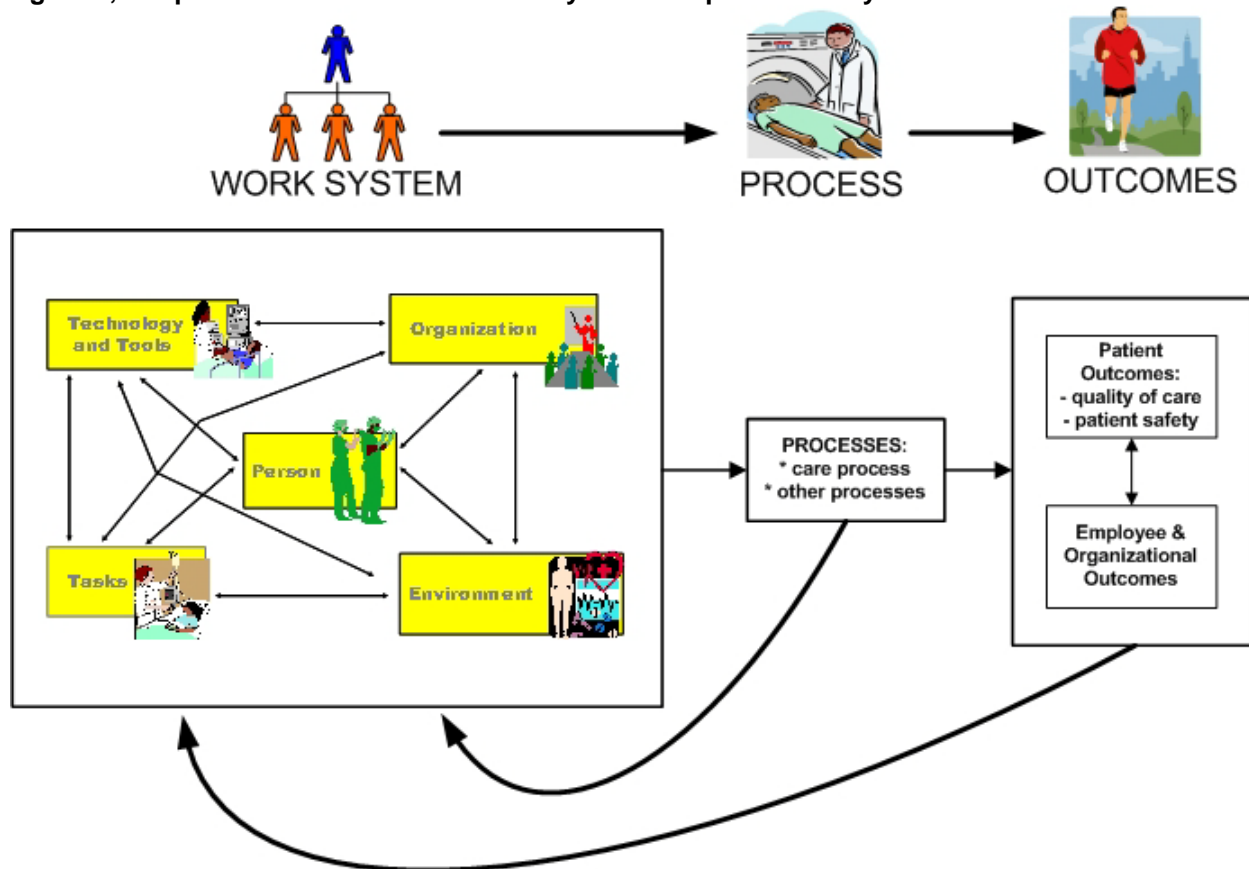
Vincent and colleagues⁸ defined seven types of system factors that can influence clinical practice and lead to patient safety incidents:

1. patient factors
2. task and technology factors
3. individual (staff) factors
4. team factors
5. work environmental factors
6. organizational and management factors
7. institutional context factors.

This framework can be used to identify factors that contribute to patient safety incidents.

The SEIPS model of work system and patient safety⁶³ (Figure 1) identifies a slightly different set of system factors: (1) individual factors (which include characteristics of the staff and patient), (2) tasks, (3) tools and technologies, (4) environment, and (5) organizational factors (which include team factors). In addition to defining the system and emphasizing system interactions,⁶⁴ the SEIPS model describes how system design can influence care processes and other connected processes (e.g., delivery of supplies, housekeeping, purchasing of medical equipment). Based on the Structure-Process-Outcome framework of Donabedian,⁶⁵ the SEIPS model proposes that system design can contribute to deficiencies in care processes and thus to patient safety incidents. Because the SEIPS model is anchored in HFE, employee and organizational outcomes are addressed along with patient safety, reflecting the fact that patient safety and worker safety and well-being are positively correlated and have common system contributing factors.⁶⁶

Figure 1, Chapter 31. SEIPS model of work system and patient safety⁶²



Reproduced from Work system design for patient safety: the SEIPS model. Carayon P, Schoofs Hundt A, Karsh BT, et al. *Quality & Safety in Health Care*. 15(Supplement 1):i50-i58. 2006 with permission from BMJ Publishing Group Ltd.

With recent emphasis on the role of health IT in patient safety, sociotechnical systems approaches have been proposed, for instance, by the IOM report on Health IT and Patient Safety.⁴ The work system of the SEIPS framework is a representation of a sociotechnical system (the technology is part of a larger system and interacts with various system elements). The sociotechnical system model proposed by the IOM⁴ includes all elements of the work system model, except for the physical environment.

Human Factors and Ergonomics as a Patient Safety Practice

HFE as a patient safety practice can take three different forms:⁶⁷

1. using HFE tools and methods,
2. increasing HFE knowledge, and
3. recruiting HFE engineers.

HFE tools and methods for patient safety include usability evaluation of technologies or devices, work system assessment for performance obstacles and hazards, and risk assessment of care processes. Other examples of HFE tools and methods are described in the section on the beneficial impacts of HFE as a patient safety practice.

Increasing HFE knowledge may involve training and educating a range of health care professionals and workers, including patient safety officers, quality improvement specialists, and

health IT staff, as well as leaders of health care organizations, policymakers, and vendors and manufacturers of medical devices and health IT applications.

Health care organizations may hire HFE engineers in order to accelerate adoption and dissemination of HFE. Integration of HFE engineers in health care organizations may enhance the impact of HFE in a wide range of relevant departments and functions of health care organizations,^{67,68} such as patient safety, risk management, quality improvement, employee health, and health IT implementation and optimization.

Why Should This Patient Safety Practice Work?

Theories and models underlying the HFE approach to improving patient safety target the design of work systems and care processes and aim to promote and facilitate performance of all individuals involved. HFE focuses on how to design work systems and processes for supporting safe behaviors and activities in both system design and operation. According to the SEIPS model of work system and patient safety,⁶³ HFE deficiencies in the design of work systems can negatively influence the safe delivery of care processes, and therefore, lead to patient safety incidents (see Figure 1).

HFE for patient safety is based on four mechanisms that connect system variables to patient safety⁶⁹ (see Table 2).

Table 2, Chapter 31. HFE mechanisms between system design and patient safety

HFE Mechanisms	Objectives of System Design
1. A work system that is not designed according to HFE design principles can create opportunities for errors and hazards (see Table 3 for examples of design principles).	The objective of HFE-informed system design is to identify and remove system hazards from the design through maintenance phases.
2. Performance obstacles that exist in the work system can hinder clinicians' ability to perform their work and deliver safe care.	The objective of HFE system redesign is to identify and remove performance obstacles. If some obstacles cannot be removed, for instance, because they are intrinsic to the job, then strategies should be designed to mitigate the impact of performance obstacles by enhancing other system elements (i.e. Balance Theory of Job Design). ⁷⁰⁻⁷²
3. A work system that does not support resilience can produce circumstances where system operators may not be able to detect, adapt to, and/or recover from errors, hazards, disruptions and disturbances.	Work systems should be designed to enhance resilience and support adaptability and flexibility in human work, ⁷³ such as allowing problem or variance control at the source. ⁷⁴⁻⁷⁶
4. Because system components interact to influence care processes and patient safety, HFE system design cannot focus on one element of work in isolation. ^{63,69,77}	Whenever there is a change in the work system, one needs to consider how the change will affect the entire work system, and the entire system needs to be optimized or balanced. ⁷⁰⁻⁷²

Human Factors and Ergonomics Design Principles

A range of HFE design principles have been proposed for optimizing specific elements or aspects of the work system. These principles can be used to design work systems to eliminate hazards and performance obstacles. For instance, The Handbook of Human Factors in Medical Device Design⁷⁸ provides a comprehensive set of principles for medical device design. Usability heuristics or rules of thumb for user interface design have been developed for health IT and medical devices;⁷⁹⁻⁸¹ these usability heuristics include consistency, a match between technology and the user's mental model, minimizing memory load, and users in control. The physical design

of the work system should minimize perception time, decision time, manipulation time, and the need for excessive physical exertion, and optimize opportunities for physical movement.^{69,82,83}

From an organizational HFE viewpoint, work systems should be designed so that tasks are reasonably demanding physically and cognitively. Workers should have opportunities to learn, adaptive levels of control over their work system, and access to social and instrumental support (e.g., support from co-workers in case of emergency) within the work environment.^{84,85} Table 3 provides some examples of HFE design principles; additional information on HFE design for specific work system elements can be found in the Handbook of Human Factors and Ergonomics.⁸⁶

Table 3, Chapter 31. Examples of HFE design principles

Focus of HFE	Examples of HFE Design Principles
Physical HFE	Minimizing perception time, decision time, and manipulation time Reducing or mitigating need for excessive physical exertion Optimizing opportunities for physical movement
Cognitive HFE	Consistency of interface design Match between technology and the user's mental model Minimizing cognitive load Allowing for error detection and recovery Feedback to users
Organizational HFE	Worker opportunities to learn and develop new skills Worker control over work system Worker access to social support Participation in system design

Given the systems focus of HFE, it is important not only that each component of the system be designed appropriately, but also that system components be aligned⁷⁵ and that system interactions be optimized.⁶⁴ For example, when a new BCMA system is introduced, it is important to ensure that the technology is designed according to HFE principles (e.g., usability heuristics). However, it is also important that the technology fits with the rest of the work system. If there is not sufficient space in which to use the BCMA (interaction between the technology and the physical environment) or if users are not provided with adequate training (interaction between the technology and the organization), then BCMA may contribute to diminished rather than improved clinician performance and patient safety.

The goal of HFE-informed design is work system that supports the work of individual and teams.^{75,81} This is the essence of the user-centered design approach.⁸⁷

HFE Implementation Principles

In addition to principles for designing work systems and processes, HFE has developed principles for changing work systems. For instance, in the context of health IT, HFE implementation principles, such as participation, communication and feedback, learning and training, top management commitment, and project management are critical to realizing the patient safety potential of health IT.^{88,89} These implementation principles are essential and applicable to the implementation of all kinds of work system design. A key HFE system implementation principle is user participation. Participatory ergonomics programs can be implemented in health care and lead to substantial improvements in occupational health and safety,^{90,91} and potentially in patient safety. However, it may be difficult to use participatory ergonomics in a high-stress, high-pressure environment, such as an ICU, where patient needs are critical and patients require immediate or continuous attention.^{90,91} Further research is needed to

refine and develop HFE implementation principles and methods for facilitating user participation in designing work systems for patient safety.

What Are the Beneficial Effects of the Patient Safety Practice?

The 2005 report by the U.S. Institute of Medicine and the National Academy of Engineering stressed the importance of using HFE as a key systems engineering tool to design health care systems and to improve quality of care and patient safety.⁹² Numerous studies use HFE tools and methods to identify system factors that contribute to medical errors; based on these data, researchers or other system designers devise recommendations for improving health care work systems and processes.

These studies are useful for highlighting the importance of HFE to patient safety; however, they do not provide empirical evidence for the value of HFE in improving patient safety. Empirical studies of how HFE-based interventions affect patient safety are few; those that are available have addressed usability of health care technologies, concomitant design of health care technologies and work system, and design of health care processes. Further research is necessary to document and demonstrate the value of HFE-based interventions and their impact on patient safety. Evidence for the effectiveness of HFE-based interventions should include data on changes in the work system, changes in the process and changes in outcomes (including both patient safety and employee outcomes). In general, this evidence is provided through the use of multiple quantitative and qualitative methods.

HFE-based interventions involve changes in work systems and processes and, like any change, may produce unanticipated effects. However, a core principle of HFE is to ensure that work systems and processes are designed to produce patient safety benefits. The purpose of an HFE approach is (1) to anticipate potential negative patient safety consequences (e.g., conducting a work system or process analysis, or a proactive risk assessment), and (2) to learn about potential negative effects on patient safety during the implementation process and fix problems as quickly as possible (e.g., system resilience).

This review is not intended to be a systematic review of HFE-based interventions for patient safety, especially given the broadly different clinical topics and the small number of studies in each clinical topic. Rather, our objective is to highlight the variety of HFE applications and to describe the details of a small number of HFE applications that produced patient safety improvements. Thus we review only four studies to demonstrate various HFE applications. These examples also show that HFE applications for patient safety do not have to wait for accidents to occur; HFE is primarily a proactive system design approach.

Example 1: Human Factors and Ergonomics in the Design of Radiotherapy Treatment Delivery System

In the first example, HFE methods were used in the design of a radiotherapy treatment delivery system.^{93,94}

Step 1: Human Factors and Ergonomics Analysis

The researchers first evaluated the existing radiotherapy treatment delivery process. Over a 3-month period, an HFE engineer conducted 30 hours of field observations of radiation therapists performing their regular tasks. Workflows of radiation therapists, in particular their interactions with the treatment-delivery system, were recorded. Based on these observations, the researchers compiled a list of tasks regularly performed by radiation therapists during treatment delivery.

Step 2: Heuristic Usability Evaluation

One experienced therapist and two HFE engineers performed a heuristic evaluation of the usability of treatment-delivery system. Since the two HFE experts were not authorized to operate the system, the therapist performed the tasks and explained the workflow to the engineers. The two HFE experts independently identified HFE issues based on 14 usability heuristics,⁷⁹ and evaluated the severity of each usability issue; they then compared their ratings and reached consensus on a final list of usability issues and their severity. A total of 75 usability issues were identified; of these, 18 were classified as having a high potential impact on patient safety (i.e. high severity), 20 were classified as medium severity, and 37 were classified as low severity. For instance, when the therapist entered notes into a patient's file, the notes could be deleted without warning if the therapist selected another patient's file before saving the notes. This usability issue violated the heuristics of feedback, error recovery, and ability to undo, and was rated with high severity. The recommendation for technology redesign was to warn therapists that their notes might be deleted if they have not saved them.

Step 3: System Redesign and Evaluation

The existing treatment delivery system was redesigned based on HFE design principles. Two focus groups with experienced radiation therapists provided feedback on the redesigned treatment delivery system, and the system was further refined. Finally, user testing with 16 radiation therapy students was conducted to compare the current and redesigned treatment delivery systems. Using each of the two systems, students went through four scenarios related to typical treatment-delivery tasks. Three of the four scenarios were designed with a high potential for certain use errors to occur (overlooking an important note, shifting the treatment couch incorrectly, and overlooking a change of approval dates). The error rates and overall time to complete each scenario were measured. At the end of the testing, participants were asked to fill out a questionnaire to compare various attributes of the two systems. Results showed that error rates for overlooking an important note and for overlooking changes in approval dates decreased significantly with the redesigned treatment-delivery system (from 73% to 33% and from 56% to 0% respectively). The redesigned treatment delivery system led to efficiency gains (the mean task completion time was reduced by 5.5%) and improvement in user satisfaction.

Example 2: Human Factors and Ergonomics in the Design and Implementation of Health IT

Various work system factors can affect the acceptance and effective use of health care technologies.^{88,95} Inadequate planning for implementation and lack of integrating health care technologies into existing work systems are associated with work-arounds and technologies falling short of achieving their patient safety goal.^{42,96-98} HFE approaches, which emphasize simultaneous design of the health care technology and the work system, are recommended for achieving a balanced work system⁷⁰⁻⁷² and fulfilling the full potential of health care technology in improving patient safety.

Beuscart-Zépher and colleagues⁹⁹ developed an HFE framework for health care technology and work system design, along with a set of structured methods to optimize the work system. The HFE framework includes 4 stages: (1) analysis of the sociotechnical system and the demands of stakeholders, (2) cooperative design of the health care technology and the work system with the institution, designers and developers, (3) iterative evaluation and redesign, and (4) assessment of the new work system and its impact on patient safety and overall performance

of the sociotechnical system. The HFE framework was used to improve the design and implementation of CPOE.¹⁰⁰

Step 1: Analysis of Medication Use Process and Recommendations for System Redesign

Researchers conducted a systematic qualitative analysis of the medication ordering–dispensing–administration process. Field observations and semi-structured interviews were performed with nurses to identify nursing tasks in the medication administration process, to characterize physician–nurse and nurse–nurse communication about medications, and to assess nurses’ interactions with paper patient records. Then more than 7,000 paper medication order sheets issued by physicians and the corresponding paper medication-administration records from nurses were reviewed.

Step 2: Cooperative System Design

The results of observations, interviews, and document review were presented to nurses for feedback; software engineering models (e.g., UML and Petri Nets) were created to model the distribution of tasks observed. Factors contributing to the safety of medication process were identified at three levels: individual (e.g., interactions between nurses and the technology when administering medications), collective (e.g., verbal communications supporting cooperation during the medication management process) and organizational (e.g., distribution of tasks across different health care professionals). Recommendations for work system redesign were proposed, such as the need to provide nurses with specific information at each step of the preparation and administration of medications, and the need for regular physician-nurse communications about patient treatment and changes to the plan of care (e.g., daily briefing either before or after medical rounds).

Step 3: Usability Evaluation of CPOE Technology

The researchers also evaluated the usability of the proposed CPOE technology. Five independent HFE experts evaluated the user interface of the software application, using a set of HFE criteria.¹⁰¹ A total of 35 issues related to workload, compatibility, control, homogeneity, guidance, and error prevention was identified and rated on a four-point scale for severity.

In laboratory user testing, 8 nurses used the think-aloud method in a simulation of the preparation of medication dispensers and the validation and documentation of medication administration. The laboratory test was designed to reproduce the nurses’ typical work environment. Scenarios were created based on the results of the initial work system analysis. Nurse participants identified a total of 28 usability issues during the test.

Step 4: Iterative Human Factors and Ergonomics Redesign

In the next phase of CPOE technology redesign, possible solutions for each of the identified usability issues were proposed and evaluated with respect to costs and benefits. Mock-ups and prototypes were developed for those solutions. Iterative usability evaluations and technology redesigns were done until all critical usability issues were addressed. To evaluate the impact of the HFE-based design of health care work system on patient safety, the researchers proposed to link the system redesign to the actual identification of adverse events.

In a recent project, the researchers used statistical data mining methods to semi-automatically identify adverse drug events and to link the identified adverse drug events to the analysis and

modeling of the work systems. The HFE framework of Beuscart-Zépher and colleagues is now routinely integrated into the IT project management of the Centre Hospitalier Universitaire of Lille, France.

Example 3: Human Factors and Ergonomics in the Physical Design of Operating Rooms

In the third example, HFE is used to address infection-control problems in the operating room (OR).¹⁰² To minimize infection risk, surgical devices were suggested to be positioned within the clean airflow in the OR according to well-known design principles.^{103,104}

Step 1: Benchmarking of System

A multidisciplinary team of hospital surgical staff learned from the experience of runway operators at an international airport regarding marking, position of materials, traffic flows, safety rules and regulations, and incident management. They applied this knowledge to OR traffic flows, position of surgical tables and materials, safety management, and the process of incident reporting.

Step 2: Human Factors and Ergonomics System Design

The multidisciplinary team designed and implemented floor marking to support consistently correct positioning of surgical devices. The implementation was carried out in three steps:

1. temporary marking was implemented in 2 of 4 ORs in February 2009,
2. temporary marking was implemented in all four ORs by June 2009, and
3. permanent floor marking was implemented in all ORs in December 2009.

Step 3: Evaluation of System Redesign

Compliance with positioning of surgical devices within the clean airflow was evaluated by observing a total of 182 surgeries before implementation of the floor marking. One month after the implementation of the temporary floor marking in 2 ORs, compliance data were collected by observing 195 surgeries in ORs with floor markings and 86 surgeries in ORs without floor markings. Four months after implementation of the temporary floor markings in all four ORs, 167 surgeries were observed to collect compliance data. Finally, 199 surgeries were observed 1 month after the implementation of permanent floor markings. Floor marking resulted in significantly increased compliance with recommended positionings of surgical devices in the clean airflow. In addition, post-implementation interviews with 3 ophthalmic surgeons, 3 surgical and anesthesia nurses, and 2 managers showed enhanced safety awareness among surgical staff. Although the researchers did not use the term “HFE” to describe their study, their approach used a systematic work system analysis and led to a solution firmly rooted in the HFE systems approach.¹⁰⁵

Example 4: Human Factors and Ergonomics in the Design of Care Processes

HFE can also help to improve the design of care processes.^{106,107} Proactive risk assessment methods, such as failure mode and effects analysis (FMEA), are HFE methods that can be used to evaluate high-risk processes in health care and provide input for health care process design.^{108,109} The fourth study we review describes an FMEA of the IV medication

administration process conducted to assess the potential HFE and safety issues of a new IV pump.¹¹⁰

Step 1: Formation and Training of FMEA Team

A multidisciplinary team consisting of representatives from anesthesiology, biomedical engineering central supply, human factors engineering, internal medicine, nursing, pharmacy, and quality improvement performed a health care failure mode and effects analysis (HFMEA)¹¹¹ to evaluate the intravenous (IV) medication administration process using both current IV pump and a Smart IV pump technology. The team members were trained for 1 to 2 hours in the VA's HFMEA method.¹¹¹

Step 2: FMEA Analysis Process

The FMEA process consisted of 46 hours of meetings over 4.5 months and unfolded in three steps:

1. Process identification and mapping
2. Failure mode identification and scoring
3. Determination of interventions and outcome measures

Multiple data sources were used to develop the IV medication administration process map. Two HFE experts conducted a total of 52 observations of nurses administering medications with the current IV pump.¹¹² Medication administration and IV pump events reported with the current pump were retrieved from the hospital's event reporting system. The FMEA team mapped the medication administration process with the current IV pump and then repeated the mapping process with the Smart IV pump. In the process map with the current IV pump, the team identified 10 steps for retrieving the medication and tubing, and 24 steps for pump programming were identified. For the Smart IV pump, the team identified 14 unique pump programming steps and new tubing setup and insertion steps.

Following process mapping, the team analyzed failure modes potentially associated with IV pump use. About 200 failure modes were identified and scored with respect to severity and probability of occurrence. A hazard score was calculated by using the product of the severity and probability of occurrence ratings. Failure modes with low or low-moderate hazard scores were assessed for detectability, and only non-detectable failure modes were considered for further action. All failure modes with moderate-to-high hazard scores were considered further.

Step 3: Recommendations for Process Redesign

Recommendations for prioritized failure modes were proposed and categorized into the five elements of the work system⁶³ (see Figure 1): (1) policies and procedures, (2) training or education, (3) physical environment, (4) people, and (5) technology software or hardware change. The evaluation of the impact of the FMEA on patient safety was based on: (1) audits of programming of pumps for errors, (2) monitoring of end-user training for time to achieve competency, and (3) monitoring and recording of IV medication administration event reports and informal and formal complaints about pump functioning. Post-implementation results suggested that the goal of mitigating risk to patients from potential or known failure modes was achieved.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

HFE can contribute to patient safety in a range of care settings. Table 4 describes selected HFE issues in various care settings. The issues are categorized as physical, cognitive, or organizational HFE issues, and are related to the various work system elements (see Figure 1). These issues interact as part of the larger work system and produce the vulnerabilities that can lead to patient safety incidents.

Table 4, Chapter 31. HFE issues in selected care settings

Care Settings	HFE Issues	Physical (P), Cognitive (C) or Organizational (O) HFE			Elements of the Work System [I, T, T/T, E, O]*				
		P	C	O	I	T	T/T	E	O
Anesthesia	Impact of fatigue and sleep deprivation on psychomotor performance and mood of anesthesiology residents ¹¹³	x	x		x	x			x
	Workload, production pressure and burnout of anesthesiologists ¹¹⁴⁻¹¹⁶	x	x	x	x	x			x
	Poor display and control design of medical devices: auditory and visual alarms affect vigilance and situation awareness of anesthesiologists ^{117,118}		x			x	x		
	Working in a multidisciplinary team: anesthesiologists working with a new surgeon or nurse may need extra effort to communicate effectively, in particular during stressful conditions ¹¹³			x	x	x			x
ED	Limited availability of information: patient history and other information are often not easily accessible by ED clinicians who had no prior contact with patient ¹¹⁷		x		x	x	x		
	Design of ED physical environment: overcrowding, noise ^{119,120}	x						x	
	Usability and workflow issues of ED status boards ¹¹⁹⁻¹²¹		x			x	x		
	Impact of shift work on cognitive and work performance of ED clinicians in particular during routine work ^{119,121}		x	x	x	x			x
	Limited opportunity for ED clinicians to maintain their skill level for risky and difficult, but infrequent, procedures ^{119,121}		x		x	x			
Home Care	Usability and acceptance of computer-based self-management tools for elderly patients with disability and functional decline: usability of interface, functional and physical accessibility ¹²²	x	x		x	x	x		
	Design problems of telemedicine applications: poor usability, e.g., extensive amount of text on screen ¹²³		x		x		x		
	Informal care giving: fatigue, musculoskeletal injuries during personal care ¹²³	x		x	x	x			x
ICUs	Varied, dynamic, rapidly-changing condition of patients that require rapid clinician responses ¹¹³		x		x	x			
	Design and implementation of guidelines and best practices, e.g., for infection control ¹¹⁴		x	x	x	x	x		x
	Workload, stress and burnout of ICU physicians and nurses ^{37,115,116}	x	x	x	x	x			x
	Information flow and decisionmaking in handoffs of patients: across units, across services; patients discharged; shift changes ¹¹³		x	x		x			x
	Design of alerts/alarms in medical devices and health IT ^{25,117}	x	x				x		
	Design and implementation technology for remote monitoring of ICU patients ¹¹⁸	x	x	x	x		x	x	x
Design of ICU patient rooms: open versus closed ^{113,119}	x						x		

Table 4, Chapter 31. HFE issues in selected care settings (continued)

Care Settings	HFE Issues	Physical (P), Cognitive (C) or Organizational (O) HFE			Elements of the Work System [I, T, T/T, E, O]*				
		P	C	O	I	T	T/T	E	O
Long-Term Care	Poor working conditions and job stressors: understaffing, training, feeling unable to meet resident needs, overtime, heavy workload, mostly standing and walking, risk of back injuries due to moving patients ¹²⁴	x	x	x	x	x		x	x
	Physical environment: doors cannot accommodate a wheelchair, layout of facility does not allow nursing station in a convenient place ¹²⁴	x						x	
Pediatrics	Cognitive, communication, and speech limitations of children and their dependency on adults result in communication challenges, and risk of delayed diagnosis or misdiagnosis ^{125,126}		x	x	x	x			x
	Equipment not designed for children: CT scan with adjustable exposure for children, cribs with adjustable height ^{125,126}	x				x	x		
	Design problems of CPOE technology: weight-based dosing, age-dependent lab normal values ¹²⁵		x		x	x	x		
	Design problems of BCMA technology: barcodes with different sizes, packaging of pediatric medications ¹²⁵	x				x	x		
Primary Care	Reliance on memory: missing diagnostic testing results, lack of tracking system; physician needs to remember ordered tests ^{127,128}		x		x	x	x		
	Multi-modal communication between patient and clinicians: retrieving and recording information, information loss ¹²⁷		x	x	x	x	x		
	Memory and information processing: patients with multiple problems, incomplete patient charts ¹²⁷		x			x	x		
	Workload and time pressure of clinicians: addressing several patient problems in limited time ¹²⁷		x	x	x	x			
Surgery	Operating room environment: clutter, noise, lighting, temperature, motion/vibration; impact on surgical performance ¹²⁹	x						x	
	Teamwork: miscommunication, lack of coordination, and lack of team familiarity and stability contribute to errors during surgery ^{129,130}			x	x	x			x
	Poor design and implementation of technology affect acceptance and use: e.g. integration of information across displays, unreliable audible alarms, shape of input controls, and lack of proper training for surgeons ^{129,130}	x	x	x	x	x	x	x	x
	Impact of physical and mental workload on performance: task duration, strength requirement, mental demands, and time pressure increase stress and fatigue, and may affect cognitive processing ¹²⁹	x	x		x	x			
	Design and implementation of surgery checklist ¹³¹		x	x			x		x
	Poor safety culture: lack of a culture to take responsibility for patient safety, report errors, learn from mistakes, and adapt individual and organizational behavior based on lessons learned from mistakes ¹²⁹			x	x				x

* NOTE: Elements of the work system include the individual (I), his/her tasks (T), tools and technologies (T/T), the physical environment (E) and the organization (O) (see Figure 1).

Are There Any Data About Costs of the Patient Safety Practice?

The integration of HFE in health care and patient safety requires leadership and commitment as well as resources (i.e., money, time, effort, knowledge, expertise, skills, methods and structures).¹³²⁻¹³⁵ Health care organizations that invest in HFE typically engage in one or several of the following activities: using HFE tools and methods, increasing HFE knowledge among their staff, and recruiting human factors engineers.⁶⁷ However, there is no information available about the costs of these different HFE approaches.

It is important to recognize the key role of HFE in the early phase of system design.¹³⁶ When HFE is used early in the design process, system issues can be identified and solved more efficiently and effectively, and with less risk that the fix to the system design will itself create other hazards. This implies that designers, manufacturers, and vendors of health IT applications, medical devices and other technologies must have in-house HFE expertise.

A case study of a medical device manufacturer demonstrates the challenges of implementing HFE.¹³⁷ Patient Controlled Analgesia (PCA) pumps that were introduced in 1988 were intended to allow patients to administer small and frequent dosages of analgesia, and reduce nurse workload. However, the poor HFE design of the device increased the likelihood of dosage programming errors, which in some cases led to death.¹³⁷ It took 6 years between the first reported incident of patient death related to PCA pump programming error and the hiring of a HFE engineer by the device manufacturer in 2001. Significant efforts may be required to speed up the dissemination of HFE to improve patient safety across the health care industry.^{12,67}

Fostering communication and collaboration between HFE and the health sciences and professions is critical achieving significant improvements in patient safety. Clinicians and HFE engineers need to learn to understand each other's perspectives.¹³² Because the HFE knowledge domain is broad and deep (see description above of the physical, cognitive and organizational aspects of HFE), learning HFE can be a significant investment. It is not sufficient to have physicians or nurses who have read a book or taken a seminar on HFE; this will not make them HFE experts.¹³² On the other hand, HFE engineers need to understand health care before they can have a significant impact on patient safety.⁶⁷ The training of 'biculturals' in both medicine (or nursing or pharmacy or other health science) and HFE can accelerate the application of HFE to improve patient safety.¹³⁸ Because biculturals have deep knowledge of and training in both HFE and a health science, they can help to 'translate' and disseminate HFE knowledge and tools.¹³⁸

Are There Any Data About the Effect of Context on Effectiveness?

Despite the critical role of HFE in improving patient safety, the application of HFE to health care may not be straightforward or spontaneous. More work is needed to understand the challenges faced by health care organizations in adopting, implementing and institutionalizing HFE in their operations. In the context of health care organizations, HFE can be conceptualized as an innovation whose adoption, diffusion, and maintenance are associated with challenges.⁶⁶ As described earlier, HFE patient safety practices include: using HFE tools and methods, increasing HFE knowledge, and recruiting HFE engineers.⁶⁶ A range of contextual factors can affect the effectiveness of these HFE-based interventions or innovations, such as structural characteristics of health care organizations (e.g., size, level of functional differentiation, and level of centralization of decisionmaking), cultural characteristics of health care organizations (e.g., leadership, strategic vision, approach to experimentation and risk, and learning style),

management and implementation tools (e.g., top management commitment, human resource issues, funding, and communications), and wider environmental factors (e.g., legal and regulatory requirements, efforts by national and international HFE organizations, and collaboration between health care organizations).^{66,140} Cultural conflicts between the HFE systems approach and health care can also impede the adoption and dissemination of HFE in health care organizations (e.g., physician autonomy may hinder the team collaboration and communication stressed by HFE).^{139,141}

The case study described by Vicente¹³⁸ shows that HFE is more likely to be integrated in the organization of a medical device manufacturer if the manufacturer (1) has leaders who support adoption of HFE, (2) experiences a profound performance crisis related to poor HFE performances, and (3) operates in an environment in which advocacy for HFE can be found at all levels of the complex sociotechnical system. Further research is needed to identify the key contextual factors that can facilitate adoption and dissemination of HFE. Specifically, studies are recommended for developing a theoretical framework to describe and evaluate contextual elements and generating empirical evidence on how different contextual elements can influence the success of HFE interventions.¹⁴⁰

Conclusions and Comment

A study conducted by an HFE leader, Al Chapanis, and his colleague in the early 1960s provided information on medication administration errors and the system factors that contributed to these errors.¹⁴³⁻¹⁴⁵ Since then, awareness of the importance of HFE in medication safety and other patient safety domains has significantly increased. Patient safety leaders call for increasing involvement of HFE in helping not only to characterize system factors that contribute to patient safety, but also to inform system design interventions.^{4,146,147} This chapter has described the range of patient safety issues and care settings that HFE can be applied to. Further research is needed to continue developing the evidence for the value of HFE-based interventions for patient safety.

Numerous chapters in this report describe how patient safety practices can benefit from HFE. For instance, chapter 6 reviews the evidence for the patient safety impact of Smart IV pump. HFE problems in the design of the pump interface and alerts have limited the patient safety impact of Smart IV pumps.¹⁴⁸ HFE can provide the design principles and methods to improve Smart IV pump technology (e.g., usability of pump interface design) and enhance its impact on patient safety.^{110,149} Chapter 34 describes the strong empirical evidence for the impact of nurse-patient ratio on patient safety. One potential mechanism for this impact is related to nursing workload.¹¹⁵ HFE principles and methods can be used in the design of work systems to reduce or mitigate nursing workload, and therefore, improve patient safety.^{37,115} Chapter 16 highlights some of the HFE challenges that can be addressed with integrated information displays in the OR, especially if these displays are designed to support team situation awareness and coordination.

These examples show that many patient safety practices can benefit from HFE. Patient safety practices target some aspect of the work system (see Figure 1) and should be designed and implemented according to HFE principles to produce patient safety benefits. HFE is a core element of patient safety improvement; therefore, every effort should be made to support HFE applications in patient safety. A summary table is following (Table 5).

Table 5, Chapter 31. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Potentially applicable to all patient safety problems	Not assessed systematically but Moderate-to-High evidence for some specific applications	Negligible	Moderate	A lot/Moderate

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Chapter 32. Promoting Engagement by Patients and Families To Reduce Adverse Events (NEW)

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How Important Is the Problem?

Patient-centeredness is now widely recognized as a central aspect of health care, including hospital care. Each patient has unique needs that should be addressed by each hospital in order to improve safety and quality.¹ Through patient engagement in their own safety, they and their families can help prevent adverse events.²⁻⁵ Such involvement is promoted by several international organizations, and educational materials have been developed to facilitate patient engagement in safety practices.⁶ In order to evaluate how patient engagement is being implemented and the effectiveness of this safety practice, we performed a systematic review of Medline, CINAHL, Embase, and Cochrane from 2000-2011, with a variety of synonyms for patient engagement and patient safety, including physician-patient relations, patient participation, and patient-centered care.

What Is the Patient Safety Practice?

Compared with other patient safety practices, promoting patient and family engagement does not lend itself to a precise definition as easily. Engagement can be seen as an “umbrella term” incorporating various approaches rather than a specific process, team, or technology. In general, definitions seem to center on patient and family participation in care, whether from the point of view of humanism, consumer rights, or care coordination, being used to encourage the patient to be active in reporting adverse events.^{7,8}

For that reason, patient and family engagement can be understood as a patient safety practice in various ways, not all of which are included in this chapter. First, patient engagement can be approached as an overarching philosophy applicable to a number of patient safety practices including reducing patient risk of suicide (Chapter 26) and improving care transitions at discharge (Chapter 37).

Secondly, patient engagement can be understood as an implementation in its own right. Few patient safety interventions are implemented with the sole primary goal of promoting patient and family engagement. For example, it is relatively common for another PSP, such as Rapid Response Systems or Rapid Response Teams (RRT), to be implemented with the primary goals of improving care quality and safety. Promotion of patient engagement may be a secondary goal, and data regarding the change in patient engagement after implementation of the RRT intervention may not be reported. Also, in some patient safety interventions, patient engagement may be treated as a contextual variable that may moderate the efficacy of the intervention.

Although engagement can be challenging to define, this review focused on the effectiveness of interventions intended primarily to elicit patient or family involvement in reducing the incidence of adverse patient safety events. In addition, patient/family engagement was examined as part of the implementation of selected patient safety practices with other primary goals (eg. RRT interventions).

Why Should This Patient Safety Practice Work?

Schwappach² provided a conceptual framework for patient engagement based on the Theory of Planned Behavior, which emphasizes the importance of beliefs and attitudes in creating intentions and changing actual behavior. Since patients are the only members of the treatment team who are always (theoretically) present at every treatment and visit, they provide important information that may not be available from other sources, such as medical records. In addition, many patients prefer to be involved in their care in general, which may also apply to the safety and quality of care.² Relating to this, patients have also been found to be highly motivated to decrease the risk of harm and ensure good outcomes.⁹ Finally, since many safety problems occur at the bedside and can be observed and potentially prevented by patients, they are both an important source of information on potential problems and a potential mechanism for improving safety.⁷

What Are the Beneficial Effects of the Patient Safety Practice?

The systematic review of the literature resulted in 4,107 unique articles that were potentially relevant to this topic. English-language studies from the U.S., UK, Canada, and Australia were included in the present review, due to potentially significantly different cultural issues in patient engagement in their health care outside of these countries, as well as potential differences in tools for promoting engagement. We included studies that focused on hospital care settings only (e.g., intensive care units), because we felt that patient engagement in safety in the home setting would be difficult to differentiate from patient self-management of their medications and care, when providers are not present. Finally, only systematic reviews focusing on effectiveness and prospective, controlled studies were included.

A total of 4,061 of these articles were excluded during abstract screening, leaving 46 for full article review. Of these 46 articles, 43 were excluded, leaving three articles that met inclusion criteria for studies evaluating the effectiveness of interventions focusing on patient engagement in patient safety in the hospital setting, focusing on the patient safety practices that are addressed in other chapters in this report. We identified one systematic review of patient and family engagement in safety.¹⁰ The authors found limited evidence, of poor quality, for the benefit of patient involvement in patient safety, and found that the available studies were mostly concerned with patient management of medications.^{7,11,12} We identified three studies that evaluated the impact of interventions for patient/family engagement in patient safety in the hospital setting (Table 1).

One study¹³ was a randomized controlled trial (N=209) of an intervention to provide patients with a personalized medication list. Both intervention and control groups were provided with general education about drug safety. Measurements to determine incidence of adverse drug events and close-calls included patient surveys and identification of incidents through interviews of pharmacists, interviews of housestaff, and electronic medical record review. The study was conducted in a teaching hospital without computerized physician order entry. This study found no statistically significant benefits of the intervention compared with the control group: in 1,053 total patient-days at risk, the adverse drug event rate was 8.4 percent in the intervention group and 2.9 percent in the control group (p=0.12). The close-call rate also showed no significant change, 7.5 percent versus 9.8 percent (p=0.57).

McGuckin and colleagues¹⁴ conducted a pre-post study for hand hygiene among 35 patients located on an inpatient rehabilitation unit in an acute-care hospital. Using a patient education

model, a 6-week study with a 3-month followup was conducted. During the intervention, patients agreed (and were encouraged) to ask all health care workers with direct contact if they had washed/sanitized their hands. Use of soap and sanitizer per resident-day was measured before, during, and after the intervention. While the intervention itself was not multifaceted, multiple methods were used to encourage patients to ask the handwashing question of their providers: a visit by a premedical student with the patient to discuss hand hygiene (HH); an education brochure; and multiple prompts for patients to ask their providers, including videos and visual aids. Hand washing or sanitizing increased from five HH uses per resident-day during the intervention to 9.7 HH per resident-day during the intervention ($p<0.001$), 6.7 HH per resident-day post-intervention (at 6 weeks) ($p<0.001$) and 7.0 HH per resident day at 3 months ($p<0.001$). Patients asked their physicians about hand hygiene 40 percent of the time, and their nurses 95 percent of the time.

Stone and colleagues¹⁵ carried out a pre-post study among 187 acute-care hospitals in the National Health System of the United Kingdom that included patient engagement as part of a multifaceted HH intervention. A HH campaign was introduced to these hospitals over a period of 7 months, including alcohol hand rub near the patients' bedside, regularly changed wall posters in the wards regarding HH, and materials telling patients to ask their providers to clean their hands. Median use of alcohol hand rub increased statistically significantly in the participating hospitals during the intervention period, from seven to 13 ml per bed-day of alcohol hand rub over 6 months ($p<0.001$); the change in soap use was not statistically significant ($p=0.06$). Rate of hospital-acquired infections did not change.

Because of the small number of studies meeting our criteria, and their heterogeneity, we could not perform evidence grading.

Table 1, Chapter 32. Patient engagement in safety: effectiveness studies

Author, Year	Description of PSP Multiple Interventions or Multifaceted Interventions	Study Design Sample Size	Outcomes: Benefits*
Weingart 2004 ¹³	Providing patients with personalized medication list to help prevent medication errors	RCT 209	Adverse drug event rate: N Close-call rate: N
McGuckin 2004 ¹⁴	Asking all health care workers who had direct contact with them, "Did you wash/sanitize your hands?"	Pre-post 35	Hand hygiene per resident day: Y
Stone 2007 ¹⁵	Instructing patients to ask health care workers to clean their hands.	Pre-post 187	Total alcohol hand rub and soap-use per patient day: Y

*Statistical significance, Y (Yes) or N (No)

What Are the Harms of the Patient Safety Practice?

None of the studies included in this review evaluated harms of interventions or surveys. Interventions to increase patient engagement, such as reminding health care workers to wash their hands, could theoretically adversely affect provider-patient relationships and patients' trust in their providers. Patients might fear adverse consequences, or health care providers could become overly reliant on patient engagement and more lax in their own safety practices.⁶

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Patient engagement is part of several key organizations’ approach to patient safety. The World Health Organization provides educational materials for patients, and The Joint Commission National Patient Safety Goals include the “Speak Up” campaign to engage patients in preventing wrong-site surgery. Bergal and colleagues assessed patients’ reliability in regard to marking the site of planned surgery and found only partial compliance (68%). A review by McGuckin and colleagues¹⁶ assessed the importance of patient role (which they term patient empowerment) in HH interventions. Three of the cited studies (themselves authored by McGuckin and colleagues) showed that, while 80 to 90 percent of patients reported willingness to ask their health care workers to wash their hands, 60 to 70 percent of patients actually did so. Because of the paucity of literature, the authors were unable to conduct a systematic review. Patient participation in safety practices may be influenced by societal norms and the health care environment, including whether the organizational culture supports patients’ participation.⁷

Patient engagement interventions have been applied to a number of individual patient safety practices addressed elsewhere in this report. These practices include hand hygiene, rapid response teams, surgical site marking, and falls. Examples of implementation studies in patient engagement are described below.

Patient Engagement in Implementation of Hand Hygiene Interventions

A review by McGuckin and colleagues¹⁷ addressed patient empowerment as an approach to motivating strategies in hand hygiene (HH) interventions (Table 2). As summarized in Chapter 8 (Hand Hygiene Compliance) above, the authors estimated from the literature the proportion of patients who stated their desire to be empowered, or engaged, in reminding health care workers to wash their hands. However, the proportion of patients who endorsed readiness for engagement (or empowerment) was not always congruent with the proportion of patients who asked their health care workers about HH. The authors identify several barriers discussed in the literature to patients’ activating their engagement, emphasizing the negative social reaction that patients might feel when asking their HCWs about HH. Finally, McGuckin and colleagues emphasize that the literature on patient empowerment in HH is lacking estimates of effectiveness.

Table 2, Chapter 32. Hand-hygiene intervention studies

Author, Year	Main Study Objective	Implementation Themes
McGuckin, 2011 ¹⁷	Review of patient empowerment motivating strategies in hand hygiene intervention	Tools: educational tools, motivation and reminder tools, and role modeling Facilitators/barriers: Social barrier of patient to confront health care workers; Lack of evidence of effectiveness

Patient Engagement in Implementation of Rapid Response Team Interventions

Three studies considered patient engagement in the context of Rapid Response Teams (RRT) (Table 3). Ray and colleagues¹⁸ implemented a pediatric RRT based on direct family activation, an approach developed to “empower family members to seek help when serious concerns arise.” The “direct family activation” itself was a direct telephone number to reach the RRT, which

families could reach from any room in the hospital. In addition, families were educated via posters in patients' rooms and flyers. In-person "family awareness surveys" assessed families' awareness of the family activation approach. Nurses were trained in how to explain the RRT activation to families. They were also given reminders in the electronic medical record and given feedback on levels of family awareness from the surveys. After implementation of family activation, the number of RRT calls per 1,000 discharges increased from 16 to 24, though no statistical tests were employed to assess significance.

Dean and colleagues¹⁹ described a similar early warning system that "empowers patients and families to serve as an additional line of patient-safety defense" by integrating them into the RRT system of a major children's hospital. This study specified the conditions under which patients or families were encouraged to call the RRT, including a noticeable medical change in a patient that had been unaddressed; a breakdown in care or uncertainty regarding treatment; the administration of a medication that causes an adverse effect or that the patient/family believed had not been sufficiently explained; or the provision of treatment that the patient or family believed was meant for another patient or contravened their doctors' wishes. Apart from the criteria under which the alert system was to be activated, this study did not detail how patients or families were to be empowered or educated to overcome any barriers to using the system. From September 2005 through August 2007, the early warning system responded to 42 calls from patients and parents; the authors state that the root cause for all calls was miscommunication between patient and provider.

Gerdik and colleagues²⁰ studied the implementation of a family- and patient-activated rapid response team in an acute care hospital. Picker's "Eight Dimensions of Patient-Centered Care" provided the conceptual framework, including the "involvement of family of friends," which includes "involving family in decision-making." However, no explicit attention to patient or family engagement was otherwise given. Implementation of the family-/patient-activated RRT involved written educational materials, informational signs, instructional labels for telephones, and scripted education and training on the part of staff. After RRT activation, patient and family satisfaction were assessed. Following implementation of the RRT, codes decreased significantly outside the ICU, from 25/month to 17/month. Patients and families alike were found to be satisfied with the RRT.

These studies of family and patient engagement in RRT evaluated implementation and did not explicitly set out to evaluate effectiveness. However, in the study by Gerdik and colleagues²⁰, after implementation of the RRT, codes outside the ICU decreased, potentially representing a measure of effectiveness.

Table 3, Chapter 32. Rapid response team intervention studies

Author, Year	Main Study Objective	Implementation Themes
Ray, 2009 ¹⁸	To implement a pediatric RRT based on direct family activation	Tools: direct telephone number to reach the RRT which families could reach from any room in the hospital, posters, flyers Staff/education: mock script to help medical team discuss RRT activation with patients/families Facilitators/barriers: physicians concerned that their role would be undermined; providers' understanding of RRT as extension of care they already provide
Dean, 2008 ¹⁹	To integrate patients and families into an RRS at a children's hospital	Tools: telephone number to activate RRT available to patients/families 24 hours, 7 days a week Staff/education: explanation by admitting unit's nurse to patient and family, reinforced by video and brochure Facilitators/barriers: leadership, provider involvement
Gerdik, 2010 ²⁰	To implement a patient- and family-activated RRT at an acute care hospital	Tools: dedicated phone line Staff/education: patient and family education Facilitators/barriers: concern that resources would be overwhelmed; endorsement of hospital administration, physicians, and staff

Patient Engagement in Implementation of Fall Interventions

Chapter 19 addresses patient safety practices to reduce the incidence of in-facility falls. While multi-modal interventions were found throughout the literature, including those incorporating patient education, none of the studies reviewed specifically address patient engagement.

Two studies were identified in the search for this review (Table 4). Krauss and colleagues²¹ implemented an educational intervention to reduce patient falls according to a quasi-experimental design among nursing staff, nursing secretaries, and patient care technicians in an academic hospital. While patient or family activation or engagement were not mentioned specifically as part of the implementation or its conceptual background, nurses were directed to educate all patients in fall prevention. For patients with high risks of falling, nursing staff were instructed to reinforce falls-prevention education with both patients and family. Staff received feedback on fall rates on their unit during the implementation via meetings and flyers. The nursing staff's knowledge and use of prevention strategies improved. The incidence of in-hospital falls decreased for 5 months but the decrease for the full 9-month intervention period was not significant.

van Gaal and colleagues²² implemented a multi-component intervention to reduce the risk of pressure ulcers, falls, and urinary tract infections in ten wards from four hospitals and ten wards from six nursing homes. Patient involvement was conceived as part of the intervention and was included because it can "enhance the implementation of innovations or improvements." Oral and written information was given to patients at risk for specific adverse events. Implementation on every participating ward included educational meetings for nurses and informational brochures

for patients at risk for any one of the adverse events addressed. Fewer falls per patient week were found the participating hospital wards and nursing homes, but the study was not powered to determine the statistical significance of the decreased incidence of particular adverse events.

Table 4, Chapter 32. Falls prevention intervention studies

Author, Year	Main Study Objective	Implementation Themes
Krauss, 2008 ²¹	To implement an educational intervention among nursing staff, nursing secretaries, and patient care technicians to reduce falls in an academic hospital	Tools: educating all patients and families in fall prevention, patient pamphlets Staff/education: Nurses, patient care technicians, and unit secretaries all took part in education modules Facilitators/barriers: staff turnover; high patient-to-nurse ratios; high patient turnover or high patient volume; competing demands on nursing staff; lack of buy-in from staff
van Gaal, 2011 ²²	To implement a multi-component intervention, including patient involvement, to reduce the risk of pressure ulcers, falls, and urinary tract infections in ten wards from four hospitals and ten wards from six nursing homes	Tools: education, patient involvement and feedback on process and outcome Staff/education: Key nurses on each unit implemented small-scale educational program, two case discussions on every ward, and distributed a CD-ROM with educational material Facilitators/barriers: complexity of intervention

Patient Engagement in Implementation of Surgical Checklist Interventions

Most studies of inventions to prevent wrong-site surgery have focused on checklists for surgeons or anesthesiologists to perform prior to surgery.²³⁻²⁵ Although patient interaction may be part of the checklist, such as verbally verifying patient identity and surgical site,²³ the provider team is the target of the intervention. Only two studies have examined patient engagement as a means to avoid wrong-site surgery (Table 5). One study, in the setting of a private foot-and-ankle practice, gave patients written instructions to mark the limb not to be operated on with the label “NO” and observed patient compliance of 59 percent on the day of surgery.²⁶ The other study, in the setting of a university-affiliated orthopedic practice, gave patients both verbal and written instructions to mark the intended surgical site with the label “YES” and provided a marking pen to do so.²⁷ Patient compliance in this study was 68.2 percent, with higher compliance in patients whose primary language was English and whose surgery occurred sooner after instructions were given.

Table 5, Chapter 32. Surgical checklist intervention studies

Author, Year	Main Study Objective	Implementation Themes
Bergal, 2010 ²⁷	To investigate patient compliance in marking surgical site	Tools: verbal and written instructions to mark surgical site, marking pen provided; assessment for compliance on day of surgery Barriers/facilitators: patients' primary language, cultural tendency to rely on physicians, younger patient age, time between enrollment and surgery
DiGiovanni, 2003 ²⁶	To investigate patient compliance in marking surgical site	Tools: written instructions to mark limb NOT to be operated on; assessment for compliance on day of surgery

Patient Engagement in Implementation of Care Transition Interventions

Patient engagement is defined in a variety of ways. Depending on the definition, the practical implications can be broader or more specific. While in the rest of this chapter we address interventions centered on patient engagement as an independent element and on interventions where patients assume a primary role in patient safety, an additional important and valuable route to patient engagement is to encourage patient activation in an existing intervention, as one part of a larger approach. Patient engagement in transitional care is an important example of this broader approach.

Interventions to improve transitional care at the time of hospital discharge are examined in Chapter 37. Patient engagement is one of many aspects of these patient safety practices. Pre-discharge interventions may include patient engagement in the form of patient and/or caregiver education. Post-discharge interventions may include outreach to patients and/or caregivers by means of follow-up phone calls or other methods. “Bridging” interventions may include a combination of these and other components.

Only one intervention, the Care Transitions Intervention (CTI), had been implemented and evaluated in multiple settings.²⁸⁻³² The CTI is designed to provide patients and caregivers with the tools and skills to take a more active role in their care. It is based on four pillars of medication self-management: a patient-centered record, follow-up, and identification of “red flags” with instructions on how to respond to them. Patients and care-givers received in-hospital visits, telephone calls, home visits, encouragement to take an active role in care, and guidance from a “transition coach.” Efficacy studies of CTI have shown reduced rates of readmission in clinical trials set in a not-for-profit capitated delivery system^{28,29} and a Medicare fee-for-service system.³³ Assessment of patient engagement as the mediator of reduced readmission have shown that patients receiving CTI reported high levels of confidence in self-management, understanding warning symptoms of worsening condition, ability to obtain needed information during follow-up visits, and understanding of how to take their medications.²⁹

Implementation studies of CTI in “real-world” settings have also shown reduced readmissions for patients who received coaching compared with those who did not. Implementation issues included the training and time commitment of transition coaches and the challenge of recruiting and retaining patients in the intervention.³¹ Studies that directly addressed sustainability emphasized the importance of leadership, hospital-community partnerships, tailoring to the needs of diverse communities and particular patient subgroups, and resource allocation (staff and funding) as important factors in implementation. Mean patient activation scores were moderately higher for sites with full sustainability plans than for sites with partial or

minor plans, suggesting that greater engagement in the program at the site level could affect engagement by patients receiving the intervention.³² Qualitative data indicate that patient perceptions of a caring relationship with transition coaches foster greater patient engagement in the program, with implications for staff training.³³

Are There Any Data About Costs?

None of the reviewed studies directly evaluated the costs or cost-effectiveness of practices designed to promote patient or family engagement with safety.

Are There Any Data About the Effect of Context on Effectiveness?

As noted above, McGukin¹⁴ recorded the frequency with which patients asked various members of the care team about their HH practices; however, this outcome was not linked to any model about how the outcome might be affected by the context in which the intervention was implemented.

Conclusions and Comment

Patient and family engagement is an emerging area in patient safety research, with few published effectiveness studies. However, it is an important part of key organizations’ patient safety initiatives, and a number of recent studies have described implementation approaches and challenges. Future work must address basic and applied concerns across the spectrum of conceptual foundations and experimental design, including the research questions that need to be answered: the definition and measurement of patient and family engagement; the safety endpoints that should be addressed; and methodological issues around study design.

Also important to address in future work is the variety of approaches that have been taken to promoting patient engagement, whether as an independent intervention or as part of an intervention focused on an existing patient safety practice. Distinguishing the features of “instrumental” patient engagement and “independent” patient engagement interventions will help clarify the nature of patient engagement as a patient safety practice. A summary table is located below (Table 6).

Table 6, Chapter 32. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common	Emerging practice (few studies available)	Uncertain	Low	Little/Moderate

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Chapter 33. Promoting a Culture of Safety

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How Important Is the Problem?

A culture of safety has been suggested as a core mechanism underlying safe, effective, and timely patient care. It has been implicated as a critical factor underlying continuous learning and effective teamwork, as well as a key driver of safety behaviors such as error reporting, and safety outcomes such as reduced adverse events.^{1,2}

A number of studies have found associations between culture and safe care practices, such as error reporting.^{1,3-5} Other studies have found associations between patient safety culture and patient outcomes, including reduced adverse event indices⁶ and mortality.^{7,8} For example, several studies have found relationships between safety culture and the AHRQ Patient Safety Indicators.^{9,10} In one study that utilized a composite of 12 AHRQ patient safety indicators results suggested that a 1 standard deviation increase in patient safety culture scores was associated with a 10% decrease in the composite PSI risk.¹⁰ Other work has indicated that culture can account for up to 6% of the variance in adverse events and 18% of the variance in patient willingness to recommend a hospital to family and friends.¹¹

What Is the Patient Safety Practice?

Compared with other patient safety practices, interventions to promote patient safety culture (PSC) are less easily defined. Effective safety cultures have been described as those in which there is shared commitment to safety as the highest priority, where engaging in safety-promoting behaviors is encouraged and reinforced by leaders and peers, and where glitches or near misses are valued as opportunities for learning and improvement. Therefore, interventions to promote safety culture include a broad range of interventions rooted in principles of promoting leadership, creating effective teamwork, and behavior change rather than a single specific process, team, or technology. For example, interdisciplinary rounding^{12,13} and executive walkrounds,^{14,15} as well as interventions designed to enhance provider communication,¹⁶ to encourage error reporting,^{14,17} and team training^{18,19} have all been labeled as interventions “to promote a culture of safety.” In the present review, for example, 11 studies described multi-faceted interventions (i.e., interventions or practices with multiple components or aspects).^{13,14,16,19-26}

Precise definition is further complicated given that few patient safety interventions are implemented with the sole primary goal of promoting safety culture. For example, it is relatively common for another PSP, such as a Rapid Response System (RRS), to be implemented with the primary goal of reducing code events or other negative patient outcomes. Promoting a culture of safety may be a secondary goal of an RRS intervention, and data regarding the change in staff perceptions of safety culture following implementation of the RRT intervention may be reported; however, improving safety culture was not the primary stated goal of the intervention. In this sense, some studies treat safety culture as a primary outcome variable, while others treat it as a contextual variable that may moderate the efficacy of another PSP.

This review is specifically focused on studies in which the primary intervention goal was explicitly to promote a culture of safety. We did not limit inclusion criteria based on a particular

type of intervention with the aim of identifying the full breadth of different practices being described as interventions to promote safety culture.

Why Should This Patient Safety Practice Work?

Patient safety culture (PSC) is defined as a holistic snapshot of enacted norms, policies, and procedures related to patient safety that guide the behaviors, attitudes, and cognitions of care providers.²⁷ In this sense, PSC is a social aspect of the work environment that shapes what providers do, think, and feel during their day-to-day work activities. More concretely, PSC has been described as a shared commitment to patient safety as the most important organizational goal that provides cues to clinicians and staff about the relative priority of patient safety in comparison to other unit or organizational goals. In this way, working in strong, positive safety cultures motivates employees to behave in ways that support safety. In such work environments, clinicians and employees feel a sense of obligation to speak up if they see a potential hazard, to lend a hand to fellow team members, to ask for help if they need it, and believe that putting patient safety first will be recognized and rewarded. Given its role as a motivational force that helps to shape clinician behaviors and attitudes, and cognitions, PSC is important for understanding issues of safety, care quality, error, and process improvement.

PSC is a facet-specific form of general organizational culture, meaning that is a specific form of organizational culture that focuses on a narrowly defined aspect of performance, namely patient safety. For example, general organizational culture refers to:

a pattern of shared basic assumptions learned by a group as it solved problems...which have worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel...²⁸

PSC therefore refers to the pattern of assumptions shared among members of a group (e.g., a unit or organization) specifically related to patient safety and can be differentiated from general organizational culture.^{29,30} More specifically, Sorra and Nieva³¹ cite the following the definition of safety culture in their work dedicated to measuring patient safety culture:

the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.³²

Definitions of safety culture also include a focus on employee safety²⁷ and several authors have started to develop theoretical models of patient safety culture.³³⁻³⁵ Overall though the theoretical development of patient safety culture as a construct in the existing peer-reviewed literature could be further developed and logic models underlying interventions to promote culture are often not reported.

Safety Culture Versus Safety Climate?

Patient safety climate is a related term often used interchangeably with culture. Patient safety climate refers specifically to provider perceptions of patient safety-related norms, policies, and

procedures that are shared among members of a group (care team, profession, unit, service, department, organization, system). The difference between culture and climate is often reduced to a difference in methodology, with studies involving surveys being categorized as measures of climate and ethnographic studies that involve detailed, longitudinal observations being categorized as studies of culture.

Practically, the differentiation between culture and climate is often viewed as a primarily academic exercise. However, the dichotomy raises an important and very practical point. If you are measuring safety culture using a survey, then you are measuring clinician and staff perceptions of culture (i.e., safety climate) and therefore in order to change culture you have to change perceptions of the relative priority of patient safety compared with other unit or organizational goals, and it must be salient to providers that their actions and attitudes supporting patient safety are actively reinforced by their peers and leaders. For example, it must be explicit that patient safety comes first relative to other unit or organizational goals, such as efficiency, and there must be visible recognition and positive outcomes related to engaging in safe behaviors.

For the purposes of this review we included studies of both patient safety culture and patient safety climate. In our discussion, we use the term patient safety culture to simplify the reporting of results.

Measuring Patient Safety Culture

Patient safety culture has primarily been measured by patient safety climate surveys that capture employee perceptions of social, technical, and environmental aspects of their workplace. While the reviews of other patient safety practices focus on patient outcomes as the primary dependent variable and culture as a contextual variable, the present review focuses on changes in employee perceptions of patient safety culture as the primary dependent variable. We also include concurrently reported patient outcomes.

At least five previous reviews have been dedicated to survey instruments used to measure and assess patient safety culture.³⁶⁻⁴⁰ Their results indicate that the degree of psychometric evidence for reliability and validity varies significantly among the surveys designed to measure patient safety culture that have been published in the peer reviewed literature. Some of the surveys with the greatest amount of psychometric evidence in the published literature to date include the Hospital Survey on Patient Safety Culture,³¹ the Safety Attitudes Questionnaire,⁴¹ and the Patient Safety Climate in Healthcare Organizations survey.⁴² To ensure a foundational level of psychometrically sound measurement, the inclusion criteria for this review required that studies use a measure with evidence of reliability and validity available in the peer reviewed literature.

What Are the Beneficial Effects of the Patient Safety Practice?

The systematic review of the literature resulted in 2696 unique articles that were potentially relevant to this topic. We excluded 2563 of these articles during abstract screening, leaving 133 for full article review. Of these 133 articles, we excluded 115, leaving 18 articles that addressed the benefits of interventions to improve patient safety culture.

Our systematic review identified 18 primary studies dedicated to evaluating safety-oriented interventions that were designed to promote a culture of patient safety, were conducted in an in-patient hospital, and measured patient safety culture/climate using a validated survey instrument.

We did not identify any prior systematic reviews specifically dedicated to interventions designed to promote a culture of safety in health care.

Of the 18 studies reviewed, 12 were pre-post studies, 2 were cluster randomized control trials, 2 were concurrent control studies, 1 was a pre-post with concurrent control, and 1 was a quasi stepped-wedge design. Eleven studies measured patient safety culture/climate using the Safety Attitudes Questionnaire (SAQ),⁴¹ 4 studies used the AHRQ Hospital Survey on Patient Safety (HSOPS),³¹ 2 studies used the Patient Safety Climate in Healthcare Organizations survey (PSCHO),⁴² and 1 study utilized the Safety Climate Scale (SCS).⁴³ Though the primary method of measuring patient safety culture/climate uses individual-level survey responses, culture is considered a group-level phenomenon. Thus, the majority of studies operationalized culture at the unit level of analysis. Three studies, however, operationalized culture at the hospital level of analysis.^{15,24,44} Sample sizes returned ranged from 5461 individual responses nested within 144 units within a single hospital system to 28 individuals nested within a single unit. Response rates ranged from 35% to 100% (see Summary Table and Evidence Tables).

The majority of interventions were multi-component interventions that combined several improvement strategies under a single overarching initiative to promote a culture of safety. For example, Belgen et al. 2010¹⁹ utilized a three component approach that included team-training, unit-based safety teams, and strategies for engaging patients in daily goal setting. Overall, 6 studies explicitly included teamwork and communication training and tools (e.g., structured briefings or debriefings), 4 explicitly included some form of executive walk rounds, and 4 explicitly used a multi-component approach known as the Comprehensive Unit Based Safety (CUSP) program (see Summary Table and Evidence Tables).

In terms of effectiveness, 9 of 18 (50%) reviewed studies reported a statistically significant impact of the intervention on the overall culture score, the safety climate score, or on at least half of reported survey items if analyzed at the item level. Several studies reported significant improvements in teamwork climate, but did not find similar improvements in safety climate (see Summary Table and Evidence Tables).²⁰ None of the studies examining multi-component or bundled interventions examined the relative effectiveness of individual intervention components. Only one study directly compared the effectiveness of different interventions by comparing a simulation-based team training intervention to didactic-only team-training intervention¹⁸. Results indicated no change in safety culture survey scores for the didactic-only and control groups. An increase in teamwork climate was reported for the simulation-training group; however, this finding did not remain statistically significant after Bonferroni adjustment.

Seven studies also reported the impact of interventions on other outcomes, along with patient safety culture. In terms of patient outcomes, one study that found significant improvements in teamwork climate²⁰ also found a significant decrease (0.56 vs. 0.15, $p < .01$) in the rate of reported errors that resulted in patient harm after implementation of a multi-faceted suite of interventions that included both cultural (e.g., feedback on errors in the form of posters and emails, education and training) and system-focused changes (e.g., CPOE, medication management protocols, changes to safety reports) implemented over 2.5 years. Another study found that the number of rapid response system activations that led to code events decreased from 29% to 22% following an intervention to promote safety culture in which paraprofessional care providers learned how to utilize structured communication methods to communicate changes in patient status. However, this difference was not tested statistically. Another study that reported a marginal increase in teamwork climate¹⁸ also found that the experimental unit's weighted adverse outcome score decreased by 37% after implementation of a team training

program designed to promote patient safety culture, compared with a 43% increase in a control unit ($p < .05$). One study also provided descriptive information on reductions in nurse turnover from 27% to 0% for two years following implementation of the CUSP program, but no statistical analysis was reported (see Summary Table and Evidence Tables).²⁶

The evidence to date suggests that several practices may help to promote a culture of safety; however, methodologic issues related to variation in the practices studied and outcomes reported, extremely small sample sizes, and lack of cluster randomized trials constrain the evidence for intervention effectiveness available to date. Robust evaluations are needed that assess the impact of practices to promote patient safety culture across multiple outcomes, based on theoretically sound evaluation models. One previous review of interventions to promote safety culture also noted methodological constraints in primary studies⁴⁵ and one previous review dedicated to strategies to improve culture concluded that there was no rigorous evidence available in the current literature to demonstrate their effectiveness.⁴⁶ While the criteria for the previous work finding no studies that met inclusion criteria⁴⁶ were more stringent than those utilized in the present review, this conclusion supports our finding that the robustness with which interventions to promote culture are studied, evaluated, and reported is in need of improvement.

In terms of grading, the strength of evidence for this topic was low. Risk of bias was generally high due to study design issues - we identified only one true cluster RCT¹⁷ Major issues affecting risk of bias for many studies included low response rates for surveys and incomplete reporting (not reporting all units or hospitals where interventions were conducted, and not reporting results for all parts of the culture survey but focusing only on those that were statistically significant). Results were inconsistent: findings in half of the studies were not statistically significant and significant findings were difficult to compare due to variations in measurement methods. With respect to directness, the intervention was often not specifically designed to improve patient safety culture, and actual patient safety outcomes were infrequently reported. Finally, with respect to precision, a number of different survey instruments were used and were often reported differently in the articles, so no conclusions could be drawn (see Evidence Table on Risk of Bias).

What Are the Harms of the Patient Safety Practice?

None of the studies included in this review explicitly evaluated harms of culture interventions or surveys.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

The effectiveness of the various methods for promoting a culture of safety likely varies based upon the characteristics of the intervention and implementation processes. The interventions reported in the 18 studies we reviewed differed in terms of the characteristics of the organizations in which they were implemented, the level of leadership support and engagement reported, and in the tools and strategies utilized to support implementation and to transfer the intervention to daily care processes. Ten studies were conducted exclusively in academic hospital settings, 3 studies were conducted in community based hospital settings, 4 studies explicitly included a mix of academic and community hospitals, and several studies did not explicitly address the hospital mix included in their sample. One study also reported that the gain

in safety culture scores was larger for faith-based hospitals; however statistical analyses of these reported differences were not reported.²³

This review also highlights the largely atheoretical nature of the research to date regarding the development and implementation of interventions to promote patient safety culture. Only 3 of the 18 reviewed studies (17%) noted any form of theoretical grounding for their improvement and implementation strategy. Conceptual theories of patient safety culture and culture change are foundational features of a clear logic model that guides intervention design and implementation. Future studies should dedicate greater effort to developing and reporting the underlying theoretical model driving intervention design and improvement efforts. Such models are a critical element to furthering our understanding of the role context plays in moderating the effects of various interventions to promote safety culture (Table 1).

Table 1, Chapter 33. Results of included studies on patient safety culture

Author, Year	Description of PSP	Study Design	Outcomes: Benefits*
Abstoss, 2011 ²⁰	4 culture & 3 system-level interventions	Pre-post	Culture survey: N Teamwork: Y Reported errors resulting in harm: Y Overall reporting rate:
Adams-Pizarro, 2011 ²⁴	Multi-component intervention	Pre-post	Culture survey: No statistical tests reported
Blegen, 2010 ¹⁹	Multi-component intervention	Pre-post	Culture survey: Y
Cooper, 2008 ⁴⁴	Crisis resource management training	pre-post with control hospitals	Culture survey: N
Donahue, 2011 ¹⁶	Paraprofessionals communication training	Pre-post	Culture survey: No statistical tests reported Use of structured communication: No statistical tests reported Rapid response events that led to code events: No statistical tests reported
Edwards, 2008 ⁴⁷	Multi-component intervention	Pre-post	Culture survey: Y
Frankel, 2008 ¹⁵	Executive walkrounds	Pre-post	Culture survey: Y
O'Leary, 2010 ¹³	Structured Inter-Disciplinary Rounds	Concurrent control	Culture survey: N Teamwork: Y
O'Leary, 2011 ¹²	Structured Inter-Disciplinary Rounds	Concurrent control	Culture survey: Y Teamwork: Y
Paine, 2010 ²⁵	Multiple interventions	Pre-post	Culture survey: Y
Pettker, 2009 ²² Pettker, 2011 ²¹	Multi-component	Pre-post	Culture survey: Y Adverse outcomes: Y
Pronovost, 2005 ⁴⁸	Comprehensive Unit-Based Safety Program	Quasi stepped-wedge design	Culture survey: Y Nurse turnover: N Length of stay: Y
Riley, 2011 ¹⁸	TeamSTEPPS training	Cluster RCT	Culture survey: N Adverse outcomes: Y
Sexton, 2011 ²³	Comprehensive Unit-Based Safety Program	Pre-post	Culture survey: Y
Thomas, 2005 ¹⁷	Executive walkrounds	Cluster RCT	Culture survey: N overall; Y when analyzed by exposure to intervention
Tiessen, 2008 ¹⁴	Multi-component intervention	Pre-post	Culture survey: N
Timmel, 2010 ²⁶	Comprehensive Unit-Based Safety Program	Pre-post	Culture survey: Y Nursing turnover: No statistical tests reported

*Overall results statistically significant – Yes or no

Are There Any Data About Costs?

None of the reviewed studies directly evaluated the cost-effectiveness of practices designed to promote a culture of safety. However, one study attempted to examine how a multifaceted intervention that included interdisciplinary rounding and regular interdisciplinary meetings affected adjusted per-patient care costs. Compared with a control unit, adjusted costs of care were reported as \$24 less for intervention unit patients; however, the study was underpowered, and this was not a statistically significant difference.¹³

Are There Any Data About the Effect of Context on Effectiveness?

None of the reviewed studies directly evaluated the effect of context on intervention effectiveness; however, there is a clear need to determine the impact of contextual features in promoting a culture of safety.

Conclusions and Comment

We found low strength of evidence that interventions to improve safety culture can improve culture as an outcome, and insufficient evidence that interventions to improve culture can improve patient safety outcomes, due to very few studies measuring these outcomes, and the heterogeneity across interventions and types of safety outcomes reported. Although there is an emerging evidence base dedicated to examining practices that promote a culture of safety, future work must make large gains in robustness of experimental design and methodologies for measuring culture in order to meaningfully advance our understanding of how to promote safety culture effectively.

The evidence to date suggests that practices to promote patient safety culture may be beneficial; however, evaluation designs and the rigor of available evidence do not support strong causal conclusions. For example, the studies reviewed did not evaluate the mechanisms through which these interventions impact culture. Additionally, most of the interventions reviewed had multiple components, but none of the studies examined the incremental impact of each component of the intervention. Future studies should strive to clearly evaluate the incremental and differential impact of individual components of multifaceted intervention strategies.

Future research efforts should also aim to further our understanding of how providers formulate their perceptions of safety culture. While there is a significant literature on the etiology of safety culture (i.e., how individuals and groups formulate their perceptions of culture) in the organizational sciences, little work has been done in health care to understand how providers formulate their individual perceptions of safety culture and how these perceptions become shared with others in their unit, department, or care team. Understanding how perceptions of patient safety culture form and come to be shared among health care workers is a critical component of understanding how to effectively promote and improve safety culture. There is a rich theoretical and empirical literature from the organizational sciences that can be drawn upon to enhance the strength of studies examining interventions to promote a culture of safety within health care.

Most important, this review underscores that the interventions designed to promote culture need to be more rigorously tested and reported. Few studies to date have applied rigorous evaluation designs or have clearly articulated critical aspects of study execution in peer reviewed outlets. Findings from our review mirror those of other reviews^{45,46,49} that examined the effectiveness of strategies to change organizational culture to improve health care performance. Collectively results suggest some homogenous evidence for interventional strategies such as

team-training, executive engagement strategies, and unit-based improvement processes. They also highlight the need for more rigorous evaluations of patient safety practices designed to promote safety culture. A summary table is following (Table 2).

Table 2, Chapter 33. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low-to-high	Low	Uncertain	Low-to-moderate (varies)	Moderate/Not difficult-to-Moderate (varies with intervention)

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Chapter 34. Effect of Nurse-to-Patient Staffing Ratios on Patient Morbidity and Mortality

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How Important Is the Problem?

A small percentage of hospitalized patients die during or shortly after their hospitalization. Evidence suggests that some proportion of these deaths could probably have been prevented with more nursing care. For example, in one early study of 232,342 surgical discharges from several Pennsylvania hospitals, 4,535 patients (2%) died within 30 days of the hospital admission; the investigators estimated that the difference between 4:1 and 8:1 nurse-to-patient staffing ratios might be approximately 1,000 deaths.¹ Other studies have resulted in roughly similar estimates, namely about 1 to 5 fewer deaths per 1000 inpatient days.

What Is the Patient Safety Practice?

What the patient safety practice “is” remains unclear, because to date no intervention studies have assessed the effect of a deliberate change in registered nurse (RN)–to–patient staffing ratios. Most studies have been cross-sectional or longitudinal assessments of differences in nursing staff variables (see below), with the most commonly assessed measure being the proportion of RN time per a measure of inpatient load and the most commonly assessed outcome being mortality. However, numerous other factors have been proposed as being causal with respect to the relationship between nursing care and reductions in hospital mortality, potentially in addition to or instead of a simple nursing staff- to- patient ratio: These factors include measures of nursing burnout, job satisfaction, teamwork, nurse turnover, nursing leadership in hospitals, and nurse practice environment.

Why Should This Patient Safety Practice Work?

Conceptual frameworks for why more effective nursing care may reduce inpatient mortality have been proposed by Tourangeau and colleagues,² Thornlow, Anderson and Oddone,³ and Despins, Scott-Cawiezell, and Rouder.⁴ Underlying all these conceptual frameworks is the belief that surveillance is a critical factor that can be improved with more staff, better educated staff, or a better working environment.⁵ As shown by Aiken and colleagues,⁶ nurse-patient ratios, along with staffing skill mix, can lead to better surveillance, which along with a number of other factors can influence the process of care and lead to better patient outcomes (see Figure 1).

Figure 1, Chapter 34. Hospital organization, nursing organization, and patient outcomes

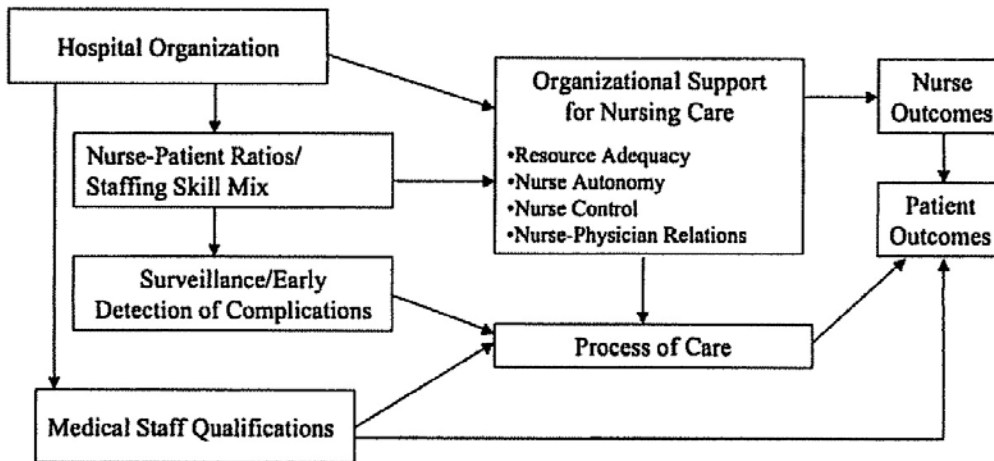


Figure taken from Aiken et al., 2002⁶

Aiken LH, Clarke SP, Sloane DM. Hospital staffing, organization, and quality of care: Cross-national findings. *Nurs Outlook*. 2002 Sep-Oct;50(5):187-94. with permission from Elsevier.

The model of Despins and colleagues (Figure 2) explicitly posits that better detection of potential signals of patients at risk of poor outcomes is the mechanism by which more effective nursing care exerts its beneficial effects; it further elaborates that organizational culture is an important component of better signal detection (e.g., high reliability organizations instill in their staff the value they place on safety). ‘Internal factors’ such as nurse fatigue also play a role in this model.

Figure 2, Chapter 34. Despins’ model on patient risk detection

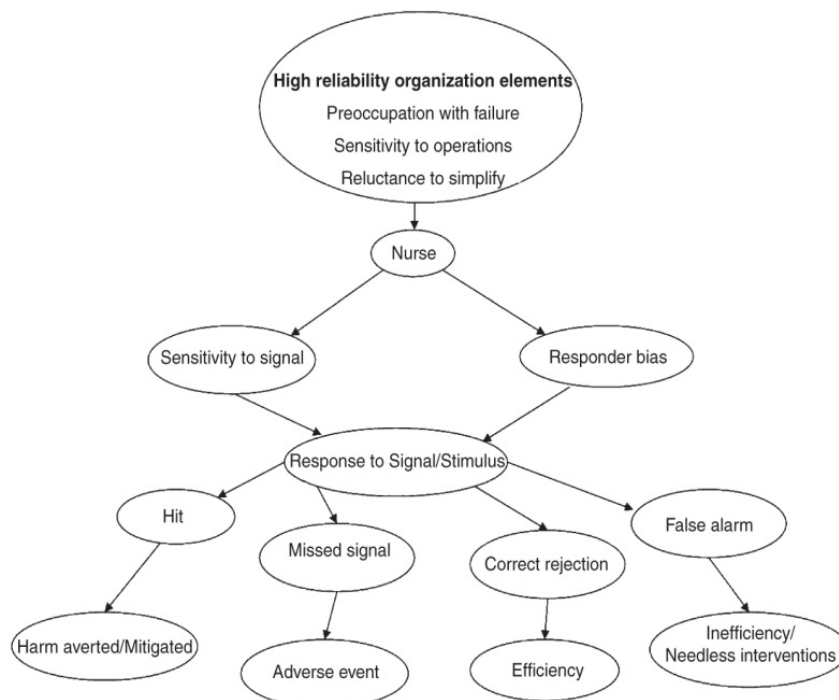


Figure taken from Despins et al., 2010⁴

Despins LA, Scott-Cawiezell J, Rouser JN. Detection of patient risk by nurses: a theoretical framework. *Journal of Advanced Nursing*. 2010. Permission granted by John Wiley & Sons, Inc.

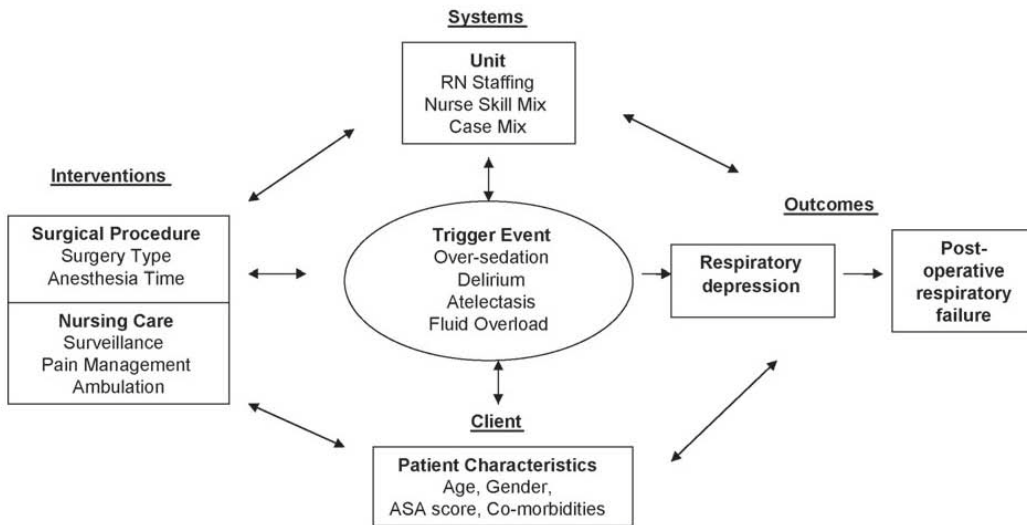
In the models proposed by Tourangeau (Figure 3) and by Thornlow (Figure 4), numerous patient, system, nurse, nurse environment, and other factors are hypothesized to play an important role in reducing inpatient mortality and other outcomes. The Tournageau model explicitly posits that the use of ‘care maps/protocols’ is associated with lowering the risk of inpatient mortality.

Figure 3, Chapter 34. Tourangeau’s model on determinants of 30-day mortality



Figure taken from Tourangeau et al., 2006²
 Tourangeau AE, Doran DM, Hall LM, et al. Impact of hospital nursing care on 30-day mortality for acute medical patients. *Journal of Advanced Nursing*. 2006. Permission granted by John Wiley & Sons, Inc.

Figure 4, Chapter 34. Thornlow’s model on cascade iatrogenesis: postoperative respiratory failure



Notes: RN Registered Nurse; ASA American Society of Anesthesiologists

Figure taken from Thornlow et al., 20093

Reprinted from International Journal of Nursing Studies. 46(11), Thornlow DK, Anderson R, Oddone E. Cascade iatrogenesis: Factors leading to the development of adverse events in hospitalized older adults. 1528-35, 2009 with permission from Elsevier.

What Are the Beneficial Effects of the Patient Safety Practice?

Prior Studies and Reviews

Nurse staffing ratio is the most commonly assessed PSP in this category of practices and will be the focus of this review. This portion of the review relied primarily on systematic reviews by Kane and colleagues at the Minnesota Evidence-Based Practice Center⁷ (EPC) and by Tourangeau;⁸ they scored 10 out of 10 relevant and 7 out of 9 relevant, respectively, on the AMSTAR criteria. We supplemented these sources with an update search (described below). For their review, the Minnesota EPC performed a thorough literature search through 2006 and assessed the relationship between RN staffing ratios and the outcomes of inpatient mortality and adverse patient events such as hospital-acquired pneumonia, failure to rescue, and surgical wound infection. The review included 28 studies, of which 17 were cohort studies, 7 were cross-sectional studies, and 4 were case-control studies (i.e., no experimental studies were identified). Most were U.S. studies, and the average level of staffing was 3.0 patients per RN for the intensive care unit (ICU) setting, 4.0 patients per RN in the surgical setting, and 4.4 patients per RN for the medical setting. This review found a consistent association between higher RN staffing and lower hospital-related mortality: An increase of one RN full-time equivalent (FTE) per patient day was associated with a 9 percent reduction in the odds of death in the ICU, a 16 percent reduction in the odds of death in the surgical setting, and a 6 percent reduction in the odds of death in the medical setting (see Table 1). The numbers of avoidable deaths per 1,000 patient days were, respectively, 5, 6, and 5. With respect to other outcomes, lower rates of hospital-acquired pneumonia, pulmonary failure, unplanned extubation, failure to rescue, and nosocomial bloodstream infections were associated with higher RN staffing in pooled analyses of multiple studies. However, several other outcomes presumed to have strong sensitivity to nurse staffing levels did not show consistent associations; these outcomes included falls, pressure ulcers, and urinary tract infections.

Table 1, Chapter 34. Pooled odds ratios of patient outcomes corresponding to an increase of one registered nurse full-time equivalent per patient day

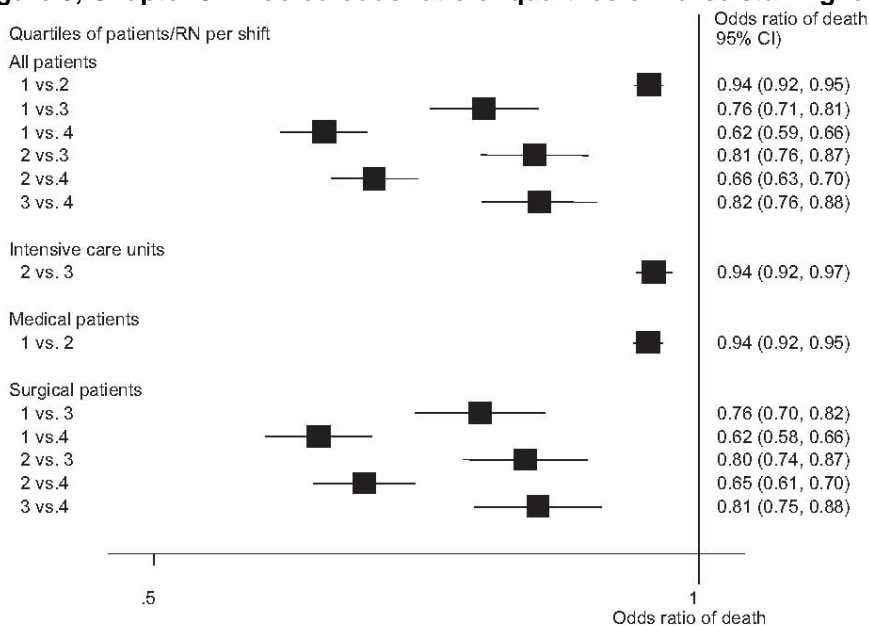
Outcome	Studies	Odds Ratio (95% CI)	No. Avoided Events/1000 Hospitalized (95% CI)
All Patients			
Mortality, intensive care units	5	0.91 (0.86; 0.96)	5 (2; 8)
Mortality, surgical patients	8	0.84 (0.8; 0.89)	6 (4; 8)
Mortality, medical patients	6	0.94 (0.94; 0.95)	5 (4; 5)
Hospital-acquired pneumonia	4	0.81 (0.67; 0.98)	1 (0; 2)
Pulmonary failure	5	0.94 (0.94; 0.94)	1 (1; 1)
Cardiopulmonary resuscitation	5	0.72 (0.62; 0.84)	2 (1; 2)
Intensive care units			
Hospital-acquired pneumonia	3	0.7 (0.56; 0.88)	7 (3; 10)
Pulmonary failure	4	0.4 (0.27; 0.59)	7 (5; 9)
Unplanned extubation	5	0.49 (0.36; 0.67)	6 (4; 8)
Cardiopulmonary resuscitation	3	0.72 (0.62; 0.84)	2 (1; 2)
Surgical Patients			
Failure to rescue	5	0.84 (0.79; 0.9)	26 (17; 35)
Nosocomial bloodstream infection	5	0.64 (0.46; 0.89)	4 (2; 5)

Table was adapted from Kane et al., 2007⁷

Kane RL, Shamliyan TA, Mueller C, et al. The association of registered nurse staffing levels and patient outcomes - Systematic review and meta-analysis. *Medical Care*. 2007 Dec;45(12):1195-204. Permission granted by Wolters Kluwer Health.

The EPC authors also conducted an indirect analysis of the potential for a “dose-response” relationship. This analysis (Figure 5) assessed the effect across studies of additional RN-level nurses per shift. In each case, comparisons of quartiles of nurse staffing levels showed the expected relationship. In other words, if the association between nurse staffing and mortality is causal, the difference in the risk for death should be greater between the 1st and the 3rd quartile of nurse staffing than it is between the 1st and the 2nd quartile, because the difference in staffing between the 1st and 3rd quartiles is greater than between the 1st and 2nd quartiles.

Figure 5, Chapter 34. Pooled odds ratio of quartiles of nurse staffing levels



Odds ratios are based on pooled analysis consistent across the studies (heterogeneity not significant).

Figure taken from Kane, 2007⁷

Kane RL, Shamliyan TA, Mueller C, et al. The association of registered nurse staffing levels and patient outcomes - Systematic review and meta-analysis. *Medical Care*. 2007 Dec;45(12):1195-204. Permission granted by Wolters Kluwer Health.

The EPC review concluded that a consistent relationship has been demonstrated but identified numerous limitations in the literature with respect to establishing that this relationship is causal. Ultimately, the authors concluded that the arguments for a causal relationship are “mixed,” and they called for future research to address the role of nurse staffing and competence on the effectiveness of patient care, “taking greater cognizance of other relevant factors such as patient and hospital characteristics and quality of medical care.”

The Tourangeau search identified literature published through 2009 and was restricted to studies that used hospital-related mortality as the outcome; the authors identified 17 studies (10 of which were not included in the Kane review, seven published since 2007). Although the Tourangeau review was narrative (not a meta-analysis like the EPC review), the two had broadly similar results: 14 of 17 studies found a statistically significant relationship between nurse staffing variables and lower mortality rates (see Evidence Table in Appendix D). In addition, Tourangeau and colleagues identified mixed findings for mortality among five studies assessing the characteristics of the nurse work environment and work relationships, three studies assessing nurses’ responses to work and the work environment (e.g., burnout), and seven studies assessing nurses’ educational preparation and experience. Only one study assessed any nursing process-of-care variables; it found a cross-sectional relationship between the use of care maps and lower hospital-associated mortality, with an estimated effect size of 10 fewer deaths per 1000 acute medicine discharged patients. Like the EPC review, the review by Tourangeau concluded that a strong relationship exists but that more research is needed to understand the reasons that this relationship between higher nurse staffing and lower hospital mortality might be causal; that is, they called for a theoretical model that explains the relationship in ways that can be tested and refined.

Thus, these two reviews came to broadly similar conclusions: Mostly cross-sectional studies consistently report that higher RN staffing is associated with lower hospital-related mortality. However, as Kane and colleagues ask, “does this association reflect a causal relationship?” If it does not, then an intervention that simply hires more RN-level nurses may not achieve the desired result. Indeed, mandates for fixed nurse-patient ratios have been critiqued as being “an inflexible solution which is unlikely to lead to optimal use of resources...”⁹

Any number of factors might confound the observed relationship: In cross-sectional studies, hospitals that are “better” in a variety of other ways might also be better staffed with RN-level nurses. For example, one published study of electronic health record (EHR) implementation showed that hospitals with EHRs have higher nurse staffing ratios and lower patient mortality.¹⁰

Longitudinal studies overcome these kinds of limitations in cross-sectional studies, but imprecision in the measures of nurse staffing and of the severity of patient illness (which may increase the risk of death via other, non-nursing-sensitive ways) constitute potential threats to the validity of the association between nurse staffing and mortality.

Update Review

To supplement the two existing reviews, we used the Web of Science to conduct an update search for articles published from 2009 onwards that cited any of four landmark articles in this field. Our update search identified 546 titles, and 4 articles came from reference mining. From 550 titles, we identified 9 longitudinal studies and 1 new systematic review.¹¹⁻²⁰ The systematic review included studies that assessed nurse staffing ratios and outcomes restricted to adult ICU settings²⁰ and reached conclusions similar to the previous reviews: a consistent relationship between increased nurse staffing and better patient outcomes in observational studies, evidence

that falls short of causality. One longitudinal study narratively reported that increased nurse staffing was related to “significantly ($P \leq 0.01$) decreased rates of decubiti, pneumonia, and sepsis,” but data were not presented.¹⁴

We discuss the 1 cross-sectional study because it addresses the effect of an “intervention” to change nurse staffing ratios, implemented in response to a 2004 California law requiring minimum nurse–patient ratios in acute care hospitals.²¹ This legislation mandated patient–nurse staffing levels of 5:1, 4:1, and 2:1 for medical or surgical units, pediatric units, and ICUs, respectively. The California legislative mandate does not require nurse staffing to be met with RNs (that is, licensed vocational [practical] nurses can also meet the mandate).

Aiken and colleagues²¹ assessed the relationship between nurse staffing and mortality in 2006, 2 years after the California mandate, comparing data from California with those of two states without mandates— New Jersey and Pennsylvania. Data about workloads were drawn from a survey of RNs in the three states—22,336 nurses in total—with a response rate of 35.4 percent. Hospital data came from the American Hospital Association, and patient and outcome data came from State hospital discharge databases.

The authors reported that their survey data showed substantial compliance with the California mandate, with 88 percent of medical/surgical, 85 percent of pediatric, and 85 percent of ICU nurses reporting that on their last shift they were within the mandated staffing ratios. This level of compliance is higher (sometimes considerably) than the values of 19 percent, 52 percent, and 63 percent for the same settings in New Jersey and 33 percent, 66 percent, and 71 percent in Pennsylvania. In logistic regression analyses adjusted for a large number of patient characteristics and three hospital characteristics (bed size, teaching status, and technology use), Aiken and colleagues found statistically significant relationships between the estimation of the average number of patients per nurse and two outcomes: 30-day mortality and failure to rescue (Table 2).

Table 2, Chapter 34. Odds ratios indicating the effect of nurse staffing on 30-day inpatient mortality and failure to rescue, in California, New Jersey, and Pennsylvania

State Hospital Sample	Odds Ratios Estimating the Effect of Nurse Staffing on	
	30-day Inpatient Mortality	Failure to Rescue
California	1.13 (1.07-1.20)	1.15 (1.09-1.21)
New Jersey	1.10 (1.01-1.22)	1.10 (1.01-1.21)
Pennsylvania	1.06 (1.00-1.12)	1.06 (1.00-1.12)

Adjusted odds ratios are based on multivariate robust logistic regression models that controlled for 132 patient characteristics, including age, sex, admission type, dummy variables for comorbidities and type of surgery, and interaction terms, and three hospital characteristics, bed size, teaching status, and technology.

Table was adapted from Aiken et al., 2010.²¹

Aiken LH, Sloane DM, Cimiotti JP, et al. Implications of the California Nurse Staffing Mandate for Other States. Health Services Research. 2010. Permission granted by John Wiley & Sons, Inc.

These associations were found for all three states. The authors also provided several measures of nurse-assessed practice environment characteristics taken from their survey responses, such as “a reasonable workload” and “enough staff to get work done;” all consistently favored California over New Jersey or Pennsylvania. The authors concluded that, 2 years after the California mandate, nurse patient care loads were significantly lower in California than in either New Jersey or Pennsylvania; on average, these loads were one patient fewer, and in the

medical/surgical units they were closer to two patients fewer. California nurses were also more likely to report favorable practice environment characteristics.

Although the study by Aiken and colleagues²¹ collected data after the implementation of California's staffing mandate, it did not test the effect of that mandate per se because it had no comparison data from the period before the mandate went into effect. The possibility that the relationship is causal is blunted by a longitudinal study that examined measures from before and after the California mandate and showed the expected changes in nurse staffing and proportion of licensed staff per patient but no improvement in two patient outcomes believed to be nursing-sensitive: falls and pressure ulcers.^{11,13} In fact an unexpected statistically significant increase in pressure ulcers was associated with a greater number of hours of care for the patient (which may have been due to greater detection). This study did not assess mortality.

Five additional longitudinal studies add further information to this picture. The first is a longitudinal assessment of nurse staffing and hospital mortality and failure to rescue in 283 California hospitals between 1996 and 2001, which had access to direct measures of nurse staffing.¹⁵ In multivariable models that included numerous hospital market characteristics as well as risk adjustment using the Medstat Disease Staging Methodology to produce a predicted probability for complications or death, the authors found that an increase of one RN FTE per 1,000 inpatient days was associated with a statistically significant 4.3 percent decrease in mortality.

The second longitudinal study assessed care at 39 Michigan hospitals between 2003 and 2006; it included adults admitted through the emergency department with acute myocardial infarction, heart failure, stroke, pneumonia, hip fracture, or gastrointestinal bleeding.¹⁷ This study simultaneously controlled for high hospital occupancy on admission, a weekend admission, seasonal influenza, and nurse staffing levels. Each factor had a statistically significant increased effect on in-hospital mortality. Each additional RN FTE per patient day was associated with a 0.25 percent decrease in mortality.

The third longitudinal study assessed the effect of a mandate in three Western Australia public hospitals to implement a new staffing method, the Nursing Hours Per Patient Day (NHPPD).¹⁸ The study assessed three time periods: 20 months before implementation 7 months of a "transition period," and 2 months post implementation. The authors found that the total nursing hours and RN nurse hours increased during the observation period. However, the percentage of total nursing hours provided by RNs decreased (from 87% to 84%). Also, the article stated that "although the nursing hours increased for all three hospitals (in the post-implementation period), the changes were not statistically significant," Mortality rates improved during this time period. Among a host of other outcomes, some improved, others did not, and some changes were inconsistent across hospitals. Although the study was described as an interrupted time series, it was analyzed as a before-and-after study.

The fourth longitudinal study assessed changes in nurse staffing over 9 years in 124 Florida hospitals and related these to changes in Agency for Healthcare Research and Quality Patient Safety Indicators.¹⁹ The study used both initial staffing ratios and changes in staffing ratios. Results were mixed but generally favored better patient safety outcomes with higher RN staffing levels.

The methodologically strongest longitudinal study is discussed here in more detail.¹⁶ In this study, Needleman and colleagues used data over time from a single hospital to assess the association between naturally occurring differences in levels of RN staffing within the same hospital and inpatient mortality. This study is further characterized by a careful matching of

nurse staffing on a shift-by-shift basis with the actual patients cared for during that shift. Knowing the actual patients cared for allowed for more sophisticated adjustments at the patient level of risk-of-death. The study was carried out at a tertiary academic hospital between 2003 and 2006 and included 197,691 admissions and 176,696 nursing shifts, across 43 hospital units. The patients themselves averaged 60 years of age, and about 50 percent were covered under Medicare. The variable of interest was exposure of the patient to nursing care that was below the target level (for that type of unit) for that shift, in other words the proportion of shifts below target level staffing, on a patient basis. An additional exposure variable was a “high turnover” shift (in other words, a shift with many admissions, discharges, or transfers). The authors found that exposure to each shift of below-target staffing or high turnover was associated with a 2 to 7 percent increase in mortality, with higher levels of risk if the high-turnover or below-target shift occurred in the first 5 days after admission (see Table 3). For patients who were not in an ICU, this increased risk rose to 12 percent or 15 percent.

Table 3, Chapter 34. Risk of death associated with exposure to a shift with an actual RN staffing level 8 hours or more below target, high patient turnover, and other variables

Variable	Hazard Ratio (95% CI)
Total of 197,961 patients	
Each shift with RN staffing level below target or high turnover during first 30 days after admission	
Shift with RN staffing level 8 hr or more below target	1.02 (1.01-1.03)
Shift with high patient turnover	1.04 (1.02-1.06)
Each shift with RN staffing level below target or high turnover during first 5 days after admission	
Shift with RN staffing level 8 hr or more below target	1.03 (1.02-1.05)
Shift with high patient turnover	1.07 (1.03-1.10)
Total of 171,041 patients with no shifts in an ICU	
Each shift with RN staffing level below target or high turnover during first 30 days after admission	
Shift with RN staffing level 8 hr or more below target	1.04 (1.03-1.06)
Shift with high patient turnover	1.07 (1.02-1.13)
Each shift with RN staffing level below target or high turnover during first 5 days after admission	
Shift with high patient turnover	1.15 (1.07-1.24)

Table adapted from Needleman et al., 2011¹⁶

Needleman J, Buerhaus P, Pankratz VS, et al. Nurse Staffing and Inpatient Hospital Mortality. *New England Journal of Medicine*. 2011 Mar;364(11):1037-45. Permission granted by Massachusetts Medical Society (MMS) publishers of the *New England Journal of Medicine*.

The data from Needleman and colleagues contribute to the “causality” determination because the study is longitudinal within one hospital, thus controlling for the “hospital effect” potentially present in all cross-sectional studies, and has detailed measures of exposure and confounding variables. These results, and the dose-response analysis from the EPC review, are the two strongest pieces of evidence in support of causality.

What Are the Harms of the Patient Safety Practice?

One finding of the survey administered by the Aiken study, which collected data 2 years after the California mandate for minimum nurse staffing ratios,²¹ was that some California nurses perceived less support from the use of LVNs, unlicensed personnel, and non-nursing support services (housekeeping, unit clerks) following implementation of the mandate. For example, 25 percent of RNs responded that they perceived decreased use of LVNs following the mandate, whereas 10 percent perceived increased use and 56 percent reported that use remained the same.

The longitudinal assessments from California¹¹ and Western Australia¹⁸ reported an increase in pressure ulcers associated with increased nurse staffing, although this development may reflect increased detection. Almost no other studies mentioned an explicit assessment of potential unexpected adverse outcomes.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Because we found no published studies of an assessment of an “implementation” per se, we cannot answer this question directly. However, the cross-sectional and longitudinal studies that have been published, and that have consistently shown an association between staffing levels and patient outcomes, have included a broad array of hospitals, often all or almost all hospitals (except for very small ones) in a state. Therefore, if the relationship between increased RN staffing and inpatient mortality is a causal one, it very likely is applicable to most hospitals and most contexts. This PSP is most likely to be carried out due to State or Federal policy.

Are There Any Data About Costs?

Four simulation studies reported information about costs. The first used 2003 data from 28 Belgian cardiac surgery centers to assess the costs and outcomes of increasing nurse staffing. Assuming a causal relationship between this staffing increase and an outcome of 5 fewer patient deaths per 1000 elective hospitalizations, the authors concluded that the incremental cost-effectiveness ratio was 26,372 Euros (approximately \$35,000) per avoided death and 2,639 Euros (approximately \$3500) per life-year gained.²²

The second simulation study was conducted by the University of Minnesota Evidence-based Practice Center, which produced the systematic review on nurse staffing.²³ It used its own meta-analysis as the basis for estimating the potential monetary benefits of increased RN staffing. Assuming that those relationships were causal and taking a societal perspective, the authors concluded that increasing RN staffing by 1 FTE per patient day was related to positive savings–cost ratios across a broad range of clinical settings. For example, the net cost of adding 1 RN FTE per 1000 hospitalized ICU patients was an estimated \$590,000, whereas the net benefit (in terms of life-years saved and productivity) was an estimated \$1.5 million, for a benefit–cost ratio of 2.51. However, hospitals did not save money because the net cost of adding an extra nurse FTE was not offset by the expected 24% decrease in length of stay.

A third simulation study used data from studies by Aiken and colleagues and Needleman and colleagues to estimate benefits in mortality and length of stay, respectively, and estimated an incremental cost-effectiveness ratio between \$25,000 and \$136,000 per life saved as patient–RN staffing ratios decreased from 8:1 to 4:1. The model was most sensitive to the estimate of effect on mortality.²⁴

Lastly, one additional study from Portugal estimated that increasing neonatal nurse staffing to “adequate” would increase staff costs more than 30% of the current rate.²⁵

Are There Any Data About the Effect of Context on Effectiveness?

As previously noted, the association between staffing and mortality that underpins this PSP has been observed in a wide variety of hospitals and contexts. We believe that the effect, if it is causal, is likely to be relatively insensitive to the usual effects of contexts considered in this review. Of note, the recent study by Needleman and colleagues was conducted in a tertiary

medical center that has a lower-than-expected in-hospital mortality rate and a reputation for excellence. Therefore, the association between increased RN staffing and lower mortality, if it is causal, is potentially applicable even to high-performing hospitals.

Conclusions and Comment

Nurse staffing ratios have a consistent association with reductions in hospital-related mortality. However, the strength of evidence for causality in this finding cannot be rated high, given the lack of evaluations of a deliberate change in RN staffing from some initial value (for example, 6 patients to 1 RN on general medical wards) to some higher RN staffing value (such as 5-to-1 or 4-to-1). Such an evaluation should be possible, either as a time series analysis or as a controlled before-and-after analysis. Studies evaluating a deliberate change in nurse staffing ratios would greatly improve our understanding of the likelihood of causality. Developing a testable conceptual framework for how increased staffing can influence outcomes would be an important addition to these and other studies.

Therefore, given the consistent associations observed in multiple cross-sectional and a few longitudinal studies, the indirect “dose-response” analysis by Kane and colleagues, and the methodologically careful single-site study by Needleman and colleagues, we grade the strength of evidence for increased RN staffing and lower hospital-related mortality as moderate. The strength of evidence for other outcomes (hospital-acquired pneumonia, failure-to-rescue, falls, pressure ulcers, etc.) remains low, owing to the sparseness of data, conflicting data, and/or lack of evidence of a dose-response relationship.

If the relationship between nurse staffing and mortality outcomes is causal, then the wide variety of hospital settings included in existing analyses suggests that the effect is likely to be relatively insensitive to hospital contexts. However, some of the nurse work environment factors, such as job satisfaction, burnout, teamwork, workload, and leadership, are potentially important effect modifiers, and this area merits further study. Summary tables are located below (Tables 4 and 5).

Table 4, Chapter 34. Summary table for increasing nurse-to-patient staffing ratios to prevent death

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Moderate	Low	High	A lot/Not difficult

Table 5, Chapter 34. Summary table for increasing nurse-to-patient staffing ratios to prevent falls, pressure ulcers, and other nursing sensitive outcomes (other than mortality)

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Low	Low	High	A lot/Not difficult

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Chapter 35. Patient Safety Practices Targeted at Diagnostic Errors (NEW)

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How Important Is the Problem?

The family of patient safety targets that includes diagnostic errors, diagnostic delays, and other diagnostic misadventures is not fully defined with clear boundaries. However, one operational definition adapted from the Australian Patient Safety Foundation by Mark Graber and colleagues is that “diagnosis is unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis ever made), as judged from the eventual appreciation of more definitive information.”¹ Alternatively and similarly, Gordon Schiff and colleagues have defined diagnostic errors as “any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis.”²

Depending on the definition and data source, the exact scope of the problem varies, although its magnitude is consistently impressive. A systematic review of 53 different series of autopsies reported a median error rate of 23.5 percent (range, 4.1% to 49.8%) for major errors (clinically missed diagnoses involving a principal underlying disease or primary cause of death) and 9.0 percent (range, 0% to 20.7%)¹ for class I errors (the most serious subset of major errors being those likely to have affected patient outcomes).³ These data translate to approximately 35,000 patients who might have survived to discharge from United States hospitals annually had misdiagnosis not happened.⁽³⁾ A Harris poll found that three in five Americans (63%) are very or extremely concerned that a diagnostic error can take place.⁴

Numerous disease-specific studies show that 2 percent to 61 percent of patients experienced missed or delayed diagnoses.⁵ Examining potential causes of delay in diagnosis for colorectal cancer (CRC), 161 of 513 patients (31.4%) with newly diagnosed CRC had at least one previously missed opportunity for their physician to initiate diagnostic workup. These patients averaged 4.2 missed imaging initiation opportunities despite a mean of 5.3 clinical indications for diagnostic workup for CRC.⁶ In a study of 587 patients diagnosed with lung cancer, 37.8 percent experienced missed clinical opportunities due to failure in recognizing predefined clinical indications for follow-up or failure to complete requested follow-ups. Patients with missed opportunities experienced a significantly longer median time to diagnosis than patients without missed opportunities (132 vs. 19 days, respectively; $p < .001$). Patient non-adherence to physician recommendations was present in 44 percent of patients with missed opportunities.⁷ In a survey administered to academic, community, and trainee pediatricians, 54 percent reported making a diagnostic error at least once per month and 45 percent noted making diagnostic errors that harmed patients at least once per year. Survey respondents reported that lack of pertinent historical or clinical information and team processes such as care coordination were contributors to errors.⁸ Furthermore, research on variation in patient outcomes related to diagnosis timing suggests room for improvement for some high stakes conditions. For example, early identification of sepsis (along with protocols for treatment pathways) has been associated with decreased mortality in surgical intensive care.⁹ Improving diagnostic speed, accuracy and triage

to treatment of such high risk, rapidly developing conditions is another important frontier for those seeking to improve consequential diagnostic delays.

Problems in care related to diagnosis are particularly prevalent among precipitating causes for lawsuits, with studies reporting 25 percent to 59 percent of malpractice claims attributable to diagnostic errors.^{5,10,11} A recent study of 91,082 diagnosis-related malpractice claims from 1986 to 2005 estimated payments summing to 34.5 billion dollars (inflation-adjusted to 2010 dollars), well over one billion dollars per year. The mean per-claim payout was \$378,858 (interquartile range: \$72,250 to \$472,000).¹² Diagnosis-related claims made up 29.1 percent of total claims and accounted for the highest proportion of total payments (35.6%). In terms of severity, lethal injuries accounted for 40 percent of total payments. Another study of 10,739 malpractice claims from the 2005-2009 National Practitioner Data Bank found that diagnosis-related reasons accounted for 45.9 percent of paid claims from outpatient settings (95% confidence interval [CI], 44.4 to 47.4), the most frequently cited reason from that setting. Diagnostic reasons were the second-most frequently cited for paid claims in the inpatient setting (21.1%; 95% CI, 20.0 to 22.3) and when both settings were involved (26.7%; 95% CI, 23.9 to 29.5).¹³

Some have asserted that diagnostic errors are more likely to be preventable and more likely to result in patient harms than other types of errors (e.g., treatment-related errors, such as wrong-site surgery or incorrect medication dose), making the problem particularly important as well as useful to address.¹⁴ Given this potential, the purpose of this review is to assess the multitude of interventions to prevent diagnostic errors and better understand their effectiveness.

What Is the Patient Safety Practice?

Many types of patient safety practices (PSPs) have been devised to address diagnostic errors, and a number haven even been tailored to specific types of diagnostic error, root causes for the error, technologies available, and other factors. Studies of the epidemiology and etiology of diagnostic errors offer the foundation for an even richer and more robust set of potential PSPs in this area. In an analysis of physician-reported errors, Schiff and colleagues found that the most common missed or delayed diagnoses that physicians recalled were pulmonary embolism, drug reactions or overdose, various cancers, acute coronary syndrome, and stroke.² Incidence rates could not be calculated from the convenience sample: The study focused on understanding the potential root causes of the errors. They determined that errors occurred throughout the diagnostic process and classified the reported cases using the “Diagnostic Error Evaluation and Research (DEER)” project tool. From analysis of the subgroup of major diagnostic errors, over 43 percent were related to clinician assessment (including failure/delay in considering the diagnosis, placing too much weight on competing/coexisting diagnosis) and 42 percent to laboratory and radiology testing (including failure to order needed tests, technical errors in processing specimens/tests, erroneous reading of a test). Some PSPs are designed to target these failure areas—for example, the design and application of algorithms, checklists, and related tools to help identify and weight potential diagnoses.

Viewing diagnostic errors from specific departments or specialties is another approach to understanding contributing factors and designing interventions to mitigate these in specific settings. As an example, Crosby developed a human- and system-oriented framework based on a decade of reviewing emergency department (ED) cases from an urban, public, teaching hospital.¹⁵ This framework examined ten areas, each one tied to points of leverage for development and testing of PSPs, and together demonstrating the broad scope of possible interventions to reduce diagnostic errors:

- Patient factors: systems may be designed around areas that are more prone to risk (e.g., improved staffing with translators).
- Human/clinician factors: interventions may aim at errors of planning separately from errors of execution, and may also be designed to address cognitive error, skill-set error, task-based error, and/or personal impairment.
- Outside care systems, ED access, and triage: consideration of these three framework areas aims to understand patterns of failure and errors that affect patients before their arrival in the ED or initiation of care.
- Teamwork: interventions in this area focus on communication, coordination, conflict resolution, personnel assignment practices (e.g., considerations of capability, workload), and training.
- Local ED environment, hospital environment, hospital administration and third parties, and community level: systems and resources at each of these four additional levels of the framework have potential for effective interventions to reduce diagnostic errors within the ED and after the patient leaves.

Within the above framework, human and clinician factors have received significant attention from researchers interested in diagnosis. Cognitive factors may affect diagnostic accuracy through rote over-learned actions or through purposive reasoning and decisionmaking processes. The cluster of automatic or quasi-automatic decisionmaking processes may be classified as heuristics, or rule-based decisionmaking processes. Heuristics aid in making decisions quickly and are important for keeping cognitive capacity high for other, more demanding, cognitive tasks. However, the very thing that makes heuristics helpful, decisions based on logical assumptions gained from experience, can also lead to systematic bias and incorrect decisionmaking when assumptions are wrong.¹⁶ Other cognitive processes affecting diagnosis involve working memory in conjunction with learned knowledge, or more plainly, information that is purposefully stored, recalled and used for completing a current goal. An example of these cognitive processes can be seen in physicians listening to their patients describe symptoms. The physician cognitively stores symptomatic information in the short term until she or he can classify the symptoms into a more general descriptive category of a diagnosis. This process is also subject to error when attention is pulled away from the task at hand or cognitive capacity is altered for others reasons (e.g., lack of sleep). The process of metacognition involves continued focusing and re-focusing attention on these cognitive processes so as to reflect on one's own potential for biases, incorrect assumptions, and reduced cognitive capacity.¹⁷ Ultimately, both human factors and the systems within which they operate have long been recognized as unique contributors to human error.¹⁸

PSPs relevant to diagnostic error are also being actively developed by those bringing more attention to this important patient safety target, and drawing on previous work in the research domains of medical problem solving, decision analytic/normative decisionmaking, and clinical diagnostic decision support.¹⁹ As health information technologies become more pervasive, electronically-supported workflow and system redesign might target preventing or mitigating diagnostic errors. PSPs in this area would be akin to computerized physician order entry with clinical decision support, though more aptly named something like computerized diagnosis management.

Why Should This Patient Safety Practice Work?

Many types of interventions, spanning a range of specialties and settings, are potentially applicable to reducing diagnostic errors. Thus, it is impossible to answer the question of why these interventions should work with one general statement. In addition to some of the frameworks described above as the bases for logic models, recent commentaries and focus group reports offer examples of why specific approaches could work (e.g., electronic clinical documentation, checklists, interventions to decrease the frequency of missed test results).²⁰⁻²² For electronic documentation, for example, researchers have suggested goals and features of redesigned systems for improved diagnosis (e.g., “aid cognition through aggregation, trending, contextual relevance, and minimizing of superfluous data”) tied to specific roles for that particular approach (e.g., “providing access to information”).²⁰

What Are the Beneficial Effects of the Patient Safety Practice?

A recently published systematic review on system-related interventions addressing organizational vulnerabilities to diagnostic errors²³ based on a search from 2000 to 2009 included 43 studies. A companion piece focused on cognitively-related interventions.²⁴ To build on the previous work, we conducted a separate systematic review, encompassing a longer time period, and with broader inclusion criteria to provide a high-level summary of categories of interventions studied. We searched MEDLINE, PSNet, bibliographies of background articles and previous systematic reviews to identify literature about effects of practices with implications for errors and delays in diagnosis. For further detail, see Appendix C.

Although numerous articles proposed or described interventions, few reported evaluations of these interventions. Singh and colleagues summarized 37 studies with no evaluations, classifying them along five process dimensions: provider-patient encounter, diagnostic test performance and interpretation, follow-up and tracking, referral-related issues, and patient-related issues.²³ Their review also identified six evaluations of interventions, of which only three reported diagnostic outcomes (incidence of delayed diagnosis of injury, incidence of missed injuries, misdiagnosis rates), and none provided information on patients’ downstream clinical course.²³

Graber and colleagues summarized 141 articles on improving cognition and human factors affecting diagnosis, 42 of which reported evaluation of interventions.²⁴ These investigators classified the literature along three dimensions. In the first dimension, interventions to increase knowledge and expertise, the authors identified seven evaluation studies, only one of which provided information on diagnostic outcomes and clinical course for actual patients. The second dimension included interventions to improve intuitive and deliberate considerations. Among the five studies evaluating interventions for this dimension, none reported resultant effects on documented diagnoses with actual patients during clinical course of care. In the largest group of studies, interventions assigned to the third dimension of getting help from colleagues, consultants and tools, 16 of 28 studies evaluated diagnostic outcomes in actual patients. Graber and colleagues note the current scarcity of evidence for any single intervention targeting cognitive and human factors in reducing diagnostic error. The authors highlighted potential for interventions that target content-focused training, feedback on performance, simulation-based training, metacognitive training, second opinion or group decision-making, and the use of decision support tools and computer-aided technologies.

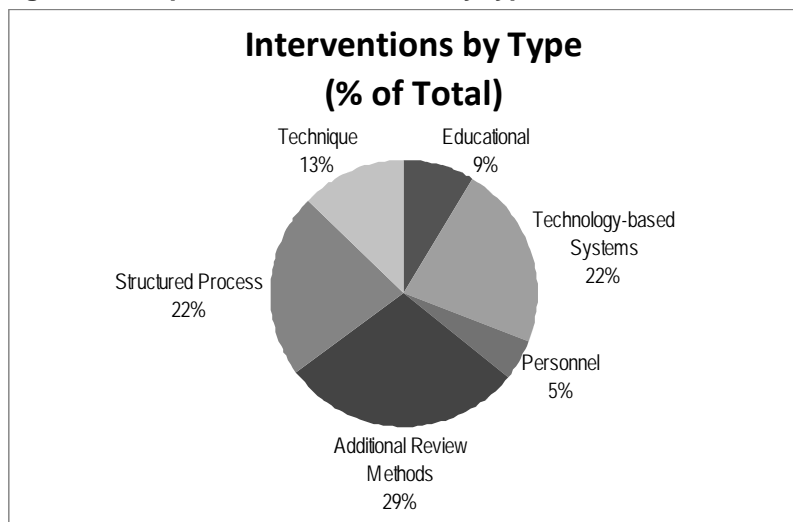
Our review identified 94 studies of PSPs targeted at patient diagnosis. These studies reported missed diagnosis, misdiagnosis, delayed diagnosis, or some other diagnostic discrepancy with

potential for clinical consequence. The Supplementary Evidence Table (see Appendix D, Table 2) provides basic descriptions of targeted diagnostic errors, intervention descriptions, patient outcome, study design and results with respect to the effectiveness of the proposed interventions.

Drawing from frameworks proposed by others, we classified interventions into one or more of the following six types (Figure 1):

- Technique (*introduction of novel technologies for testing, adaptations of testing equipment, or changes in medical interventions potentially affecting diagnostic performance*)
- Additional Review Methods (*introduction of additional steps from the interpretation through reporting of test results*)
- Personnel Changes (*introduction of additional health care members and/or replacing certain professionals with others*)
- Educational Interventions (*implementation of educational strategies*)
- Structured Process Changes (*implementation of feedback systems or additional stages in the diagnostic pathway*)
- Technology-based Systems Interventions (*implementation of technology-based tools at the system level—computer assistive diagnostic aids, decision support algorithms, text message alerting, pager alerts, etc.*)

Figure 1, Chapter 35. Interventions by type



This pie chart illustrates the percentage of studies as categorized to the six intervention types: Technique, Educational, Technology-Based Systems, Personnel Changes, Additional Review Methods, and Structured Process Changes.

All six of the evaluative studies identified by Singh and colleagues,²³ many of the evaluative studies identified by Graber and colleagues,²⁴ and most of the studies included in our systematic review, reported beneficial effects along the diagnostic pathway for a broad array of intervention types. Because the evidence is predominantly from uncontrolled before-after study designs or other uncontrolled study types (Table 1) with markedly different outcomes, the strength of the evidence about interventions to reduce diagnostic errors is insufficient to draw any strong conclusions. Furthermore, the magnitude of difference attributable to interventions varied by study and clinical process. For example, some researchers demonstrated what would be moderate-to-large effects on diagnosis if the assumption of causality were made (e.g., Perno and colleagues, 2005),²⁵ although methodologies were not designed to test causality, whereas other

studies were designed to demonstrate the absence of change in diagnostic outcomes despite intervention (e.g., Thomas and colleagues, 2003).²⁶

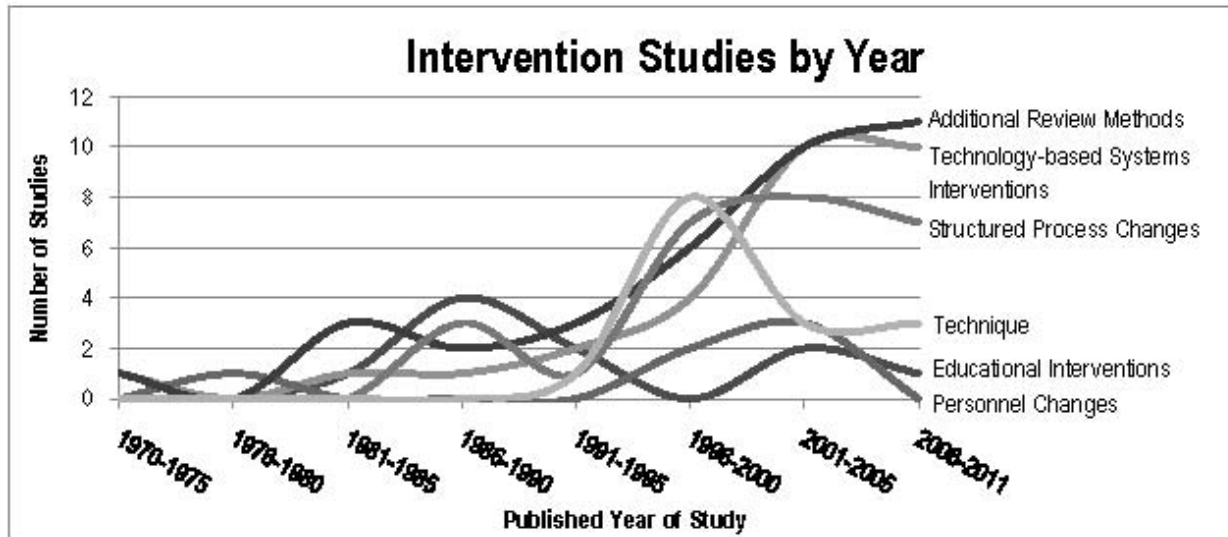
Table 1, Chapter 35. Study design distribution

Study Design	Description	Number of Studies*
Randomized, controlled trial (RCT)	A standard randomized controlled trial involving two groups; a control and the intervention group.	14
Experimental Design	Study with a concurrent usual care control group, or another method for controlling and comparing between experimental and usual care non-experimental groups (but not including the pre/post method)	12
Pre/Post	A before and after study comparing pre-intervention to post-intervention results.	16
Other	Evaluative studies not matching the aforementioned designs.	58

*Number of studies adds to more than 95 because several had multiple designs.

As a result of the state of the science in this area, no meta-analyses have been conducted. Pooled analysis may be feasible in the near future as the evaluative literature is growing rapidly in some intervention categories. Figure 2 shows particular increases for several classes of interventions: Additional Review Methods, Technology-based Systems Interventions, and Structured Process Changes. The other intervention types have not been studied much over the entire period.

Figure 2, Chapter 35. Intervention studies by year



The graph illustrates a timeline of the included studies broken down by the six intervention types.

Few studies (5 randomized, controlled trials and 8 other designs) have evaluated patient-level clinical outcomes to reduce diagnostic errors.^{9,27-38} Diagnostic errors have a complex relationship with direct patient outcomes because they can play a role at many different time points in a patient's care; that is, many opportunities exist to catch diagnostic errors. If a diagnostic error is caught at any of these opportunities, then negative effects on clinical outcomes could potentially be avoided. Thus, examining the direct relationship between diagnostic errors and clinical

outcomes is complex and explains why many of the articles do not report on hard patient outcomes. The remainder of this section summarizes the findings of the review.

Results of Randomized, Controlled Trials

Primary and secondary comparative quantitative outcomes data were available in 13 randomized trials, and are summarized in Appendix Table 1 (See Appendix D). Seven trials (9 comparisons) addressed diagnostic accuracy outcomes, and 3 trials (5 comparisons) addressed outcomes related to further diagnostic test use. Six trials (8 comparisons) addressed outcomes related to further therapeutic management. Five trials (7 comparisons) addressed direct patient-related outcomes. Three trials addressed composite outcomes (diagnostic accuracy and therapeutic management, and therapeutic management and patient outcome). One trial addressed time to correct therapeutic management, and another trial addressed time to diagnosis.

Trials evaluated various interventions. The control group used most often was usual care. No trials had high risk of bias, whereas 9 and 5 trials had moderate and low risk of bias, respectively.

Statistically significant improvements were seen for at least 1 outcome in all but 3 trials. Of the 3 trials with non-statistically significant improvements, one was a noninferiority trial that showed no more diagnostic errors occurred during work-up of abdominal pain among patients given morphine and those not given morphine²⁶. Two trials that involved patients with mental conditions^{38,39} reported no beneficial diagnostic error effects from computerized decision-support systems. Only 1 trial³⁴ reported improvements in direct patient outcomes; whether improvements were related to the comparison against the randomized concurrent control group or a preintervention period was unclear.

Use of Additional Review Methods

The most common intervention type evaluated was the review of test interpretation (n=36).^{9,29-31,40-71} Most studies showed a positive impact on diagnostic performance of an additional review step (usually by a separate reader, sometimes from the same specialty and other times from another specialty). However, in some cases, the detection of errors came at a high cost in terms of additional false positives. Not all studies reported the tradeoffs between sensitivity and specificity. Some of the studies targeted higher risk patients for enriched review. However, the systems to support such targeting were neither described nor evaluated.

Diagnostic Techniques

The studies of interventions related to medical techniques (n=14)^{26,31,72-83} demonstrated that technologies as well as diagnostic test selection might either enhance diagnosis (e.g., visual enhancements via ultrasound-guided biopsy, changes to number of biopsy cores, cap-fitted colonoscopy) or impede it (e.g., medical interventions for pain relief in patients with abdominal pain). In the latter cases, the interventions hypothesized to impede diagnosis did not have that effect, and interventions expected to enhance diagnostic accuracy did not always do so.

Personnel Changes

Six studies^{36,37,67,69,84,85} compared the impact on diagnosis of substituting one type of professional for another, or adding another professional to the care team. The three studies^{67,69,85} that added a specialist to examine the interpretation of a test result reported an increase in case detection, although the studies were quite small and targeted narrow patient populations.

Educational Interventions

Ten studies employed educational interventions^{35,61-64,86-90} for various targets: consumers, community doctors, and intensive care unit doctors and nurses. Strategies targeted at professionals produced improvements. Only two studies targeted consumers (parents, candidates for screening) and both intervened on a behavior that occurs much earlier than actual diagnosis (e.g., awareness of symptom seriousness with the intent of reducing office visits in ways that would not adversely affect diagnosis)⁸⁶

Structured Process Changes

Twenty six studies^{25,35,36,38,39,63,65,69,70,79-82,89,91-102} examined interventions that added structure to the diagnostic process; this structure included, among other things, triage protocols, feedback steps, and quality improvement processes (“Q-Track”, Toyota Production Process). Most interventions included the addition of a tool, often a checklist or a form (i.e., to guide and standardize physical examination of a patient). Some of the studies centered on laboratory processes, whereas others occurred during clinical management. Results were mixed for these types of interventions, with positive results (e.g., improved diagnosis) only among studies that were not randomized, controlled trials (RCTs). Two of the three RCTs tested interventions in mental health diagnosis.

Technology-Based Systems Interventions

Twenty nine studies^{9,27,28,32-34,103-117} included computerized decision support systems and alerting systems (e.g., for abnormal lab results), most associated with improvements to processes on the diagnostic pathway (e.g., critical laboratory value relayed to clinician in a more timely manner).

Some interventions related to specific symptoms (e.g., computer aided diagnostic tool for abdominal pain interpretation), while others intervened at the level of a particular test (e.g., electronic medical record alert for positive fecal occult blood (FOBT) cancer screening test results).

Studies With Interventions that Corresponded to Multiple Categories

Twenty-four studies^{9,31,35,36,38,61-63,65-70,79-83,85,89,90,102,118} combined approaches in a variety of ways and also covered a broad range of clinical areas, with mixed results. These studies are included in the categories above. Twenty of the 23 studies combined two categories of intervention in almost every permutation possible (11 of 15 combinations). All but three studies included at least one of the two predominant categories in this set of multiple category interventions: Additional Review Methods (11/23) and Structured Process Changes (13/23). With combined approaches comes an inherent complexity in the intervention. However, the results from studies of combined intervention strategies largely parallel those reported above. With only one to four studies for any combination set, it is not possible to draw any conclusions about whether benefits are enhanced with more complex interventions. In addition, these more complex approaches may be more costly, but this information was not reported.

Notifying Patients of Test Results

Another potential grouping of PSPs focuses on the interface between the system and the patient. Indeed interim care processes such as patient notification of test results has gained attention at the national level.¹¹⁹ However, no studies evaluated this intervention with

comparative designs. The review by Singh and colleagues identified seven studies of patient preferences or satisfaction with different options for receipt of test results.²³ However, they also found no studies that tested ways to reduce error using an intervention that affected test notification. One of the articles identified in the Singh review by Casalino and colleagues found a 7.1 percent rate of apparent failures to inform patients of an abnormal test result, and identified an association between use of simple processes by physician practices for managing results and lower failure rates.¹²⁰ A systematic review of failures to follow-up test results with ambulatory care patients reported that failed follow-ups ranged from 1 percent to 62 percent depending on type of test result, and these failures were associated with missed cancer diagnoses. Electronic record systems appeared to exert a mild protective effect against failed follow-ups, although the authors note the pool of literature was small in this analysis.¹²¹

What Are the Harms of the Patient Safety Practice?

In general evaluations of PSPs have not assessed unintended adverse effects. However, some of the screening test literature is applicable to maintaining a balanced perspective on diagnostic error reduction. For example, an excluded study by Molins and colleagues¹²² reported on the negative effects of multiple mammogram screening (patient anxiety, higher costs, poorer subsequent screening attendance). Although this study did not involve an intervention to reduce diagnostic error per se, it was similar to some of the included interventions with added testing. Although none of the studies in our review evaluated direct patient harm, some reported false positive rates.

How Has the Patient Safety Practice Been Implemented, and In What Contexts?

The context in which a PSP is implemented depends on the specific type of diagnostic error and PSP being examined. The studies identified in our literature search covered a range of subspecialties, settings, and patient populations, with varying contexts. Most of the interventions studied have not been tested in more than one site, with some even more appropriately categorized as proof of concept. For diagnostic practice, another important context is the sequence of events and the role of time itself. Sometimes these factors are embedded in the patient safety target analyzed, as is the case for delayed diagnosis, which was an outcome in 26 studies included in the Appendix Supplementary Evidence Table.

Are There Any Data About Costs?

The main source of information about costs related to diagnostic error is derived from malpractice claims, as noted in an earlier section. In terms of costs of implementing some of the PSPs reviewed, no information was reported, but would likely range from low to high depending upon the PSP. For example, a PSP that involves an additional reviewer of imaging tests might double the cost of that step in the diagnostic process for all patients, meaning a relatively large investment per diagnostic error averted. For PSPs that compared the results of one technology to another, the cost might be more or less, though often, technologies that perform with greater accuracy cost more because they deliver a clinical benefit. For PSPs that revise a workflow to follow a structured process, the start-up cost would depend on whether a structured process is already available and can be adapted inexpensively or if workgroups have to spend significant time to reengineer a local process. In either case, the cost may still be relatively low compared

with interventions that have ongoing incremental costs. Finally, information technology PSPs to reduce diagnostic errors may be relatively expensive, though these costs could vary as well.

Are There Any Data About the Effect of Context on Effectiveness?

The evidence base for this topic does not yet include an examination of the influence of contextual factors during implementation.

Conclusions and Comment

The original “Making Health Care Safer” report did not consider diagnostic errors because just a decade ago, few studies had quantified the prevalence and clinical consequence of this patient safety target. As a result, much of the literature over this period has focused on quantifying the scope of the problem, and elucidating potential causal pathways that result in failures in diagnosis. Very few intervention studies have tested strategies to reduce diagnostic errors. However, frameworks for filling in the evidence gaps are beginning to emerge.

This review identified over 90 evaluations of interventions to reduce diagnostic errors, many of which had a reported positive effect on at least one end point, including statistically significant improvements in at least one end point in 10 of the 13 randomized trials. Mortality and morbidity end points were seldom reported.

We also identified two previous systematic reviews of cognitive and systems-oriented approaches to improve diagnostic accuracy that mostly found proof-of-concept strategies not yet tested in practice. Our review built on the previous systematic reviews by grouping PSPs targeting diagnostic errors from an organizational perspective into changes that an organization might consider more generically (techniques investment; personnel configurations; additional review steps for higher reliability; structured processes; education of professionals, patients, families; and information and communications technology-based enhancements), as opposed to individual clinicians looking for ways to improve their own cognitive processing in specific diagnostic contexts. Although many of the PSPs tested thus far target diagnostic pathways for specific symptoms or conditions, grouping interventions into common leverage points will support future development in this field by the various stakeholders who seek to reduce diagnostic problems. Involvement of patients and families has received minimal attention, with only two studies addressing education of consumers.

Data synthesis is difficult because few studies have used randomized designs, comparable outcomes, or similar interventions packages. The existing literature may be susceptible to reporting biases favoring “positive” results for different interventions. It is expected that with heightened awareness of the problem, the number of studies in this field will increase further in the future, including more randomized trials and studies testing different approaches: for example, policy-level efforts. However, the range of outcomes assessed in the studies that we reviewed highlights the known lack of tools to routinely measure the effect of interventions to decrease diagnostic errors. Additional work is needed on appropriate measurements of diagnostic errors and consequential delays in diagnosis. A final limitation, especially for synthesis, is the diversity of interventions that are reverse-engineered on the basis of the many diagnostic targets; the diverse tailored needs for each clinical situation (for example, protocols designed for specific work-up pathways); and the variety of specialized personnel, and even patients, receiving educational or cognitive-support approaches.

Evidence is also lacking on the costs of interventions and implementation, particularly how to reduce diagnostic errors without producing other diagnostic problems, such as overuse of

tests. Eventually reaching the correct diagnosis with inefficient testing strategies (for example, some sequences of multiple test ordering) is not the appropriate pathway to improved diagnostic safety. Our review found a paucity of studies that assessed both sensitivity and specificity of interventions addressing diagnostic performance in the context of mitigating diagnostic errors. Thus, although we found several promising interventions, evaluations need to be strengthened before any specific PSPs are scaled up in this domain.

Alongside the literature scoping the problem and generating ideas for potential solutions, some are also working on policy level efforts. Singh and Vij describe potential institutional-level policies for communicating test results within the clinical team and to the patient.¹²³ These types of policies respond to national attention (e.g., the Joint Commission Patient Safety Goals), spotlighting this part of the diagnostic pathway as ripe for intervention. They note that the area of notifying patients about their test results is an emerging area for intervention testing.

In conclusion, our review demonstrates that the nascent field of diagnostic error research is growing, with new interventions being tested that involve technical, cognitive, and systems-oriented strategies. The framework of intervention types developed in the review provides a basis for categorizing and designing new studies, especially randomized, controlled trials, in these areas. A summary table is located below (Table 2).

Table 2, Chapter 35. Summary table

Scope of the Problem targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Emerging practice (few studies available)	Uncertain	Varies	Varies

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Chapter 36. Monitoring Patient Safety Problems (NEW)

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How Important Is the Problem?

Adverse events (AEs) associated with medical treatments are a major source of morbidity and mortality.¹⁻⁴ Studies showed that the incidence of AEs varied from 3 percent to 17 percent of hospitalized patients,⁵ and about 50 percent of the AEs were judged to be preventable. Most AEs resulted in minor or temporary disability, but a proportion of the AEs, 4 percent to 21 percent, contributed to death.⁵

In 1999, the Institute of Medicine (IOM) published a landmark report on medical errors titled “To Err Is Human: Building a Safer Health Care System.”⁶ Since IOM released the report, several studies have examined progress in patient safety and have found little evidence of systematic improvements in the health care system.^{1,7-10} According to a 2008 Healthcare Cost and Utilization Project statistical brief, drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7% of all stays) and 838,000 treat-and-release emergency department visits (0.8% of all visits).¹⁰ The Institute for Healthcare Improvement estimated that nearly 15 million instances of medical harm occur in the United States (U.S.) each year.¹¹ Over the five years from 2004 to 2008, drug-related adverse outcomes in the inpatient setting increased by 52 percent.¹⁰ This increase in AEs could be the result of the intensified effort in incident reporting; still, keeping patients from being harmed by preventable medical errors will continue to be a challenging goal for the medical community.

As used in this review, an AE is defined as an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.¹² A medical error is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.¹² AEs include medical errors as well as more general substandard care that can result in harm, such as harm caused by incorrect diagnoses or lack of patient monitoring during treatment.¹³ Therefore, AEs do not always involve errors, negligence, or poor quality of care and may not always be preventable.

“Near miss” is another term often used in patient safety monitoring. It is defined as an event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention.¹²

What Is the Patient Safety Practice?

Health care organizations use a wide array of methods to uncover and monitor AEs and errors in medical care. These methods include incident reporting, direct observation of patient care, chart review, analysis of malpractice claims, patient complaints and reports to risk management, executive walk rounds, trigger-tool use, patient interviews, morbidity and mortality conferences, autopsy, and clinical surveillance.¹⁴⁻¹⁹ These methods vary in the timing of finding AEs (retrospective or “real-time”), and each has advantages and limitations.¹⁴⁻¹⁸

Historically, medical errors were revealed retrospectively through morbidity and mortality committees, autopsy, and malpractice claims data.^{6,14-16,18} While these methods provide valuable information on medical errors, they are not appropriate for measuring the incidence or prevalence of the errors or events. They might also be limited by hindsight bias (e.g., a tendency

to rate care in the context of a bad outcome as substandard), if the evaluators are not blinded to outcome.¹⁵

Chart review was often used as the benchmark for estimating the extent of medical harms in hospitals or as the gold standard in patient safety studies to quantify AE rates.^{15,16} However, chart review is generally resource-intensive.¹⁵ Incomplete documentation in the medical record can affect the ability to detect the potential causes of AEs.¹⁵ Near misses that produce no injury are rarely detected by this method.^{15,16} The reliability (precision) of the judgments about the presence of AEs by chart reviewers could also be low.¹⁵

Incident reporting systems are a popular mechanism that the majority of hospitals rely on to uncover internal threats to patient safety.^{1-4,20,21} Since IOM endorsed using incident reporting systems in its landmark report on patient safety, 27 states and the District of Columbia have established hospital AE reporting systems.^{13,22} Reporting systems include surveys of providers and structured interviews and can provide rich information about medical errors that lead to AEs. Incident reporting systems can identify latent errors (“system problems”) not uncovered by some other methods; thus, they can be used to improve patient safety.^{13,15,16} In comparison with comprehensive chart reviews, incident reporting is also relatively inexpensive.¹⁵

However, like other methods for detecting safety problems, incident reporting has its own limitations. Incident reporting systems alone cannot reliably measure incidence and prevalence rates of errors and AEs.^{20,23} Providers may not report errors because of busy schedules, concerns about potential lawsuits, fear their reputations could be tarnished, or misperceptions about what constitutes patient harm.²⁰ As a result, reported incidents may represent only a portion of serious incidents and may misguide detailed investigation efforts to less important targets.^{16,18,20,23,24} Additionally, the rates of incidents reported over time may not reflect real changes in safety in an institution, because an increased rate may simply indicate an improved commitment by the institution to identify medical errors rather than a true rise in medical hazards.²³

In recent years, with the adoption of electronic medical records, computerized surveillance, including using electronic triggers, has become an increasingly popular method for identifying certain types of medical errors or AEs, particularly those related to use of medications.²⁵⁻²⁸ By integrating multiple data sources (e.g., electronic medical records, laboratory, pharmacy, billing), computerized surveillance may efficiently detect medical errors and AEs and could provide real-time information for preventing harm to patients from errors in medical treatment.²⁵⁻²⁸ Use of electronic medical record-based surveillance of diagnostic errors was also reported.²⁹ However, the accuracy and reliability of the tools for computerized surveillance need further study.³⁰ The initial cost of the systems remains another barrier to implementation.²⁵

Similarly, other methods for detecting and monitoring patient safety problems (e.g., chart audits assisted with trigger tools, direct observation of patient care, executive walk rounds, administrative data analysis, data warehouses) also have their strengths and weaknesses. We have identified several documents that provide an overview of these methods based on systematic or targeted literature review.¹⁴⁻¹⁶ Table 1 summarizes the purposes of different patient safety problem detecting methods. Tables 2 and 3 summarize the strengths and weaknesses of these methods. Because the original documents used different taxonomies for the methods, we compiled the adapted tables together in this chapter to provide a more comprehensive overview. As a result, some contents in these tables may overlap.

Table 1, Chapter 36. Overview of the purposes of different methods for detecting patient safety problems

Method	Adverse Event Counting (Frequency Assessment)		Adverse Event Understanding (Root Cause Analysis) Latent Causes/ Contributory Factors
	Harm	Active Errors	
Review of medical records	X	X	?
Studies based on interviews with health-care providers	X	X	X
Direct observation	X	X	X
Use of incident reporting systems	?	?	X
External audit and confidential inquiries	NR	NR	X
Studies of claims and complaints	NR	NR	X
Use of information technology and electronic medical records	X	NR	NR
Analysis of administrative data	X	NR	NR
Analysis of autopsy reports	X	NR	NR
Analysis of mortality and morbidity data	X	NR	X

Source: Michel P. 2003.¹⁴ Used with permission.

X Method is relevant for the purpose

? Relevance of the method for the purpose is to be confirmed

NR not relevant

Table 2, Chapter 36. Advantages and disadvantages of different methods used to measure errors and adverse events in health care (from the Thomas and Petersen study)

Method	Advantages	Disadvantages
Morbidity and mortality conferences and autopsy	<ul style="list-style-type: none"> • Can suggest latent errors • Familiar to health care providers and required by accrediting groups 	<ul style="list-style-type: none"> • Hindsight bias • Reporting bias • Focused on diagnostic errors • Infrequently and nonrandomly utilized
Malpractice claims analysis	<ul style="list-style-type: none"> • Provides multiple perspectives (patients, providers, lawyers) • Can detect latent errors 	<ul style="list-style-type: none"> • Hindsight bias • Reporting bias • Nonstandardized source of data
Error reporting systems	<ul style="list-style-type: none"> • Can detect latent errors • Provide multiple perspectives over time • Can be a part of routine operations 	<ul style="list-style-type: none"> • Reporting bias • Hindsight bias
Administrative data analysis	<ul style="list-style-type: none"> • Utilizes readily available data • Inexpensive 	<ul style="list-style-type: none"> • May rely upon incomplete and inaccurate data • The data are divorced from clinical context
Chart review	<ul style="list-style-type: none"> • Utilizes readily available data • Commonly used 	<ul style="list-style-type: none"> • Judgments about adverse events not reliable • Expensive • Medical records are incomplete • Hindsight bias
Electronic medical record	<ul style="list-style-type: none"> • Inexpensive after initial investment • Monitors in real time • Integrates multiple data sources 	<ul style="list-style-type: none"> • Susceptible to programming and/or data entry errors • Expensive to implement • Not good for detecting latent errors
Observation of patient care	<ul style="list-style-type: none"> • Potentially accurate and precise • Provides data otherwise unavailable • Detects more active errors than other methods 	<ul style="list-style-type: none"> • Expensive • Difficult to train reliable observers • Potential Hawthorne effect • Potential concerns about confidentiality • Possible to be overwhelmed with information • Potential hindsight bias • Not good for detecting latent errors
Clinical surveillance	<ul style="list-style-type: none"> • Potentially accurate and precise for adverse events 	<ul style="list-style-type: none"> • Expensive • Not good for detecting latent errors

Source: Thomas EJ and Petersen LA. 2003.¹⁵ Used with permission.

Table 3, Chapter 36. Advantages and disadvantages of different methods for hospitals to monitor for internal patient safety problems (from the Shojania study)

Method	Advantages	Disadvantages
Traditional incident reporting	<ul style="list-style-type: none"> • Process already ubiquitous • Can identify latent errors (“system problems”) 	<ul style="list-style-type: none"> • Underreporting of serious incidents • Frequent reporting of events not suited to individual analysis (e.g., falls) • Can be demoralizing when staff do not perceive meaningful improvements resulting from incidents they have reported • Cannot assess changes in safety (over time)
Stimulated/facilitated incident reporting	<ul style="list-style-type: none"> • Builds on an existing process • Improves frequency of events and broadens range of events • Can contribute to improvements in culture 	<ul style="list-style-type: none"> • More labor intensive than traditional incident reporting • Greater engagement of staff increases importance of making meaningful improvements (i.e., even more demoralizing than usual if improvements not made) • Cannot assess changes in safety
Patient complaints	<ul style="list-style-type: none"> • Process or data already exist • Highlights important problems about patient experience often not captured elsewhere 	<ul style="list-style-type: none"> • May be dismissed by clinicians as “service problems” • May require more up-front work (compared with incident reporting) to identify incidents worth analyzing in detail for potential safety improvements • Cannot assess changes in safety
Malpractice claims	<ul style="list-style-type: none"> • Process or data already exist • Details about causes of the event and its impact on the patient usually collected as part of medicolegal process • Complements incident reporting for capturing rare but serious events (e.g., wrong-site surgery) 	<ul style="list-style-type: none"> • Heavily biased toward detecting diagnostic issues and procedural complication (though these are usually not detected by other systems) • Cannot assess changes in safety
Risk management reports	<ul style="list-style-type: none"> • Probably similar to malpractice claims, but not clear 	<ul style="list-style-type: none"> • Probably similar to malpractice claims, but not clear
Executive walk rounds	<ul style="list-style-type: none"> • Engages frontline staff without requiring much work for them • Provides a human face to problems management usually learns about through impersonal pie charts and time trends • Alerts management to problems faced daily by frontline staff 	<ul style="list-style-type: none"> • Demoralizing to frontline staff if management focuses only on improved public relations (“management cares”) and does not seriously address the problems identified • Tempting for management to focus on easy fixes (e.g., related to equipment) not deeper problems or those requiring substantial investments of resources (e.g., staffing, skill mix, or work-load problems)

Table 3, Chapter 36. Advantages and disadvantages of different methods for hospitals to monitor for internal patient safety problems (from the Shojania study) (continued)

Method	Advantages	Disadvantages
Chart audits (commonly operationalized with “trigger tools”)	<ul style="list-style-type: none"> Types of events captured may be more likely to engage frontline clinicians (especially physicians) Produce rates that can be monitored over time, not just counts or frequencies susceptible to changes in reporting biases 	<ul style="list-style-type: none"> Requires willing clinicians to participate Many important events not documented in charts and contributing factors for documented events typically unclear Many triggers have low specificity
Electronic triggers (e.g., drug-lab combinations, use of “antidotes” suggestive of medication errors)	<ul style="list-style-type: none"> Very efficient Potentially high sensitivity capture for the events captured 	<ul style="list-style-type: none"> Captures only certain types of events (small subset of events involving medications or laboratory tests) Trade-offs between sensitivity and specificity
Performance indicators derived from administrative data	<ul style="list-style-type: none"> Data easily available In principle, event rates can be tracked over time, but in practice probably applies only for frequent event types in large health care systems 	<ul style="list-style-type: none"> Low signal-to-noise ratio Various methodologic problems leading to misleading characterizations of performance Managers and clinicians tend to distrust these data (often with good reason) Requires intensive effort to investigate if poor performance is real and further effort to determine causes
Data warehouses	<ul style="list-style-type: none"> Richness of detail (e.g., from medications data, laboratory results, time stamps) addresses many of the limitations of administrative data Can generate data that will engage both managers and clinicians Event rates can be followed over time 	<ul style="list-style-type: none"> Requires substantial up-front investments and appropriate clinical and methodological expertise Requires organizational culture and management structures conducive to driving change on the basis of these novel data
Modifying traditional morbidity and mortality rounds with modern patient safety framework	<ul style="list-style-type: none"> Builds on format familiar to clinicians Types of events captured and richness of detail more likely to engage physicians 	<ul style="list-style-type: none"> Care required to avoid traditional focus on individual errors and blaming other departments New processes required to follow-up systematically on issues identified (traditional rounds heavy on discussion, with follow-up occurring only haphazardly) Addressing problems identified often requires host department to engage and collaborate with other departments—departures from traditional norm
Discrepancies between clinical and autopsy diagnoses	<ul style="list-style-type: none"> Builds on a traditional process of improvement Detects problems likely to engage clinicians 	<ul style="list-style-type: none"> Likely to succeed only in select hospitals because of low autopsy rates and decreased interest in autopsies among clinicians and pathologists at most hospitals
Monitoring pathologic discrepancies (e.g., between cytology and histology or antemortem biopsies and autopsies)	<ul style="list-style-type: none"> Relatively efficient Can identify patterns of problems amenable to substantial improvement projects Event rates can be followed over time 	<ul style="list-style-type: none"> Requires interest on the part of pathologists to undertake this nontraditional form of quality assurance and willingness of clinical departments to collaborate in improvement projects
Corrected laboratory results/reports	<ul style="list-style-type: none"> Relatively efficient Event rates can probably be followed over time 	<ul style="list-style-type: none"> Fairly narrow focus Requires interested laboratory medicine personnel

Table 3, Chapter 36. Advantages and disadvantages of different methods for hospitals to monitor for internal patient safety problems (from the Shojania study) (continued)

Method	Advantages	Disadvantages
Natural language screening of electronic portions of medical records	<ul style="list-style-type: none"> • Relatively efficient once implemented • Reasonable sensitivity and specificity for certain types of events 	<ul style="list-style-type: none"> • Requires appropriate technical expertise and initial investment of time to develop and refine combinations of search terms with acceptable sensitivity and specificity for safety problems
Direct observation (e.g., audits of hand hygiene compliance, medication administration, operating room procedures daily rounds)	<ul style="list-style-type: none"> • Richer, more accurate data than by many other methods • Identifies problems particularly difficult to detect by other means • Event rates can be followed over time 	<ul style="list-style-type: none"> • Somewhat labor intensive (but short periods of measurement may provide ample data) • Requires appropriately trained observers • Care must be taken not to create mistrust among frontline staff
Active surveillance (combination of chart-based trigger tool applied in quasi-real time, stimulated reporting, and other interactions with frontline staff)	<ul style="list-style-type: none"> • Rich data that are more likely to include information about causal factors than record review alone • Process can engage frontline staff and stimulate them to participate in subsequent improvement efforts • Event rates can be followed over time 	<ul style="list-style-type: none"> • Somewhat labor intensive (but short periods of measurement may provide ample data) • Requires appropriately trained observers • Care must be taken not to create mistrust among frontline staff
Telephone calls to patients (can be automated)	<ul style="list-style-type: none"> • Identifies problems typically not captured by other methods (e.g., post-discharge adverse events and problems occurring between ambulatory visits) 	<ul style="list-style-type: none"> • Requires appropriate technology and, even with automation, still requires investment of personnel time (e.g., at least one nurse case manager and a physician) to respond in real-time to clinical problems

Source: Shojania KG. 2010.¹⁶ Used with permission.

As Tables 2 and 3 have demonstrated, health care organizations have been using a wide array of methods to detect AEs and medical errors.¹⁴⁻¹⁹ Many of these methods (e.g., trigger tools) can be further categorized by the targeted problems (e.g., medication-related medical errors or iatrogenic infections), tools, algorithms, and data source used. Given the limited timeframe for this review, we focus this chapter on general approaches to detecting patient safety problems that involve using multiple methods (e.g., incident reporting, executive walk rounds, clinical surveillance, chart review, and trigger tools) to collect data.

We primarily reviewed studies that compared the utilities of different methods. However, comparison studies that used any method as a gold standard to validate another method were not included for this chapter, because, in essence, these studies still focused on one individual method (i.e., the method being validated). We believe that understanding the strengths and weaknesses of various methods is crucial for decisionmakers who need to form an effective strategy for monitoring patient safety problems that is appropriate for their organizations.

Readers who are seeking information on individual methods can refer to studies and reviews specifically focusing on those methods. As we reviewed the literature for this chapter, we identified a large number of publications focusing on individual methods, particularly in the areas of incident reporting, chart review, and trigger tools. Some systematic or targeted reviews provided insightful summaries about commonly used methods.^{13,18,22,31,32}

Why Should This Patient Safety Practice Work?

Detection of AEs is a primary step to achieving a safe health care system. In the report, “Safe Practices for Better Healthcare—2010 Update,” the National Quality Forum stated that health

care organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach to continuously drive down rates of preventable patient harm.³³ As several landmark studies have suggested, medical errors are often a system failure where care practices are inconsistent among health care professionals.^{6,34,35} By systematically uncovering these errors and analyzing their causes, health care institutions can identify defects in processes of care and design system changes to prevent the errors.^{18,19,23}

In the 1999 report, “To Err is Human: Building a Safer Health Care System,” the IOM also acknowledged the need to learn from medical errors and recommended establishing mandatory incident reporting systems as part of an approach to improving safety.⁶ The report noted that one of the causes of medical errors is lack of reliable data on the number of medical errors, which limits the ability to identify the problem’s origins and develop initiatives to resolve the problem. A subsequent IOM report, “Crossing the Quality Chasm: A New Health System for the 21st Century,” reinforced the need for reliable data and noted a need for evidence-based policies and practices.³⁶ By performing root-cause analyses (an in-depth examination of the data to identify factors in the care process that contribute to the errors) and implementing corrective action plans, health care organizations may be able to address system and process failures to ensure that potential errors are prevented in the future.^{5,7,22,23}

What Are the Beneficial Effects of the Patient Safety Practice?

Measuring the beneficial effects of a safety-problem detection approach is not always straightforward. Few studies have measured changes in health outcomes that are brought about by implementing a safety-problem detection method. Designing rigorous studies to establish a direct connection between the method and any patient safety outcomes is challenging. The effectiveness, if any, of a safety-problem detection method may not always translate into better patient outcomes. These outcomes rely not only on how promptly and accurately the problems are identified but also on how the safety data are used in root-cause analyses and whether the corrective action plans are implemented effectively.^{5,6,22,23,36} If the safety data were misinterpreted or the action plans were not executed successfully, no improvement in safety outcomes would be observed regardless of the effectiveness of the detection method per se.^{6,22}

Additionally, accurately estimating the true prevalence of safety problems is almost impossible, particularly with medical errors that did not cause any harm.²³ While chart review has been used as the gold standard in some patient safety studies to quantify AE rates, it rarely detects medical errors that produce no harm and may also miss other safety problems because of incomplete documentation in the medical record.^{15,16} When an increased number of medical errors is identified, determining whether the finding reflects a deteriorating performance in risk management or is the result of improved efforts in uncovering these errors is difficult. Likewise, a decreased number of detected safety problems could be the result of effective risk management or simply reflect inadequate efforts to find the problems.

Because of these reasons, empirically measuring the impacts of safety-problem detection methods on patient outcomes is almost unlikely. The beneficial effects of these detection methods have often been judged partly on data and partly on assumptions. If data suggest that a method helped detect medical errors that had not been found via other means or detected more errors in a more timely fashion than other mechanisms, the method would be assumed beneficial to patient safety. While these assumptions appear reasonable, the data do not provide direct evidence that the detection method will lead to improved patient safety outcomes.

As discussed, we primarily reviewed studies that compared the utility of different methods. Our search identified one systematic review published by the World Health Organization (WHO) in December 2003.¹⁴ This study by Michel reviewed methods for assessing the nature and scale of harm caused by health systems. The objective of the study was to identify the strengths and weaknesses of available methods according to a defined set of criteria. These criteria included the following:¹⁴

- Effectiveness in capturing the extent of harm (in different environments).
- Availability of reliable data (judged by interobserver reliability).
- Suitability for large-scale or small, repeated studies. (Large-scale studies refer to national and regional studies. Small, repeated studies are carried out for a limited period at the hospital or local level.)
- Costs (financial, human resources, time, and burden on system).
- Effectiveness in influencing policy (focused on national, regional, or local policy or strategic programs).
- Effectiveness in influencing hospital and local safety procedures and outcomes.
- Synergy with other domains of quality of care.

This set of criteria was defined by the WHO Working Group in “Patient Safety: Rapid Assessment Methods for Assessing Hazards” in December 2002. The first four criteria focused on the intrinsic characteristics of the methods, their validity, reliability, and cost. The last three criteria were more related to the ability of the methods to trigger improvements in safety cultures and the quality of safety programs. The study reviewed 262 relevant studies. With the exception of comparative studies available for the assessment of effectiveness in capturing the extent of harm, the literature consisted mostly of descriptive studies. For the review, Michel considered the data reported in the included studies as well as the opinions of the authors of the studies.

The study rated each method on all seven criteria to produce a summary of its key strengths and limitations.¹⁴ When valid information was available, the author rated the criteria from 1 (least favorable) to 4 (most favorable). A study was defined as “valid” when an appropriate description of the method (sampling strategy, data collection, and data analysis) in line with “current standards” was available. The lowest level (1) indicates low effectiveness, suitability, or availability, or it means very high cost. Where the amount of evidence-based data was small, the author noted “to be confirmed.” The evidence-based ratings for each method in the seven areas are provided in Table 4. In the absence of valid data, the author used a subjective rating scale from 1 (least favorable) to 4 (most favorable), based on the opinions of the studies being reviewed. These opinion-based ratings are provided in Table 5. Both Table 4 and Table 5 were based on literature from developed countries. The author also reviewed literature from developing countries, but that information is not discussed in this chapter.

The WHO study revealed that the methods for assessing the nature and scale of harm caused by health systems have different purposes (Table 1), strengths, and limitations (Table 4 and Table 5).¹⁴ The main conclusion of the study was that these methods do not compete with each other. Instead, they complement each other by providing different levels of qualitative and quantitative information. The list of methods and the illustrative ratings (Table 4 and Table 5) provided by the study may serve as a starting point for choosing appropriate methods for detecting harms caused by health organizations. The author suggested that identification of appropriate methods must take into account the distinct environmental factors faced by each health care organization or region.

This WHO study also had limitations.¹⁴ First, the studies included for review varied in quality and quantity. For some methods of interest, such as interviews with health care providers, analysis of administrative data, or confidential inquiries, few studies were available for review. Some other methods that the author thought might be useful for detecting safety problems, such as single case analysis and focus group discussions, were not covered by the study. Second, the rating systems and criteria used in the study for judging the strengths or weaknesses of the methods were not adequately validated. The assessment of the methods was generally subjective rather than objective. Third, because of the wide variety of studies reviewed, the author was not able to use explicit criteria for quality assessment of the studies.

In addition to the WHO review, we also identified several primary studies that compared the utility of various methods for monitoring AEs or medical errors. In 2007, Olsen and colleagues compared the use of incident reporting, pharmacist surveillance, and local real-time record review for the recognition of clinical risks associated with hospital inpatient care.³⁷ Using the three methods, they prospectively collected data on AEs on 288 patients discharged from an 850-bed general hospital in the National Health System in the UK. The study found little overlap in the nature of events detected by the three methods. Record review detected 26 AEs and 40 potential AEs (PAEs) occurring during the index admission. Incident reporting detected 11 PAEs and no AEs. Pharmacy surveillance found 10 medication errors, all of which were PAEs. The study concluded that incident reporting does not provide an adequate assessment of clinical AEs and that a variety of methods need to be used to provide a full picture of the safety condition in a health care organization.

In 2008, Wetzels and colleagues compared the validity and usefulness of five methods for identifying AEs in general practice.³⁸ The five methods included physician reported AEs, pharmacist reported AEs, patients' experiences of AEs, assessment of a random sample of medical records, and assessment of all patients who died. In this prospective observational study, a total of 68 events were identified using these methods. The patient survey identified the highest number of events and the pharmacist reports identified the fewest. No overlap among the methods was detected. The authors concluded that a mix of methods is needed to identify AEs in general practice.

A study by Ferranti and colleagues compared results from two adverse drug event (ADE) detection methods—voluntary reporting and computerized surveillance—at a large academic medical center.³⁹ This 2008 study analyzed the medications most likely to cause harm and evaluated the strengths and weaknesses of each detection system. During a 7-month period, computerized surveillance detected 710 ADEs (6.93/1,000 patient days), whereas voluntary reporting identified 205 ADEs (1.96/1,000 patient days). For each major drug category (anticoagulants, hypoglycemia, narcotics and benzodiazepines, and miscellaneous), the two methods detected significantly different event rates.³⁹ Most surveillance-identified events were hypoglycemia-related, whereas most voluntarily-reported events were in the miscellaneous category. Of all unique ADEs (875), only 40 were common between the systems. The study's findings underscored the synergistic nature of the two ADE detection approaches. Although surveillance provides quantitative data to estimate the actual rate of ADEs, voluntary reporting contributes qualitative evidence to prompt future surveillance rule development and identify areas of emerging risk. The authors concluded that the two detection methods should be used together to provide a full picture of ADE-related patient safety problems.

In 2010, Levtzion-Korach and colleagues published a study that examined and compared five AE detection methods in one hospital.⁴⁰ The methods included a Web-based voluntary incident

reporting system, medical malpractice claims, patient complaints, the hospital risk management database, and executive walk rounds. These methods varied in the timing of the reporting (retrospective or prospective), severity of the events, and profession of the reporters. The five disparate data sources at the hospital captured about 15,000 problems. The authors systematically classified the detected problems into 23 categories using a taxonomy that they developed. The study found that each method identified important safety problems that were generally not captured by any of the other methods.⁴⁰ The following are the common categories of safety problems detected using the five methods compared in the study:

- Spontaneous reporting: patient identification issues, falls, and medication problems
- Malpractice claims: issues with clinical judgment related to diagnosis and treatment, communication, and technical skills and problems with medical records (incomplete, illegible, or missing)
- Patient complaints: issues with communication, ancillary services (e.g., patient transport, kitchen, housekeeping), and administration (admission and discharge processes, scheduling)
- Risk management: issues with technical skills, patient and family behavior (compliance issues, unusual behavior by a patient or family members), administration, and clinical judgment
- Executive walk rounds: problems with equipment, electronic medical records and other such technologies, and infrastructure (work environment, security)

Communication problems were common among patient complaints and malpractice claims. Clinical judgment problems were the leading category for malpractice claims. Walk rounds identified issues with equipment and supplies. AE reporting systems highlighted identification issues, especially mislabeled specimens. The authors concluded that, to obtain a comprehensive picture of their patient safety problems and to develop priorities for improving safety, hospitals should use a broad portfolio of approaches and then synthesize the messages from all individual approaches into a collated and cohesive whole.

In another 2010 study, the Office of Inspector General of the Department of Health and Human Services compared the usefulness of five safety event screening methods: nurse reviews, analysis of present-on-admission (POA) indicators, Medicare beneficiary interviews, hospital incident reports, and analysis of patient safety indicators.⁴¹ The study used a sample of 278 Medicare beneficiary hospitalizations selected from all Medicare discharges from acute care hospitals in two selected counties during a 1-week period in August 2008. The investigators compared events flagged by each screening method to the 120 events identified and/or confirmed through physician reviews. The study found that nurse reviews and POA analysis identified the greatest number of safety events. Nurse reviews identified 93 of the 120 confirmed safety events and POA analysis identified 61 events. Beneficiary interviews identified 22 events, and the remaining two screening methods identified 8 events each. Of the 120 events, 55 (46%) were identified by only one screening method. Nurse reviews identified 35 events (29% of the 120 events) not flagged by any other screening method. POA analysis alone flagged 14 events (12% of the 120 events).

We also reviewed a study by Tinoco and colleagues that compared a computerized surveillance system (CSS) with manual chart review (MCR) for detecting inpatient ADEs and hospital-associated infections (HAIs).²⁵ The authors retrospectively analyzed the events detected using the two methods by type of events. From a sample of 2,137 patient admissions between

October 2000 and December 2001, the authors identified AEs that were detected only by MCR, only by CSS, or by both methods. The study found that CSS detected more HAIs than MCR (92% vs. 34%); however, a similar number of ADEs was detected by both systems (52% vs. 51%). The agreement between systems was 26 percent and 3 percent for HAIs and ADEs respectively. The study also found that MCR detected events missed by CSS using information in physician narratives and that some events found by MCR were missed by CSS. The authors concluded that integrating information from physician narratives with CSS using natural language processing would improve the detection of ADEs more than HAIs.

A compelling theme emerged among the findings of the studies reviewed for this section. That is, different methods for detecting patient safety problems overlap very little in the safety problems they detect. These methods complement each other and should be used in combination to provide a comprehensive safety picture of the health care organization. Detailed information on the studies reviewed in this section (except for the WHO report¹⁴) is provided in Appendix D. Because the body of evidence consists of studies of different designs, the overall strength of evidence is not assessed.

Table 4, Chapter 36. Evidence-based rating of the main methods used in developed countries for estimating hazards in health care systems

Criteria	Ad Hoc Studies Based on Epidemiological Designs and Systematic Data Collection			Methods Based on Reporting		Analysis of Routinely Collected and Existing Data				
	Review of Medical Records	Studies Based on Interviews With Health-Care Providers	Direct Observation	Incident Reporting Systems	External Audit and Confidential Inquiries	Studies of Claims and Complaints	Electronic Medical Records	Administrative Data	Autopsy Reports	Mortality and Morbidity Conferences
Effectiveness in capturing the extent of harm	4	4	No evidence available	2	No evidence available	2	3	2	2	2, to be confirmed*
Availability of reliable data	2	4 for harm assessment, to be confirmed*	No evidence available	No evidence available	No evidence available	3	No evidence available	2	3, to be confirmed*	No evidence available
Suitability for large-scale studies	3	3, to be confirmed*	No evidence available	4	3	3	2	4, to be confirmed*	1	4
Suitability for small, repeated studies	3	3	No evidence available	4	Not applicable	4	4	4, to be confirmed*	No evidence available	4
Costs	1	1 for prospective; 2 for cross-sectional	No evidence available	3	No evidence available	4	3	4	No evidence available	4
Effectiveness in influencing policy	3	No evidence available	No evidence available	3	3, to be confirmed*	3, to be confirmed*	No evidence available	No evidence available	No evidence available	4
Effectiveness in influencing hospital and local safety procedures and outcomes	3	No evidence available	No evidence available	3, to be confirmed*	No evidence available	3, to be confirmed*	4	3, to be confirmed*	No evidence available	3, to be confirmed*
Synergy with other domains of quality of care	4	4	4	2	No evidence available	3	4	4	No evidence available	4

Adapted from Michel P. Strengths and weaknesses of available methods for assessing the nature and scale of harm caused by the health system.¹⁴

Rating scale from 1 to 4, the most favorable level being 4

* “to be confirmed”— where the amount of evidence-based data is small

Table 5, Chapter 36. Subjective rating, where there was no evidence-based data, of the main methods used in developed countries for estimating hazards in health care systems

Criteria	Ad Hoc Studies Based on Epidemiological Designs and Systematic Data Collection			Methods Based on Reporting		Analysis of Routinely Collected and Existing Data				
	Review of Medical Records	Studies Based on Interviews With Health-Care Providers	Direct Observation	Incident Reporting Systems	External Audit and Confidential Inquiries	Studies of Claims and Complaints	Electronic Medical Records	Administrative Data	Autopsy Reports	Mortality and Morbidity Conferences
Effectiveness in capturing the extent of harm	*	*	4	*	2	*	*	*	*	*
Availability of reliable data	*	1-2 for cause analysis	4 for harm assessment, 2-3 for cause analysis	2-3	2-3	*	2	*	*	3-4
Suitability for large-scale studies	*	*	1 for global assessment, 3 for limited focus	*	*	*	*	*	*	*
Suitability for small, repeated studies	*	*	2-3 (videotaping)	*	Not applicable	*	*	*	3	*
Costs	*	*	1	*	1-2	*	*	*	3-4	*
Effectiveness in influencing policy	*	3-4	3-4	*	*	*	3-4	3-4		*
Effectiveness in influencing hospital and local safety procedures and outcomes	*	2-3	3-4	*	1-2	*	*	*	2	*
Synergy with other domains of quality of care	*	*	*	*	2-4	*	*	*	1	*

Adapted from Michel P. Strengths and weaknesses of available methods for assessing the nature and scale of harm caused by the health system.¹⁴

Rating scale from 1 to 4, the most favorable level being 4

* Evidence-based rating is available (see Table 4)

What Are the Harms of the Patient Safety Practice?

None of the studies that we reviewed reported any harm directly caused by the implementation of a method for monitoring patient safety problems. However, in theory, a method that often fails to capture important AEs or medical errors may mislead the health care organization about its true safety status and cause a delay in addressing safety problems, likely leading to patient harms. Additionally, various detection methods may compete with each other for the limited resources available for risk management in an organization. Adopting a relatively ineffective method might shift resources from more effective alternatives and, thus, decrease the organization's overall performance in uncovering safety problems. This loss of detection capability, in turn, could lead to an increase in harms to the patients treated in the organization. However, designing rigorous studies to empirically test these hypotheses is difficult.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

As previously described, a wide variety of methods exist for detecting patient safety problems, and this chapter focuses on evidence only from studies that compared these methods. The methods being compared were implemented differently due to their differences in the primary problems targeted, tools used, resources required, staff involved, and the timing (retrospective or “real-time”) of the detection (see Appendix D, the “Description of PSP” column).¹⁴⁻¹⁹

Some of these methods (e.g., incident reporting and trigger tools) can be further categorized (e.g., mandatory or voluntary incident reporting systems), and each method in the subcategories can also be implemented differently. For example, at least 27 states and some Government agencies (e.g., the U.S. Food and Drug Administration) in the U.S. have established some form of incident reporting systems. These various incident reporting systems or programs could be implemented differently in terms of data collected, tools used, reporting process, and how data are shared or used.^{1,2,13,18,21,22}

Similarly, many different types of trigger tools and automated systems exist.^{31,32} These tools or systems target different problems (e.g., general AEs, ADEs, nosocomial infection, decubitus ulcers, surgical complications) and may involve different data sources, equipment, software, or algorithms. It is not feasible for this chapter to cover the implementation issues for all these methods. Therefore, we describe only the relevant information reported in the comparison studies reviewed for this chapter. This information is provided in Appendix D (refer to the “Description of PSP” and the “Context” columns).

Are There Any Data About Costs?

Accurately estimating the cost associated with implementing strategies for detecting patient safety problems is difficult. The direct cost for this activity may include expenditures for equipment and materials (e.g., computers, software, photocopy machines, paper), facilities and space, and labor for collecting and analyzing data. Indirect, overhead expenses also may need to be counted. These direct and indirect costs vary across health care organizations and regions and constantly change over time.

Our search identified sporadic data about costs for implementing safety problem detection methods. The most recent and relevant data came from the study by Levtzion-Korach.⁴⁰ This study estimated the direct cost of the five methods used in one hospital (Table 6). It showed that

the hospital's expenditures on these systems were estimated to be a one-time cost of \$120,000 and an annual cost of almost \$1 million. Additionally, we identified some general discussions about which detection methods are generally more expensive or labor-intensive (Table 2 and Table 3). Our search did not identify any full economic evaluation (e.g., cost-effectiveness analysis from the public's perspective) of the burden related to the implementation of various methods for detecting AEs or medical errors.

Table 6, Chapter 36. Estimated costs of systems for detecting patient safety problems in one hospital

	Incident Reporting	Patient Complaints	Risk Management	Malpractice Claims	Executive Walk Round
Software					
One-time expense	\$72,400	\$42,580	\$0	Not directly supported by the institution	\$0
Annual support	\$9,000	\$3,395	\$0	Not directly supported by the institution	\$0
Manpower					
Annual support	0.5 FTE PS manager: \$43,340 0.2 FTE RM analyst: \$18,000 0.1 FTE PS analyst: \$4,500	12 FTE PS analyst: \$540,000	3.5 FTE risk management analyst: \$318,500	Not directly supported by the institution	0.2 FTE PS manager: \$17,380 0.3 FTE PS analyst: \$12,780 A weekly hour of CEO, CMO, CNO, and COO: \$10,500
Sum					
One-time expense	\$72,400	\$42,580	\$0	Not directly supported by the institution	\$0
Annual support	\$74,840	\$543,395	\$318,500	Not directly supported by the institution	\$40,660

Source: Levtzion-Korach O. et al. 2010.⁴⁰ Used with permission.

Abbreviations: FTE PS=full-time equivalent patient safety; FTE RM=full-time equivalent risk management; CEO=chief executive officer; CMO=chief medical officer; CNO=chief nursing officer; COO=chief operating officer.

Are There Any Data About the Effect of Context on Effectiveness?

For this chapter, we focus on the evidence only from studies that compared different methods for detecting patient safety problems. It is not feasible for the chapter to review the effect of context on effectiveness for each individual method. We collected data only on the context for the methods being compared in the included studies. These data fall into five categories: the external context, organizational characteristics, teamwork, leadership, and culture (see Appendix D, the "Context" column). However, based on the data collected, no conclusion can be drawn regarding the effect of context on the effectiveness of the detection methods, mainly because these studies were not designed to assess such links.

Nevertheless, the importance of strong leadership, teamwork, and organization-wide safety culture to successful implementation of patient safety practices as a whole has been well documented in literature that is beyond the scope of this chapter.^{3,6,22,23} It is reasonable to expect that leadership, teamwork, and safety culture have the same impact on the implementation of patient safety monitoring strategies. Additionally, the external factors (e.g., how governments or the Joint Commissions use the safety data reported by hospitals) should also have a significant impact on the effectiveness of the strategies.^{13,18,21}

Conclusions and Comment

The studies reviewed for this chapter consistently suggested that each method for detecting AEs or medical errors has advantages and disadvantages. These various methods do not compete with each other. They identify fairly distinct problems and complement each other by providing different levels of qualitative and quantitative information about patient safety.

Health care organizations are generally faced with a variety of safety problems, such as misdiagnoses, misidentified patients, falls, procedural complications, and medication-related errors. All these problems need to be identified adequately so that hospitals can effectively prioritize the problems on the basis of the burden of harm and costs associated with the problems, the availability of effective prevention strategies, and the likelihood of local success in implementing such strategies.^{3,6,22,23} Therefore, health care organizations should use a broad portfolio of methods to uncover safety problems and then synthesize the data collected into a comprehensive picture.⁴⁰

For administrators and risk management professionals, a primary challenge is how to make a rational choice among a large number of methods to build a portfolio appropriate for their organizations.⁴⁰ While no simple formula exists to guide the decisionmaking process, the composition of the portfolio generally depends on the safety problems most relevant to the organization and the resources available for the risk management effort.¹⁶ The bottom line is that the choice of a specific method by a health care organization might not be as important as the decision to use more than one method.¹⁶ The information that we compiled in this chapter is intended to serve as a starting point for health care organizations to reconsider their general approach to monitoring patient safety problems. Future research needs to assess the effectiveness of different portfolios of methods and provide practical guidance on how to combine the information collected using different methods into one safety picture. A summary table is located below (Table 7).

Table 7, Chapter 36. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Low-to-High	Low	Negligible	High	Moderate/Difficult

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Chapter 37. Interventions To Improve Care Transitions at Hospital Discharge (NEW)

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How Important Is the Problem?

The term “transitions of care” refers to any instance in which a patient moves from one health care setting to another.^{1,2} More often than not, the care of a patient with chronic illness involves multiple settings (e.g., inpatient, outpatient, or long term care) and several different health professionals. These transitions are inevitable, but because they can increase the risk of adverse events and poor clinical outcomes, they warrant particular attention.

Hospital discharge represents a particularly risky care transition, especially for older adults. Multiple studies document that adverse events occur in approximately one in five adult medical patients within 3 weeks of discharge.^{3,4} Nearly 20 percent of older Medicare patients discharged from a hospital will be readmitted within 30 days.⁵ A broad spectrum of adverse events can occur after discharge, including both diagnostic and therapeutic errors, but adverse drug events (ADEs) are particularly common and harmful. Recent studies indicate that nearly 100,000 elderly patients are hospitalized every year due to ADEs.⁶ Additionally, 1 in 67 emergency hospitalizations are the result of an ADE. Particularly in the face of an aging population, ensuring safe care transitions for patients with complex, chronic illnesses will remain an important patient safety issue.

The Patient Protection and Affordable Care Act (PPACA) contains provisions specifically focused on decreasing preventable readmissions and improving care transitions. Under this legislation, hospitals will be financially penalized for high readmission rates. The Centers for Medicare & Medicaid Services already publicly reports hospitals’ risk-adjusted 30-day readmission rates for specific diagnoses on its Web site, Hospital Compare.⁷ Therefore, hospitals and health care organizations have considerable incentives to improve transitional care at hospital discharge.

What Is the Patient Safety Practice?

A wide range of interventions have been proposed and studied in order to ensure smooth transitions of care at hospital discharge. Therefore, this patient safety practice (PSP) comprises multiple interventions. Broadly speaking, we defined a “transitional care strategy” as an intervention or a series of interventions that occurs among health care practitioners and across settings in order to ensure the safe and effective transfer of patients from one level of care to another or from one type of setting to another. This definition is based on two widely used definitions of the broader concept of transitional care,^{2,8} which both refer to the movement patients make between health care practitioners and settings as their condition and care needs change during the course of a chronic or acute illness.

Within this broader definition, we sought to more specifically define PSPs targeting the particular problems of adverse events, readmissions, and emergency department visits after hospital discharge. Adverse events (AEs) have been previously defined as an adverse outcome or injury resulting from medical management, and can range in severity from laboratory

abnormalities to symptoms to permanent disability and death.^{3,4} AEs can be further categorized as preventable, ameliorable and not preventable. Prior studies have found that the most common preventable AEs after hospital discharge include procedural complications, hospital-acquired infections, and adverse drug events (ADE).^{3,4} An ADE is defined as harm associated with the appropriate or inappropriate use of a drug.⁹

For this report, the PSP refers to any intervention to improve transitions from acute care hospitals to the outpatient setting, with the goals of (1) bridging gaps in continuity of care and coordination of care across the health care continuum and (2) preventing adverse events, emergency department (ED) visits, and rehospitalizations after hospital discharge. This definition explicitly excludes formal care programs that do not primarily target discharge from the acute hospital setting. Examples of such excluded interventions include disease management programs, emergency services-based programs, Hospital at Home programs, day hospital care programs (including psychiatric day hospitals), palliative care and hospice programs, and interventions targeting discharge from the hospital to other acute or subacute settings.

In order to analyze a disparate body of literature, we developed a taxonomy of transitional care interventions based on analysis of existing systematic reviews in the field^{8,10-14} and expert consensus. We grouped individual interventions into three broad categories: pre-discharge, post-discharge, and “bridging” interventions (Box 1).

Box 1. Taxonomy of interventions to improve transitional care at hospital discharge

Pre-discharge interventions	<ul style="list-style-type: none"> • Assessment of risk for adverse events or readmissions • Patient engagement (for example, patient or caregiver education) • Creation of an individualized patient record (customized document in lay language containing clinical and educational information for patients’ use after discharge) • Facilitation of communication with outpatient providers • Multidisciplinary discharge planning team • Dedicated discharge advocate or coach • Medication reconciliation
Post-discharge interventions	<ul style="list-style-type: none"> • Outreach to patients (including follow-up phone calls, patient-activated hotlines, and home visits) • Facilitation of clinical follow-up (including facilitated ambulatory provider follow-up) • Medication reconciliation after discharge
Bridging interventions	<ul style="list-style-type: none"> • Inclusion of at least one pre-discharge component and at least one post-discharge component

“Bridging” interventions included both pre- and post-discharge components, and often emphasized longitudinal relationships in the pre- and the post-discharge periods, as well as the role of the patient or caregiver in maintaining safe transitions.¹⁵

The purpose of this systematic review is to analyze published literature to determine the effectiveness of the kinds of interventions described in Table 1 to reduce adverse events, ED or unscheduled acute care visits, and readmissions after hospital discharge of adult patients, and to assess the feasibility of implementing successful interventions on a larger scale. We included randomized controlled trials (RCTs) and non-randomized clinical controlled trials (CCTs) that evaluated one or more of the above interventions in adult general medical patient populations, utilized at least one intervention prior to discharge, and reported rates of ED visits, readmissions,

or adverse events (AEs) after discharge. We included studies that reported costs if they also reported one of the other targeted outcomes.

Why Should This Patient Safety Practice Work?

AEs after discharge and readmissions have been attributed to many factors, including poor communication and transfer of information between inpatient and outpatient providers;¹⁶ medication changes during hospitalization;¹⁷ inadequate patient comprehension of diagnoses, medications, and follow-up needs;¹⁸ and failure to complete planned outpatient diagnostic or treatment plans.¹⁹ Interventions to improve care transitions after hospital discharge generally target one or more of these documented deficiencies in care. In addition to these specific factors, more general patient-related factors and health care system-related factors may influence an individual patient's risk for AEs or readmissions after discharge. Figure 1 in Appendix C depicts the theoretical construct underpinning the role of interventions in reducing AEs and readmissions after discharge. In brief, patients' risk factors for an AE depend on patient and health care system factors. Specific interventions target known deficiencies in care transitions, aiming to improve continuity of care and decrease AEs after discharge. A reduction in AEs after discharge should, in theory, result in fewer readmissions and ED visits.

This framework has two main limitations: (1) many readmissions may not be preventable, and (2) transitional care interventions for general medical patients are comparatively less well-defined than are those for disease-specific populations, where the link between interventions and improved outcomes is clearer.²⁰

No clear consensus exists on the proportion of readmissions of adult patients that are preventable. A recent study²¹ has suggested that as few as one in five 30-day readmissions may be truly preventable, and that the proportion of preventable readmissions may vary widely among individual hospitals. Another recent study²² found that no method reliably predicts an individual patient's readmission risk. Given these limitations, hospitals face difficulties determining which patients should be targeted for transitional care interventions. Indeed, Hansen and colleagues¹⁵ recently published a systematic review of interventions to reduce 30-day rehospitalization, and found that no single intervention was consistently associated with reduced risk.

Prior research in this field has identified some interventions that have reduced readmission risk, but these successes have largely been achieved in disease-specific populations, such as patients with congestive heart failure. Multiple systematic reviews^{23,24} have found that multidisciplinary transitional care programs are associated with reduced readmission risk and improved mortality in elderly CHF patients. Naylor and colleagues⁸ summarized 21 randomized clinical trials of transitional care interventions targeting chronically ill adults, including both disease-specific studies and studies conducted in general medical populations. They identified nine interventions that demonstrated positive effects on measures related to hospital readmissions. Many of the successful interventions shared similar features, such as assigning a nurse as the clinical manager or leader of care and including in-person home visits to discharged patients. However, the majority of these successful interventions were conducted in disease-specific patient populations. A 2010 Cochrane review conducted by Shepperd and colleagues examined RCTs that compared an individualized discharge plan with routine discharge care in both general and disease-specific populations.¹⁴ They found that a structured and individualized discharge plan led to small reductions in hospital length of stay and readmission rates for older people admitted with a medical condition; but again, most of the successful studies focused on a

specific disease process. Unlike the Naylor review, this review did not consider interventions that occurred after the patient was discharged.

While some aspects of transitional care interventions for disease-specific populations may apply broadly to general medical populations, others may not be generalizable or may be less effective. In CHF patients, for example, a clear link exists between dietary and medication adherence and readmission risk; therefore, many successful interventions incorporate extensive patient and caregiver counseling around diet, medication adherence, and weighing daily at home. However, an elderly patient who is debilitated after a lengthy hospitalization for pneumonia may not derive the same level of benefit from medication and dietary counseling, as would a younger CHF patient, but might benefit from an intervention emphasizing restoring functional status and close clinical follow-up.

As several recently published systematic reviews evaluated the role of transitional care interventions in disease-specific populations and because the outcomes of such interventions appear to be different in disease-specific and more undifferentiated patient populations, we chose to focus our review on studies that evaluated only interventions conducted in adult general medical populations. In contrast to another recent review¹⁵ that evaluated only studies of interventions to reduce readmissions, we also included studies that sought to reduce adverse events or ED utilization after discharge.

What Are the Beneficial Effects of the Patient Safety Practice?

We conducted a systematic literature search of Medline, CINAHL, EMBASE, and the Cochrane Database of Controlled Trials using a search strategy developed with the assistance of a medical librarian. We identified 15,905 citations, of which 454 underwent full-text review (Appendix C, Figure 2, Chapter 37). Forty-three studies met all inclusion criteria, including 25 RCTs²⁵⁻⁵⁰ and 18 CCTs⁵¹⁻⁶⁷ (Appendix D, Table 1, Chapter 37). Studies used an average of 4 separate interventions (range 1-8) based on our taxonomy. Thirty-one studies used a bridging intervention, of which 21 were RCTs,^{25-30,32,34-38,40-45,47,48,50,52,53,55,56,59,64-66,68} and 12 studies (3 RCTs)^{31,33,46,49,51,57,58,60-63,67} included only hospital-based interventions. We used the Cochrane Effective Practice and Organization of Care (EPOC) criteria to evaluate the methodologic quality of included studies (Appendix D, Table 2, Chapter 37). Included studies generally had fair methodologic quality.

The interventions assessed in the studies included a variety of components (Appendix D, Table 3, Chapter 37). Five studies included risk assessment as part of the intervention.^{33,39,48,63,66} Thirteen of the 43 included studies used an individualized health record that included a list of diagnoses, warning signs or symptoms, medication list with side effects, and contact information.^{25-28,32,34,35,39,41,43,53,68} Most studies (34) included patient engagement, with varying levels of interaction that ranged from patient education to counseling to symptom management.^{25-30,32-35,37,39-48,50-54,56,58,60,62-66} Twenty-two studies included direct communication between inpatient and outpatient providers,^{25,26,32-35,37,39,41,43-46,48,50,53,55,60,62,64,66} and 16 included facilitated clinical follow-up either through directly scheduled appointments or telephone availability following hospitalization.^{25,26,28,30,36,39,43,44,47,48,50,53,55,56,64,66} Only 11 studies included medication reconciliation prior to discharge,^{26,33-35,37,41,45,46,60,62,66} and 10 studies included post-discharge medication reconciliation,^{26,27,32,34,37,41,43,45,65,68} done either by telephone or in the home visit. Of the 31 studies that included a bridging intervention, 24 included an identified health provider who took a primary role in the transitional period, with contact in the hospital and in the outpatient setting.^{26-28,30,32,34-36,39,40,43,45,47-51,53,55,56,64,67,68} Seventeen studies included a

multidisciplinary team, including at least two providers, as part of the intervention.^{28,34,35,38,41,42,47-50,55,57,59,61,63,64,67,69} Twenty-eight studies included post-hospitalization outreach, either by telephone (22),^{5,25-30,32,35-37,39,40,43,45,47,50,55,59,65,66,68,69} home visit (18)^{26-29,37-39,41-43,47,48,52,53,55,59,65} or both telephone contact and at least one home visit (10).^{26-29,37,43,55,59,65,68} None of the studies specifically addressed end of life issues, palliative care, or counseling as part of the interventions. However, studies evaluating the Care Transitions Intervention (CTI) did include advanced directives in the patient-centered health record.^{27,43,65}

Interventions To Reduce 30-Day Readmissions

All but one study reported readmission rates, including 18 studies (10 RCTs) that reported ED visit or hospital readmission rates 30 days or less after discharge^{25,27-30,34,35,37,43,45,52,56,57,63,65-68} (Appendix D, Table 4, Chapter 37). Sixteen of these studies (10 RCTs) reported these outcomes at 30 days after discharge,^{25,27-30,34,35,37,43,45,52,56,57,63,65-68} and two studies reported 14-day readmission rates^{52,63}. We focused our analysis on the studies reporting 30-day ED visit and/or readmission rates, given the policy importance of this outcome (i.e., Medicare’s decision to use this time horizon for public reporting and readmission penalties).

We identified six studies (four RCTs, two CCTs) that reported significant reductions in 30-day ED visit or readmission rates.^{27,34,35,43,65,68} Overall, these studies were of similar fair methodologic quality compared with the other studies. All of these studies used a bridging strategy with five or more separate interventions. Coleman 2004 (CCT) and Coleman 2006 (RCT) evaluated the CTI in hospitalized geriatric patients in large managed care and capitated delivery systems respectively.^{27,68} This transitional care program focuses on engaging patients and caregivers to be active participants in self care in four areas (“pillars”): medication self-management, a flexible and dynamic patient-centered record, outpatient provider followup, and identification and management of “red flags” including signs or symptoms of a worsening condition. The intervention includes hospital and home visits and several telephone contacts, all of which emphasize the importance of self care of chronic illness through education, role modeling, and counseling during the transitions period. Two subsequent studies implemented the CTI in Medicare fee-for-service populations in Colorado and Rhode Island.^{43,65} Both of these studies also found reductions in 30-day readmission rates, reaching statistical significance in the Rhode Island study.

Jack and colleagues evaluated the ReEngineered Discharge Program (Project RED) in a single site RCT at a large urban safety net hospital.³⁴ The intervention focuses on an in-hospital component, where a nurse discharge advocate develops a comprehensive patient-centered after-hospital care plan, including medication and contact information, pending tests and appointments, and a post-hospitalization pharmacist telephone call that includes communication with primary providers. The study reported significant reductions in ED utilization after discharge; readmission rate was reduced as well, but this outcome did not achieve statistical significance.

A 2009 report by Koehler and colleagues evaluated a supplemental geriatric “care bundle” as part of a multidisciplinary team-based program with care coordinators and pharmacists around patient education on medications and self-management (including use of a personal health record), as well as post-discharge telephone follow-up calls.³⁵ A 2009 report by Courtney and colleagues evaluated a nursing and physiotherapy program for hospitalized elders that included individualized exercise instruction, nurse-led discharge planning with a focus on activities of

daily living, medical treatment, social support, and followup with a home visit and telephone contact in the post-hospitalization period.²⁸

These six studies share several similarities. Five studies were done in geriatric populations.^{27,28,35,43,65,68} All had bridging interventions that included five or more separate interventions, including a dedicated transitional provider across the continuum of care, individualized personal health records, and post-hospitalization outreach to patients. All six studies also involved patient contact at multiple points during and after hospitalization. These interventions likely require a considerable amount of time, resources, and additional staff (dedicated transitional provider) to facilitate the coordination of care from hospital to home. Although the relative intensity of the interventions could not be measured directly, the multifaceted nature of these interventions means they likely were more intensive than those described in studies that did not find reduced readmission rates. The CTI is the only program shown to reduce readmissions in multiple studies in different health care settings.^{27,43,65,68}

Interventions To Prevent Adverse Events After Discharge

A total of nine studies reported adverse events (AEs) following discharge^{25,30-33,40,44,45,58} (Appendix D, Table 5, Chapter 37). Of these, five specifically reported rates of adverse drug events (ADEs)^{32,33,44,45,58} and/or reactions--i.e., events that could be attributed to the use of a drug. Five studies reported more generally on rates of other types of AEs,^{25,30,31,33,40} including falls, post-discharge infection rates, failure to complete recommended outpatient follow-up, and composite rates of all AEs. All studies except for one were RCTs.⁵⁸

Only three studies demonstrated a significant decrease in event rates (specifically, ADEs) following implementation of a transitional care intervention.^{32,45,58} Gillespie and colleagues reported that a comprehensive pharmacist intervention in elderly patients 80 years of age and over resulted in fewer medication-related (re)admissions. Hellstrom and colleagues reported that a comprehensive pharmacist-led inpatient intervention, including systematic medication reconciliation on admission and discharge, resulted in a reduction in the composite rate of drug-related admissions and emergency department visits. Schnipper and colleagues reported that an intervention consisting of pharmacist medication reconciliation at discharge, patient counseling, and telephone follow-up resulted in a lower rate of preventable ADEs 30 days after hospital discharge.

Each of these successful interventions was pharmacist led, while among unsuccessful interventions, only one was pharmacist led. In addition, all successful interventions had substantial and multi-faceted inpatient components, including some form of medication reconciliation and patient education focused on enabling patient self-management. Two of the three interventions also had bridging components, including a follow-up phone call by a pharmacist after patient discharge.^{32,45} One intervention also included the creation of an individualized patient record of medications, which was faxed to the outpatient provider at discharge.³² In contrast, the majority of unsuccessful interventions had only inpatient components that were focused on intervening at a single step of the discharge process. Regarding intervention context, all three studies were performed at teaching hospitals. Two of the three studies^{32,58} took place in Sweden; only one of the three was based in the U.S.⁴⁵ Authors used varying strategies to classify events as ADEs. Gillespie and colleagues used the electronic medical record to ascertain if admissions were medication-related – physicians caring for patients were blinded to study assignments and were required to record if an admission was thought to be medication-related. Hellstrom and colleagues had a multidisciplinary team— who

were blinded to group allocation—review electronic medical records for unscheduled hospital readmissions and ED visits to determine if they were drug related. Schnipper and colleagues used a combination of structured screening via patient report by the Bates method⁷⁰ and chart review by blinded physician reviewers using the Naranjo algorithm to assess causality.⁷¹

What Are the Harms of the Patient Safety Practice?

None of the studies reported any harms associated with transitional care interventions. One study reported a significantly increased rate of readmission in the intervention group,⁵⁰ which was considered a result of heightened vigilance on the part of providers and patients to identify issues arising after hospitalization.

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

Heterogeneity of Target Populations and the Exclusion of High-Risk Groups

To maximize the generalizability of our findings, we limited our analysis to studies examining the effectiveness of transitional care interventions in general medical inpatients only (31 of 43 studies)^{25,26,28-32,34-38,40-42,45-47,49,51-53,55-59,61,62,66,67} or mixed patient populations (12 of 43)^{27,33,39,43,44,48,50,60,63-65,68}. Despite attempting to capture studies aimed at a general medical population, we found that the majority of studies targeted a specific demographic among medical patients. Twenty six studies (60%)^{26-29,31,32,35-43,46,47,49,52,53,58,59,63-65,68,72} were interventions targeted specifically at elderly populations, although definitions of “elderly” varied widely (>55-80 years of age).²⁶ Seven (16%) of studies targeted patients with a specific payor,^{25,37,43,50,51,65,68} including members of a specific health plan (three studies^{25,51,68}); Medicare or Medicare fee-for-service (three studies^{37,43,65}); or individuals receiving care through the Veterans’ Administration Health Care System (one study⁵⁰). Eleven studies (26%) targeted individuals who were thought to be at ‘high risk’ for readmissions or adverse events,^{27,28,33,35,37,39,48,53,57,63,66} although definitions of “high risk” were inconsistent across studies. Eight studies targeted individuals based on medication-related indications,^{26,35,37,41,44,46,62,66} including polypharmacy, or being on a “high-risk” medication; again, definitions of “polypharmacy” and “high risk” were inconsistent across studies. The heterogeneity of target populations for interventions may limit the generalizability of study findings to a general medical inpatient population at a single given institution.

Additionally, individuals with characteristics that may place them at higher than average risk for readmission and adverse events were often excluded from study populations. The most common clinically relevant exclusion criteria were as follows: presence of cognitive impairment or dementia (14 studies);^{27,28,31,34-37,40,42,43,50,52,53,65} non-English speaking, or not fluent in dominant language of country in which intervention took place (15 studies);^{27,33-35,37,40,43,45,50,72} no telephone (ten studies);^{27,33-35,37,40,43,45,50,72} terminal illness or too ill (nine studies);^{31,33,41,42,47-50,53} homeless (four studies);^{27,29,37,40,69} presence of mental illness (four studies);^{26,27,36,53} and inadequate caregiver support (one study).³⁷ The exclusion of these individuals may limit the generalizability of study findings to specific groups generally considered to be at lower risk for readmission and adverse events.

Limited Generalizability Due To Wide Variation in Health Care System Factors

Most studies were conducted at teaching hospitals (25 studies or 57%;^{28,30-36,42,44,45,47,50,51,53,55,56,58,60-62,65-67,72}), of these, five were multi-site studies^{39,50,60,62,65}). Six studies took place in a community hospital setting;^{37,41,43,46,49,63} of these, three were multi-site studies.^{41,46,63} Four studies took place in safety net systems.^{25,34,48,56}

Only about one-third of studies (14 studies) reported the health system context in which the intervention was implemented. Three studies took place within the context of an integrated delivery system;^{25,26,68} two studies took place within an HMO or capitated system;^{27,51} four studies were in a safety net system;^{25,34,48,56} and six studies took place in a variety of other settings, ranging from open non-integrated systems^{43,65,68} in countries with national health systems^{36,46} to the Veterans' Administration health system.⁵⁰ Virtually no studies reported on aspects of local quality improvement structures or safety culture that could influence intervention success.

Only about half of analyzed studies (22 studies) were conducted within the U.S.^{5,25,27,29,33,35,37,39,40,43-45,47,49-51,55,56,65-68} Of the remaining 21 studies, 4 took place in the United Kingdom,^{26,38,41,52} 3 took place in Canada,^{30,59,60} and 14 took place in other countries, including Australia,^{28,36,48,53,61} Sweden,^{32,58,64} Ireland,^{31,46,62} Germany,⁴² New Zealand,⁵⁷ and Belgium⁶³.

Given the heterogeneity of hospital sites, health care system contexts, and countries in which the interventions took place, data are insufficient to allow broad generalization of various study findings across different types of health care settings. Additionally, the large number of studies taking place within academic settings may limit the generalizability of study findings to care settings without an infrastructure and resources similar to those found within academic settings.

Limited Information on Resources Needed To Initiate and Sustain Transitional Care Interventions

Fewer than one-third of studies (11 studies^{25,33-35,38,41,44,46,60,63,65}) described training protocols or resources needed to implement a transitional care intervention. Most studies included at least a general outline of the intervention (30 studies^{25-27,30-35,37,39-47,49-52,55,56,59,61,65,66,68}) and a majority (25 studies) reported a detailed timeline^{26,27,29,30,34,35,37-43,45-48,50,52,55,58,62,63,65,68} with explicit descriptions of the components of the intervention. No studies reported a plan for sustainability or plans for long-term incorporation of the intervention into current clinical practice. Thus, information on the types of resources and/or training needed to conduct an intervention was limited, and data on sustainability of interventions over time were markedly absent. However, our results suggest that the most effective interventions also tended to be the most resource intensive. Both the paucity of data on what resources are necessary for implementation and sustainability, and the fact that the level of needed resources for a successful intervention is likely to be quite high may represent significant barriers to implementation of transitional care interventions in most settings.

Lack of Demonstrated Replicability of Interventions, Except for the Care Transitions Intervention

We found that only one intervention, the CTI,⁶⁸ had been implemented and evaluated in multiple settings. The five studies of the CTI^{27,43,65,68,73} have been conducted in a range of hospitals, including tertiary care academic medical centers and community hospitals with and without teaching programs, and in both integrated and non-integrated health care systems. All

other studies that demonstrated reductions in 30-day readmissions or ED visits were single-center studies that have not been replicated in other settings or patient populations.

One study⁷³ evaluated the implementation of the CTI in ten California hospitals, using a qualitative approach to identify key factors associated with successful implementation. Leadership support and early engagement of hospital and community stakeholders were identified as important steps in ensuring early implementation success; maintaining a cadre of funded transition coaches was thought to be essential for ensuring CTI sustainability.

Are There Any Data About Costs?

Cost outcomes were reported in 14 studies, although no studies actually reported the costs associated with intervention implementation itself. The studies that did report costs generally compared the health care utilization and associated costs for patients in the intervention group with those of patients receiving usual care. These costs were measured over varying intervals after discharge, and used cost estimates from different sources. As a result, it is difficult to draw any firm conclusions on the effect of transitional care interventions on overall health care costs. Prior systematic reviews of interventions conducted in disease-specific and general medical populations also did not reach any definitive conclusions regarding cost savings from transitional care interventions.^{8,14,15}

The lack of information on the cost of intervention implementation is particularly problematic for health care organizations that are planning strategic approaches to reducing readmissions. We found that only relatively intensive bridging interventions—which generally required additional personnel and other resources—successfully reduced readmissions. This finding suggests that hospitals may have to make considerable up-front investments in order to implement such programs. Doing so will likely require a strong business case that the investment will eventually be at least cost-neutral, if not cost-saving (perhaps driven by upcoming CMS penalties on excessive readmissions). However, the data required to make this business case are currently lacking.

Are There Any Data About the Effect of Context on Effectiveness?

As the CTI is the only method evaluated in different patient populations and health care systems, we are not able to draw conclusions regarding the effect of context on effectiveness. As discussed above, only a minority of studies reported important contextual details such as the structure of the health care system in which the study was conducted or relevant measures of culture or teamwork, and at the patient level, studies generally excluded patient populations that might be at a higher risk of readmission. Transitional care is inherently complex, with myriad patient- and system-level factors that may influence the success of an intervention. It is therefore quite likely that contextual factors do influence the effectiveness of transitional care strategies; however, this issue is not well explored in the existing literature.

Conclusions and Comment

Hospitals and health care organizations are under increasing pressure to improve transitional care, particularly at hospital discharge, due to a growing body of literature documenting unacceptably high rates of AEs after discharge and short-term ED visits and readmissions. We systematically reviewed the literature to identify Patient Safety Practices that were effective at

reducing AEs, ED visits, and readmissions after discharge, and determine what is known about the influence of contextual and implementation factors on the success of these interventions.

Only a limited number of relatively high-intensity bridging interventions appear to reduce readmissions and ED visits, and only one of these (the Care Transitions Intervention) has been implemented in multiple contexts. Pharmacist-led interventions do appear successful at reducing ADEs after discharge, but the overall literature base of interventions specifically targeting common AEs after discharge is small. The studies we identified unfortunately provided little information about implementation factors, contextual factors affecting the success of the intervention, or costs of implementation. Such information will be needed to allow health care system leaders and policymakers to plan strategically as they consider implementing programs to prevent readmissions and other harms associated with transitions of care. A summary table is located below (Table 1).

Table 1, Chapter 37. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Low	Negligible	Moderate-to-high	Little/Difficult

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Chapter 38. Use of Simulation Exercises in Patient Safety Efforts

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How Important Is the Problem?

Every July, patients are treated by new residents and fellows who have started their training programs only days before. Given that error rates drop with experience,¹⁻⁴ an important challenge is how to train physicians while minimizing the potential for patient harm. Many medical educators now regard the traditional medical training model “See one, Do one, Teach one,” as unstructured and inadequate.^{5,6} For example, before performing a procedure like airway intubation on a patient for the first time, a trainee likely would have read about the theory with some visuals, but may or may not have touched the equipment, discussed the detailed steps and common pitfalls, or necessarily observed an experienced physician performing the procedure. Before being a team leader, for example before coordinating a cardiac arrest resuscitation, a senior resident would likely have participated in prior resuscitations but may never have formally debriefed the experience to learn from it. However, simulation exercises or drills allow residents and trainees to practice the necessary steps in a safe situation. Then, a debrief is often structured with dedicated time to reflect upon what worked well and what did not during the exercise to identify ways to improve the next resuscitation. Without such simulations, the team leader would by definition never have practiced being the leader before “going live” in this role for the first time. While all physicians still must perform procedures on and manage critical events for an actual patient for the first time, simulation is likely to make this first time safer and more efficient.

However, the use of patient safety efforts that involve simulation target not just inexperience. Clinical expertise and mastery within a specialty does not increase simply as a function of experience,^{7,8} and, likewise, patient safety issues are not likely to decrease simply as a function of more practice hours: experienced surgeons are involved in a notable proportion of malpractice claims.⁹ Simulation with debriefing, or other forms of “deliberate practice” and reflection are needed to continuously improve care. With experience, comes increased pressure in supervising roles and increased clinical demand to treat the most complex, difficult, and rare conditions. The likelihood of desirable outcomes can be increased, even among experienced clinicians, as simulation allows adjustment of the complexity of the procedures and regular practice with treatment for rare conditions. At times, the most senior clinicians will be called on to perform tasks outside of their specialty due to medical necessity or availability of resources (e.g., in rural areas). Simulation may provide a mechanism for clinicians to practice responding to these high-stakes situations without harm to patients. In addition to developing these “advanced” techniques, experienced clinicians must maintain proficiency in a wide array of skills, some of which are known to deteriorate over time without practice.^{10,11} Simulation can serve to maintain clinical skills and may be part of maintenance of board certification, as is the case for The American Board of Anesthesiology.¹²

Simulation can also address team and organizational issues that challenge patient safety. Technical errors may occur in a team care environment as a result of nontechnical factors (e.g.,

communication), and specific simulation-based training protocols have been developed for enhancing team performance. These protocols include Anesthesiology Crisis Resource Management.¹³ Likewise, simulation may provide a way to assess the efficiency and safety of system-level practices that may be difficult to control in real time or unsafe to test empirically.

Simulation has received increased recognition since the release of “Making Health Care Safer” and seminal Institute of Medicine reports on preventable medical errors and mortality.^{14,15} The Agency for Healthcare Research and Quality (AHRQ) continues to fund a number of projects dedicated to enhancing patient safety through simulation.^{16,17} Accrediting bodies from the American Association of College of Nurses, American College of Surgeons, American Association of Anesthesiologists, and Society for Simulation in Healthcare have all supported simulation training centers.¹⁸⁻²⁰

Studies evaluating the relationship between the benefits of simulation exercises and patient safety outcomes, including potential harms, have not been thoroughly evaluated. Therefore, the purpose of this chapter is to systematically review evidence on the benefits and harms of using simulation to improve patient safety in medicine.

What Is the Patient Safety Practice?

The use of simulation has a long history in health services education.²¹⁻²³ However, recent advances in simulation have been inspired by aviation and other high-reliability, high-stakes industries that emphasized the inherent value of allowing initial practice of all crucial skills during simulation, as a lower-stakes context, but with sufficient realism for the skills to transfer effectively. In the 1990s, Gaba and Howard developed simulation courses for Anesthesia Crisis Resource Management built upon Crew Resource Management (CRM) principles from aviation (see the chapter “Team-Training in Healthcare: Brief Review” for more information on CRM in health care).¹³ In addition to enhancing team performance, use of simulations to improve understanding of technological advances and effective practices among individuals and care systems has increased substantially in the past decade.

Simulation is considered a technique rather than any one patient safety practice. Importantly, this technique is versatile as it may be applied across specialties and levels of intervention.²⁴ Simulation to enhance patient safety has four general purposes²⁵ :

1. Education
2. Assessment
3. Research
4. Health System Integration

These purposes are not mutually exclusive, and each may span a range of complexity. Simulation serves an educational role in transitioning trainees from content knowledge to experiential practice, in continuing education, and in moving toward advanced practices. A classic low-fidelity example is training intramuscular medication administration through simulated practice inserting a needle into an orange. More complicated “partial task training” may now include high-fidelity simulations that utilize anatomically accurate mannequins with realistic surgical equipment monitored by computer. Patient safety may also be enhanced through “full scenario management,” a fully-simulated care environment such as entire operating rooms and care teams. In addition to educational aims, simulators can provide structure for critical assessment in quality control or quality improvement through systematic research into clinician behaviors, care team processes, and integrating health system-level processes.

Simulation is particularly useful for research into processes that cannot be varied in a study without undue harm to patients. Specific considerations in implementing simulation are detailed in a later section of this chapter.

On a basic level, simulations improve patient safety by allowing physicians to become better trained without putting patients at risk and, importantly, by providing a protected time for reflection and debriefing. The challenge is matching the best simulation method and training details for the desired learning objectives, while recognizing the costs of each method.²⁴ Because simulation is a broad technique, rather than a specific technology, faculty training and time are often considered a more important investment than are specific expensive simulation equipment. Given that most clinicians are not trained in simulation and debriefing, specific practitioners with interest in the area must be appropriately trained to effectively use simulation techniques, as well as any specific desired technologies, in order to accomplish the relevant training or systems probing goals. The significant investment of time requires that faculty are provided time to develop and teach meaningful simulations. Besides some procedural skills that may require mainly repetitive practice, most simulations require an extensive debriefing component, during which much of the learning takes place. Learning to effectively facilitate debriefings is often the most time-intensive component of faculty training.^{26,27}

The simulation itself needs to feel *real enough* for participants to be able to “suspend disbelief,” acting and thinking much as they would in a similar but real scenario.²⁵ If the learning objective is mainly to practice cognitive skills for diagnosis or treatment, a verbal simulation such as “What would you do if...” may be sufficient. In contrast, if time pressure and/or team communication are the focus, a more accurate replication of the actions and team presence become important for the simulation experience.

Why Should This Patient Safety Practice Work?

Research demonstrating the benefits of simulation comes from studies *about* simulation as well as studies *using* simulation.²⁸ Research *about* simulation directly examines the effect of a simulation technique as an intervention on behaviors and actions at the health professional or team level that *could* directly improve patient safety if that training were widely implemented. Studies *using* simulation harness these techniques as a laboratory to investigate new technologies and human performance for insights into potential causal pathways to improve safety. Strategies that employ simulation techniques may do so as part of a multicomponent intervention or may focus on the simulation alone. The versatility of simulation techniques affords those working to improve patient safety a number of benefits.

First, simulation is initiated on command and may be practiced repeatedly. Additionally, the content of simulated exercises may be structured to meet particular goals. Thus simulation has been utilized to enhance the reliability of clinician behaviors in order to reduce medical error associated with inexperience or undesirable levels of competency.¹⁻⁴ A systematic review of simulation with deliberate practice added to traditional training models reported in favor of simulation for enhancing clinicians’ technical skills performance (pooled effect size = 0.71, 95% CI, 0.65 to 0.76, $p < .001$).²⁹ Simulation has been associated with improved knowledge acquisition and clinical reasoning beyond traditional training in other studies as well,³⁰ and one meta-analysis reported that training with computerized virtual patients enhanced performance in actual patient care (pooled effect size = 0.50; 95% CI, 0.34 to 1.19).³¹ The nature of simulation also allows practitioners experience with rare and unpredictable care scenarios (e.g., mass

casualty incidents),³² with rare clinical events, and with advancing to mastery levels in a specialty.^{7,8}

Second, simulation may be particularly valuable in duplicating complex high-stakes scenarios that involve care teams and complex factors that affect performance.^{33,34} During an Anesthesiology Crisis Resource Management simulation (including realistic emergency scenarios, team communication, and complex decisionmaking), Blum and colleagues planted “probes” of clinically pertinent information known only to a single member of the care team.³⁵ These researchers found that participants shared only 27 percent of the probes with the team, electing instead to share redundant information already available to others. Authority and power differentials between senior and junior clinicians may also hinder effective communication, and reluctance to challenge superiors may result in medical errors in high-stakes scenarios. The field of aviation uses a method called the two-challenge rule to train all team members in a technique known as advocacy-inquiry, giving junior team members the language to “speak up” while seeking clarification. To study use of the two-challenge concept in debriefing anesthesiology trainees, Pian-Smith and colleagues structured emergency simulations with contraindicated decisions made by attending clinicians.³⁶ The researchers discovered that trainees were initially reluctant to challenge their superiors, but after debriefing, they were significantly more likely to make an effective and clear challenge to contraindicated decisions by attending clinicians.

Third, errors are allowed in simulation and utilized as learning experiences through reflection and debriefing. Training with real patients requires that supervising clinicians intervene if certain errors occur, disallowing trainees to carry out the remainder of the procedure or to protect time for debriefing. Additionally, as Fanning and colleagues note, reflective practices are considered a cornerstone of life-long education in medicine.²⁶ Simulation may facilitate highly accurate measures of specific care-related behaviors and processes (technical or non-technical) for the purpose of debriefing and reflection.^{26,27} Debriefing has exerted an increased performance effect over self-study in high-fidelity simulated assessments.³⁷

Fourth, simulation may be used to test new technologies, especially complex ones that involve new learning curves in even the most experienced of clinicians.³⁸ Likewise, new team processes or innovative practices may be simulated prior to implementing in real time.³⁹ Simulation may also help resolve disputes between best care practices. For example, cardiopulmonary arrest of a woman pregnant for greater than 20 weeks requires cesarean delivery within 5 minutes of onset, to protect both mother and fetus. However, debate has existed as to whether the procedure should be performed in the labor room or in an operating room after transporting the patient. Clearly, one would not consider placing actual patients in harm’s way just for the purpose of settling this debate in research. However, utilizing simulation in a randomized design, Lipman and colleagues determined that the average time to incision was three and half minutes longer in teams instructed to transport patients to the operating room.⁴⁰

Lastly, teams can simulate patient care flow in situ, for critical events⁴¹⁻⁴³ as well as new facility “usual care,” to check for the proper equipment (e.g., severe hemorrhage drills on various hospital units or new operating rooms, respectively).^{44,45} Researchers have utilized simulation-based communication training to enhance inter-agency processes such as telephone referrals,⁴⁶ but this use remains a relatively under-studied area.

What Are the Beneficial Effects of the Patient Safety Practice?

Questions regarding the details of a simulation intervention and its measurable impact on patient outcomes are difficult to answer for many reasons, so there have been relatively few

studies in this arena. The measurable outcome may vary substantially based on the specific behavior or process under investigation. For example, small gains may be expected on patient outcomes from additional simulation exercises when assessing clinicians who must first demonstrate a minimum acceptable level of competency before practicing on actual patients. Likewise, comparing experienced to expert clinicians requires a highly sensitive and specific methodology that is still being developed currently among simulation experts.^{7,8} A plethora of simulation research has been conducted on what translational science refers to as T1, or “laboratory-only,” outcomes.^{12,47} As noted above, T1 studies, or research *about* simulation, support the logic for why simulation matters for patient safety. This section on beneficial effects of simulation focuses on studies that reported T2 or T3 outcomes and that were published since “Making Health Care Safer,” or those studies that translate interventions directly to patient-level and systems-level outcomes, respectively.^{12,47} Studies are grouped into simulation exercises that assessed patient outcomes related to practitioner technical performance, team-level, and system-level outcomes. Following these sections is an in-depth review of literature on patient outcomes related to central venous catheterization.

Practitioner Performance

This section focuses on the technical aspects of physician performance during procedures. Although technical skills are a crucial component to effective and safe health care, there is potential for simulation to improve cognitive and other decision-making processes that impact the delivery of services.

Diagnostic procedures. In a randomized trial with first-year gastroenterology fellows, simulation-trained fellows out-performed traditionally-trained fellows during standardized assessment of performance on the first 80 colonoscopy procedures ($p = 0.03$). The difference between groups did not persist beyond 80 procedures, and the researchers determined that both groups required the entire 200-colonoscopy training experience to achieve a desirable level of procedure mastery.⁴⁸ Another randomized study of first-year gastroenterology fellows reported similar results, with simulation-trained clinicians successfully reaching the cecum in 38 percent of their first 15 colonoscopies compared with 20 percent in the control group ($p = 0.027$). Differences between groups were also observable through 30 procedures, but differences did not persist beyond 30 procedures.⁴⁹ Other studies have reported earlier acquisition and higher performance in first colonoscopies performed among trainees who received simulation training,⁵⁰⁻⁵² and one reported that simulation-trained clinicians reached the cecum 4.5 times more often on average than did clinicians in the control group during their first 10 procedures (95% CI, 1.89 to 11.60, $p = 0.001$).⁵⁰ Similar effects of simulation on increased early performance enhancement, and, subsequently, absence of differences between study groups, were reported for upper gastrointestinal endoscopy.⁵³ In a randomized study, bronchoscopy simulation exerted no effect on procedure time.⁵⁴ Safety outcomes reported in these studies focused primarily on patient discomfort (e.g., insufflation), and simulation training was associated with lower discomfort in one study,⁵⁰ no difference in another,⁴⁸ and higher patient discomfort in a third.⁴⁹

In a before and after design, thoracenteses performed after implementing simulation in a training curriculum involved fewer pneumothoraces (8.7% before vs. 1.1% after, $p = 0.003$) and procedures advancing to thoracostomy (6% before vs. 0% after, $p = 0.003$) than those performed prior to simulation-based training.⁵⁵ In a similar type of research design examining

cordocentesis, procedure time was lower (6.4 min vs. 13.2 min, $p < 0.001$) and success rate was higher (98.8% vs. 94.8%, $p < 0.001$) after implementing simulation training. There was no difference between the before- and after-simulation study periods in procedure-related fetal loss or overall fetal loss.⁵⁶

Surgical procedures. A meta-analysis of laparoscopic training with virtual reality simulators reported that procedure time was no faster, but was more accurate (standardized mean difference [SMD] 0.68, 95% CI 0.05 – 1.31) in simulation-trained clinicians compared with traditional video-trained clinicians. These authors reported no difference between simulation-trained and other-trained clinicians in conversion rate to open surgery.⁵⁷ Surgical residents who were randomized to simulation training on laparoscopic cholecystectomy exhibited fewer errors in exposing (control mean = 53.4, simulator mean = 15.0, $p < 0.04$), clipping (control mean = 7.1, simulator mean = 1.9, $p < 0.008$), and dissection (control mean = 29.5, simulator mean = 11.5, $p < 0.03$) during their first ten cholecystectomies. Three-fold fewer total errors and an eight-fold decreased variation in error making totals were found among simulation-trained clinicians.⁵⁸ Another study reported that “warming up” with laparoscopic simulation led to increased observed structured assessment of technical skills (OSATS) global rating on actual cholecystectomies in trainee- and experienced clinicians (warm-up mean = 28.50, control mean = 19.25, $p = 0.042$), but no significant differences were reported on any one technical skill.⁵⁹ Compared with no simulation training among surgery residents, simulation training for extraperitoneal hernia repair was associated with larger increases in OSATS scores over a baseline procedure for knowledge of procedure ($p < 0.05$), knowledge of instruments ($p = 0.05$), and use of assistants ($p < 0.05$), but not global score.⁶⁰ Researchers have utilized simulation for other surgical modalities as well. In one study, urology residents trained with simulators performed prostate resection faster ($p = 0.025$), and with higher performance scores on a structured assessment ($p = 0.021$) than those not trained with simulation.⁶¹

Other procedures and processes. Pediatrics interns ($n = 38$) were randomized to simulation training on basic procedural skills or training as usual for bag-mask ventilation, venipuncture, peripheral venous catheter placement, and lumbar puncture. Interns in the simulation group exhibited a higher, but not significantly higher, rate of successful venipuncture ($p = 0.08$). No significant differences were observed between groups on the other procedural skills, although performance scores on all measures were higher in the simulation group.⁶² Simulation has shown additional benefits over traditional training in other areas of patient safety. Bachelor’s level nursing students randomized to traditional pharmacology coursework or coursework with additional simulation training were observed for medication administration errors in subsequent external training placements. Students who trained with simulation made fewer medication administration errors (7 of 31 total errors observed, $p < 0.05$), and these results were consistent across both maternal health (control group = 8 errors, simulation group = 0 errors) and medical-surgical settings (control group = 16 errors, simulation group = 7 errors).⁶³ In another study, paramedic students who received simulation training for endotracheal intubation performed similarly to traditionally-trained students on their first 15 intubations for overall success rate, success rate on first attempt, and in complications resulting from the intubation procedure.⁶⁴

Although central venous catheter (CVC) placement is a specific procedure, the in-depth review of literature on CVC is reviewed below. Again, the physician is not only a technician but an actor that must balance being cognitively engaged with direct patient care as well as the

system within which she or he works. These systems include interpersonal dynamics such as dyadic relationships (e.g., doctor-nurse pairs), larger team relationships (e.g., cardiac resuscitation), and the care culture and environment (e.g., patient safety culture, and available resources). Simulation has the potential to impact care processes and relationships at each of these levels.

Team and Systems Performance

A 1-day workshop and training program implemented simulation for seven common obstetric emergencies in the third year of a 6-year study period: shoulder dystocia, postpartum hemorrhage, eclampsia, delivery of twins, breech, adult resuscitation, and neonatal resuscitation. The researchers compared live-term births in the period prior to simulation ($n = 8,430$) to live-term births after implementing simulation ($n = 11,030$) into the training workshop. Births with 5-minute APGAR less than or equal to 6 decreased from 73/10,000 births ($SD = 86.6$) pre-simulation to 49/10,000 births ($SD = 44.4$) after implementing simulation training ($p < 0.05$). The rate of hypoxic-ischemic encephalopathy also decreased from 23/10,000 births ($SD = 27.3$) to 15/10,000 ($SD = 13.6$, $p < 0.05$). The rate of moderate to severe hypoxic-ischemic encephalopathy decreased, but not significantly.⁶⁵

Primary care physicians ($n = 51$) in a large, multidisciplinary medical group were randomized to simulation training alone, simulation training with physician-leader feedback, or a control group. Medical records were evaluated for metformin prescriptions to patients with diabetes who had regularly attended care for two years ($n = 2,020$) and that had either known congestive heart failure or a laboratory result with elevated creatinine. The rate at which control-group physicians prescribed renal-contraindicated metformin was not statistically different compared with either simulation group alone. However, when simulation groups were combined, the simulation-trained physicians prescribed metformin in these unsafe scenarios significantly less often (range from -3.8 to -10.3% across simulation groups, $p = 0.03$).⁶⁶

Year-four postgraduate anesthesiology residents ($n = 20$) were randomized to a full mission-type simulation for patients weaning from cardiopulmonary bypass that included a complete operating room environment and care team. Residents were scored during actual performance in elective coronary artery bypass graft (CABG) with a structured anesthesiologist's nontechnical skills (ANTS) assessment before and after the simulation. The simulation-trained grouped exhibited significantly increased scores after the simulation training over the increases realized in the control group (control mean = 11.8, simulation mean = 14.3, $p < 0.001$) and at 5-week followup (control mean = 11.7, simulation mean = 14.1, $p < 0.001$).⁶⁷

Two studies reported patient outcomes after simulation-based training for resuscitation teams. In one study, internal medicine residents were trained in team management for resuscitation scenarios. These authors reported no differences attributable to simulation training for actual team performance on ventilation rate, return of spontaneous blood circulation, or survival to discharge rates. Of note, both of the latter rates were higher in the simulation group.⁶⁸ However, another study examined resuscitation outcomes after implementing the TeamSTEPPS team-building program coupled with simulation. This study reported a number of significant communication improvements during observed resuscitations, such as leadership ($p = 0.003$), situation monitoring ($p = 0.009$), mutual support ($p = 0.004$), and communication ($p = 0.001$). Post-simulation reductions were also noted in average time to computed tomography (26.4 min vs. 22.1 min, $p = 0.005$), to intubation (10.1 min vs. 6.6 min, $p = 0.49$), and to operating room (130.1 min vs. 94.5 min, $p = 0.021$).⁶⁹ A team-response and educational curriculum coupled with

debriefing was provided to second-year internal medicine residents (n = 38) whose performance on subsequent resuscitations was compared with third-year residents (n = 40) who did not receive simulation training. Based on American Heart Association standards, simulation-trained residents made 68 percent correct responses compared with 44 percent in the non-simulation-trained residents (mean difference = 44%, $p < 0.001$).⁴¹

In-Depth Look at Simulation and Central Venous Catheterization

Central venous catheters (CVC) are used to obtain vascular access as well as hemodynamic monitoring and are common fixtures in ICU settings. In fact, 48 percent of patients in the ICU have indwelling CVC, which corresponds to 15 million CVC patient days per year.^{70,71} Despite the broad presence of CVC in the ICU, significant morbidity and mortality are associated with CVC.^{71,72} Although catheter-related blood stream infections (CRBSI) have been studied extensively, and a separate companion evidence report is dedicated to Healthcare Associated Infections, simulation promises to exert protective effects against risks involved with the insertion process, including pneumothorax, arterial puncture, bleeding, and deep vein thrombosis.⁷³ Due to these risks, Federal agencies such as the National Quality Forum and AHRQ have listed CVC practices as a top patient safety concern.^{74,75}

Trainees in internal medicine, emergency medicine, and surgical specialties commonly insert CVC in academic settings.⁷⁶ Despite requirements to demonstrate knowledge about indications, contraindications, complications, and sterile technique for CVC insertions,^{77,78} trainees remain uncomfortable with performing the procedure.⁷⁹ Training had previously consisted of the apprenticeship model with learning at bedside on actual patients; however, this method is often found to be inadequate.^{41,80} A recent meta-analysis has shown that simulation-based education in CVC techniques improves both learner outcomes and performance during actual procedures: fewer needle passes (standardized mean difference = -0.58, 95% CI -0.95 to -0.20) and reduced pneumothoraces (relative risk = 0.62, 95% CI 0.40 to 0.97).⁸¹

In addition to the articles included in this meta-analysis, studies have demonstrated that simulation improves learner outcomes such as knowledge, confidence, and performance on simulators as well patient outcomes such as fewer needle passes, fewer pneumothoraces, and less CRBSI (Table 1 below). These studies may not be direct replication of each other, but the consistency in observed benefits of simulation across a variety of clinical specialties and care settings is promising. Additionally, these studies have been conducted across numerous research teams in academic or teaching hospitals. Many of these studies used a high-fidelity mannequin partial-task trainer on CVC insertion. However, more involved simulations include sanitation techniques and incorporate the entirety of the operation rather than any specific operative technique. Additionally, once operational, these simulators have been utilized for differing patient needs such as for pediatric medicine instead of adult medicine as well as other types of CVC, including hemodialysis catheters.^{82,83} Future and ongoing investigations will give us further insight into long term maintenance of CVC skills with simulation.⁸⁴

Harms

Studies included in this review generally provided additive or supplemental interventions to training as usual, and no study reported data indicating increased potential for or actual harm to patients that resulted from implementing simulation techniques. However, it is conceivable that simulation exercises would place demand on valuable resources that could be applied elsewhere

in patient safety efforts. Such considerations were not evaluated in literature captured for this review.

How Has the Patient Safety Practice Been Implemented and in What Context?

Context for Simulation

A meta-analysis of computer-aided simulation in education programs for health professionals determined that 564 of the 609 studies included in the review (92.6%) examined effects of simulation provided through dedicated simulation centers. Thirty-four additional studies (5.6%) examined simulation provided in the clinical environment, and 11 studies (1.8%) reported from both contexts.³¹ Across studies cited in this review that reported the context in which simulation was implemented, academic medical systems and academically-affiliated hospitals predominate.^{48,51,53-56,59-64,68,73,76,83,85-92} However, studies also reported outcomes specific to implementing simulation in tertiary care facilities,^{52,68,85,87} in trauma centers,^{69,89} and in multispecialty medical groups.^{65,66} Only one study in our review reported patient outcomes by care setting⁶³; however, these outcomes are not specific to the simulation training site but to a subsequent external training placement.

Table 1, Chapter 38. Literature on simulation training for central venous catheterization

Study	Study Design	Patient Safety Simulation Practice	Simulation Participants	Setting, Results, and Patient-Related Outcomes
Andreatta et al. (2011) ⁹³	Randomized controlled, blinded, trial	One hour minimum practice time with high-fidelity partial task trainer and ultrasound system, with supervision and individualized training program	PGY-1 and PGY-2 radiology residents (n = 32) performed 32 peripherally inserted central catheters	In interventional radiology at a single academic health system, simulator-trained residents outperformed bedside-trained residents on a number of performance criteria such as ultrasound use, vein compressibility, needle localization and guiding, and exchanging the needle/catheter via the guidewire (p < 0.05 for all). All simulator-trained residents placed the catheter successfully, whereas 4 of 16 bedside-trained residents were unable to place the catheter independently within three attempts.
Barsuk et al. (2009) ⁸⁸	Non-randomized observational cohort with historical cohort for controls	Minimum proficiency/mastery model on standardized checklist of CVC insertion with expert panel review of performance using a high-fidelity partial task trainer with computer interface, simulation exercises performed with deliberate practice and individualized feedback components	PGY-2 and PGY-3 internal medicine and emergency medicine residents (n = 103) performed 407 internal jugular and subclavian CVCs	In the medical ICU of a single academic institution, there were no significant differences in the outcomes of subclavian line insertion; however, residents who were simulator trained reported fewer needle passes (p < 0.0005), arterial punctures (p < 0.0005), catheter adjustments (p = 0.002), and higher success rate (p = 0.005) in overall central venous catheter placement.
Barsuk et al. (2009) ⁷⁶	Pre-post, non-randomized observational cohort	Minimum proficiency/mastery model on standardized checklist of CVC insertion with expert panel review of performance using a high-fidelity partial task trainer with computer interface, simulation exercises performed with deliberate practice and individualized feedback components	PGY-2 and PGY-3 internal medicine and emergency medicine residents (n = 92), number of CVCs performed NR	In the medical ICU of a single academic institution, fewer CRBSI occurred after simulation, and the rate of CRBSI after simulation training reduced from 3.2 per 1000 catheter-days to 0.5 per 1000 catheter-days (p = 0.001). Comparing the medical (MICU) to the surgical ICU during the study period revealed a lower incidence ratio for CRBSI in the MICU (0.16, 95% CI, 0.05 – 0.44, p = 0.001).
Barsuk et al. (2009) ⁷³	Observational cohort study	Minimum proficiency/mastery model on standardized checklist of CVC insertion with expert panel review of performance using a high-fidelity partial task trainer with computer interface, simulation exercises performed with deliberate practice and individualized feedback components	PGY-2 and PGY-3 internal medicine residents (n = 41) performed 46 internal jugular and subclavian CVCs	In the medical ICU of a single academic institution, although the groups did not differ significantly regarding complications (pneumothorax, arterial puncture or CVC adjustment), the simulator-trained group required fewer needle passes (M = 1.79, SD = 1.0) than the traditionally trained group (M = 2.78, SD = 1.77, p = 0.04).

Table 1, Chapter 38. Literature on simulation training for central venous catheterization (continued)

Study	Study Design	Patient Safety Simulation Practice	Simulation Participants	Setting, Results, and Patient-Related Outcomes
Britt et al. (2009) ⁸⁹	Randomized controlled trial	Minimum proficiency model with deliberate practice and individualized feedback from attending surgeon on a partial-task high-fidelity trainer, added to standard lecture on CVC technique	Junior surgical residents (n = 34, PGY-NR) that had not completed a trauma ICU rotation performed 73 ultrasound-guided and subclavian CVCs	At a single Level I trauma teaching hospital ICU, a higher level of comfort and ability was found in the simulator-trained group (p = 0.03). The simulator-trained group outperformed the traditionally-trained group in 7 of 10 performance variables measured, although none of these were statistically significant. More complications (pneumothorax, arterial puncture, inability to complete the procedure) were found in the traditional group than in the simulator-trained group (p = 0.07).
Evans (2010) ⁸⁵	Randomized controlled, blinded, trial	Minimum proficiency model with deliberate practice and individualized feedback from attending surgeon on a partial-task high fidelity trainer, added to standard lecture on CVC technique	PGY-1 and PGY-2 residents from emergency medicine, internal medicine, general surgery, anesthesia, and obstetrics-gynecology (n = 115) performed a total 495 internal jugular, subclavian, and femoral vein CVCs	In the emergency department, medical ICU, and surgical ICU at a single teaching hospital, simulation-trained residents succeeded in cannulation with first attempt more often (51% vs. 37%, p = 0.03) and successfully inserted the catheter on their first attempt more often (78% vs. 67%, p = 0.02). No differences seen between groups on measures of technical errors such as standard precautions, insertion steps, and use of sterile technique, or on measures of mechanical complications (e.g., pneumothorax, transient arrhythmia, catheter tip malposition, or arterial puncture).
Khouli, et al. (2011) ⁹⁰	Randomized controlled, blinded, trial	Full-immersion operation room simulation, including partial task trainer, in addition to video training and structured assessment training on sterile techniques.	PGY-2 and PGY-3 internal medicine (n = 47), and subsequently emergency residents (n = 58 total) with prior certification in CVC placement, number of CVCs performed NR	At a single academic hospital, the simulator plus video-trained group had higher median scores than the video-only group on a survey of preparedness and confidence (p < 0 .001). After additional simulator training with both emergency and internal medicine residents (n = 58), the rate of CRBSI among patients in the MICU decreased from 3.5 per 1,000 catheter days prior to the intervention to 1.0 per 1,000 catheter-days after the intervention. The rate of CRBSI remained steady in the surgical ICU over that same time period - 3.4 per 1,000, where surgical residents had received traditional training during the study period.

Table 1, Chapter 38. Literature on simulation training for central venous catheterization (continued)

Study	Study Design	Patient Safety Simulation Practice	Simulation Participants	Setting, Results, and Patient-Related Outcomes
Martin et al. (2003)	Pre-post observational cohort design, compared with historical cohort	Didactic training on anatomy and CVC techniques coupled with supervised practice on fresh human cadavers, whereby supervisors provided immediate individualized feedback on performance as well as video tape review with debriefing	Medical students trained in their 4 th year, performing CVC during PGY-1, number of total CVCs performed by health system ranged from 1,682 – 1,884 annually	In a two-hospital academic health system, across the emergency, surgery, and critical care, the incidence of pneumothorax decreased significantly ($p = 0.004$) after implementing the simulation-based training program. When limiting analyses to the initial 3-month period that residents would begin the rotation, the incidence of pneumothorax dropped from 34.0% to 3.8% after implementing simulation.
Miranda et al. (2007) ⁹⁴	Prospective controlled cohort design	Follow didactic training, practice in placing CVC and sterile technique was overseen by experienced residents and attending internists	Internal medicine residents ($n = 150$, PGY-NR) performed 54 internal jugular and subclavian CVCs	In the general medical service at a single academic teaching hospital, femoral vein catheterizations decreased non-significantly in the simulation-trained group. The simulation group was more likely to use masks during the procedure (risk ratio 2.2, 95% CI, 1.3-2.7, $p = 0.008$), but there was no difference between groups in the proper use of other sterile techniques. There was no difference between groups in the rate of CRBSI per 1,000 catheter-days. The simulation group demonstrated significantly increased knowledge of complications of femoral vein catheterizations.
Sherertz et al. (2000) ⁹¹	Pre-post, non-randomized observational design	One hour course on basic infection control, followed by 1 hour of simulation with mannequins for practicing blood stream access techniques (including CVC) in the presence of senior clinical staff	3 rd year medical students and PGY-1 physicians ($n > 100$, actual number NR), total CVCs performed at system during study period 5,099	Medical students' and physicians' perceived need for full-sized sterile drapes increased from 22% prior to the course to 73% 6 months after the course ($p < 0.001$). Across six ICUs and one step-down unit at a single academic institution, the documented use of full-size sterile drapes increased from 44% to 65% ($p < 0.001$), and the CRBSI rate decreased from 4.51 per 1,000 patient days prior to the course to 2.92 per 1,000 patient days 18 months after the course. The estimated cost savings of decreases in CRBSI is between \$63,000 and \$800,000.
Smith et al. (2010) ⁸⁷	Randomized controlled trial	Didactic training followed by partial task trainer practice of entire CVC placement under supervision with immediate feedback, simulation group was then allowed to continue simulated practice unsupervised	Internal medicine residents PGY-1 and PGY-2 ($n = 52$), number of CVCs performed NR	At medical ICU of a single teaching hospital, the simulation group demonstrated a non-significantly improved performance on a number of structured checklist items in initial simulation tasks (13.2, SD = 4.9 vs. 9.7, SD = 5.0, $p = 0.07$). No differences observed between groups in adverse outcomes or complications of CVC placement.

Table 1, Chapter 38. Literature on simulation training for central venous catheterization (continued)

Study	Study Design	Patient Safety Simulation Practice	Simulation Participants	Setting, Results, and Patient-Related Outcomes
Velmahos et al. (2004) ⁹²	Randomized controlled trial	Three hour CVC surgical skills course consisting of didactic training, and small group practice with high-fidelity mannequin and supervising instructor; each intern practiced CVC insertion a minimum of 4 times in the exercise	Surgical interns (n = 28), number of CVCs performed NR	In a single academic surgery department, scores on a CVC technical competency exam were similar between groups on the pretest; however, the simulation-trained group scored significantly higher on the posttest (p = 0.03). The simulation group also achieved a significantly higher score (p < 0.001) on structured checklist evaluation of performance during CVC placement and required fewer attempts to find the vein (p = 0.046).

Catheter-related blood stream infection (CRBSI), Intensive care unit (ICU), Not reported (NR), Post-graduate year (PGY).

Implementing Simulation

Gaba conceptualized a framework that captures the versatility of simulation.²⁴ In this framework, each of 11 dimensions assist those looking to implement simulation to define their needs and goals: (1) the purpose and aims of simulation activity; (2) the unit of participation in the simulation—individuals or teams; (3) the experience level of simulation participants; (4) the health care domain in which the simulation is applied; (5) the health care disciplines of personnel participating in the simulation; (6) the type of knowledge, skill, attitudes, or behavior addressed in simulation; (7) the age of the patient being simulated; (8) the technology applicable or required for simulations; (9) the site of simulation—*in situ* clinical setting versus dedicated simulation center; (10) the extent of direct participation; and (11) the feedback method accompanying simulation. Gaba further delineates implementation mechanisms for health care settings as well as a variety of professional and governmental organizations.

In addition to the 11-dimensional framework by Gaba,²⁴ which lays out implementable aspects of types of simulation, a number of other factors must be considered before using simulation:⁹⁵

1. People: are both trainee and training participants available and appropriately trained in simulation techniques?
2. Time: is sufficient time dedicated to meaningful simulations not only as adjunctive training experiences provided in the flow of regular care activities?
3. Equipment: are simulation-specific materials (e.g., mannequin) and actual medical equipment or devices available to recreate a desirable realism in simulated environments?
4. Space: is adequate space available for dedicating to simulated environments? Even *in-situ* simulations will require storage and preparation of materials.
5. Supplies: if the simulation requires the use of real medical supplies, are these available?
6. Technical Support: implementation phases, especially of high-tech or complex simulators, may require support, and there may be upkeep and maintenance to simulation equipment.

People and time are likely to be the most expensive aspects of simulation in the long run. However, startup costs vary substantially with the complexity of the simulation, which also depends on the purpose. Large simulation centers may find financial support in philanthropic sources or may be subsidized by participants and other organizational entities. Other expenses will include the upkeep of simulation equipment and space dedicated to simulation.

Rosen and colleagues discussed the importance of considering components most likely to enhance success in simulation techniques. For example, these authors differentiate the importance of cognitive fidelity in a simulated exercise from physical fidelity. That is, simulations that engage the participant in ways that, cognitively, most reflect the actual task are likely to be more effective.²⁵ Debriefing is considered crucial when implementing simulation,^{25,26} a recommended best practice according to one review of simulation-based medical education.⁹⁶ Other national efforts have delineated future directions for simulation research.⁹⁷ At an international level, researchers have identified three primary foci to further understanding of best practices in simulation: instructional design, outcomes measurement, and translational activities.⁹⁸

Are There Any Data About Costs?

The cost of implementing simulation exercises varies from low to high depending on type of exercise and the personnel and equipment resources involved. In addition, start-up costs for a comprehensive simulation center may be accounted for differently than ongoing costs for exercises, which complicates the ability to categorize the expected cost for simulation as a patient safety practice. Future and ongoing investigations will give us further insight into the cost-effectiveness of simulation exercises in general, and simulation that targets improvement in patient safety. Unfortunately, research addressing cost savings attributable directly to simulation remains sparse, but research has reported up to a 7-to-1 return on simulation costs through the reduction in hospital days for blood stream infection.^{91,99}

Are There Any Data About the Effect of Context on Effectiveness?

This review did not find published data about the effect of context on the effectiveness of simulation exercises to improve patient safety. Therefore, this is an area for future research.

Conclusions and Comment

Simulation has continued to garner momentum in patient safety efforts in the past decade. Various professional organizations have endorsed the use of simulation through accreditation standards, and government agencies have continued to fund investigations into the use of simulation for enhancing care. On a basic level, simulation allows for exercising and improving aspects of health care without risk to patients. Simulation has been utilized in patient safety for the purposes of education, assessment, research, and integrating system-level practices. These efforts have been reported in the literature as research *about* simulation, that is, research that can help elucidate and understand leverage points in enhancing patient safety. In the past decade, researchers have also begun focusing on *using* simulation, which has increased our understanding of benefits (especially with respect to patient outcomes) likely to be realized in the translation of simulation techniques into practice.

The review found that studies reporting outcomes with actual patients, or systems of care, have occurred primarily in academic settings, although researchers have reported on the use of simulation for a variety of clinical specialties, experience levels, and care settings. These studies varied in terms of individual quality, but the bulk of studies were randomized or methodologically controlled designs. Researchers have replicated standardized simulation training for CVC placement, and although promising for patient safety in CVC, we did not find other examples of replication studies in our review. We did not find analysis of contextual effects (e.g., MICU analyzed against SICU) on the validity of simulation to improve patient safety. Thus the transferability of simulation techniques to increase patient safety similarly to that reported in this review remains unknown. It is likely that these results will generalize to other settings, but generalizability of any one technique is likely to vary depending on a number of factors such as those in Gaba's 11-dimensional framework²⁴ and adequacy of resources dedicated to simulation (e.g., debriefing).

At this juncture, simulation appears to have a favorable impact on quicker acquisition and improved performance of technical skills. Although not yet thoroughly studied, simulating complex or high-stakes procedures appears to be a promising technique to increase patient-safe behavior at the clinician- and team-levels. Simulation has the potential to enhance patient safety through structured assessment and debriefing in quality improvement initiatives. It has been used

to assess practices that would be difficult or unsafe to study empirically in real-time with actual patients. Likewise, simulation has been endorsed for ongoing competency and continuing education, as well as advancing to mastery-level practices.

Previous systematic reviews have reported that simulation contributes to enhanced knowledge acquisition and improved clinical performance.²⁹ Simulation techniques have been utilized in translating results from within simulation lab to patient and health care system-level outcomes.¹⁰⁰ Protecting time for debriefing in a learning experience has been suggested as a crucial component to simulation techniques in a systematic review.¹⁰¹ This review is the first to examine effects that simulation exercises exert on patient safety outcomes, and in particular, outcomes with patients outside of simulation laboratory settings (i.e., during clinical care).

Reviewing the literature on simulation approaches broadly resulted in several limitations. First, it is possible broad search strategies missed studies that may otherwise be captured with targeted and comprehensive strategies dedicated to each simulation technique, clinical specialty, or application. Second, given relative infancy of the research into simulation exercises, the field may be prone to selective reporting of studies with positive findings, leading to potential publication bias in our review. Third, we limited our assessment of quality of evidence to study design and did not perform structured assessment of the strength of evidence. Therefore, overall strength of the evidence for simulation exercises to improve patient safety should be interpreted with caution based on the current review.

Simulation is a versatile technique that continues to garner momentum in a variety of clinical settings and applications, including patient safety strategies. Although evidence is largely heterogeneous at this time, our review suggests potential for simulation exercises to contribute to patient safety through increased technical and procedural performance, and through improved team performance. Limited research using health system-level observations suggests that simulation may enhance patient safety, although more research is needed on the potential for simulation to contribute to system-level differences in patient safety outcomes. Systematic reviews of simulation for specific procedures have begun reporting patient safety outcomes,^{57,102} and more reviews of this nature would enhance our understanding of the overall contribution of simulation techniques to patient safety. Future systematic reviews would benefit from investigators using a consistent framework to describe the intervention, its context and its implementation, such as Gaba's framework.

Simulation implies a spirit of innovation in a world with quickly evolving technologies. As a specialty field, it may be in an "end of the beginning" phase, and some of the benefits of simulation may not be realized from a short-term perspective.²⁴ As a developing field, certain aspects may remain under discussion, such as standardized definitions of "validity" in simulated environments.¹⁰³ However, the breadth of applications and even purposes has not yet been fully realized.²⁴ As only one further example of simulation's potential role in making care better and safer, a recent systematic review of simulation and video games for patients post-stroke reported increased upper extremity functionality.¹⁰⁴ A summary table is located in Table 2.

Table 2, Chapter 38. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate-to-high	Moderate to high for specific topics	Uncertain	Moderate	Moderate

*Cost varies based on the simulation technique and resources involved. For example, exercises involving fully simulated operating room environments may have higher costs to implement relative to those that require a simple mannequin or patient actors.

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Chapter 39. Obtaining Informed Consent From Patients: Brief Update Review

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Introduction

In health care, informed consent refers to the process whereby the patient and the health care practitioner engage in a dialogue about a proposed medical treatment's nature, consequences, harms, benefits, risks, and alternatives.¹ Informed consent is a fundamental principle of health care.

The process of informed consent can be considered a patient safety issue from several perspectives. At the extreme, performing a procedure on a patient without his or her consent has been considered by the courts to be a form of battery.² Informed consent may also be indirectly related to patient safety in that, when done well, it opens a dialogue between the patient and provider so that the patient can ask questions, knows what to expect during and after procedure, and can at least theoretically help to avert medical errors.³

In general, studies have shown improved patient outcomes with effective physician-patient communication and increased patient empowerment.^{4,5} Patient education has also been associated with preventing medical errors.⁶

A review on this topic conducted in 2001 found few studies linking informed consent with health outcomes and few studies on the impact of procedures used to obtain informed consent on the quality of consent obtained; studies suggested that the value of informed consent might be modestly enhanced by augmenting standard patient provider discussions with additional learning and retention aids and that the process of consent can be modestly enhanced by using structured interviews and asking patients to recall and restate the key elements of the discussion.

This update review focuses on what we have learned about the informed consent process and the effectiveness of interventions that have been implemented to try to improve it. We conducted a search of the health care and health services literature for the time interval 2001 to present and reviewed all studies relevant to informed consent in the clinical setting.

What Is Informed Consent?

The document a patient signs to verify that he has engaged in a dialog with a health care practitioner about a proposed medical treatment is commonly referred to as an "informed consent." However, it is the dialog itself that constitutes the actual informed consent process.³ Informed consent is used in both clinical and research settings; this review focuses primarily on informed consent in the clinical setting.

Although no evidence currently links informed consent with improved adherence to medication or other self-care procedures, to prevention of medical errors, or to improved overall health outcomes, some evidence links increased patient-physician communication with more realistic expectations, increased patient satisfaction, and fewer medical malpractice claims.⁷⁻⁹

How Has Informed Consent Been Implemented?

A complete informed consent process consists of seven elements: (1) Discussing the patient's role in the decision-making process; (2) Describing the clinical issue and suggested treatment; (3) Discussing alternatives to the suggested treatment (including the option of no treatment); (4) Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives); (5) Discussing related uncertainties; (6) Assessing the patient's understanding of the information provided; and (7) Eliciting the patient's preference (and thereby consent).¹⁰ Not every detail needs to be discussed, but all details needed for a "reasonable person" to make a decision must be provided.¹¹ Therefore, all risks of serious complications, even if they occur very rarely, need to be discussed. Less serious risks need to be discussed if they occur more commonly.¹¹ This process of informed consent may occur within one encounter, or across multiple encounters.¹²

Although informed consent is often used prior to invasive procedures, designated radiologic examinations, and other high-risk medical treatments (e.g., chemotherapy), the process of informed consent, or informed decision-making, is applicable to all medical care decisions where one or more alternatives exist (including the alternative of no treatment or procedure).¹³ Recently, there has also been increased attention to the importance of informed consent in screening procedures and genetic testing.^{14,15} As such, the informed consent process has considerable overlap with the principles of "shared decisionmaking."¹³

What Have We Learned About Informed Consent?

Most Informed Consent Procedures Are Incomplete

Various studies have examined the completeness of informed consent procedures in various settings and scenarios. In an examination of the informed decisionmaking process in 1057 audio-recorded outpatient encounters in the offices of primary care physicians and surgeons, regarding mostly low-risk decisions, only 9% were deemed to contain all the elements of complete informed decision-making.¹⁶ The most common element missing was an explicit assessment of patient understanding. However, risks and benefits, and their associated uncertainties were also commonly not included in the discussions. Among 141 discussions regarding orthopedic surgical interventions, in no case were all elements fully discussed.¹⁷ Ninety-two percent had some mention of the nature of the decision, 62% listed alternatives, 59% discussed pros and cons, 14% discussed the patient's role in the decisionmaking, and 12% of the time the patient's understanding was assessed. In an analysis of informed decision-making for 145 patients considering high-risk elective major vascular surgery, audio-recorded discussions across multiple visits for each patient contained all informed consent elements in 45% of the cases.¹⁸ In 23% of the cases, the surgeon failed to discuss one or more of the "basic" elements of consent: clarifying the patient's role in the decision-making; explaining the clinical condition; or eliciting the patient's preferences for treatment.

Reading Level of Informed Consent Documents Is Often Too High

A number of studies have examined the reading level of informed consent documents and their utility for people with limited English proficiency. In a survey of informed consent forms for iodinated contrast material from 160 academic and private United States (U.S.) hospitals, average reading level exceeded 12th grade and only 5% had an 8th grade reading level or below.¹⁹ Similarly, in a survey of surgery and other procedure informed consent forms from 616

U.S. hospitals, the mean reading level was 12.6 years and only 7% of the forms had an 8th grade reading level or below.²⁰ Regarding the content of informed consent documents, a separate survey of a random sample of consent forms from 157 U.S. hospitals showed significant variability in content and 74% omitted the nature of the procedure, risks, benefits, or alternatives.²¹ Perhaps related to the readability of these documents, studies have shown patients often do not read the consent forms provided to them and, in one study, patients who reported reading the consent forms given to them were no better informed than those who did not.^{22,23}

Patients with limited English proficiency (LEP) are at particularly high risk for receiving inadequate informed consent. In a study of 30 Latina women who were offered amniocentesis at 8 prenatal clinics without trained interpreters, the informed consent process contained all, or nearly all, of the essential informed consent elements for 9% of the LEP compared with 68% of the non-LEP women.²⁴ When charts of 74 LEP Spanish and Chinese-speaking patients were compared with those of 74 English-speakers, all of whom underwent thoracentesis, paracentesis, or lumbar puncture at a teaching hospital where trained interpreters in Spanish and Chinese were available, 28% of LEP patients had informed consent documented compared with 53% of English speakers.²⁵

Most Patients Are Unable To Recall—or Don't Understand—Content of Informed Consent Documents

Multiple studies have shown that most patients are unable to recall or do not understand most of the information that is presented to them in the informed consent process. Post-operative interviews with patients 1 to 8 weeks after they underwent head and neck surgery revealed that, on average, they could recall 48% of the main three or four complications (depending on the surgery) they were counseled about pre-operatively.²⁶ Interviews with 17 surrogates who provided consent for surgery in pediatric patients, showed that 2 to 4 weeks after the surgery, only three (18%) could recall any specifics of the procedure.²⁷ Interviews 3 hours after consent in 100 patients scheduled for transurethral prostatectomy revealed that less than 50% of the patients could accurately recall the risks of potential complications.²⁸ Sixty five percent of 104 patients consented for neurosurgery could remember no more than two of six major risks associated with their surgery 2 hours after informed consent was obtained.²⁹ Among 633 patients who were offered coronary artery bypass grafting (CABG) or percutaneous coronary interventions (PCI), there was very low concordance between what physicians reported telling the patients about expected symptom benefits and what the patients reported as their expectations, and there was no correlation between what physicians and patients expected regarding potential mortality benefit (with patients believing there would be a survival benefit even when physicians reported telling them there was not).³⁰

Lower levels of education are consistently associated with being less likely to recall information in the informed consent process. Among 54 patients who underwent head and neck surgery, 72% of those having a university education recalled more than 50% of the complications, compared with 36% of those without a university education ($p=0.04$).²⁶ In another study of 200 patients with cancer, those who had completed high school had 35% higher scores on tests asking them to recall, within 1 day of undergoing informed consent, written and oral information provided to them in the informed consent process ($p<0.001$).²²

Older age is also associated with being less likely to recall informed consent information. Among 265 patients undergoing intrathoracic, intraperitoneal, and vascular surgery procedures, patients over 60 years of age had less knowledge about their planned procedure immediately

after the informed consent process (median score on a knowledge test one point out six less at both time periods, $p < 0.001$).²³ Among 54 patients who underwent head and neck surgery, patients who recalled more than 50% of the complications they were told were, on average 7.6 years younger than those who recalled less than 50%.²⁶ However, the association between older age and less informed consent recall may be related to a lower average educational attainment among older people. In a study of 200 patients with cancer who underwent informed consent for radiation therapy, chemotherapy, or surgery, recall by age did not vary when adjusted for educational attainment.²²

Limited health literacy is also likely associated with less comprehension of informed consent. Health literacy is the “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” In the 2003 National Assessment of Adult Literacy (NAAL) 36% of Americans had basic or below basic health-related literacy.³¹ Older age, lower educational attainment, and being African-American or Latino are all associated with lower health literacy levels.³² In a study of men using a CD-ROM shared decisionmaking tool about prostate cancer treatment options, lower levels of health literacy were associated with lower prostate cancer knowledge after using the tool (Pearson correlation = 0.65, $p < 0.001$).³³ In a study of consent documents for a research study on chemotherapy agents, patients reading at or below an 8th grade level had, on average, 28 percentage point lower comprehension scores compared with participants with higher reading levels, even when the consent form was modified to a 7th grade reading level.³⁴ Similarly, in another study of a research consent form, modified to a 6th grade reading level, patients with lower literacy were significantly less likely to respond correctly to comprehension questions asked after a first reading of the consent form, adjusting for other sociodemographic factors.³⁵

Studies have also shown that minority race or ethnicity may be an independent risk factor for having lower levels of comprehension in the informed consent process. Among 396 patients being consented for surgery, African-American patients scored an adjusted average 9 percentage points lower than white patients in a comprehension test administered immediately after the consent process. This association was independent of education, age, and health literacy score.³⁶ In the study of a research consent form cited above, in addition to those with lower health literacy, patients who were Black or Asian/Pacific Islander were also less likely, when adjusting for other factors, to respond correctly to comprehension questions.³⁵

Other factors associated with lower informed consent recall are lower intelligence levels and having cognitive dysfunction.²³ Patients with cognitive dysfunction are particularly vulnerable in the informed consent process. Cognitive dysfunction may be a long-term state (e.g., dementia) or transient (e.g., after a medical procedure.) In one study of 302 acutely-ill medical inpatients, 48% were estimated to have cognitive dysfunction such that they potentially lacked capacity to give informed consent.³⁷ However, not all patients with cognitive dysfunction lack informed consent capacity: A structured assessment must be done to determine competence.^{38,39} If a patient does not have capacity and his or her cognitive dysfunction is not expected to improve (or a decision needs to be made prior to it improving), a surrogate decisionmaker must be established, except in an emergency situation where the physician can determine the choice a “reasonable person” would make.³⁸

What Methods Have Been Used To Improve Informed Consent?

Multiple potential methods have been proposed for improving the informed consent process. These methods include simplifying informed consent forms; providing supplemental written

materials; using decision aids; using video educational tools; using interactive computer-based educational tools; having structured discussions; and using “repeat back” methods.

Simplifying Informed Consent Forms May Improve Satisfaction, if Not Comprehension

Although the effects of simplifying informed consent forms in clinical settings have not been studied, some studies have assessed simplified forms for consenting participants for research, with mixed results. In a randomized-controlled study comparing a standard pharmaceutical industry consent form to a simplified form, participants who read the modified form had a 23% higher score on a 13-item multiple choice test about the study details ($p < 0.001$).⁴⁰ In another randomized-control trial of 456 parents, comprehension was compared between parents receiving a standard research consent form, written at an 11th grade level, and those who received a consent form modified to be at an eighth grade reading level.⁴¹ Those who received the simplified consent form demonstrated a 13% better overall understanding of the study ($p < 0.001$), as well as better specific understandings of the study protocol (33%, $p < 0.001$), duration (178%, $p < 0.001$) and direct benefits (7%, $p < 0.001$). There was a non-significant trend to better understanding of the risks. These differences were seen across parents with high and low reading abilities. Eighty-one percent of the parents reported preferring the simpler form. In a third randomized trial that simulated research recruitment of 233 low-income children, there was no difference ascertained in comprehension between parents receiving standard and simpler forms; however, among the 124 parents with reading comprehension scores at or below 8th grade, those who received the simpler form had nearly-significant higher comprehension scores ($p = 0.06$).⁴² In contrast to these findings, in a controlled (but not randomized) study comparing a chemotherapy research consent form written at a 7th grade reading level to a standard one, comprehension levels were similar for both forms, even among participants with reading levels of 8th grade or less. However, literacy patients stated preference for receiving the simpler form.³⁴ Another trial of a chemotherapy consent form simplified to the 8th grade level, with 44 institutions randomized to using the simplified or standard consent form, also showed no difference in knowledge, but patients at the institutions using the simplified form had 9% higher patient satisfaction scores ($p = 0.004$).⁴³

Providing Supplemental Written Materials Improves Recall and Comprehension

Multiple randomized controlled trials have demonstrated that that providing patients with supplemental written materials, in simplified language, results in higher patient recall of informed consent information. In a study of 192 patients who underwent intraperitoneal, intrathoracic or vascular surgery at a large teaching hospital, “information cards” which explained in a simplified manner the procedure and what the patient could expect during and after the surgery were given to half of the patients by random assignment. Both groups had the same level of knowledge 1 hour after signing the consent form but those who received the information cards had better information recall on the day of hospital discharge ($p = 0.04$).²³ Among 125 patients who underwent thyroidectomy or parotidectomy at an academic tertiary center, those who were randomly assigned to receive a pamphlet with illustrations and written information about the procedure were able to recall 50% of the risks compared with the control group recalling 30% of the risks ($p < 0.001$).⁴⁴ In another randomized-controlled study of 126 patients who underwent total hip arthroplasty, a 1.5 page written information sheet in simplified

language with an illustration, given to patients at the pre-operative visit, resulted in patients having 25% higher knowledge scores on admission for the procedure ($p=0.004$) compared with patients who received a structured verbal discussion.⁴⁵ Finally, in a randomized-controlled trial of information leaflets describing risks and benefits, sent by mail 2 weeks prior to surgery to patients scheduled for elective orthopedic procedures, the group receiving the leaflets had a median comprehension score 30 percentage points higher than those who did not ($p<0.001$).⁴⁶

Decision Aids Improve Knowledge and Participation in Shared Decisionmaking

Decision aids are tools specifically designed to help patients make choices by having a “detailed, specific, and personalized focus on options and outcomes.”⁴⁷ For example, one randomized-controlled study examined the effect of a touch-screen decision aid that provided detailed information, including outcome probabilities, to the patient based on the information the patient entered regarding his or her age and diagnosis.⁴⁸ Patients had the option of getting more detailed information, if desired, on pharmacologic and alternative medicine options. When this decision aid was tested against an educational booklet, those who used the decision aid had an adjusted six percentage point increase in knowledge compared with those who did not ($p=0.05$).⁴⁹ Another example, which is not technology-dependent, is an illustrated pamphlet decision-aid for informed consent in prostate cancer screening which, in a randomized-controlled trial, increased knowledge by 6% ($p<0.01$). A 2009 Cochrane review of 55 studies on the efficacy of decision-aids for screening or treatment decisions found that, overall, they improve knowledge scores by an average of 15 percentage points, improve patients’ participation in decisionmaking, result in lower “decisional conflict,” and increase accuracy of risk perceptions.⁴⁷

Video Educational Tools Also Improve Knowledge

Randomized-controlled trials of video educational tools (that are not also decision aids) have also shown positive results. A randomized-controlled trial of an informational video for women considering laparoscopic tubal ligation showed that women who watched the video, in addition to standard consent procedures, demonstrated 56% higher knowledge scores than women who were engaged in standard consent procedures alone ($p<0.001$).⁵⁰ And, in a randomized-controlled trial of an informational video on colonoscopy, those who watched the video in addition to having a physician discussion had 19% higher knowledge scores than patients who had the physician discussion alone ($p<0.001$).⁵¹ In a randomized-controlled trial of patients scheduled for intravenous contrast for computed tomography, English and Spanish-speaking patients were exposed to a low-literacy video in their preferred language. Participants who watched the video displayed, in comparison to controls, 20 percentage point higher knowledge (95% CI 13-28%) and 10 percentage point higher satisfaction scores. This result was consistent for both Spanish and English speakers and Spanish and English speakers in the intervention group had similar post-consent knowledge scores while Spanish speakers in the control group had significantly lower post-consent knowledge scores than English-speaking controls.

Interactive Computer-Based Educational Tools Show Mixed Results

Limited studies of computer-based educational tools (that are not also decision aids) have shown mixed results. In a randomized-controlled trial of a computer program that augments practitioner-patient discussions with graphical content and illustrations, when used in patients considering cardiology or endoscopy procedures, resulted in 43% higher patient knowledge

scores ($p=0.006$) as well as 34% higher satisfaction scores ($p<0.001$).⁵² A randomized-controlled trial of an interactive computer program about colonoscopy indications, risks, and benefits, tailored to an 8th-grade reading level, showed 16% higher knowledge scores among patients who received the intervention.⁵³ However, in a randomized-controlled trial of 101 patients consenting to chemotherapy, recall of treatment information showed no difference in knowledge between patients who received an interactive CD-ROM detailing treatment information and those who received standard written information.⁵⁴ In another randomized controlled trial of 44 patients receiving standard genetic counseling versus education by an interactive computer program as part of an informed consent process prior to cystic fibrosis carrier-status testing, both groups had similar increases in knowledge.⁵⁵

Structured Informed Consent Discussions Need Further Testing

Structured discussions for informed consent are those in which the practitioner engaging the patient uses a written guide to structure the conversation. Two studies, limited by using non-randomized designs, have examined structured discussions for informed consent. In a study of patients considering cardiac catheterization, patients exposed to a half-hour structured informed consent discussion had 29% higher knowledge scores compared with controls ($p<0.001$).⁵⁶ In another study of patients being consented for head and neck surgery, the group of patients for which the provider used a structured interview guide were told about 65% more complications.⁵⁷ However, in a study that did use a randomized design, and is mentioned above in the section on “supplemental written materials,” structured verbal discussion compared with a 1.5 page simplified and illustrated information sheet showed that patients had lower knowledge scores with the structured discussion compared with the information sheet ($p=0.004$).⁴⁵

“Repeat Back” Methods May Be Effective but Time Consuming

The “repeat back” method, also known as “teach back,” is an interactive communication strategy in which the patient is asked to explain, in his or her own words, what has been told to the patient. Then, as needed, the practitioner clarifies or tailors the explanation, serially reassessing and re-explaining until the patient demonstrates recall and comprehension.⁵⁸ In a randomized-controlled study of 575 patients undergoing elective surgery, a computer prompted and guided the practitioner in conducting the repeat-back procedure during the informed consent discussion. Information comprehension, tested immediately, showed that patients receiving “repeat back” comprehended 71% of the information while the control group comprehended 68% of the information ($p=0.03$). Discussions using “repeat back” took, on average, 2.6 minutes longer.⁵⁹ In a randomized-controlled trial of 20 patients who underwent repair of their anterior cruciate ligament, 100% of patients whose discussions used “repeat back,” compared with 33% of patients in the control group, were able to correctly answer a 3-item questionnaire about the risks and benefits 1 month later ($p=0.03$).⁶⁰

Conclusions and Comment

Informed consent is a process in which patients and health care practitioners dialogue about a proposed medical treatment’s nature, consequences, harms, benefits, risks, and alternatives. Although more evidence is needed on the potential specific association between informed consent and patient safety, studies have shown that improved communication between practitioners and patients leads to improved patient outcomes, less medical errors, and lower rates of malpractice claims. Adequacy of the informed consent process has been more firmly

linked to patient satisfaction. Despite its importance, multiple studies have demonstrated that, in practice, the informed consent process is often incomplete and patient recall and comprehension of the discussion is usually low. Patients who are older, less educated, LEP, are of minority race, or have cognitive dysfunction or low intelligence levels are particularly vulnerable in the informed consent process.

Multiple methods have been proposed for improving the informed consent process. Studies have shown that, in general, providing patients with simplified supplemental written materials, using decision-aids, using video educational tools, and using the “repeat back method” improves informed consent patient recall and comprehension. Studies using interactive computer programs have had mixed results and further research is needed in this area. Studies using structured informed consent discussion have also been limited. Studies of simplifying the informed consent documents that have been done for research-related forms have shown mixed results on patient recall and comprehension, but generally improve satisfaction; studies examining this effect among informed consent documents in nonresearch clinical settings are lacking. A summary table is located below (Table 1).

Table 1, Chapter 39. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Moderate	Negligible	Low	Moderate/Not difficult

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Chapter 40. Team-Training in Health Care: Brief Update Review

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Introduction

Deficiencies in communication and teamwork have long been cited as a frequent contributor to adverse events. Precise estimates of the extent of the problem are difficult to make, given definitional issues as well as reporting and measurement problems. However, a variety of studies support the notion that teamwork and communication are critical components of safe health care systems. Previous reviews have reported linkages between various aspects of teamwork (e.g., situational monitoring, communication, leadership, trust, shared mental models) and clinical performance.¹⁻³ For example, observational studies in the surgical domain have shown increased odds of complications and death (odds ratio 4.82; 95% confidence interval, 1.30 –17.87) when surgical teams exhibit less frequent teamwork behaviors (e.g., less information sharing during intraoperative and handoff phases, and less briefing during handoffs).⁴ Reviews of malpractice claims indicate that communication problems are major contributing factors in 24% of cases that result in such claims.⁵ Other studies using root cause analysis to examine contributing factors have found teamwork and communication issues cited as root causes in 52% to 70% of adverse events.^{6,7} Additionally, teamwork and communication dimensions of safety culture have been significantly related to adverse clinical events.^{8,9}

The 2001 Making Health Care Safer report reviewed the topic of team-training in a review entitled, Crew Resource Management and Its Application in Medicine. This review discussed early conceptualizations of team-training in other high reliability industries such as aviation and summarized early studies attempting to translate team-training principles developed elsewhere into health care settings. The development and implementation of team-training programs has grown dramatically in the last decade with improvements in the content and methods of training.¹⁰ Additionally, there is over 30 years of evidence examining team performance processes and the impact of team-training across a wide variety of highly complex, high-risk work environments.¹¹ This review provides an update on the implementation and effectiveness of team-training in health care.

While there has been no previous comprehensive formal systematic review dedicated uniquely to team-training in health care to date, a systematic review of interventions to improve team effectiveness in health care found that the majority involved some form of team-training (42 of 48 reviewed studies).¹⁰ Several systematic reviews with narrowly defined foci have investigated the effectiveness of team-training for obstetric emergencies,¹² for enhancing communication in surgery,¹³ and classroom-based team-training interventions^{13,14} for example. Additionally, several narrative reviews have investigated the content, design, and delivery of team-training and the impact of team processes in health care.^{2,15,16} We draw on results from these previous reviews to describe articles on interventions involving team-training.

What Is Team-Training?

Team-training is defined as a constellation of content (i.e., the specific knowledge, skills, and attitudes that underlie targeted teamwork competencies), tools (i.e., team task analysis,

performance measures), and delivery methods (i.e., information, demonstration, and practice based learning methods) that together form an instructional strategy.¹⁷ In this sense, team-training is a systematic methodology for optimizing the communication, coordination, and collaboration of health care teams that combines specific content with opportunities for practice, formative feedback, and tools to support transfer of training to the daily care environment.

As described in the National Quality Forum's "34 Safe Practices for Better Healthcare" in the 2010 Update, teamwork training and skill building is defined as follows:¹⁸

"Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients...training programs should systematically address and apply the principles of effective team leadership, team formation [and team processes]"

Borrowing from other high reliability communities, the concept of team-training in health care originated in the form of Crew Resource Management (CRM), a specific team-training strategy focused on developing a sub-set of teamwork competencies generally related to hazard identification, assertive communication, and collective management of available resources (e.g., people, tools, and information).¹⁹⁻²¹ However, the practice of team-training has become much more broadly conceptualized in health care as the science dedicated to understanding team processes, and performance has grown. Today, team-training is an overarching term that encompasses a broad range of learning and development strategies, methods, and teamwork competencies. The critical element is that the learning activity focuses on developing, refining, and reinforcing knowledge, skills, or attitudes that underlie effective teamwork. This differentiates team-training activities from technical or procedural learning activities that are focused on developing technical clinical skills (e.g., cognitive skills such as differential diagnosis and procedural skills).²² Prior narrative reviews of team-training interventions in health care have found that the most commonly targeted teamwork competencies include communication, situational awareness, leadership, role clarity, and coordination.^{13-16,23,24}

What Is the Context for the Use of Team-Training?

Previous reviews highlight that team-training has been implemented across a broad range of contexts using a variety of implementation strategies and learning modalities.^{2,3,16,23,25} This includes academic hospitals (e.g.,²⁶) and community based hospitals (e.g.,²⁷),²⁸ as well as medical centers affiliated with the VA and the Military Health System.²⁹ Additionally, team-training programs have focused on a variety of audiences including both current practitioners (e.g.,³⁰⁻³²) and trainees (e.g.,³³).

In terms of implementation strategy, both train-the-trainer and direct train-the-staff strategies have been utilized. For example, a train-the-trainer model formed the foundation for the National Implementation of TeamSTEPPS Project,³⁴ a collaborative effort of Department of Defense (DoD), the Agency for Healthcare Research and Quality (AHRQ), and the American Institute for Research (AIR) designed to create a national training and support infrastructure for health care entities implementing team-training. Through a national network of five team resource centers, individuals interested in leading the implementation of team-training within their organization could become TeamSTEPPS Master Trainers by participating in an intensive 3-day training

session. Master Trainers then train administrators and frontline personnel within their own organization using the customizable TeamSTEPPS curriculum. A slightly different approach was utilized in the large-scale implementation of team-training throughout the Veterans Administration (VA). As part of the VA National Center for Patient Safety Medical Team Training (MTT) program learning sessions for participating VA medical centers were facilitated directly by an interdisciplinary team (physician, nurse) of dedicated MTT faculty.^{35,36} Both strategies, however, include local facility change teams, implementation of on-the-job tools (e.g., process checklists, scripts) to support training transfer, and measurement and evaluation processes as integral implementation components.

What Have We Learned About Team-Training Effectiveness?

Team-training provides an opportunity for health care providers to learn, refine, and practice different strategies for communication, leadership, coordination, and collaboration. A meta-analysis of team-training that included 93 effect sizes across a broad range of industries found that participation in team-training can account for nearly 20% of the variance in team processes ($\rho = 0.44$) and outcomes ($\rho = 0.39$).¹⁷ Additionally, similar effect sizes were found for teams who worked together on a regular basis (intact teams $\rho = 0.48$) and teams who did not (ad-hoc teams $\rho = 0.44$). Previous reviews examining the relationship between teamwork and patient safety reported significant relationships between both provider ratings and observer ratings of teamwork, risk-adjusted mortality and length of stay.³

While no previous comprehensive systematic review has been dedicated uniquely to team-training in health care to date, a descriptive systematic review through April 2008 of interventions to improve team effectiveness in health care found that the majority involved some form of team-training (42 of 48 reviewed studies); other interventions focused on tools to support team effectiveness (e.g., checklists, goal lists; 8 studies) and organizational interventions (e.g., redesign of care processes or team structures, 8 studies).¹⁰ This review included 32 studies dedicated specifically to some form of team-training, including 7 studies of simulation-based team-training, 8 studies of training based in CRM, 6 studies of interprofessional training, and 11 studies dedicated to other forms of team-training.¹⁰ The review found no studies that evaluated exactly the same intervention. This lack of study homogeneity is an important consideration in evaluating the evidence for such patient safety practices, given that local customization is a common practice, and underscores the need for high quality implementation studies designed to study variation in training design and implementation. Another descriptive systematic review limited to classroom-based team-training interventions published through March 2010 included 18 studies.¹⁴ This review excluded web-based, simulation-based, mono-disciplinary studies as well as studies conducted outside of the hospital setting. Based in Kirkpatrick's four-level model of evaluation,³⁷ this review found 6 studies evaluated participant reactions to training, 9 studies evaluated training effects on behavior change, 7 studies evaluated processes measures, and 4 studies evaluated the impact of team-training on patient outcomes.

Overall, prior reviews concluded that team-training interventions are effective in improving teamwork and patient safety related attitudes, producing learning, and changing teamwork and communication behaviors in a variety of clinical areas.^{12,14,28,38,39}

More recently, some studies have shown a significant impact of teamwork training programs on safety and quality metrics. An evaluation of the Veteran's Affairs Medical Team-Training program showed significant and sustained decreases in preoperative delays (from 16% to 7% of cases, $p = .004$), increased antibiotic prophylaxis compliance (from 85% to 97%, $p < .0001$),

decreases in equipment issues/case delays (from 24% to 7% of cases, $p < .0001$), decreased handoff issues (from 5.4% to 0.3% of cases, $p < .0001$), and most notably a reduction in mortality ($p = .01$).^{36,40,41} Additionally, a dose-response relationship was established such that for each quarter the program was in place at a facility, a decrease of 0.5 deaths per 1000 procedures ($p = .001$) was observed. Implementation of a related team-training program jointly developed by the Agency for Healthcare Research and Quality and the Department of Defense, TeamSTEPPS[®], has been associated with increased efficiency in clinical processes for multi-disciplinary trauma teams (e.g., decreased times from arrival to surgery from 130.1 to 94.5 minutes ($p < .05$), endotracheal intubation from 10.1 to 6.6 minutes (n.s.), and CT scan from 26.4 to 22.1 minutes ($p < .01$)⁴²) as well as an 83% reduction in medication and transfusion errors ($p < .001$) and a 70% reduction in needlestick injuries and exposures ($p < .05$) in a U.S. Combat Support Hospital deployed in Iraq.²⁹ Other studies have also reported significant reductions in clinical decision time ($p < .05$)⁴³ associated with team-training, as well as one study showing a reduction in adverse clinical events and a 50% reduction in high severity malpractice claims (pre-training 11 high severity claims, post-training 5 high severity claims, no statistics reported).⁴⁴

Overall, the systematic review by Buljac-Smardizic¹⁰ concluded that the majority of studies reviewed were of low to moderate level quality; however, eight of the reviewed team-training studies were categorized as high or moderate quality (i.e., RCT or high quality pre-post study). In the review by Rabøl³⁸ of classroom-based team-training interventions 15 of the 18 reviewed studies were uncontrolled and 17 studies were rated at a moderate or high risk for bias.

What Have We Learned About Team-Training Design and Delivery?

Several narrative reviews of team-training and team processes in health care have also examined how team-training curricula are being designed and delivered as described in the published literature.^{1,13,15,23,24,38,45,46} These reviews find variation among team-training programs in terms of how much time learners spend in training, how often clinicians and staff are participating, and other details regarding content, delivery strategies, and evaluation efforts.

For example, programs vary in the instructional methods utilized. Instructional methods can be conceptualized in terms of three broad categories: (1) information-based methods (e.g., didactic lecture), (2) demonstration-based methods (e.g., behavioral modeling, videos), and (3) practice-based methods (e.g., simulation, role-playing). Previous reviews have found that the majority (83%) of team-training programs integrated both information and practice-based methods and that 68% reported using simulation-based learning in order to provide trainees with the opportunity to practice and refine teamwork skills, as well as receive formative feedback.²³ Only 35% of studies in this prior review, however, reported incorporating demonstration-based learning opportunities.

Variation in program duration is an additional example. A review of 18 studies evaluating classroom-based team-training interventions found course duration varied from 4 hour to 3 days with several studies describing longer train-the-trainer programs.³⁸ Another review found that 53% of 40 reviewed team-training programs were designed to last less than 1 day.¹⁴

In terms of structure, team-training in health care has been conducted with both in-tact (i.e., teams who have worked together currently) and ad-hoc teams (i.e., teams formed for training purposes only). For example, Weaver¹⁴ found 8 studies reported training in-tact teams and 5 studies reported training in ad-hoc teams.

Overall, no comprehensive meta-analysis to date has directly examined training duration, format, or other variations in design or delivery as boundary conditions influencing the effectiveness of health care team-training programs. Multi-site studies such those of the VA Medical Team Training program and TeamSTEPPS[®] and comparative effectiveness studies are important for establishing robust evidence regarding questions of how much, how often, and through which modalities team-training is most effective for inpatient, outpatient, and long-term care health care settings.

Conclusions and Comment

In summary, previous reviews of team-training in health care and more recent publications have found that can improve teamwork processes (e.g., communication, coordination, and cooperation), and that implementation of team-training programs has been associated with improvements in patient safety outcomes (e.g., reductions in adverse events, reductions in mortality). Several narrative reviews have examined how team-training is being developed and delivered in health care.^{15,17,23,24} In terms of the strength of evidence, the previous systematic review¹⁰ included several studies that utilized RCT or controlled pre-post designs and several large-scale studies examining the impact of comprehensive team-training strategies have been published since this review. However, it is important to also note that previous reviews reflect a wide range in the quality of evidence—with several studies of team-training being limited due to small sample sizes, weak study design, and limited detail regarding the team-training curriculum or implementation strategy.^{10,23}

Our non-systematic brief review included several studies that have been published since the systematic review conducted by Buljac-Samardzic, as well as findings from previous narrative reviews. Overall, there is some moderate to high quality evidence that team-training can positively impact health care team processes and patient outcomes, as well as toolkits available to support the development and implementation of team-training programs. For example, the comprehensive TeamSTEPPS[®] curriculum is available publically through AHRQ (www.teamstepps.ahrq.gov) and there are five Team Resource Centers available nationally that provide TeamSTEPPS Master Training. Additionally, the VA Medical Team Training program is available to VA Medical Centers through the National Center for Patient Safety (www.patientsafety.gov/mtt). There is also a large body of work dedicated to examining the effectiveness of team-training interventions across a wide range of industries available to inform training design and delivery decisions.⁴⁷

To continue building this evidence base, future work should continue to evaluate team-training. This includes evaluating the impact of team-training on patient safety outcomes, evaluating team-training in other settings (e.g., primary care, outpatient dialysis care settings), examining the comparative effectiveness of different methods for delivering team-training, and examining implementation methods to support sustainment of behavior changes achieved through training. For example, there is little evidence available to date that provides insight into the frequency of retraining or dedicated practice needed to develop and maintain effective teamwork skills. Additionally, there is a need to examine how dynamic team composition (i.e., changes in team membership) moderate team processes and the effects of team-training. Methodologically, robust validation studies are needed to strengthen the evidence surrounding the indices used to measure teamwork processes within health care and more studies that utilize robust experimental designs are needed. Finally, longitudinal studies and studies that address the integration of team-training concepts throughout the career development of health care

professionals, from basic through continuing education, are needed to continue building this base of evidence. A summary table is located in Table 1, Chapter 40.

Table 1, Chapter 40. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/High	Moderate	Low	Moderate	Moderate/Moderate-to-difficult

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Chapter 41. Computerized Provider Order Entry With Clinical Decision Support Systems: Brief Update Review

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Introduction

Adverse drug events are one of the most common types of harmful errors in both hospitalized and ambulatory patients. Studies have shown that preventable adverse drug events occur in 7 to 10 of every 100 hospital admissions,¹⁻³ and may even occur more frequently in the ambulatory setting.⁴ Prescribing errors are likely responsible for at least half of these events.^{5,6}

What Are Computerized Provider Order Entry With Clinical Decision Support Systems?

Computerized provider order entry (CPOE) refers to any system in which clinicians directly enter orders for medications, tests, or procedures into an electronic system, which then transmits the order directly to the recipient responsible for carrying out the order (e.g., the pharmacy, laboratory, or radiology department). These systems were initially implemented in the inpatient setting as a strategy to reduce medication errors, and their use is increasingly being broadened to include entry of all types of orders in both the inpatient and outpatient settings. A CPOE system, at a minimum, ensures standardized, legible, and complete orders and thus has the potential to greatly reduce errors at the prescribing and transcribing stages.

How Have Computerized Provider Order Entry With Clinical Decision Support Systems Been Implemented?

Clinical decision support systems (CDSS) are often integrated with CPOE systems. CDSS provide clinicians with reminders or recommendations in order to optimize the safety and quality of clinical decisions. For example, a medication CDSS may offer default values for doses, routes of administration, and frequency for commonly used drugs. Such systems may also offer more sophisticated drug safety features such as checking for drug allergies or drug-drug interactions, providing reminders for appropriate laboratory monitoring (e.g. reminders to check coagulation parameters if a patient is prescribed warfarin), or even suggesting appropriate orders based on patient-specific factors (e.g., reminders to order prophylaxis against deep venous thrombosis in a patient admitted with a hip fracture).

At the highest level of sophistication, the combination of CPOE and CDSS can therefore prevent errors of commission and errors of omission. Optimal use of CPOE with CDSS in this fashion requires integration across multiple hospital and ambulatory information systems, including the medical record, clinical laboratory, radiology, and pharmacy.

Despite recommendations from a broad range of governmental and non-governmental organizations, the pace of uptake of CPOE and CDSS has remained slow in both the inpatient and outpatient environments.^{7,8} The use of CPOE and CDSS will likely increase with the implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA). HITECH stipulates that health care providers must demonstrate the “meaningful use” of

electronic health records (EHR) by 2015, and will include penalties for failing to achieve that standard by 2016. The “meaningful use” criteria requires in part that EHRs must include one clinical decision support rule applied to a specialty or high-priority condition, as well as the ability to track compliance with that rule.

Given that only CPOE systems with an integrated CDSS meet the HITECH criteria for meaningful use, this brief update review will assess the state of the evidence regarding the effectiveness, cost, and implementation issues related to CPOE systems with CDSS capabilities (CPOE+CDSS).

The 2001 “Making Health Care Safer” report reviewed evidence on the effectiveness of CPOE+CDSS, as well as isolated CDSS, at improving medication safety.⁹ The review defined level 1 outcomes as adverse drug events (ADEs), and level 2 and 3 outcomes as medication errors and change in prescribing practices, respectively. These definitions were used in order to distinguish the effects of CPOE and CDSS on clinical outcomes (e.g., preventable ADEs) and surrogate outcomes that may not have caused patient harm (e.g., medication errors).

The 2001 review included four studies of CPOE+CDSS, three of which were conducted at the same academic medical center. These studies all found improvement in level 2 and 3 outcomes, but did not document a reduction in preventable ADEs. All of the studies included in the report evaluated “homegrown,” institution-specific systems (as opposed to commercial system purchased from vendors) and often focused on safety of a specific medication or medication class (such as antibiotics). These factors limit the generalizability of these studies to general ADE prevention and to other institutions. The review also noted the high cost and complex implementation issues that accompany CPOE+CDSS, stating, “CPOE requires a very large up-front investment with more remote, albeit substantial returns. In addition, CPOE affects clinicians and workflow substantially. Its complexity requires close integration with multiple systems, such as the laboratory and pharmacy systems. Failure to attend to the impact of such a large-scale effort on organizational culture and dynamics may result in implementation failure (page 71).”

The overall conclusion of the review was that CPOE+CDSS can lower the rates of medication errors and can promote appropriate prescribing, but evidence of its impact on actual patient-level harm was limited. This conclusion proved to be somewhat controversial. In response, followup commentaries¹⁰ took issue with the fact that CPOE+CDSS received only a “medium strength of evidence” recommendation in the report. The objection to this conclusion centered around the argument that CPOE+CDSS are difficult and costly to evaluate in controlled trials, particularly when evaluating a relatively infrequent single adverse event such as an ADE, and that the face validity of such systems indicated that proof of clinical benefit should not be required before wider adoption. The evidence report’s authors responded that using evidence to evaluate the effectiveness and generalizability of these patient safety practices was essential to their appropriate prioritization and application.¹¹

What Have We Learned About Computerized Provider Order Entry and Clinical Decision Support Systems Since the “Making Health Care Safer Report?”

Evidence for the Effectiveness of Computerized Provider Order Entry With Clinical Decision Support Systems

Three systematic reviews published since 2008 have evaluated the effectiveness of CPOE+CDSS at preventing ADEs. Wolfstadt and colleagues¹² identified ten trials of CPOE+CDSS, nine of which were conducted in the inpatient setting and one in the ambulatory setting. The majority of these studies evaluated homegrown systems, and none were randomized controlled trials. The review concluded that CPOE+CDSS are effective at reducing ADEs, with five of the ten studies finding a statistically significant reduction in ADEs and four others reporting a nonsignificant improvement.

Schedlbauer and colleagues¹³ identified 20 studies that evaluated a total of 27 forms of electronic reminders and prompts embedded in CPOE systems. Only four of these studies were randomized controlled trials (RCTs). The authors classified the alerts as “basic” (including only information about allergies, drug-drug interactions, and default dosing), “advanced” (including alerts targeting errors of omission and patient-specific dosing and safety guidelines), and “complex” (including features of both basic and advanced systems). This review also found that CPOE+CDSS are effective, with 23 of the 27 reminder types demonstrating improvement in targeted outcomes. However, only four of these studies evaluated clinical adverse drug events; three of them did find statistically significant reductions in preventable ADEs. Although the four studies of “complex” alert systems all found significantly improved prescribing practices, only one of these studies found a statistically significant improvement in preventable ADEs.

Van Rosse and colleagues’ review¹⁴ specifically focused on the effectiveness of CPOE+CDSS in adult and pediatric intensive care units, where patients are particularly vulnerable to ADEs. The 12 observational studies they identified collectively demonstrated reductions in medication prescribing errors; however, no overall effect was found on ADEs or mortality rates.

These three reviews almost exclusively identified studies conducted in the inpatient setting. These studies generally included relatively small patient populations, often within a single hospital or health system, and relatively short intervention periods. The use of CPOE+CDSS in the ambulatory care setting is less extensively studied. Two recent studies^{15,16} conducted in large, community-based practice settings found that mandatory use of CPOE+CDSS achieved reductions in prescribing errors, but not clinical ADEs—mirroring the evidence from the inpatient setting.

Taken together, these reviews indicate that hospitals implementing CPOE+CDSS cannot assume that these systems will reliably reduce clinical ADEs. Insight into the mechanism of this (lack of) effect was provided by a systematic review by Shojania and colleagues¹⁷ that evaluated the effect of electronic point-of-care reminders on changing physician behavior. This quantitative review found that reminders overall resulted in only small changes in provider behavior, a degree of behavior change that was generally insufficient to yield clinically significant improvement. The authors further concluded that evidence was insufficient to identify key features of systems that could result in clinically significant changes in provider behavior, as the subset of studies reporting the largest effects all originated from a single hospital (Brigham and Women’s

Hospital in Boston). The conclusions regarding CPOE+CDSS in the 2001 edition of “Making Health Care Safer” thus appear to stand largely unchanged a decade later.

Computerized Provider Order Entry With Clinical Decision Support Systems Can Affect Workflow and Patient Care Adversely

The growth in use of CPOE+CDSS has yielded a more nuanced appreciation of the unintended consequences of the technology. These unintended consequences were classified in a seminal 2006 article:¹⁸

- More or new work for clinicians
- Unfavorable workflow issues
- Never-ending system demands
- Problems related to persistence of paper orders
- Unfavorable changes in communication patterns and practices
- Negative feelings toward the new technology
- Generation of new types of errors
- Unexpected changes in an institution’s power structure, organizational culture, or professional roles
- Overdependence on the technology

Surveys of clinicians in settings where CPOE was recently implemented have confirmed that clinicians perceive these unintended consequences to be common and to affect patient care adversely.¹⁹ An illustration of this phenomenon was provided in a recent study²⁰ that evaluated the effect of a “hard-stop” warning that essentially prevented co-prescribing of the anticoagulant warfarin and the antibiotic trimethoprim-sulfamethoxazole—a combination associated with serious bleeding risks. The warning was abandoned after 6 months because four patients experienced delays in needed treatment with one of the drugs. Another potential effect of these electronic programs is the potential to create more workarounds, or bypassing a recognized problem as a temporary solution, that may then lead to future systems failures.

One particular problem, “alert fatigue,” was discussed in the original “Making Health Care Safer” report and has been further studied over the past decade. Alert fatigue refers to the tendency of clinicians to ignore warnings that are not perceived as being clinically significant, which may result in inappropriately ignoring critical alerts. Alert fatigue is now a well-documented phenomenon in both the inpatient and ambulatory settings,²¹ as most existing CPOE+CDSS systems lean toward providing comprehensive alerts for all potential drug safety problems rather than focusing alerts on the most clinically significant problems. In one study of an outpatient CPOE+CDSS system,²² more than 300 alerts were required to prevent one ADE, and another study found that clinicians ignored 75 percent of even “critical” drug-drug interaction alerts.²³

CPOE+CDSS systems thus have the potential to affect clinician workflow and patient care adversely. These unintended consequences have forced health care systems to pay very close attention to how this technology is configured and implemented.

Implementation and Costs

Implementation issues around CPOE+CDSS chiefly involve two aspects: the technical specifications of how the system is configured to minimize alert fatigue and other workflow-

related consequences, and how the transition from paper-based systems to an electronic system is handled.

Some studies have successfully “tailored” alerts by incorporating patient-specific characteristics into algorithms for displaying drug warnings. Seidling and colleagues²⁴ implemented a tailored alert system at a German hospital and found a reduction in prescribing errors; this study is notable because providers accepted nearly 25 percent of warnings, much higher than rates generally reported in the literature. However, efforts to tailor drug warnings are currently limited by the lack of standardized consensus definitions for drug-drug interactions that are likely to lead to ADEs and unclear malpractice implications for users and manufacturers of CDSS systems²⁵ should patients be harmed if an alert is not provided. Recent commentaries^{25,26} have called for better guidance and legal protections to allow greater tailoring of alerts to minimize alert fatigue and improve the safety performance of decision support systems, and a recent consensus conference²⁷ identified the key issues in developing more effective alert mechanisms.

At the institutional level, it is clear that careful attention must be paid to the implementation process of CPOE+CDSS, particularly with regard to how systems are integrated into existing clinician workflow. Unfortunately, no clear consensus exists on the optimal implementation methods in either the hospital or ambulatory setting. The “CDSS five rights” provides a framework on implementation to improve medication management and outcomes by linking each intervention with a specific objective. This framework includes each “right” be addressed to ensure an optimal CDS program: *right* information, to the *right* person, in the *right* format, through the *right* channel, at the *right* point in workflow.²⁸ The Agency for Healthcare Research and Quality has published the online “Guide to reducing unintended consequences of electronic health records” (www.ucguide.org), and several case studies of implementation of commercial CPOE+CDSS systems have also been published²⁹⁻³¹ These reports likely provide the most useful guides for decisionmakers regarding implementation issues.

We did not identify any formal cost-effectiveness analyses of CPOE+CDSS published in the past 5 years. Individual institutions with homegrown CPOE+CDSS systems have estimated considerable cost savings³² due to ADE prevention and optimizing medication use, but these data may not be generalizable to other settings and systems. A 2009 review of the costs and benefits of health information technology³³ found “a paucity of meaningful data on the cost-benefit calculation of actual IT implementation”, and concluded, “although there is some empirical evidence to support the positive economic value of an EHR system and the component parts of EHRs, projections of large cost savings assume levels of health IT adoption and interoperability that we are nowhere near achieving.”

Conclusions and Comment

The 2001 “Making Health Care Safer” report concluded that evidence for the safety benefits of CPOE (with or without CDSS) was only moderate. Unfortunately, a decade of wider CPOE+CDSS implementation and intensive research does not appear to change that conclusion. CPOE+CDSS appear to be effective at reducing medication prescribing errors, but there is no clear evidence that these systems reduce clinical ADEs in either the inpatient or outpatient setting. Reminder systems can stimulate provider behavior change to improve appropriate care, although these benefits may be relatively small.

Significant progress has been made in understanding the unintended consequences and potential for adverse events associated with CPOE+CDSS implementation, but a lack of

consensus exists on implementation processes, especially for health systems implementing commercial applications. Therefore, while the HITECH act and related measures provide health care organizations with considerable incentive to implement health IT, the actual process of implementation may continue to consist of exercises in trial and error, and the return on investment in health IT systems is not predictable. Health information technology certainly has great potential to improve patient safety, but for the specific example of CPOE+CDSS, it appears that potential remains unrealized. A summary table is located below (Table 1).

Table 1, Chapter 41. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues How Much do We Know?/How Hard Is it?
Common/Moderate	Low-to-moderate	Low-to-moderate	High	Moderate/Difficult

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Chapter 42. Tubing Misconnections: Brief Review (NEW)

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How Important Is the Problem?

Tubing lines connect patients to devices and allow for the delivery of medication or nutrition therapy. Liquid-to-liquid misconnections can introduce fluids, medications, or nutritional formulas into the wrong body part.¹ Gas-to-liquid misconnections can deliver gas into the vasculature or liquid into the respiratory tract.² The consequences of tubing misconnections include severe patient harm and death.

Although misconnections have been recognized as a serious problem for years, incidents are still common.³ One of the first publications of a tubing misconnection (enteral) was in 1972 reporting the inadvertent intravenous (IV) administration of breast milk.² From January 1, 2000 to December 31, 2006 the United States Pharmacopeia (USP) collected a total of 24 reports of tubing misconnections of an enteral feeding formula, other solutions, or medications intended for the feeding tube but administered via the wrong route.² Eight (33%) of the reports resulted in permanent injury, life threatening situation, and/or death.² Between January 2008 and September 2009, the Pennsylvania Patient Safety Authority received 36 reports of tubing misconnections, with the incidents ranging from near misses to serious events; 35 were liquid-to-liquid events and one was liquid-to-gas.³

Factors that contribute to misconnections include lines that have been disconnected and need to be reconnected, the use of adapters to permit connections that are meant to be impossible, luer fittings (male and female components) allowing a variety of lines to be connected with no indication that the connection might be inappropriate, and line connectors with similar features.¹ Luer fittings have been listed by ECRI Institute as one of the top 10 technology hazards for 2011¹

Human error is one factor resulting in tubing misconnections. Clinicians are often under time pressure, experience rotating shift work and fatigue, and attempt to use short-term recall for large amounts of information.² Inadequate training and lighting, moving patients from one setting or service to another, and using tubes or catheters for unintended purposes (e.g., IV extension tubing for epidurals, irrigation, etc.) can also result in tubing misconnections.²

What Is the Patient Safety Practice?

Engineering (i.e., design) controls and the implementation of administrative controls (hospital policies and work practices) are the two basic means that can minimize misconnections. Human error is inevitable and may cause fatalities when tubing lines are misconnected. Therefore, the Joint Commission has urged product manufacturers to implement appropriate “designed incompatibility” to prevent dangerous misconnections of tubes and catheters.²

According to ECRI Institute, engineering controls to reduce misconnections fall into three categories: connectors with physical incompatibilities (leaving users with little or no choice but to make the correct connection), connectors with locking mechanisms (to prevent accidental disconnection), and connectors with a distinct physical appearance (size, shape, or color).⁴ In 2000, The European Standards Organization created a standard using a graduated catheter tip on the distal end of enteral tubing and standardized the proximal end of the tubing by replacing the

spike with a screw-type connection.⁵ In 2007, a catheter-adapter tip (i.e., “Christmas-tree” connector) was standardized in the United States for the distal end of enteral feeding tubing to prevent staff from plugging it into IV equipment.⁵

Until appropriately designed tubing is developed and consistently supplied, it is recommended that hospitals incorporate both design solutions and work practices to decrease and eliminate any tubing misconnections.^{1,6} Organizations such as The Joint Commission, The International Organization for Standardization, and ECRI Institute have published tubing misconnection risk reduction strategies for clinical and non-clinical staff (e.g., Clinical/biomedical engineering, risk management, purchasing, etc.), and specific to general tubing and enteral tubing. We have listed the general tubing misconnection risk reduction strategies below and organized the list by the target audience.

Clinical Staff^{1,7}

- Trace all lines back to their point of origin to verify that correct connections are made
- Recheck connections and trace all lines to their point of origin after the patient’s arrival to a new care area or as part of a handoff process
- Do not force connections
- Only use adapters in accordance with hospital policy for a specific indication
- Label certain high-risk catheters as to the type of catheter (e.g., epidural, intrathecal)
- Route lines with different purposes in unique and standardized directions (e.g., IV line towards patient’s head, enteral feeding line towards patient’s feet)
- Identify and manage conditions that may contribute to worker fatigue, which could result in inattentiveness when making connections

Non-Clinical Staff^{1,7}

- Provide regular misconnection prevention education to all personnel working in the patient care environments (e.g., explain the need to request help rather than attempting to disconnect or reconnect lines).
- Assess the need for adapters throughout the facility, and establish policies to limit or restrict their routine use
- Revise and/or establish purchasing policies that include, when possible, purchasing equipment with misconnection safeguards (e.g., avoid purchasing nonintravenous equipment)

The risk reduction strategies suggested for enteral feeding misconnections for clinical and non-clinical staff include the following.

Clinical Staff^{1,7}

- Do not use standard luer syringes for oral medications or enteral feedings
- Do not modify or adapt IV or enteral feeding devices
- Route lines with different purposes in unique and standardized directions (e.g., route IV lines towards patient’s head, route enteral feeding lines towards patient’s feet)
- Identify and manage conditions that may contribute to worker fatigue
- Review identification labels before administering solutions to ensure that the intended delivery route is correct

- Placing labels with warnings - “WARNING” for Enteral Use Only – Not for IV Use

Non-Clinical Staff^{1,7}

- Ensure that an adequate number of distinctly labeled enteral pumps are purchased to reduce or eliminate the use of infusion pumps for enteral administration to adult patients
- Reinforce existing purchasing policies that mandate purchasing only enteral feeding sets that are incompatible with female luer connectors
- When possible purchase only non-IV compatible enteral feeding containers
- Secure enteral administration sets with enteral feeding containers (e.g., with rubber band) or pre-attached sets from the manufacturer before sending them to the patient care unit
- Perform pre-purchase evaluations of enteral feeding systems under the guidance of a multidisciplinary task force before purchasing decisions are made

According to ECRI Institute, the single most important work practice solution for clinicians is to trace all lines back to their origin before connecting or disconnecting any devices and infusions.⁸ Additional strategies that may be useful include ensuring proper lighting when making connections, contacting manufacturers to determine if luer fittings can be replaced with different connector types, storing medications for different delivery routes in different locations, and using a color-code system.¹

Why Should the Patient Safety Practice Work?

Theoretically, the combination of engineering controls and a change in work practices will prevent any tubing misconnections. The engineering controls have varying levels of effectiveness.⁴ The forcing function is the most reliable approach since it leaves the user with little or no choice but to make the correct connection.⁴ Other solutions will prompt users to make the correct connection by identifying the appropriate connector size, etc.

Work practice solutions such as tracing lines back to the point of origin verifies that the correct lines will be connected and ultimately avoids errors. Trainings provided by manufacturers will help users understand the equipment and its safeguards. While trainings provided by the facility will increase the awareness of clinical and non-clinical staff of appropriate tubing misconnection policies and procedures (e.g., potential consequences), only trained staff should reconnect disconnected lines.

What Are the Benefits of the Patient Safety Practice?

The hospital environment is filled with lines and cables connecting medical devices with patients and can cause confusion when patients are being connected or reconnected to the lines.¹ The most important benefit of implementing equipment design solutions and changes in work practices is the reduction and elimination of severe patient harm or death as a result of tubing misconnections.

Searches performed for this report identify three studies that implemented work practice and engineering controls. Each facility’s needs varied and the PSP implemented was based on the specific needs. The multidisciplinary staff at Beaumont Commercialization Center in Royal Oak, Michigan identified and examined potential connector hazards, produced educational materials, provided hands-on training, and revised equipment purchasing procedures and staff guidelines.⁹ Woods and Schultz (2006)¹⁰ reported the standardization of labeling procedures and

nomenclature used by materials management and clinical staff at Columbus Children's Hospital.¹⁰ In-house equipment was also assessed for potential to contribute to misconnections and revisions were made for future purchasing policies. Both studies report the elimination of tubing misconnections. A third study by Lawton (2010)¹¹ assessed the use of a new non-luer device and a color-coding system.¹¹ Clinicians involved in the study report that the device would benefit patient safety and would be willing to adopt the non-luer device with resolutions to design concerns.

Although the solutions implemented in these studies varied, each facility used a combination of equipment and work practice solutions to address the tubing misconnection problem.

What Are the Harms of the Patient Safety Practice?

Labeling and color-coding tubing lines have been suggested as ways to reduce misconnections. The Joint Commission and U.S. Pharmacopeia Medication Safety Forum have acknowledged the potential in these methods. However, in the tubing misconnection Sentinel Event Alert, The Joint Commission noted that users may rely on color-coding rather than assuring a clear understanding of correct connections between tubes or catheters and body inlets.⁷ Ongoing education and training about the color-coding system would be necessary for staff on-site, as well as temporary or traveling staff. One study identified in our search results mentioned a concern regarding the use of a color-coding system. Clinicians involved in a study by Lawton (2010)¹¹ were concerned with this system since visual discrimination is not possible in poor lighting conditions.¹¹ Another variable of consideration is the potential for various facilities within the same geographic area to use different color-coding systems which could lead to confusion, particularly for temporary or travel staff.⁷

How Has the Patient Safety Practice Been Implemented, and in What Contexts?

One of the first steps to implementing a risk reduction strategy is to formally assess the current state of the work practices, equipment, and identify areas of improvement. One facility is likely to have specific misconnection risks that require special attention compared with the needs of another facility.⁴ A multidisciplinary task force should perform a formal risk assessment to gauge the overall risks and the strategies that will reduce these risks.⁴

In 2004, the Beaumont Commercialization Center in Royal Oak, Michigan undertook a program to address the problem of tubing misconnections.⁹ The task force collected all equipment from the pediatric intensive care unit, developed human factors testing protocols, and examined the connectors to identify potential misconnections and their severity.⁹ Along with educational materials, employees had the opportunity to receive hands on training by performing correct and incorrect connections via a "training bear". This allowed staff to identify the right and wrong way to connect tubing lines. As a result of this process, a corporate Misconnection Prevention Policy was created and covered equipment purchases, technical and safety testing, risk assessment, guidelines for clinical staff, and orientation and education.⁹ Also, Beaumont reports that its misconnection rate dropped to zero.⁹

Lawton (2010) investigated the potential for and implementation of non-luer compatible equipment for use in spinal procedures.¹¹ The findings indicated that clinicians were enthusiastic about the use of new well-designed devices for intrathecal chemotherapy, but not spinal (i.e., epidural) anesthesia as they were not convinced the devices will help tackle the problem of

spinal drug errors.¹¹ The clinicians were also concerned with color-coding since visual discrimination is not possible in poor lighting conditions, non-translucent devices preventing the ability to see what a needle is doing and if it has reached the right place during injections, and drug leakage.¹¹ Overall, if the identified design issues are resolved, clinicians would be willing to adopt the non-luer devices because they believe patient safety will benefit from implementation.¹¹

In 2004, the Columbus Children's Hospital conducted a Health Failure Mode and Effects Analysis (HFMEA) to identify the inherent risks of use and labeling of various enteral, parenteral, and other tubing types in patient care and the potential for harm.¹⁰ Woods and Shultz (2006) found three common themes causing all failure modes: non-standardized labeling of tubing, lack of knowledge of nomenclature or alias, and inconsistent inventory.¹⁰ Labeling of tubing with infused mechanisms happened 85% of the time in the pediatric intensive care unit, 53% of the time during surgery, and 93% of the time during interventional radiology. The risk reduction methods subsequently implemented involved the standardization of the labeling process throughout the organization (e.g., color of labels, content on label, size and placement of tubing), and the development of an online pictorial catalog listing all available supplies by category and the nomenclature used by materials management and "common names" used by clinical staff.¹⁰ The third risk reduction method conducted an inventory with the help from clinical staff and materials management to identify currently used tubing, connectors that fit properly and those that needed to be removed from practice, and devices that needed to be purchased. According to the authors, several recommendations have been implemented and no tubing misconnections have been reported.¹⁰

Another point of consideration when implementing the PSP for tubing misconnections is cost. In 2008, Peter Angood, the chief patient safety officer and vice president of The Joint Commission stated that "the cost of acquiring new devices, identifying risky connections and practices, and implementing training and testing will no doubt impact hospitals."¹² However, "the cost of *not* making such changes could, of course, be much greater in terms of lives lost – erroneous connections between tubes and catheters can create catastrophic outcomes, even death" says Angood.¹²

Conclusions and Comments

Ideally, the combination of engineering controls and a change in work practices should eliminate all tubing misconnections. Organizations such as The Joint Commission, The International Organization for Standardization, and ECRI Institute have been consistent with suggestions for solutions to reduce the risks of tubing misconnections. In general, suggestions for work practice solutions include tracing lines back to the point of origin, rechecking connections and tracing lines when moving a patient or when work shifts change, not forcing connections, using appropriate adapters, labeling high-risk catheters, routing lines in different directions, and addressing and managing conditions contributing to worker fatigue. Equipment design solutions involve assessing the need for adapters, revising purchasing procedures, and educating clinical staff on correct equipment use. Angood states, "this area of healthcare is difficult to get under control because the issues cut across several sectors within the industry. It will take time before a coordinated approach occurs to address these issues. In the interim, organizations and all practitioners must be highly vigilant about preventing misconnections."¹² Chapter 31 reviews the evidence for Human Factors and Ergonomics (HFE). The goal of HFE is to address physical,

cognitive, and organizational issues of devices. The importance of designing devices that help reduce human error is discussed further in this chapter.

As seen in the previously mentioned studies, each facility will have specific needs and inherent risks that require the implementation of different risk reduction strategies. Again, one of the most important work practice solutions involves the tracing of lines back to the point of origin. Regardless of the differences between facilities, it is recommended that facilities perform a risk assessment to determine their ultimate needs in equipment changes and work practice policy updates. A summary table is located below (Table 1).

Table 1, Chapter 42. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Low	Low	Low	Moderate/Not Difficult

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Chapter 43. Limiting Individual Providers' Hours of Service: Brief Update Review

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Introduction

Long and unpredictable work hours have been a staple of medical training for centuries, but the effects of fatigue among residents on patient safety garnered little attention until March 1984, when a young woman died at a teaching hospital in New York. Her death was attributed in part to a medication prescribing error made by residents in the midst of a 36-hour shift. This seminal event led to the passage of regulations in the State of New York limiting residents' shift duration to 24 consecutive hours and overall work week to 80 hours. However, at the time of the original Making Health Care Safer¹ report in 2001, widespread violations of the New York regulations were common, and it was not unusual for residents still to work 36 hour shifts and over 100 hours per week in other states as well).

A considerable body of evidence from health care and other industries² links acute and chronic sleep deprivation to impaired cognitive performance. Some studies have also shown that sleep deprivation can affect psychomotor skills.³ Working extended duration shifts can be harmful for both clinicians and patients. Studies have shown that residents who work more than 16 consecutive hours have an increased risk of motor vehicle accidents after their shift⁴ and of suffering a needlestick injury during their shift.⁵ Working over 16 consecutive hours in the intensive care unit has been shown to result in interns committing more diagnostic and therapeutic errors.⁶ Among nurses, shift duration of greater than 12 hours is also associated with a significantly increased risk of committing errors.⁷ In response to these and other data, the Accreditation Council for Graduate Medical Education (ACGME) implemented formal work hour restrictions for resident physicians in 2003, and made these regulations even more stringent in 2011.⁸

Despite these known risks, the extent to which patients are harmed by clinician fatigue is difficult to determine. Fatigue on the part of an individual provider may only be one of several latent causes of a preventable adverse event, especially in the complex hospital environment. Few studies have attempted to directly address the connection between clinician fatigue and adverse clinical outcomes. Two recent studies^{9,10} examined whether attending surgeon's fatigue was linked to an increased risk of complications, and reached conflicting results; one study¹⁰ found an increased risk of complications when the surgeon had the opportunity to sleep for less than 6 hours the night prior to the procedure, but the other⁹ did not find the same association.

Despite the lack of hard data linking fatigue and complications, the traditional residency work hours that existed prior to 2003 could not be justified from an educational, humanistic, or patient safety standpoint. The implementation of regulations to reduce residents' work hours have resulted in fundamental changes to residency education over the past decade, and the regulations' effect on patient safety has been extensively studied.

The 2001 report reviewed the evidence linking sleep deprivation and fatigue to medical errors, and reached four conclusions:

- "Sleep deprivation and disturbances of circadian rhythm lead to fatigue, decreased alertness, and poor performance on standardized testing."

- “Although data from non-medical fields suggest that sleep deprivation leads to poor job performance, this link has not yet been established in medicine.”
- “Forward rather than backward shift rotation [i.e., progressing from day to evening to night shifts, rather than the reverse], education about good sleep hygiene, and strategic napping before or during shifts may reduce fatigue and improve performance. High face validity, low likelihood of harm, and ease of implementation make these promising strategies, although more evidence of their effectiveness in medicine is warranted.”
- “Given that medical personnel, like all human beings, probably function suboptimally when fatigued, efforts to reduce fatigue and sleepiness should be undertaken, and the burden of proof should be in the hands of the advocates of the current system to demonstrate that it is safe.”

In this review, we assess the evidence that has accumulated since 2001 for the effect of limiting individual providers’ hours of service on patient safety outcomes. Although other countries have significantly more stringent regulations (for example, trainees in the European Union are limited to 48 hours per week), the focus of this review will be on studies conducted in the United States.

What Efforts Have Been Made To Reduce Clinician Work Hours?

Specific attempts have been made to reduce clinician work hours in order to improve safety by minimizing fatigue. The vast majority of the research in this area pertains to resident physicians in the United States. In 2003, the ACGME passed regulations intended to significantly reduce work hours for trainees. These regulations included four principal components:

- A maximal limit of 80 hours worked per week
- No more than 24 consecutive hours on duty (an additional 6 hours were allowed to ensure safe transitions of care, meaning that residents could work a maximum of 30 consecutive hours)
- “On-call” frequency of no more than once every 3rd night
- At least 4 days off per month

These regulations became effective on July 1, 2003 (some specialties received partial exemption from the regulations). Since that date, the effect of the regulations has been intensively studied, and forms the largest body of evidence specifically addressing the patient safety effects of reducing individual providers’ hours of service.

What is the Context for Current Efforts To Reduce Work Hours?

The Institute of Medicine issued a report¹¹ in 2008 that took into account the initial data on the effect of the 2003 ACGME regulations, as well as the evolving evidence base in the area of fatigue and performance. The IOM’s recommendations included the following:

- Continued maximal limit of 80 hours per week
- No more than 16 consecutive hours on duty, after which residents must be off duty completely or provided 5 hours of protected sleep time
- No more than 4 consecutive night shifts
- 1 full day off per week, and 1 full weekend off per month

The revised resident duty hour regulations published by the ACGME in 2010, and implemented July 1, 2011, did not incorporate all of the IOM's recommendations. The 2011 regulations have four key components:

- Continued 80-hour work week limit
- No more than 16 consecutive hours on duty for first-year residents only. Second-year and more senior residents can work 24 hours on duty, with an additional 4 hours allowed for transitions of care
- No more than 6 consecutive night shifts
- Continued minimum of 4 days off per month and on-call frequency of no more than once every 3rd night

Although excessive work hours are linked to errors among nurses, regulation of nurses' work hours is less uniform. Currently, 16 states do restrict mandatory overtime for nurses, but many nurses still routinely work more than 12 hours per shift.⁷ There are also no regulations on working hours for practicing physicians, despite some data indicating that many practicing physicians work schedules that would be prohibited were they still residents.¹²

What Have We Learned About Limiting Physician Work Hours?

Recent Reviews and Systematic Evaluations

Multiple systematic reviews have addressed the patient safety effects of reducing shift length for residents. One systematic review that included only studies of the effect of the 2003 ACGME regulations¹³ identified 20 studies that assessed mortality and 24 studies that assessed other patient safety outcomes before and after implementation of the regulations. Meta-analysis of the mortality studies did show a statistically significant decline in mortality after 2003 (OR 0.9, 95% CI 0.84 – 0.95), which was consistent in studies examining either medical or surgical patient populations. However, considerable unexplained heterogeneity was present ($I^2=83%$), and the subset of studies that used a contemporaneous control group of non-teaching hospitals generally did not find a difference in mortality. The authors acknowledged that as they were unable to control for secular trends or changes in patient characteristics, the mortality improvement could be due to overall improvement in the quality of care during the time period studied. The studies examining patient safety outcomes yielded mixed results, with no clear pattern of improvement or worsening across studies.

Another review¹⁴ identified 36 studies that examined the association between reduced trainees' working hours and patient outcomes. This study also included studies performed outside the U.S.. The conclusions were largely similar to that of the previous review: Mortality and patient safety outcomes appeared unchanged after implementation of duty hour limits. Both reviews found that limiting work hours appeared to improve residents' quality of life.

The question of why patient safety outcomes have not improved after reducing resident work hours is a subject of intense debate. Reduced shift length almost certainly led to greater discontinuity among providers, and the resultant handoffs of care may have had deleterious effects on patient safety. Adherence to work hour limitations was (and is) likely suboptimal.^{15,16} In addition, studies have shown that changing residents' work schedules to meet the regulations did not actually result in residents sleeping more.¹⁷ Finally, although resident quality of life improved, in some studies objective measurements of burnout and depression among residents

did not change.¹⁸ Burnout and depression are themselves linked to impaired job performance, independent of acute or chronic fatigue.¹⁹

The 2003 duty hour regulations still allowed all residents to work a maximum of 30 consecutive hours. These extended duration shifts are still longer than those allowed in virtually any other industry, and studies have found an association between working more than 16 consecutive hours and an increased risk of self-reported errors and attentional failures.²⁰ A 2010 systematic review²¹ that identified 13 studies in which shift length for clinicians was purposefully reduced found consistent evidence among the higher-quality studies that both objectively-measured and self-reported errors decreased after shift length reduction. One particularly high quality study⁶ found a significant reduction in serious medical errors for medical interns assigned to work a 16-hour shift in the intensive care unit, compared with interns working a traditional 30-plus hour shift. However, the reviewers were unable to reach a firm conclusion regarding the optimal shift length, due to heterogeneity between shift lengths used in the primary literature.

Thus, the totality of the evidence on the 2003 ACGME duty hour regulations indicates that reducing resident duty hours does not improve—or worsens—patient safety or mortality. The association between extended duration (>16 hour) shifts and adverse events ultimately was a factor in the ACGME’s decision to enact a 16-hour shift length limit for first-year residents as part of the 2011 regulations.

New Studies for Effectiveness of the Patient Safety Practices

As the ACGME’s latest regulations were implemented earlier this year, no further data are available in addition to those summarized above.

Potential for Harm

The greatest potential harm of work hour regulations is an increase in adverse events due to increased handoffs of care between providers. Although this association is certainly plausible, and handoffs have unquestionably increased after both the 2003 and 2011 regulations, studies have not specifically examined whether errors attributable to handoffs have increased after the regulations were implemented.

The other oft-cited adverse consequence of duty hour reduction is decreased clinical experience for trainees, limiting their ability to practice independently once training is completed. Studies of the 2003 duty hour regulations generally did not find that objective clinical experience worsened, when measured by criteria such as surgical case volume. However, both faculty^{22,23} and residents²⁴ have voiced concerns that duty hour regulations have actually compromised their educational experience, and most residents²⁵ appear unconvinced that further duty hour reductions will improve either patient safety or their educational experience.

Costs and Implementation

Implementing the 2011 ACGME regulations is likely to be extremely costly for teaching hospitals. A 2011 cost-effectiveness analysis²⁶ estimated that implementing the new ACGME regulations would cost teaching hospitals \$1.6 billion if the decreased workload of interns was replaced entirely by attending physicians, and \$1.34 billion if interns were replaced by physician extenders (nurse practitioners or physician assistants). A 7.2% decrease in preventable adverse events would be required in order to make the regulations cost-neutral to society, but teaching hospitals would still encounter considerable costs. The expenses associated with the need to

replace the housestaff workforce with alternative providers and the need to provide greater supervision for residents by senior physicians is likely to be considerable.

Conclusions and Comment

Sleep deprivation and fatigue have clear deleterious consequences for patients and providers. However, the most prominent effort to improve patient safety by reducing fatigue—limiting the work hours of resident physicians—has not yielded the expected benefits. It is conceivable that the 2003 ACGME duty hour regulations were simply not stringent enough, given that extended duration shifts were still permitted and those shifts are associated with preventable adverse events. Alternatively, it may be that advocates underestimated the complexity of the relationship between duty hours and safety, or the detrimental impact of handoffs. The 2011 regulations further restrict hours, particularly for first-year residents. The effects of these new regulations are as yet unknown, and unfortunately, the existing evidence does not offer us great clarity regarding the optimal work hour structure that would improve safety by decreasing clinician fatigue with minimal potential for unintended consequences. A summary table is located below (Table 1).

Table 1, Chapter 43. Summary table

Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Common/Moderate	Low	Moderate (at least) Includes lack of training time	High	Moderate/Difficult

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Part 3. Discussion

Chapter 44. Discussion

Introduction

Progress Since the 2001 Report

Over 2000 years ago, Hippocrates reminded physicians to, “first, do no harm.” In 1863, Florence Nightingale wrote, “It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm.” Notwithstanding these commonsensical admonitions, it was not until the turn of this century that a systematic effort to improve patient safety began, catalyzed by the publication of the IOM report, “To Err is Human.”¹

The year following the publication of the IOM report, AHRQ commissioned a group of investigators, led by the UCSF-Stanford EPC, to synthesize the world’s literature on PSPs, an effort that culminated in the 2001 report, “Making Health Care Safer.”² This report was widely used by clinicians, safety workers, researchers, and policymakers, and it informed a variety of other initiatives including the National Quality Forum’s Safe Practices list.

Since 2001, research in the patient safety field has exploded, with literally thousands of published studies. In fact, some of today’s popular safety practices—rapid response teams, disclosure of errors to patients, or any of the “checklist”—based interventions—had barely been invented at the time of the 2001 report.

In light of this maturation of the field, AHRQ asked a group of investigators, many of whom were involved in producing the earlier report, to synthesize the vast amount of new information on PSPs that has emerged since the release of “Making Health Care Safer.” Using a similar method, which combined explicit criteria, detailed evidence reviews, and an international panel of expert advisors, this report reviewed the evidence on 41 PSPs. In Table 1, below, we provide a summary of this evidence, followed by a discussion of the evidence in the context of prior work on patient safety, and then present priorities for adoption of PSPs

Table 1, Chapter 44. Summary table*

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Practices Designed for a Specific Patient Safety Target					
Adverse Drug Events					
High-alert drugs: patient safety practices for intravenous anticoagulants; in-depth review	Common/Moderate	Low	Low-to-moderate	Low	Little/Moderate
Use of clinical pharmacists to prevent adverse drug events; brief review	Common/Low	Moderate-to-high	Low	High	Little/Moderate
The Joint Commission’s “Do Not Use” list; brief review	Common/Low	Low	Negligible	Low	Little/Probably not difficult
Smart infusion pumps; brief review	Common/Low	Low	Low	Moderate	Moderate/Moderate

Table 1, Chapter 44. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Infection Control					
Barrier precautions, patient isolation, and routine surveillance for the prevention of healthcare-associated infections; brief review	Common/Moderate	Moderate	Moderate (isolation of patients)	Moderate-to-high	Moderate/Moderate
Interventions to improve hand hygiene compliance; brief review	Common/Moderate	Low	Low	Low	Moderate/Moderate
Reducing unnecessary urinary catheter use and other strategies to prevent catheter-associated urinary tract infections; brief review	Common/Moderate	Moderate-to-high	Low	Low	Moderate/Moderate
Prevention of central line-associated bloodstream infections; brief review	Common/Moderate	Moderate-to-high	Low	Low-to-moderate	Moderate-to-difficult/Not difficult (implementation of a “bundle”)-to-moderate (understanding organization culture and context)
Ventilator-associated pneumonia; brief review	Common/High	Moderate-to-high	Low	Low-to-moderate	Moderate/Moderate
Interventions to allow the reuse of single use devices; brief review	Common/Low	Low	Low	Low	A lot/Not difficult
Surgery, Anesthesia, and Perioperative Medicine					
Preoperative checklists and anesthesia checklists to prevent a number of operative safety events, such as surgical site infections and wrong site surgeries; in-depth review	Common/Moderate	High	Negligible	Low	A lot/Moderate
The use of ACS-NSQIP report cards and outcome measurements to decrease perioperative morbidity and mortality; in-depth review	Common/High	Moderate-to-high	Low	Moderate	Moderate/Moderate
New interventions to prevent surgical items from being left inside a patient; brief review	Rare/Low	Low	Negligible	Low if it simply involves more frequent manual counting; high if RFID is used	Little
Operating room integration and display systems, such as a centralized display of consolidated data; brief review	Common/Low-to-high	Low	Negligible	Moderate	Moderate/Moderate

Table 1, Chapter 44. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Use of beta blockers to prevent perioperative cardiac events; brief review	Common/High	High evidence harms may equal or exceed benefits	High (death, stroke, hypotension, and bradycardia)	Low	NA
Use of real-time ultrasound guidance during central line insertion to increase the proportion correctly placed on the first attempt; brief review	Common/Low-to-moderate	High	Negligible	Low-to-moderate	A lot/Moderate
Safety Practices for Hospitalized Elders					
Multicomponent interventions to prevent in-facility falls; in-depth review	Common/Low	High	Moderate (increased use of restraints and/or sedation)	Moderate	Moderate/Moderate
Multicomponent interventions to prevent in-facility delirium; in-depth review	Common/Low	Moderate	Low	Moderate	Moderate/Moderate
General Clinical Topics					
Multicomponent initiatives to prevent pressure ulcers; in-depth review	Common/Moderate	Moderate	Negligible	Moderate	Moderate/Moderate
Inpatient, intensive, glucose control strategies to reduce death and infection; in-depth review	Common/Moderate	Moderate-to-high evidence it doesn't help	High (hypoglycemia)	Low-to-moderate	NA
Interventions to prevent contrast-induced acute kidney injury; in-depth review	Common/Low	Low	Negligible	Low	Little/Not difficult
Rapid-response systems to prevent failure-to-rescue; in-depth review	Common/High	Moderate	Low	Moderate	Moderate/Moderate
Medication reconciliation supported by clinical pharmacists; in-depth review	Common/Low	Moderate	Low	Moderate	Moderate/Moderate
Identifying patients at risk for suicide; brief review	Rare/High	Low	Low	Moderate	Little/Moderate
Strategies to prevent stress-related gastrointestinal bleeding (stress ulcer prophylaxis); brief review	Rare/Moderate	Moderate	Moderate (pneumonia)	Moderate	Little/Not difficult
Strategies to increase appropriate prophylaxis for venous thromboembolism; brief review	Common/Moderate	High	Moderate (bleeding)	Low	Little/Moderate
Preventing patient death or serious injury associated with radiation exposure from fluoroscopy and computed tomography through technical interventions, appropriate utilization, and use of algorithms and protocols; brief review	Rare/High	Moderate	Negligible	Low	Moderate/Not difficult

Table 1, Chapter 44. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Ensuring documentation of patient preferences for life-sustaining treatment, such as advanced directives; brief review	Common/Moderate	Moderate	Low	Low	Moderate/Moderate
Increasing nurse-to-patient staffing ratios to prevent death; in-depth review	Common/High	Moderate	Low	High	A lot/Not difficult
Practices Designed To Improve Overall System/Multiple Targets					
Increasing nurse-to-patient staff ratios to prevent falls, pressure ulcers, and other nursing sensitive outcomes (other than mortality); in-depth review	Common/High	Low	Low	High	A lot/Not difficult
Incorporation of human factors and ergonomics in the design of health care practices by hiring an expert or training clinicians in human factors; in-depth review	Potentially applicable to all patient safety problems	Not assessed systematically, but moderate-to-high evidence for some specific applications	Negligible	Moderate	A lot/Moderate
Promoting engagement by patients and families to reduce adverse events (such as patients encouraging providers to wash their hands); in-depth review	Common	Emerging practice (few studies available)	Uncertain	Low	Little/Moderate
Interventions to promote a culture of safety; in-depth review	Common/Low-to-high	Low	Uncertain	Low-to-moderate (varies)	Moderate/Not difficult-to-moderate (varies with intervention)
Patient safety practices targeted at diagnostic errors; in-depth review	Common/High	Emerging practice (few studies available)	Uncertain	Varies	Varies
Monitoring patient safety problems; in-depth review	Common/Low-to-high	Low	Negligible	High	Moderate/Difficult
Interventions to improve care transitions at hospital discharge; in-depth review	Common/Moderate	Low	Negligible	Moderate-to-high	Little/Difficult
Use of simulation-based training and exercises; in-depth review	Common/Moderate-to-high	Moderate-to-high for specific topics	Uncertain	Moderate	Moderate
Obtaining informed consent from patients to improve patient understanding of potential risks of medical procedures; brief review	Common/Moderate	Moderate	Negligible	Low	Moderate/Not difficult
Team-training in health care; brief review	Common/High	Moderate	Low	Moderate	Moderate/Moderate-to-difficult
Computerized provider order entry (CPOE) with clinical decision support systems (CDSS); brief review	Common/Moderate	Low-to-moderate	Low-to-moderate	High	Moderate/Difficult
Interventions to prevent tubing misconnections; brief review	Common/Moderate	Low	Low	Low	Moderate/Not difficult

Table 1, Chapter 44. Summary table* (continued)

Patient Safety Practice	Scope of the Problem Targeted by the PSP (Frequency/Severity)	Strength of Evidence for Effectiveness of the PSPs	Evidence or Potential for Harmful Unintended Consequences	Estimate of Cost	Implementation Issues: How Much do We Know?/How Hard Is it?
Limiting trainee work hours; brief review	Common/Moderate	Low	Moderate (at least); includes lack of training time	High	Moderate/Difficult

Abbreviations: ACS NSQIP=American College of Surgeons National Surgical Quality Improvement Program; NA = not available; PSP: Patient Safety Practice; RFID = radio-frequency identification.

*In some cases, the text in the “PSP” column differs slightly from the chapter heading for that PSP. This difference is attributable to our Technical Expert Panel’s desire to include the target safety problem (if the practice is in fact targeted at a specific safety problem), more specification, or an example of the PSP (e.g., adding “such as a centralized display of consolidated data” to the PSP designated as “operating room integration and display systems”).

Rating Scales:

Scope of the problem targeted by the PSP (frequency/severity): frequency = rare or common; severity = low, moderate, or high.

Strength of evidence for effectiveness of the PSPs: low, moderate, or high.

Evidence or potential for harmful unintended consequences: negligible, low, moderate, or high.

Estimate of cost: low, moderate, or high.

Implementation issues: How much do we know? = little, moderate, or a lot; How hard is it? = not difficult, moderate, or difficult.

One of the great challenges in measuring patient safety is determining whether to assess primary outcomes (“harms”), intermediate outcomes (“errors”) or processes (such as adherence to evidence-based safety practices). Each of these methods has advantages and disadvantages. Over the past few years, the safety field has increasingly emphasized primary outcomes (namely, harm measures), and the IHI Global Trigger Tool (GTT) has emerged as an increasingly popular method for such assessment. In fact, several studies using the GTT³⁻⁵ have come to the same disappointing conclusion: that rates of harm remain high and, at least in a group of North Carolina hospitals, did not improve during the first several years of the patient safety movement. Although the Global Trigger Tool has demonstrated better test characteristics than other outcomes-oriented methods of measuring safety, such as voluntary incident reports and the AHRQ Patient Safety Indicators,³ one of the main insights to have emerged from recent patient safety research is that multiple lenses are needed to get a broad, and true, view of progress in safety. Shojania has called this issue the “elephant of patient safety,” in that one gets a different view depending on what part one is looking at.⁶

Because of the limitations of outcome measures in patient safety, it is important that we continue to assess the degree to which we now understand and have implemented effective PSPs. The present report, conducted by many of the same investigators, as 2001’s “Making Health Care Safer” illustrates both the progress and the challenges in this area of safety research.

Over the past decade, we have achieved greater agreement on what constitutes evidence of effectiveness and the importance of implementation and context (this new understanding was codified in a prior AHRQ report, “Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria”⁷ and in the peer-reviewed articles that drew on this report).⁸⁻¹² In the current review, 20, or about half of the PSPs reviewed, had the strength of evidence for their effectiveness rated as at least “moderate,” which represents significant progress since 2001. The evidence base supporting implementation strategies is also improving. For 26 of the PSPs reviewed in the present report, we judged that there was at least moderate evidence about how to implement the practice; the area of implementation was so underdeveloped a decade ago that “Making Health Care Safer” did not even consider it.

However, for almost no PSPs do we understand with confidence the potential role that context plays in effectiveness. This area remains a major gap in our knowledge base about how to select and implement PSPs; and it is a particularly crucial gap as institutions and individuals try to implement “best practices,” and policymakers, accreditors, and payers seek to create incentives for implementation via transparency- or payment-related initiatives.

Priorities for Adoption of Patient Safety Practices

We identified sufficient evidence about effectiveness and implementation for our technical experts to judge that some PSPs are ready to be “strongly encouraged” for adoption by health care providers. Table 2 shows the “strongly encouraged” PSPs. For particular targets for which we discussed multiple PSPs, (such as catheter-associated urinary tract infection), the table describes a particular PSP or category of PSPs.

Table 2, Chapter 44. Strongly encouraged patient safety practices

- Preoperative checklists and anesthesia checklists to prevent operative and post-operative events
- Bundles that include checklists to prevent central line-associated bloodstream infections
- Interventions to reduce urinary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols
- Bundles that include head-of-bed elevation, sedation vacations, oral care with chlorhexidine, and subglottic-suctioning endotracheal tubes to prevent ventilator-associated pneumonia
- Hand hygiene
- “Do Not Use” list for hazardous abbreviations
- Multicomponent interventions to reduce pressure ulcers
- Barrier precautions to prevent healthcare-associated infections
- Use of real-time ultrasound for central line placement
- Interventions to improve prophylaxis for venous thromboembolisms

The conclusions in this report explicitly represent a combination of the available evidence with the judgment of our technical expert panelists interpreting that evidence.

Additional PSPs were judged by our technical experts as having sufficient evidence about effectiveness and implementation that they should be “encouraged” for adoption. Table 3 presents the “encouraged” PSPs.

Table 3, Chapter 44. Encouraged patient safety practices

- Multicomponent interventions to reduce falls
- Use of clinical pharmacists to reduce adverse drug events
- Documentation of patient preferences for life-sustaining treatment
- Obtaining informed consent to improve patients’ understanding of the potential risks of procedures
- Team training
- Medication reconciliation
- Practices to reduce radiation exposure from fluoroscopy and computed tomography scans
- Use of surgical outcome measurements and report cards, like the American College of Surgeons National Surgical Quality Improvement Program
- Rapid response systems
- Utilization of complementary methods for detecting adverse events/medical errors to monitor for patient safety problems
- Computerized provider order entry
- Use of simulation exercises in patient safety efforts

The 22 PSPs in Tables 2 and 3 represent practices that health care providers can consider for adoption now. This recommendation particularly applies to the 10 “strongly encouraged” practices in Table 2, which, at least in the judgment of our technical experts, providers have sufficient knowledge to implement and doing so will likely result in safer care. And while future evaluations will probably strengthen our knowledge base regarding how best to implement these practices to make them most effective, our technical experts believe that providers should not delay consideration of adopting these practices while waiting for more research: enough is known now to permit health care systems to move ahead.

Limitations

Because of limited resources and time, the current report does not cover the entire patient safety field, which has grown exponentially since the last report, both in the number of potential PSPs and in the amount of data about individual PSPs). We used an explicit and transparent process to select the PSPs we did evaluate, and our final list should include most PSPs of highest priority to policymakers and providers.

Secondly, we did not do in-depth reviews of all the PSPs. Again, in order to make the best use of the available time and resources, we tailored our methods to the needs of our stakeholders, targeting those PSPs of greatest interest (or for which there was perceived to be the most new information) for in-depth reviews; others received briefer reviews. It was crucial that the decisions about which PSPs would receive in-depth review and which would receive brief review were made by a broadly representative stakeholder committee. The in-depth reviews, while thorough, did not conform to all of the criteria in the 2011 IOM report, “Finding What Works in Health Care: Standards for Systematic Reviews,”¹³ nor all the criteria in the EPC Methods Guide (for example, we did not publicly post a protocol for each individual review). We used our collective experience as EPCs to adapt existing EPC methods that we judged best preserved the essence of a systematic review while allowing us to complete 18 in-depth reviews within 9 months and the available budget.

Additionally, over time, we will likely improve our methods for assessing evidence regarding how patient safety interventions affect health care processes and outcomes. The methods we used for this report incorporate new perspectives regarding the importance of implementation and context, which was the focus of the “Context Sensitivity” report; likewise, in the future, we can expect to increase our understanding of the interactions between multiple intervention, implementation, and organizational variables and how these influence safety outcomes. If future research reveals that these variables interact in ways that our current understanding of theory and logic models cannot explain, we will need to modify the methods of evaluating PSPs again.

Lastly, we relied on the judgment of our technical experts at every important step of the project: Therefore our results are as much a product of these judgments as of our systematic review methods. Hence, our results might be sensitive to the selection of particular experts on our technical expert panel. However, we mitigated this potential bias by including more than double the number of experts on our technical expert panel as we typically would for an EPC review, which allowed us to include a diverse set of stakeholders from the U.S., Canada, and the United Kingdom; from PSP developers and evaluators to patient safety policymakers to experts in design and evaluation methods. Rather than regarding the tight linkage between the needs of the stakeholders and the work of the EPCs as a limitation, we view it as a strength that increases the likelihood that the results of the review will be meaningful to providers, payors, and patients, and that the report’s results will lead to meaningful change.

Conclusions

In 2001, when we published “Making Health Care Safer,” the literature on PSPs was limited, for several reasons.

First, the dominant cognitive model for patient safety was that errors represented human lapses; thus, there seemed little to study. The key PSP, one might say with only slight hyperbole, was to admonish caregivers to be more careful next time.

Moreover, no business case existed for institutions or individuals to focus on patient safety, no public pressure was exerted to improve safety, and no research funding was available for safety studies. The fact that the literature on safety was relatively primitive was anything but surprising.

This picture changed completely over the ensuing decade. AHRQ’s Patient Safety Network, the organization’s main portal for safety literature, now lists more than 3000 research studies, with 400 of these deemed by the editors as “Classics.” Safety research receives substantial support from AHRQ and others, the business case for safety improvement has grown, and policymakers are intensely interested in safety research as they consider what they can do to promote safety.

We found evidence of this progress in our current review of the literature on patient safety. There are now over a dozen practices for which the evidence of effectiveness is strong or very strong, and data are emerging on the contextual factors that so often determine the outcome of implementation. With the Federal investment in safety (under the “Partnership for Patients”) of about \$1 billion, and an investment of more than 20 times that amount in information technology implementation, we are on the cusp of an exploding database of research on safety practices.

Yet recent studies of rates of harm have demonstrated how difficult improving safety really is and have caused policymakers and researchers to redouble their efforts to identify and implement safe practices in hospitals, nursing homes, and clinics. Individuals and institutions seeking to improve safety would do well to scrutinize the practices described in this report—widespread implementation is likely to save hundreds, if not thousands, of lives. It will also help us continue to refine our efforts to identify the factors associated with successful implementation of PSPs, and to pinpoint, and hopefully prevent, any unintended consequences.

Future Research Needs

Our technical expert panel judged the following topics to be high priority for future research:
General issues:

- Sufficient data about the costs of PSPs to support cost-effectiveness analyses or return-on-investment analyses
- More patient safety measures for ambulatory care
- Better measures of the major causes of harm

Specific PSPs that are the highest priority for future research:

- Interventions to improve care transitions at hospital discharge
- Medication reconciliation
- Multicomponent interventions to reduce falls
- Simulation methods
- Team training
- Use of human factors engineering and ergonomics in the design of health care practices

- Surgical outcome report cards
- Systems and decision aids to reduce diagnostic errors
- Measures to encourage a culture of patient engagement in patient safety

Some PSPs were not included in this review because they were not deemed sufficiently developed, and new PSPs will subsequently be developed. Thus a strategy of surveillance should be adopted regarding evidence on PSPs. Future research also requires advancing the “basic science” of safety measurement such as standardized methods for rare events and for evaluating studies that assess only process-related outcomes relative to those that assess patient outcomes.

Future Research Needs Specific to Context Sensitivity

As part of our project on developing criteria to assess context sensitive PSPs, we worked with this same panel of technical experts to determine future research needs with respect to context. They bear repeating here.

- 1. Developing and validating measures of patient safety culture.** Discussion at the panel meetings indicated that several technical experts considered patient safety culture to be the overarching important construct. This view may explain why patient safety culture received majority support as a high priority for future research, whereas research on leadership and teamwork measures did not. Specific suggestions for future research included:
 - a. Developing validated measures of cultural adaptability to change.
 - b. Assessing the potential distinction between a culture of safety, a culture of excellence, and organizational culture.
 - c. Establishing connections between aspects of patient safety culture and patient outcomes or processes of care.
 - d. Assessing correlations between measures.

Additionally several TEP members commented that teamwork and leadership are important concepts for which several measures are currently available. Several TEP members felt researchers should use these measures working to mature and build the evidence about this construct.

- 2. Developing criteria and recommendations for what constitutes “reporting the intervention in sufficient detail that it can be replicated.”** More precise criteria for how PSP interventions should be described warrant additional research. In particular, the guidance described here, along with that provided by Standards for Quality Improvement Reporting Excellence (SQUIRE) and the National Quality Forum (NQF), need to be evaluated. Doing so will help determine which PSP elements need to be described and in what detail in order to evaluate whether the PSP is truly effective. This also will help maximize the possibility of successful PSP replication with similar outcomes. Further research could also evaluate the effect of applying these draft criteria regarding PSP descriptions on the quality of PSP projects and published articles. Thoroughly describing PSPs also can help readers determine the relevance of an evaluation study to other PSPs or other contexts. For example, if a PSP requires an individual behavior change such as hand-washing, then knowing intervention details may help readers of the study assess whether the given results are relevant only to hand-washing interventions or if they could be applied to other types of PSPs requiring

individual behavior change. Knowing the details of the intervention also could help readers of the study determine how much the success of the PSP implementation depended on contextual issues (e.g., organization or teamwork).

3. Understanding the important items to measure and report on for implementation.

Experts consider having comprehensive information about implementation key to being able to replicate a PSP. However, little empirical evidence exists about what makes a description of the PSP adequate for reporting. Assessing what implementers need to know, if they are to be able to implement or adapt an intervention in their own settings, is critical. Most experts considered “understanding the important items to measure and report on for implementation” to be related to or even the same as “reporting the intervention in sufficient detail that it can be replicated.” This view suggests that the distinction between “the intervention” and “the implementation” may be an arbitrary line, and that ideal evaluations of PSP interventions need to consider the implementation as part of the intervention.

4. Developing a theory-based taxonomy or framework with which to describe and evaluate key elements of interventions, contexts, and targeted behaviors.

Although the current project made a promising start on meeting this need, progress in this area will require additional development to produce a taxonomy that would be both sufficiently broad based and flexible enough to be widely useful. Issues to be considered include whether a taxonomy is the preferable way to proceed, or whether a more useful strategy might be to create an explicit methodology that researchers could apply to specific problems and contexts. Yet another approach might be to devise an “assessment framework.” Some experts sounded cautionary notes on this topic. They reported that outpatient PSP research may be too new to apply a taxonomy at this stage. They also reported that a single “unified” taxonomy may not be sufficiently flexible for diverse PSPs, and multiple taxonomies may be needed in any case. The countervailing view to these cautionary notes was that the field would not be well-served by having a proliferation of taxonomies. Instead, they reported, what is needed is a coherent, sufficiently comprehensive taxonomy that can accommodate the challenges of the subject.

5. Refining a framework for assessing the strength of a body of evidence. The research team did developmental work on an adaptation of the GRADE and Evidence-based Practice Center (EPC) systems for assessing the strength of evidence across studies of a PSP. This work warrants further development.

6. Generating empirical evidence that the contextual factors identified in this project influence the success of the PSP. The research team acknowledges that most of the recommendations in the report have a thin empirical evidence base, which simply reflects the relatively immature state of research in this still relatively young field. Building a stronger evidence base will help future efforts at refining the recommendations presented here.

Future Methodological Needs

Despite over a decade of effort, there is little evidence that patient outcomes (broadly measured) have significantly improved. Yet there have been patches of success, generally focused on efforts to reduce one type of harm, usually using one method of improvement. For

example, efforts have focused on reducing blood stream infections, improving teamwork, or enhancing patient engagement.

If health care is to make significant improvements in patient safety, research should inform and guide these efforts, just as it has done in every other field. We have learned much about how to improve safety, yet we need to learn much more. Acquiring this knowledge will require investments in patient safety research, including “basic” methodological research. To date, investments in patient safety research have fallen far short of the magnitude of the problem.

To achieve progress in improving patient safety, research is needed in a number of areas:

- “basic” patient safety research to develop new tools and measures and ensure that the tool matches the problem;
- a larger number of valid measures of patient safety;
- better methods to measure context and how an intervention was implemented;
- methods to identify and provide the necessary skills, resources, and accountability (i.e., a safety management infrastructure) at each level of the health care system; and
- more effective and less burdensome methods of improvement so that clinicians, researchers, and administrators work on reducing all types of harms patients are at risk of suffering rather than a select few. Below we briefly discuss each of these.

Basic patient safety research. Largely driven by an appropriate desire to reduce patient harm from medical errors immediately, the field has often invested in quick fixes that may have lacked sufficient theory or validated evaluation tools. For example, although the need to evaluate context when implementing patient safety interventions is widely recognized, few validated instruments have been developed to accomplish this task. Just as the hundreds of thousands of deaths from heart disease or cancer each year inspire rather than obfuscate the need for basic research, so too should the large number of deaths from preventable harm. To improve patient safety, the Federal Government will need to invest in “basic” patient research, to diagnose different types of safety problems, to match the theories and methods to the type of problem, to better evaluate implementation efforts and their surrounding context, and to evaluate whether patient safety is indeed improving

The future research needed to advance the science of basic patient safety research was covered in “Context Sensitivity,”⁷ where this technical expert panel rated as highest priority topics such as “development of a theory-based taxonomy with which to describe and evaluate key elements of interventions, contexts, and targeted behaviors” and “understanding the important items to measure and report in implementation.”

Larger number and more valid tools to measure safety. Despite more than a decade of effort, the health care system remains unable to quantify the magnitude of preventable harm or to use valid tools to evaluate progress in improving patient safety over time or among provider organizations. Moreover, for most of the patient safety harms discussed in this report, the field lacks valid, broadly accepted definitions for—and the mechanisms to monitor—progress in reducing patient harm. Thus, despite significant efforts to improve patient safety over the last decade, no one—including patients, providers, researchers, payors, and policymakers—knows whether care is safer. The need for evaluation tools is urgent.

Better methods to measure context and to describe an intervention. In contrast to most clinical research interventions, patient safety interventions are iterative, evolve over time, are

context dependent, and are strongly influenced by the organizations in which they are implemented and the personnel involved. Both this report and “Context Sensitivity” have demonstrated that too often, the intervention is insufficiently described and the context is barely mentioned; the result is stalled learning and reduced generalizability. Research is needed to better understand how an intervention was implemented over time, the most salient iterations the intervention has undergone, and the critical contextual domains that may have supported or mitigated the improvement effort. For example, while leadership and teamwork are widely regarded as important in implementing patient safety interventions, the field lacks consensus both on how best to measure these domains and on a theory that explains how various domains of context support or hinder the success of an intervention.

The topics “more patient safety measures for ambulatory care” and “better measures of the major causes of harm,” which were judged as high priority by our technical expert panel, fall into this domain.

Methods to build a safety management infrastructure. Health care is largely organized around the care of individual patients, yet patient safety requires the management of populations of patients and accountability for complications. While physicians have profound individual accountability for their patients, especially for complications that are directly related to their care, their accountability often diminishes for complications less directly related to the care they provide, or complications that are influenced by the care of a care team or how care is organized; infections are an example of such complications.

If patient safety requires the management of a population of patients, an infrastructure should be in place to help monitor risks and prioritize interventions, to implement interventions, and to monitor progress. At multiple levels of a provider organization (clinic or unit; department or region; hospital or group practice), an infrastructure is needed to ensure that safety leaders have sufficient resources, skills, and accountabilities to improve safety. Little is known regarding the specifics of the infrastructure that is needed. Nevertheless, the existing infrastructure is largely underdeveloped.

Specifically, researchers and managers must determine how much physician, nurse, and other staff support are needed at each unit/clinic, department/groups of clinics, hospital/health system levels to ensure patient safety; what skills they need, and how they should be held accountable for the safety of the care provided. For example, if an employee’s job is to evaluate progress in patient safety, does he require training in clinical epidemiology? If an employee’s job is to implement interventions, does she require training in human factors engineering and implementation science? Finally, how will managers and researchers create a cascading accountability system in which unit and clinical leaders hold individual clinicians accountable, department or regional leaders hold unit/clinical leaders accountable, and hospital or health systems leaders hold department and regional leaders accountable. Although this type of infrastructure exists in other industries, little is known about its benefits and costs. Investments are needed to understand, implement, and evaluate a safety management infrastructure in health care.

The topic, “more data about the costs of patient safety practices,” which was judged high priority by our technical expert panel, falls into this domain.

More effective and efficient system interventions to reduce multiple, rather than single types of harm. Our technical expert panel strongly advocated for a systematic approach to

preventing harm and exploring the concept of mutually reinforcing practices that reduce many kinds of harm.

The Center for Medicare and Medicaid Services (CMS) is now embarking on an ambitious national effort to reduce 10 types of preventable harm. However, because of the burden of implementing the interventions, hospitals are generally selecting interventions to reduce only a subset of the harms. Yet most patients are at risk for all 10 harms and many others as well.¹⁴

In health care, too many improvement efforts rely on the heroism of clinicians rather than safely designed systems. In other industries, as the amount of information has increased, technological improvements are implemented, with the result that productivity and safety increase. Health care productivity remains flat and clinicians use technologies that generally do not talk to each other. For example, the infusion pump does not talk to a respiratory monitor. If such intercommunication occurred, a respiratory monitor would automatically shut off an infusion pump if a patient developed a dangerously low respiratory rate from an infusion of narcotics, a common cause of respiratory arrest. Preciously few examples exist of safe design in health care. Such an approach will require close collaboration with systems engineers.

Patient harms do not occur in isolation, and they are not independent. Rather, they are interdependent; thus, the solutions must be as well. Hospitalized patients are at risk for multiple complications. For example, a patient on a breathing machine after surgery is at risk for 9 of the 10 complications targeted for reduction by CMS (the tenth, which is an obstetric complication, would not apply in this case).

Complex patients suffer the same fate. Because these patients have a variety of chronic diseases, they are at risk for a variety of harms, yet few efforts have been undertaken to systematically reduce the risk for all types of harm.

Yet there is an alternative. Health care could more fully embrace systems engineering. The need to develop and demonstrate a system framework that addresses the universal and fundamental challenges in contemporary health care delivery remains a critical challenge. In the 2005 report, “Building a Better Delivery System—A New Engineering/Health Care Partnership,” the National Academy of Engineering (NAE) and the IOM noted:

a systems approach to healthcare delivery could transform the U.S. health care sector from an underperforming conglomerate of independent entities into a high-performance system in which every participating unit recognizes its interdependence and influence on every other unit...

Ideally, the new and improved health care delivery system should include: 1) an integrated, ubiquitous, distributed, responsive, expansive, flexible, affordable and resilient system; 2) personalized delivery facilitated by secure information flow and optimized information that runs smoothly, efficiently, and safely.

The IOM/NAE report highlighted the observation that health care is significantly under-engineered and called for greater input from systems engineers to make health care safer. Future research in patient safety needs to take a systems approach, focusing on all the harms a patient suffers, clarifying the therapies that may reduce harm, and ensuring that patients always receive them. This research could include three key areas: a focus on engaging patients and their families, ensuring patients receive therapies to reduce harm, and creating a learning and accountability system. Few examples of successful collaboration between engineering and medicine currently exist. One example of such a collaboration is the Systems Engineering

Initiative for Patient Safety (SEIPS) program at the University of Wisconsin-Madison, which brings human factors and systems engineers together with clinicians to work on solving complex patient safety problems.¹⁵ This model, developed by Carayon, views the work system as an interaction among people, tasks, tools and technologies, organization, and environment. Another example, occurring at Johns Hopkins University, involves a collaboration with the Johns Hopkins University Whiting School of Engineering, Applied Physics Laboratory, the School of Medicine, the Bloomberg School of Public Health, the Carey Business School, the School of Nursing, and the private sector. The purpose of this collaboration is to develop a model to eliminate preventable harm.

As a part of these collaborations, clinicians and researchers are exploring ways to apply systems engineering to patient safety. For example, providers might consider all potential harms of being hooked up to a breathing machine. The resulting list includes 9 of the 10 harms enumerated by CMS and several more, including patient-centered harms from loss of dignity, autonomy, and respect. The clinicians and engineers would then consider the tasks or treatments to prevent those harms and the barriers to performing those tasks and ultimately design a system that ensures patients receive the recommended therapies and monitors and improve performance.

For example, clinicians could be provided visual displays indicating when a treatment is due and when it has been completed. As discussed above, at present, few of the technologies responsible for care processes are integrated: these technologies, which include the medical devices including the bed, the ventilator, the infusion pump, the monitors, and the electronic health record, do not communicate. Research into how to better integrate systems engineering into health care could help improve safety and allow clinicians and managers to work on preventing all types of patient harm.

A part of adopting a systems approach dictates including patients and their families. Patients and their families are an integral part of the health care system, yet often, are not adequately engaged or provided with sufficient information. Future research needs to explore how best to engage and activate patients to help improve safety and how best to view patients as an integral part of the health care system.

Efforts to improve patient safety are often fragmented into specific clinical or academic disciplines. While each approach and method is necessary, it is unlikely any one, by itself, will be sufficient to address the entire patient safety problem and reduce all types of harms. These “systems” approaches that link clinicians, human factors and systems engineers, social scientists, health services researchers, informatics specialists, economists, and biostatisticians, offer hope for realizing broad improvements in patient safety. Although such diverse groups pose management challenges, they have enormous potential to rebuild the health care system, which remains largely broken. If we are to make progress, science must guide us, an endeavor that will require investments in patient safety research. The research agenda outlined above may point health care in the right direction.

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Abbreviations/Acronyms

AAGBI	Association of Anaesthetists of Great Britain and Ireland
AANA	American Association of Nurse Anesthetists
AAPM	American Association of Physicists in Medicine
ACCP	American College of Chest Physicians
ACGME	Accreditation Council for Graduate Medical Education
ACR	American College of Radiology
ACS NSQIP Project	American College of Surgeons National Surgical Quality Improvement Project
ADE	Adverse Drug Event
ADL	Activities of Daily Living
ADR	Adverse Drug Reaction
AE	Adverse Event
AHRQ	Agency for Healthcare Research and Quality
AIR	American Institute for Research
AMI	Acute Myocardial Infarction
AMSTAR	A measurement tool to assess systematic reviews
AORN	Association of periOperative Registered Nurses
APN	Advanced Practice Nurses
APOE4	Apolipoprotein E4
ARRA	American Recovery and Reinvestment
ASA	American Society of Anesthesiologists
ASATT	American Society of Anesthesia Technicians and Technologists
ASRT	American Society of Radiologic Technologists
AV	Audio/Video
BATS	Brain Attack Teams
BC/BS	Blue Cross/Blue Shield
BG	Blood Glucose
BIS	Bispectral Index
BMI	Body Mass Index
BPMH	Best Possible Medication History
BPOC	Barcode-Enabled Point of Care
C	Comparator
CAN-NSQIP	Canadian National Surgical Quality Improvement Collaborative
CAUTI	Catheter-Associated Urinary Tract Infections
cc	Milliliter
CCAs	Critical Care Areas
CCOT	Critical Care Outreach Team
CCT	Clinical Controlled Trial
CCTA	Cardiac Computed Tomography Angiography
CCU	Coronary Care Unit
CDC	Centers for Disease Control
CDC HICPAC Practices Advisory Committee	Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee
CDSS	Clinical Decision Support Systems
CHF	Congestive Heart Failure
CHG	Chlorhexidine

CI	Confidence Interval
CI-AKI	Contrast-induced Acute Kidney Injury
CKD	Chronic Kidney Disease
CLABSI	Central Line-Associated Bloodstream Infections
CMS	Centers for Medicare & Medicaid Services
CNA	Certified Nursing Assistant
CNS	Clinical Nurse Specialist
CPOE	Computerized Provider Order Entry
CPRS	Computerized Patient Record System
CPSI	Canadian Patient Safety Institute
CRBSI	Catheter-related Bloodstream Infection
CRCPD	Conference of Radiation Control Program Directors
CRM	Crew Resource Management
CSO	Constant Special Observation
CSRS	Cardiac Surgery Reporting System
CSS	Computerized Surveillance System
CT	Computed Tomography
CTA	Computed Tomography Angiography
CTI	Care Transitions Intervention
CTPA	Computed Tomographic Pulmonary Angiography
CTSQC	Connecticut Surgical Quality Coalition
CUSP	Comprehensive Unit Based Safety Program
CVA	Cerebrovascular Accident
CVC	Central Venous Catheters
CWOCN	Certified Wound Ostomy Continence Nurse
DEER	Diagnostic Error Evaluation and Research
DERS	Dose Error Reduction System
DM	Diabetes Mellitus
DNR	Do Not Resuscitate
DoD	Department of Defense
DRG	Diagnosis-Related Group
DVT	Deep Venous Thrombosis
EAST	Eastern Association for the Surgery of Trauma
EBA	European Board of Anesthesiology
EBP	Evidence-based Practices
ED	Emergency Department
eMARs	Electronic Medication Administration Records
EMR	Electronic Medical Record
EPC	Evidence-Based Practice Center
EPOC	Effective Practice and Organization of Care
ESA	European Society of Anesthesiology
FDA	Food and Drug Administration
FHA	Florida Hospital Association
FMEA	Failure Mode and Effects Analysis
FPTK	Fall Prevention Tool Kit
FSCI	Florida Surgical Care Initiative
FTE	Full Time Employment
FTE	Full-time Equivalent

GAO	Government Accountability Office
GI	Gastrointestinal
GRAM	Geriatric Risk Assessment Medguide
HAI	Hospital-associated Infections
HAPU	Hospital-acquired Pressure Ulcer
HAT	Heart Attack Team
HELP	Hospital Elder Life Program
HFE	Human Factors and Ergonomics
HFMEA	Healthcare Failure Mode and Effects Analysis
HH	Hand Hygiene
HICPAC	Healthcare Infection Control Practices Advisory Committee
HITEC	Health Information Technology for Economic and Clinical Health
HR	Hazard Ratio
HS	At Bedtime
HSOPS	Hospital Survey on Patient Safety
ICDSC	Intensive Care Delirium Screening Checklist
ICU	Intensive Care Unit
IEA	International Ergonomics Association
IHI	Institute for Healthcare Improvement
IIDs	Intelligent Infusion Devices
IIT	Intensive Insulin Therapy
INR	International Normalized Ratio
IOM	Institute of Medicine
IOCM	Iso-osmolar Contrast Media
ISMP	Institute for Safe Medication Practices
ISQIC	Illinois Surgical Quality Improvement Collaborative
IT	Information Technology
IV	Intravenous
JC	Joint Commission
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KPNCRNC	Kaiser Permanente Northern California Regional NSQIP Collaborative
kV	Kilovolts
LEB	Lower Extremity Bypass
LEP	Limited English Proficiency
LMWH	Low Molecular Weight Heparins
LVN	Licensed Vocational Nurses
MCR	Manual Chart Review
MCSQC	Mayo Clinic Surgical Quality Consortium
MDS	Minimum Data Set
MET	Medical Emergency Team
MHCS	Making Health Care Safer
MICU	Medical Intensive Care Unit
MRSA	Methicillin-Resistant Staphylococcus Aureus
mSv	Millisievert
MS	Morphine Sulfate
MTT	Medical Team Training
NAAL	National Assessment of Adult Literacy
NAC	N-acetylcysteine

NCHS	National Center for Health Statistics
NCSQC	Northern California Surgical Quality Collaborative
NGC	National Guideline Clearinghouse
NHSN	National Healthcare Safety Network
NPSA	National Patient Safety Agency
NPSG	National Patient Safety Goal
NPUAP	National Pressure Ulcer Advisory Panel
NQF	National Quality Forum
NR	Not Reported
NS	Not Statistically Significant
NSAIDs	Non-steroidal Anti-inflammatory Drugs
NVASRS	National VA Surgical Risk Study
OEMs	Original Equipment Manufacturers
OR	Operating Room
OR	Odds Ratio
OSATS	Observed Structured Assessment of Technical Skills
PAC	Pre-Anesthesia Checkout
PACS	Picture Archiving and Communication Systems
PAE	Potential Adverse Event
PCA	Patient-Controlled Analgesia
PDA	Personal Digital Assistant
PDSA	Plan-Do-Study-Act
PE	Pulmonary Embolism
PGY	Post-graduate Year
PICC	Peripherally Inserted Central Catheters
POLST	Physician Orders for Life-Sustaining Treatment
PPACA	Patient Protection and Affordable Care Act
PPV	Positive Predictive Value
ProFaNE	Prevention of Falls Network Europe
PSC	Patient Safety Culture
PSCHO	Patient Safety Climate in Healthcare Organizations
PSP(s)	Patient Safety Practice(s)
PTT	Partial Thromboplastin Time
PU	Pressure Ulcer
QA	Quality Assurance
QD	Once Daily
QI	Quality Improvement
QM	Quality Measures
QS	Quality System
RCA	Root Cause Analysis
RCT	Randomized Controlled Trial
RED	ReEngineered Discharge Program
RFID	Radio-frequency Identification
RN	Registered Nurse
RR	Relative Risk
RR	Rate Ratio
RRS	Rapid Response System
RRT	Renal Replacement Therapy

RSNA	Radiological Society of North America
SAQ	Safety Attitudes Questionnaire
SCHA	The South Carolina Hospital Association
SCIP	Surgical Care Improvement Project
SCOAP	Surgical Care and Outcome Assessment Program
SCR	Surgical Clinical Reviewer
SCS	Safety Climate Scale
SHEA	Society for Healthcare Epidemiology of America
SHS	Summa Health System
SICU	Surgical Intensive Care Unit
SMD	Standardized Mean Difference
SQAN	Surgical Quality Action Network
SSI	Sliding Scale Insulin
STS	Society of Thoracic Surgery
SUD	Single-Use Devices
SURPASS	SURgical PATient Safety System
T	Treatment
TBD	To Be Determined
TCPS	Tennessee Center for Patient Safety
TEP	Technical Expert Panel
TIA	Transient Ischemic Attack
TIW	Three Times A Week
TSA	Team Situation Awareness
TSQC	Tennessee Surgical Quality Collaborative
TURP	Transurethral Resection of the Prostate
U	Units
U.K.	United Kingdom
U.S.	United States
UCSF	University of California, San Francisco
UHC	University Health System Consortium
UP	Universal Protocol
VA	Veterans Affairs
VAP	Ventilator Associated Pneumonia
VRE	Vancomycin-Resistant Enterococci
VRSA	Vancomycin-Resistant S. Aureus
VTBI	Volume-To-Be-Infused
VTE	Venous Thromboembolism
WHO	World Health Organization
WOCN	Wound, Ostomy and Continence Nurses Society
WON	Wound Ostomy Nurse

Appendix A. Original List of Patient Safety Practices

PSPs From Making Health Care Safer (MHCS—2001 AHRQ Report)

Computerized physician order entry (CPOE) with clinical decision support system (CDSS) (Medication errors and adverse drug events (ADEs) primarily related to ordering process)

Clinical pharmacist consultation services (Medication errors and ADEs related to ordering and monitoring)

Use of computer monitoring for potential ADEs (ADEs related to targeted classes (analgesics, KCl, antibiotics, heparin) (focus on detection))

Monitoring for patient safety problems (more general topic of monitoring)

Protocols for high risk drugs: nomograms for heparin (Adverse events related to anticoagulation)

Anticoagulation services and clinics for coumadin⁸ (Adverse events related to anticoagulation)

Patient self- management using home monitoring devices (Adverse events related to chronic anticoagulation with warfarin)

Unit-dosing distribution system (ADEs in dispensing medications)

Use of automated medication dispensing devices (ADEs in drug dispensing and/or administration)

Improved hand washing compliance (via education/behavior change; sink technology and placement; washing substance) (Hospital-acquired infections)

Barrier precautions (via gowns & gloves; dedicated equipment; dedicated personnel) (Serious nosocomial infections (e.g., vancomycin- resistant enterococcus, *C. difficile*))

Hospital-acquired infections (overall topic)

Limitations placed on antibiotic use (Hospital-acquired infections due to antibiotic-resistant organisms)

Use of silver alloy- coated catheters (Hospital-acquired urinary tract infection)

Use of suprapubic catheters (Hospital-acquired urinary tract infection)

Bundles for central venous catheter-related blood infections (overall topic)

Use of maximum sterile barriers during catheter insertion (Central venous catheter-related blood infections)

Antibiotic- impregnated catheters (Central venous catheter-related blood infections)

Cleaning site (povidone-iodine to chlorhexidine) (Central venous catheter-related blood infections)

Changing catheters routinely (Central venous catheter-related blood infections)

Use of heparin (Central venous catheter-related blood infections)

Tunneling short- term central venous catheters (Central venous catheter-related blood infections)

Routine antibiotic prophylaxis (Central venous catheter-related blood infections)

Bundle for ventilator-associated pneumonia (overall topic)

Semi-recumbent positioning (Ventilator- associated pneumonia)

Continuous oscillation (Ventilator- associated pneumonia)

Continuous aspiration of subglottic secretions (CASS) (Ventilator- associated pneumonia)

Selective decontamination of digestive tract (Ventilator- associated pneumonia)

Sucralfate (Ventilator- associated pneumonia)

Localizing specific surgeries and procedures to high volume centers (Mortality associated with surgical procedures)

Surgical checklists (overall topic)
Appropriate use of antibiotic prophylaxis (Surgical site infections)
Maintenance of perioperative normothermia (Surgical site infections)
Use of supplemental perioperative oxygen (Surgical site infections)
Perioperative glucose control (Surgical site infections)
Use of real-time ultrasound guidance during central line insertion (Morbidity due to central venous catheter insertion)
Counting sharps, instruments, sponges (Surgical items left inside patient)
Use of preoperative anesthesia checklists (Complications due to anesthesia equipment failures)
Intraoperative monitoring of vital signs and oxygenation (Critical events in anesthesia)
Use of perioperative beta- blockers (Perioperative cardiac events in patients undergoing noncardiac surgery)
Fall prevention (overall topic)
Use of identification bracelets (Falls)
Interventions to reduce the use of physical restraints safely (Restraint-related injuries; Falls)
Use of bed alarms (Falls)
Use of special flooring material in patient care areas (Falls and fall- related injuries)
Use of hip protectors (Falls and fall injuries)
Use of pressure relieving bedding materials (Pressure ulcers)
Multi-component delirium prevention program (Hospital-related delirium)
Geriatric consultation services (Hospital-acquired complications (e.g., falls, delirium, functional decline, mortality))
Geriatric evaluation and management unit (Hospital-acquired complications (functional decline, mortality))
Appropriate VTE prophylaxis and methods for implementation (broader topic)
Appropriate VTE prophylaxis (Venous thromboembolism (VTE))
Risk assessment and prevention of contrast-induced renal failure (overall topic)
Use of low osmolar contrast media (Contrast-induced renal failure)
Hydration protocols with theophylline (Contrast-induced renal failure)
Hydration protocols with acetylcysteine (Contrast-induced renal failure)
Various nutritional strategies (Morbidity and mortality in post- surgical and critically ill patients)
H₂-antagonists (Stress-related gastrointestinal bleeding)
Education interventions and continuous quality improvement strategies (Clinically significant misread radiographs and CT scans by non- radiologists)
Methods to increase pneumococcal vaccination rate (Pneumococcal pneumonia)
Use of analgesics in patients with acute abdomen without compromising diagnostic accuracy (Inadequate pain relief in hospital patients with abdominal pain)
Pain management (overall topic)
Acute pain service (Inadequate pain relief)
Non- pharmacologic interventions (e.g., relaxation, distraction) (Inadequate postoperative pain management)
Change in ICU structure—active management by intensivist (Morbidity and mortality in ICU patients)
Changes in nursing staffing (Morbidity and mortality)
Promoting a culture of safety (Any safety problem amenable to culture)

Use of human factors principles in evaluation of medical devices (Medical device related adverse events)

Refining performance of medical device alarms (e.g., balancing sensitivity and specificity of alarms, ergonomic design) (Adverse events)

Transitions in care (broader topic)

Information transfer between inpatient and outpatient pharmacy (Adverse events related to discontinuities in care)

Handoff protocols (broader topic)

Standardized, structured sign- outs for physicians (Adverse events during cross- coverage)

Use of structured discharge summaries (Adverse events related to information loss at discharge)

Protocols for notification of test results to patients (Failures to communicate significant abnormal results (e.g., pap smears))

Use of bar coding (Adverse events due to patient misidentification)

“Sign your site” protocols (Performance of invasive diagnostic or therapeutic procedure on wrong body part)

Team training (broader topic)

Application of aviation style crew resource management (e.g., Anesthesia Crisis Management; MedTeams) (Adverse events related to team performance issues)

Simulator-based training (Adverse events due to provider inexperience or unfamiliarity with certain procedures and situations)

Limiting individual provider’s hours of service (Adverse events related to fatigue in health care workers)

Fixed shifts or forward shift rotations (Adverse events related to fatigue in health care workers)

Napping strategies (Adverse events related to fatigue in health care workers)

Specialized teams for inter-hospital transport (Adverse events due to transportation of critically ill patients between health care facilities)

Mechanical ventilation (Adverse events due to transportation of critically ill patients within a hospital)

Asking that patients recall and restate what they have been told during informed consent (Missed, incomplete or not fully comprehended informed consent)

Use of video or audio stimuli (Missed, incomplete or not fully comprehended informed consent)

Provision of written informed consent information (Missed, incomplete or not fully comprehended informed consent)

Computer- generated reminders to discuss advanced directives (Failure to honor patient preferences for end-of-life care)

Use of physician order form for life- sustaining treatment (POLST) (Failure to honor patient preferences for end-of-life care)

Additional PSPs From Our Prior Project and Updated Review of NQF, Joint Commission, IHI, Leapfrog, PSNet Taxonomy, Other Suggestions From Team

Universal protocol/preoperative checklist (Wrong-site surgery, perioperative infections)

Rapid response teams

Medication reconciliation and process redesign (Medication errors- wrong medication or dose)

Non-reimbursable serious reportable events (i.e., do not pay for never events) (CMS)

Do not use abbreviations, acronyms, symbols, and dose designation campaign (education/campaigns, removal from forms, audit/feedback) (Medication errors – wrong medication) (Joint Commission)

Read back or computerized system (verbal or telephone orders or critical test results) (Medication errors,

Implement a standardized process to ensure that critical results are communicated quickly to a licensed healthcare provider so that action can be taken. (NQF)

Adverse event reporting

Periodic inspection of medication storage areas (Medication errors – use of contaminated drugs)

Drug labeling (Medication errors – dispensing)

Institute protocols for managing Look Alike, Sound Alike Medications; standard methods for labeling and packaging medications (Medication errors – dispensing, administration) (NQF)

Identify all high-alert drugs, and establish policies and processes to minimize the risks associated with the use of these drugs. (NQF)

Identifying patients at risk for suicide (Patient suicide or attempted suicide) (NQF)

Immunize healthcare workers and patients who should be immunized against influenza (Nosocomial influenza)

Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event (NQF)

Ensure that written documentation of the patient’s preferences for life-sustaining treatments is prominently displayed in his or her chart (NQF)

Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time. (NQF)

Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes. (NQF) –protocols and order sets

When CT imaging studies are undertaken on children, “child-size” techniques should be used to reduce unnecessary exposure to ionizing radiation (NQF)

Institutional safety plan (NQF, PSNet)

Health literacy improvement (PSNet)

Hospitalists (PSNet)

Discharge interventions (care transition interventions, Project Red, calling patients after discharge, etc) (Preventable readmissions)

Techniques to prevent diagnostic errors (teaching heuristics/meta-cognition; artificial intelligence programs)

Red Rules/Stop the Line (Rules that must be followed to the letter- any deviation from a red rule will bring work to a halt until compliance is achieved)

Environmental modifications for health care workers, e.g., quiet place for nurses to mix meds (Medication errors – administration)

Patient engagement strategies (patients questioning their providers; patients on safety committees)

Unit based safety teams

Executive walk rounds

Bundles and checklists as a general strategy (not just for specific indications)

Methods for reducing inappropriate prescribing in the elderly
Cognitive aids as more general strategy –simulations, debriefings
Protocols for standardizing/improving patient transitions/handoffs as a broader category
CT dosage adjustments for height/weight/sex
(Excessive diagnostic imaging increasing lifetime cancer risks)
Evaluating whether diagnostic imaging studies are actually warranted or can be done through non-radiation-based modality (Excessive diagnostic imaging increasing lifetime cancer risks)
Public health messages about harms of over diagnosis
Physician-patient discussion/education about appropriate scenarios for testing (Risks from unnecessary cancer screening)
Institutional algorithms to ensure testing occurs in patients with risk factors for disease (to prevent high number of false positives) (Risks from unnecessary cancer screening)
Review of hospital staffing patterns, nurse-to-patient ratios, physician handovers (Increased morbidity and mortality associated with hospital care on weekends and in evenings) (may be related to work hours, shift work)
Education of hospital staff to be aware of possible changes in care during these time periods (Increased morbidity and mortality associated with hospital care on weekends and in evenings)
Algorithms to determine if patients truly require prophylaxis on admission
Reducing non-indicated prescribing prior to discharge (Harms of inappropriate use of acid-suppressing medications)
Protocols and order sets (Risks from inappropriately dosed chemotherapy)

New Potential Device-Related Technologies (Some Overlap With List Above)

Free-flow protection in IV's (Medication error- administration – prevent overdose)
Smart pumps (Medication errors – wrong dose, wrong drug)
Radiofrequency identification (RFID) tags (Retained foreign bodies following surgery)
Dose reduction technologies for CT systems to prevent unnecessary radiation exposure
Processes related to reprocessing single-use medical devices (Healthcare associated infections) – *1.6
Remote monitoring of ICU patients by critical care physicians (Reduce in-hospital mortality and/or complications from cardiac events)
Operating room (OR) data integration and display systems (Surgical adverse events resulting from lack of availability of critical patient information and access to intraoperative consults from remote providers)
Robot assisted surgery (Reduce surgical complications)
Color-coded patient wristbands (Apprise staff of patient risk factors for adverse events and to reduce risk of inappropriate care)
Device-related strategies for preventing tubing misconnections (e.g., labeling lines, color coding) (Adverse events related to tubing misconnections (e.g., connecting drains to nasogastric tubes))
IV infiltration alarms to prevent infiltration/extravasations (Complications from intravenous therapy)
Patient lift devices (Falls and caregiver injury)
Environmental modifications to prevent patient self-harm (e.g., hinge less door systems) (Reduce suicide or other self-harm)
Active electrode monitoring for laparoscopic electro surgery (Perioperative burns)

Air embolism detection devices for CT contrast injectors (Pulmonary emboli)
Alarm integration systems (Adverse events related to caregiver response time to patients in need of assistance)
Electro surgery return electrode contact quality monitors (Perioperative burns)
Endoscope reprocessors (Healthcare-associated infections)
Ferromagnetic detectors in MR suites (Patient and provider injury from metal objects being drawn into the MRI bore)
Laser resistant endotracheal tubes (Surgical fire)
Surgical and exam gloves (i.e., to prevent infection from clinician to patient)
RFID-type tracking of patient location (e.g., for wandering) (Wandering and elopement in patients/residents with dementia, or infant abduction)
Treatment planning systems for radiation therapy (Radiation under/overdoses)
Use of Vocera-style communication devices for alarm notification (Adverse events related to caregiver response time to patients in need of assistance)

Appendix B. AMSTAR: A Measurement Tool To Assess Systematic Reviews

Additional File 1 – AMSTAR*

<p>1. Was an ‘a priori’ design provided? The research question and inclusion criteria should be established before the conduct of the review.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>7. Was the scientific quality of the included studies assessed and documented? ‘A priori’ methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

<p>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

*The AMSTAR criteria was taken from Shea et al, 2007 "Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews." BMC Med Res Methodol 7: 10.

Appendix C. Literature Searches and Topic-Specific Methods

Chapter 3. High-Alert Drugs: Patient Safety Practices for Intravenous Anticoagulants

SECTION A. Literature Search

SEARCH METHODOLOGY

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2000-11/4/2011

LANGUAGE:

English

SEARCH STRATEGY #1:

Heparin

AND

intravenous OR infusion

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” OR “medication errors/prevention and control” OR “Medical Errors/adverse effects” OR “Safety Management” OR “Cross Infection/prevention and control” OR “infection control” OR error*[tiab] OR safe*[tiab] OR overdos* OR adverse[tiab] OR ((infection OR infections OR iatrogenic) AND (prevent OR prevention OR preventive OR preventing)) OR protocol* OR nomogram* OR “inpatient coagulation service” OR “inpatient coagulation services” OR “human factors” OR “decision support”

NUMBER OF RESULTS: 908

SEARCH STRATEGY #2:

“Heparin/adverse effects”[Mesh] OR “Heparin/contraindications”[Mesh] OR

“Heparin/injuries”[Mesh] OR “Heparin/poisoning”[Mesh] OR “Heparin/toxicity”[Mesh]

AND

intravenous OR infusion*

NOT

Results of Search #1

NUMBER OF RESULTS: 432

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

Embase – 2000-11/18/2011

LANGUAGE:

English

SEARCH STRATEGY:

'intravenous heparin' OR heparin NEAR/5 infus*

AND

error* OR 'cross infection' OR 'infection control' OR safe* OR overdos* OR adverse OR (infection OR infections OR iatrogenic AND (prevent OR prevention OR preventive OR preventing)) OR protocol* OR nomogram* OR 'inpatient coagulation service' OR 'inpatient coagulation services' OR 'human factors' OR 'decision support'

AND

'article'/it OR 'article in press'/it OR 'conference abstract'/it OR 'conference paper'/it OR 'review'/it

NUMBER OF RESULTS: 791

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane – 2000-11/21/2011

LANGUAGE:

English

SEARCH STRATEGY:

"heparin AND (intravenous OR infusion) in Title, Abstract or Keywords

AND

adverse OR Error* OR Safe* OR overdos* OR ((infection OR infections OR iatrogenic) AND (prevent OR prevention OR preventive OR preventing)) OR protocol* OR nomogram* OR "inpatient coagulation service" OR "inpatient coagulation services" OR "human factors" OR "decision support" in Title, Abstract or Keywords

NUMBER OF RESULTS: 803 (Cochrane Reviews [11], Other Reviews [4], Clinical Trials [781], Methods Studies [1], Economic Evaluations [6])

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

CINAHL – 2000-11/21/2011

LANGUAGE:

English

SEARCH STRATEGY:

heparin AND (intravenous OR infusion)

AND

adverse OR Error* OR Safe* OR overdos* OR ((infection OR infections OR iatrogenic) AND (prevent OR prevention OR preventive OR preventing)) OR protocol* OR nomogram* OR “inpatient coagulation service” OR “inpatient coagulation services” OR “human factors” OR “decision support”

NUMBER OF RESULTS: 269

SECTION B. Methods

PICOTS

Elements	
Population	Patients in inpatient healthcare settings (adult and pediatric)
Intervention	Any intervention with a goal to improve safety of intravenous heparin administration
Comparator	Usual practice
Outcomes	Effectiveness of the intervention
Timing	Before and after the intervention
Settings	Any inpatient setting

Inclusion/exclusion criteria:

No restrictions were made by language, country of study, or indication for use of heparin.

Chapter 4. Clinical Pharmacist’s Role in Preventing Adverse Drug Events: Brief Update Review

SECTION A. Literature Search

SEARCH METHODOLOGY

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2000-10/19/2011

LANGUAGE:

English

SEARCH STRATEGY:

clinical pharmacist*

AND

adverse OR harm* OR side effect* OR safe* OR reaction*

NUMBER OF RESULTS: 320

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane Databases – 2000-10/24/2011

SEARCH STRATEGY:

clinical pharmacist*

AND

adverse OR harm* OR side effect* OR safe* OR reaction*

NUMBER OF RESULTS: 84

SECTION B. Methods

Titles and abstracts were reviewed by a physician health services researcher with experience in both systematic reviews and in clinical pharmacist services. Included studies were those most relevant to clinical pharmacist interventions on medication errors and adverse drug events in various health care settings. The focus was on studies that addressed the possible association between clinical pharmacist activities and improved prescribing practices and/or assessed whether such activities might lead to reduced medication errors and adverse drug events. Included studies were narratively summarized by the author.

Chapter 5. The Joint Commission’s “Do Not Use” List: Brief Review (NEW)

SECTION A. Literature Search**SEARCH METHODOLOGY****DATABASE SEARCHED & TIME PERIOD COVERED:**

PubMed – 2000-10/21/2011

LANGUAGE:

English

SEARCH STRATEGY:

abbreviation*

AND

safe* OR unsafe* OR adverse OR harm*

NUMBER OF RESULTS: 142

NUMBER OF RESULTS AFTER FILTERING FOR HUMAN ONLY AND REMOVING OTHER NON-RELEVANT REFERENCES: 71

SECTION B. Methods

Titles and abstracts were reviewed by a physician health services researcher with experience in both systematic reviews and in prescribing errors. The search was expanded by using Google to search for possibly pertinent articles and links; additional articles were identified by reference mining. The focus was on United States-based studies, since the “Do Not Use” list is a US regulatory issue. Clinical trials, observational studies, reviews, and anecdotal reports on

implementation were the primary resources and given priority in the order above. The synthesis was narrative.

Chapter 6. Smart Pumps and Other Protocols for Infusion Pumps: Brief Review (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
PubMed	2000 –November 8, 2011	National Library of Medicine
Cochrane Library	2000- November 9, 2011	Wiley
ECRI Institute website	2000- November 8, 2011	ECRI Institute
Health Devices	2000- November 9, 2011	ECRI Institute
Institute for Healthcare Improvement	2000-November 9, 2011	http://www.ihl.org
Joint Commission	2000-November 10, 2011	http://www.jointcommission.org/
Patient Safety Network	2000-November 9, 2011	Agency for Healthcare Research and Quality (AHRQ): http://psnet.ahrq.gov/
Pennsylvania Patient Safety Authority PASR (PA Safety Authority-patient safety reporting system)	2000-November 9, 2011	http://patientsafetyauthority.org/Pages/Default.aspx#

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute’s collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in PubMed syntax. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), and Keywords

Conventions:

PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract
- [ti] = keyword in title

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Infusion pumps	Infusion pumps[majr]	"infusion pump*" "smart pump*" "IV pump*" "drug delivery system" "drug infusion system" (infusion OR medication OR intravenous] OR "IV" OR drug OR smart) AND (pump] OR pumps])
Safety	medication errors[mh] safety[mh] safety management[mh] risk management[mh])	error* mistake* safe safety risk* malfunction* overdos* wrong

PUBMED

English language, human, remove overlap

Set Number	Concept	Search statement
1	Infusion pumps	infusion pumps[majr]
2		"infusion pump*" OR "smart pump*" OR "IV pump*" OR "drug delivery system" OR "drug infusion system"
3		infusion[ti] OR medication[ti] OR intravenous[ti] OR "IV"[ti] OR drug[ti] OR smart[ti] AND (pump[ti] OR pumps[ti])
5	Safety issues	medication errors[mh] OR safety[mh] OR safety management[mh] OR risk management[mh]
6		(error*[tiab] OR mistake*[tiab] OR safe[tiab] OR safety[tiab] OR risk*[tiab] OR malfunction*[tiab] OR overdos*[tiab] OR wrong[tiab])
7	Combine sets - Mesh headings	1 AND 5
8	Combine sets – keywords for in process citations (i.e. not yet indexed with MeSh headings and therefore not captured in set 7)	2 AND 6 AND (in process[sb] OR publisher[sb])
9	Combine sets – keywords in title (to ensure retrieval of any relevant records that were not picked up in the previous sets)	3 AND 6
10	Combine sets	7 OR 8 OR 9
11	Eliminate records on proton pump inhibitors	10 NOT proton*
12	Eliminate case reports, comments, editorials, letters, and news items	11 NOT (case reports[pt] OR comment[pt] OR editorial[pt] OR letter[pt] OR news[pt])
13	Apply limits	Human; English; with Abstract

Total Downloaded	Total Retrieved	Total Included
53	150	18

SECTION B. Methods

Titles and abstracts were reviewed by a health services research methodologist with experience in both systematic reviews and medical devices. Included studies were those most relevant to evaluation of smart pumps and related protocols for reduction of medication errors and adverse drug events in various health care settings. The focus was on studies that compared medication

error rates and adverse drug events following implementation of these technologies in hospitals compared to a control period when the technologies were not active or in place. Potential barriers to implementation (e.g. user compliance) were also assessed. Included studies were narratively summarized by the author.

Chapter 7. Barrier Precautions, Patient Isolation, and Routine Surveillance for Prevention of Healthcare-Associated Infections: Brief Update Review

SECTION A. Literature Search

A structured search of the PubMed database and review of the bibliographies of relevant articles identified 158 articles published from 2001 to 2011 that assessed barrier precautions for the prevention of health care-associated pathogen transmission. Search terms included “active surveillance,” “active detection,” and “contact precautions.” Few of these studies utilized the cluster randomized trial design and most were quasi-experimental studies. Low quality studies that did not include a control group were excluded from this review.

SECTION B. Methods

Titles and abstracts were reviewed by an epidemiologist with special expertise in health care-associated infections. An evidence table was constructed that included study design, population, setting, and the principal outcomes. The synthesis was narrative.

Chapter 8. Interventions To Improve Hand Hygiene Compliance: Brief Update Review

SECTION A. Literature Search

For this topic we did not do a formal literature search, as the principal reviews and trials were already known to the authors as part of their work on recent a recent report, where previous comprehensive searches had been performed to identify the most pertinent and up to date literature.

SECTION B. Methods

These reviews and studies were reviewed by a health services researcher and epidemiologist with expertise in hand hygiene quality improvement. The synthesis was narrative.

Chapter 9. Reducing Unnecessary Urinary Catheter Use and Other Strategies To Prevent Catheter-Associated Urinary Tract Infection: Brief Update Review

SECTION A. Literature Search

The 14 studies for the previously published systematic review and meta-analysis (Meddings et al, *Clin Infect Dis*, 2010) were obtained from a comprehensive search of the world’s literature for

interventions from 1950 to 2008 to decrease catheter-associated urinary tract infections by means of the MEDLINE and Cochrane databases (using Ovid), the PubMed Journals and Medical Subject Heading (MeSH) datasets, the ISI knowledge databases (Web of Science and Biosis Previews) and the CINAHL and EMBASE databases. The MEDLINE and Cochrane database searches were conducted by exploding and combining the following Medical Subject Heading (MeSH) terms: *urinary tract infection, urinary catheterization, indwelling catheter, inpatient, reminder system, device removal, intervention studies*. The MeSH *reminder system* was also searched separately. We included the following terms in a keyword search (with wildcard indicated with *): *urinary tract infection; ((urin* or uret*) and cath*) or catheter*; nosocomial or inpatient or hospital*; reminder, removal, and intervention*. We used similar strategies with the other databases. A research librarian provided guidance to improve search completeness. This search yielded 6679 citations, including many duplicate citations. As our initial search was broad and yielded many guidelines and reviews published regarding prevention of catheter-associated urinary tract infection, we also evaluated these articles' reference lists for additional studies; 1 additional reference was located in this manner. More detailed review was required for 118 articles to determine whether they met inclusion criteria. After applying inclusion and exclusion criteria to focus on human studies of adults admitted to acute care hospitals reporting at least one outcome involving catheter use or CAUTI events as a result of the intervention, and with a comparison group (either pre- versus post-intervention or a separate control group); this yielded 16 studies for further review. Two authors of the systematic review (J.M. and M.M.) independently reviewed and abstracted data from the 16 articles that appeared to meet inclusion criteria, including setting, study population, inclusion/exclusion criteria, definitions used, health outcomes, and quality issues. A third investigator (S.S.) resolved any differences in abstraction and reviewed the joint decisions made to exclude 2 of the 16 articles that no longer met inclusion criteria after further review. As a result, this systematic search in 2008 yielded the 14 articles reviewed in the previously published meta-analysis.

To update the prior literature search for *Chapter 9*, a search was performed of MEDLINE and Cochrane databases (using Ovid) and PubMed for intervention studies (published from August 2008 to February 2012) to reduce use of unnecessary urinary catheters in the acute care of adults, using the same detailed search strategy as employed in the 2008 search. Yet, unlike the 2008 search which was focused on removal of recently placed indwelling catheters (which excluded emergency environments), the patient population for the 2012 search was expanded to include emergency department patients because use of interventions to restrict initial placement was an additional topic of interest for *Chapter 9*. The 2012 search results were also supplemented with prior lists of articles excluded from the prior 2008 search that were focused on emergency department interventions. A secondary evaluation of the CINAHL database was also performed for interventions developed and implemented by nurses related to urinary catheter use. In light of the somewhat different terminology on the topic found in the nursing literature, we searched CINAHL using variations of the following terms: *reminder, removal, urinary catheter, nurse empowered, nurse directed, nurse protocol*. No date limits were employed in the CINAHL search, which retrieved 5 records. Overall, the MEDLINE and CINAHL searches yielded 479 citations, including 353 from MEDLINE through Ovid, 9 additional from PubMed, 117 from the Cochrane EBM databases, and 7 duplicates. Studies were included if at least one outcome involving catheter use or CAUTI events (Table 1 in *Chapter 9*) was reported as a result of the intervention with a comparison group. A review of reference lists for additional studies was also

performed, yielding one additional study. After applying inclusion and exclusion criteria to focus on human studies of adult patients with at least one outcome involving catheter use or CAUTI events reported as a result of the intervention, and with a comparison group, this updated search yielded 12 intervention studies published since the prior meta-analysis.

SECTION B. Methods

As summarized in the previously published meta-analysis for the 14 selected studies from 2008 or earlier, a systematic review process was performed. Correspondence with 24 authors was initiated to clarify details regarding the interventions and outcomes with responses received from 11 authors, and 4 authors provided unpublished numeric data necessary for statistical pooling. Two physician reviewers performed a detailed abstraction of the 14 studies. Details of the statistical analyses for obtaining the pooled effects are detailed in the prior published analyses, and were not replicated or expanded for writing *Chapter 9*.

A similar review and abstraction process was performed by one physician (J.M.) for the 12 recent articles in the updated search. No contact was initiated with authors, and these articles were analyzed and compared in a narrative process rather than a meta-analysis.

Details of the 14 prior and 12 recent studies are summarized in the Appendix Table for *Chapter 9*, regarding study design, patient population size and care environment, and details of the interventions used to either avoid inappropriate placement or to prompt removal of unnecessary catheters. Other important interventions that could possibly influence the outcomes of the studies were also summarized in this table. Important outcomes of the 14 prior studies as previously published in the meta-analyses were summarized in Figure 2; similar outcomes for the 12 recent studies were summarized in Figure 3.

Chapter 10. Prevention of Central Line-Associated Bloodstream Infections: Brief Update Review

SECTION A. Literature Search

DATABASES SEARCHED:

Medline Via Ovid
Cochrane Central Register of Controlled Trials Databases
Cochrane Database of Systematic Reviews
Cochrane Database of Abstracts of Reviews of Effects
Cochrane Methodology Register
Health Technology Assessment
NHS Economic Evaluation Database
ACP Journal Club

TIME PERIOD COVERED:

January 1, 2000 – January 1, 2012

LANGUAGE:

English language articles only

SEARCH STRATEGY:

Medical Subject Headings (MeSH) “Bacteremia” and “Catheterization, Central Venous,” and the MeSH subheadings “Prevention & control” and “Adverse effects,” as well as the keywords “central line-associated bloodstream infection,” “central line,” and “central venous catheter.” Search terms included variations of the keywords “bacteremia,” “bloodstream infection,” “central line,” “central venous catheter,” “prophylaxis,” and “prevention,” using wildcards and truncation to capture alternate spellings and endings.

NUMBER OF RESULTS:

1,087 unique manuscripts were retrieved by the search of which 337 articles were relevant for this report.

SECTION B. Methods

All relevant titles and abstracts were reviewed by a physician health services researcher (VC) with experience in both systematic reviews and in the topic of central line associated bloodstream infections (CLABSI). Studies included were those most relevant to prevention of CLABSI; in addition, studies that reported on local and national policies, economic impact and interventions associated with CLABSI reduction were included in this report.

Chapter 11. Ventilator-Associated Pneumonia: Brief Update Review

SECTION A. Literature Search

For this topic we did not do a formal literature search, as the principal reviews and trials were already known to the authors as part of their quality improvement work where previous comprehensive searches had been performed to identify the most pertinent and up to date literature.

SECTION B. Methods

These reviews and studies were reviewed by an intensive care unit physician health services researcher with clinical and quality improvement experience with ventilator-acquired pneumonia. The synthesis was narrative.

Chapter 12. Interventions To Allow the Reuse of Single-Use Devices: Brief Review (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
ECRI Institute members website	2001-November 3, 2011	ECRI Institute
Institute for Healthcare Improvement	2001-November 3, 2011	Institute for Healthcare Improvement
PSNet	2001-November 3, 2011	Agency for Healthcare Research and Quality
PubMed	2001-November 2, 2011	National Library of Medicine
FDA	2001-November 8, 2011	The Food and Drug Administration
JCAHO	2001-November 3, 2011	Joint Commission (JCAHO)
NCQA	2001-November 3, 2011	National Committee for Quality Assurance (NCQA)

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute’s collections were routinely reviewed. Non-journal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature as well as related citation searches using the Scopus database. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.) A number of organization websites were searched for relevant information, including: ECRI Institute members website, the Institute for Healthcare Improvement (ISI), and the Agency for Healthcare Research and Quality’s Patient Safety Network (PSNet).

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in PubMed syntax.

Medical Subject Headings (MeSH) and Keywords

Conventions:

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

- [pt] = publication type
 [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
 [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
 [tiab] = keyword in title or abstract

Topic Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Equipment	surgical instruments equipment and supplies disposable equipment	surgical medical cutting instrument* tool* equipment* device* trocar* scalpel* shaver* raz* drill* catheter* syringe* needle* mask* gown glove* endoscop* instrumentation
Reprocessing	equipment reuse	reuse reusing reus* reprocess reprocessing reprocessed reprocess* recycled recycling recycle* repurposed repurposing repurpose*
Single-Use		"single use" "single-use" disposable "one-time" "one time"

PubMed

English language, human, date limit: January 1, 2001-November 2, 2011

Set Number	Concept	Search statement
1	Equipment	surgical instruments[mh] OR equipment and supplies[mh] OR disposable equipment[mh] OR ((surgical[tiab] OR medical[tiab] OR cutting[tiab]) AND (instrument*[tiab] OR tool*[tiab] OR equipment* OR device*)) OR trocar*[tiab] OR scalpel*[tiab] OR shaver*[tiab] OR razor*[tiab] OR drill*[tiab] OR catheter*[tiab] OR syringe*[tiab] OR needle*[tiab] OR mask*[tiab] OR gown[tiab] OR glove*[tiab] OR endoscop*[ti] OR instrumentation[sh]
2	Reprocessing	equipment reuse[mh] OR reuse[tiab] OR reusing[tiab] OR reus*[tiab] OR reprocess[tiab] OR reprocessing[tiab] OR reprocessed[tiab] OR reprocess*[tiab] OR recycled[tiab] OR recycling[tiab] OR recycle*[tiab] OR repurposed[tiab] OR repurposing OR repurpose*[tiab]
3	Single Use	"single use"[tiab] OR "single-use"[tiab] OR disposable[tiab] OR "one-time"[tiab] OR "one time"[tiab]
4	Combine	S1 AND S2 AND S3

Total Downloaded	Total Retrieved	Total Included
75	11	15

SECTION B. Methods

Titles and abstracts were reviewed by a health services research methodologist with experience in both systematic reviews and medical devices. Included studies consisted of systematic reviews and clinical studies that compared patient outcomes following use of new versus reprocessed single-use devices as well as laboratory studies that tested an array of reprocessed single-use devices for microbiological contamination. Data regarding potential cost-savings of reprocessed single-use devices was also presented. Included studies were narratively summarized by the author.

Chapter 13. Preoperative Checklists and Anesthesia Checklists

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
EMBASE (Excerpta Medica)	1996 – August 23, 2011	OVID SP
MEDLINE	1996 – August 23, 2011	OVID SP
PreMEDLINE	1990 – August 23, 2011	OVID SP

Name	Date limits	Platform/provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	Searched June 10, 2011	EBSCOHost
Cochrane Library	Searched June 14, 2011	Wiley
PubMed	Searched August 17, 2011	National Library of Medicine
Scopus	Searched October 24, 2011	Science Direct

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute’s collections were routinely reviewed. Non-journal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature as well as related citation searches using the Scopus database. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE and MEDLINE. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree and Keywords

Conventions:

OVID

- \$ = truncation character (wildcard)
- exp = “explodes” controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary’s hierarchy)
- .de. or
- / = limit controlled vocabulary heading
- .fs. = floating subheading
- .hw. = limit to heading word
- .md. = type of methodology (PsycINFO)
- .mp. = combined search fields (default if no fields are specified)
- .pt. = publication type
- .ti. = limit to title
- .tw. = limit to title and abstract fields

PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Anesthesia	Anesthesia/ Anesthesiology/ Exp perioperative care/in, ae, mt, st	Analges\$ Anaesthe\$ Anesthe\$ Sedat\$
Checklist	Checklist/ World Health Organization/	Checklist\$ "safety checklist\$" Checkout Checkt-out "WHO" "world health" "*world health organization"
Context/Setting	Exp general surgery/ Exp perioperative care/ Exp surgical procedures, operative/ Operating room/ Operating rooms/	Intraoperat\$ Operat\$ Patient\$ operating room\$ intraoperat\$ Perioperat\$ Preoperat\$ or pre-operat\$ Perioperat\$ or peri-operat\$ Postoperat\$ or post-operat\$ Surg\$ Surgical suite\$
Equipment	Electronics, medical/ Equipment failure/ Equipment failure analysis/ is.fs.	Alarm\$ Apparatus Check-out or checkout Electronic checklist\$ Equipment Error\$ Failure fault Machine\$ Monitor\$ System\$
Hospital Procedures/Administration/Protocol	Anesthesia department, hospital/og, st Surgery Department, Hospital/og, st Operating Rooms/og, st Exp patient care/	Administrat\$ Organization\$ Patient care Patient safety Polic\$ Protocol\$ Standard\$
Incidence	Exp incidence/	Decrease\$ Incidence Prevalence Reduc\$ Number

Concept	Controlled Vocabulary	Keywords
Interventions	Checklist/ Intraoperative complications/pc Medical errors/pc Postoperative complications/pc Nursing staff, hospital/og, st, ut Exp Perioperative care/mt, og, st Exp Preoperative care/mt, st	Anesthesia adj2 check\$ "Anesthesia safety checklist" Checklist\$ Communicat\$ Document\$ Guideline\$ Implement\$ Information adj shar\$ Instrument\$ Knowledge "Missed step\$" Precaution\$ Practice\$ Preoperative Pre-op\$ proactive Postoperative procedure\$ Safety measure\$ Strateg\$ Surg\$ adj2 check\$ "Surgical safety checklist" Team briefing\$ Tool\$
Obstacles	Attitude/ Attitude of health personnel/ Exp Medical staff, hospital/ Nursing staff, hospital/og, st, ut	Anesthesiologist\$ Anesthetist\$ Attitude\$ Barrier\$ Competen\$ Educat\$ Gap\$ Knowledge Nurse\$ Obstacle\$ overload Resident\$ Resource\$ Surgeon\$ time Train\$
Organizational Culture	Health care delivery/ Organizational culture/	Change\$ Context\$ Culture\$ Direct\$ Hospital\$ Manage\$ Organization\$ Staff Team\$ Unit\$

Concept	Controlled Vocabulary	Keywords
Outcomes	Safety management/	Adverse event\$ Adverse effect\$ Cardiac arrest coma Complication\$ CPR Culture change\$ Death\$ Heart attack Infection\$ Injur\$ Myocardial infarction of "MI" Outcome\$ Patient safety Perform\$ Renal failure Resuscitat\$ Risk management sepsis Transfusion\$ Ventilat\$
Quality Management	Health care quality/ Total quality management/	Health\$ Healthcare\$ Hospital\$ Quality "TQM" Total quality management
Surgery	Exp surgical procedures, operative/ Exp general surgery/ Operating rooms/ su.fs.	Operat\$ operating room\$ Surg\$ Surgical suite\$

Embase/Medline/Premedline

English language, human, remove overlap

Set Number	Concept	Search statement
1	Anesthesia	(anesthesia/ OR anesthesiology/ OR (anaesthes\$ OR anesthes\$.ti,ab.) OR anesthesia department, hospital/og, st OR exp patient care/og, st
2	Context/Setting	operating rooms/ OR operating room/ OR exp perioperative care/in, ae, mt, st, og OR exp surgical procedures, operative/ OR exp general surgery/ OR su.fs. OR surgery department, hospital/og, st OR operating rooms/og, st OR exp patient care/og, st
3		((("OR" OR operating room\$ OR operat\$ OR surg\$ OR surgical suite\$.ti,ab.) OR ((pre?operative OR pre?op OR peri?operative OR pre?surgical OR intra?op\$.ti,ab.)
4	Combine sets for Anesthesia and Context/Setting	1 OR 2 OR 3
5	Patient Safety	patient safety/ OR (patient adj safety).ti,ab.
6		(safe\$ AND ((policy OR policies OR protocol\$ OR standard\$ OR administration OR organization) AND (anesthes\$ OR anaesthes\$)).ti,ab.
7		(safe\$ AND ((policy OR policies OR protocol\$ OR standard\$ OR administration OR organization) AND (surg\$ OR operate OR operating OR operative))).ti,ab.
8	Combine sets for Patient Safety	5 OR 6 OR 7

Set Number	Concept	Search statement
9	Equipment	((exp equipment failure/ OR electronics, medical/ OR is.fs.) AND check\$.ti,ab.) OR ((equipment or machine\$ OR apparatus OR system\$ OR monitor\$) AND (check\$ OR checklist OR check-out OR checkout)).ti,ab.
10		((anesthesia OR anaesthesia) AND simulation\$ AND check\$).ti,ab.
11	Combine sets for Equipment	9 OR 10
12	Incidence	exp incidence/ OR (decrease\$ OR incidence OR prevalence OR reduc\$ OR number\$).ti,ab. OR ((before and after) OR (preintervention OR preintervention OR pretest OR pre-test OR postintervention OR postintervention OR posttest OR post-test)).ti,ab.
13	Medical errors	medical errors/pc OR postoperative complications/pc OR ((error\$ OR complication\$ OR adverse event\$ OR "intraoperative awareness" OR wrong\$) AND (prevent\$ OR control)).ti,ab.
14	Staff	exp medical staff, hospital/ OR nursing staff hospital/og, st, ut OR attitude of health personnel/ OR attitude/ OR ((nurse\$ OR anesthetist\$ OR anesthesiologist\$ OR resident\$ OR surgeon\$) AND (knowledge OR attitude\$ OR competen\$ OR train\$ OR educat\$)).ti.
15	Safety checklists	("safety checklist\$" OR ((an?esthesia OR surg\$) adj2 check\$) OR ((surg\$ OR pre?surg\$ OR pre?op\$ OR peri?op\$ OR intra?op\$) AND (checkout\$ OR checkout\$))).ti,ab.
16		Checklist/
17	Combine for Checklists	15 OR 16
18	Safety management	safety/ OR safety management/ OR safety.ti,ab. OR ((preop\$ OR pre-op\$ OR periop\$ OR peri-op\$ OR pre?surg\$) AND (safety OR precaution\$)).ti,ab.
19	Combine sets for Safety Management and Patient Safety	8 OR 18
20	Total Quality Management	total quality management/ OR health care quality/ OR ((health\$ OR healthcare OR hospital\$) AND (quality OR "TQM" OR "total quality management")).ti,ab.
21	Organizational culture	health care delivery/ OR organizational culture/ OR ((organization\$ OR hospital\$ OR unit\$ OR team\$ OR staff) AND (culture\$ OR change\$ OR manage\$ OR direct\$ OR context\$)).ti,ab.
22	Combine sets for TQM and Staff attitudes and Organizational Culutre	14 OR 20 OR 21
23	World Health Organization checklist	(("world health organization/ OR "World Health Organization".ti,ab. OR "world health".ti,ab.) AND checklist\$.mp.)
24	Combine Context/setting and Checklists	4 AND 17
25	Combine Context/setting and Checklists with Medical Errors/pc	24 AND 13
26	Combine Context/Setting and Checklists with Incidence	24 AND 12
27	Combine Context/Setting and Checklists with Safety	24 AND 18
28	Combine	25 OR 26 OR 27
29	Combine Checklists and Equipment	11 AND 15
30	Combine with medical errors/pc and safety	29 AND (13 OR 19)
31	Combine Context/Setting and Checklists with TQM	24 AND 22
32	Combine concepts for Checklists	28 OR 30 OR 31

Set Number	Concept	Search statement
33	Combine with WHO checklist	32 OR 23
34	Combine for final set	32 OR 33
35	Apply limits	Limit 34 to yr="2000-2011"
36		Limit 35 to English language
37	Remove duplicates	Remove duplicates from 36

Total Downloaded	Total Retrieved	Total Included
459		

SECTION B. Methods

Patient safety problem: Preoperative checklists can help prevent errors and complications related to surgery. Checklists are often implemented within a multifactorial strategy of interventions, therefore they cannot be judged alone as a patient safety practice. The World Health Organization Surgical Safety Checklist is a prominent example of a preoperative checklist intended to ensure safe surgery and minimize complications; it has been translated into at least six languages.¹ One family of errors involves wrong site surgery (such as wrong procedure, wrong site, wrong person), and in 2004, the Joint Commission created the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.² It comprises three sets of steps: pre-operative verification process, marking the operative site, and a “time out” immediately before the operation. A checklist can be used to clarify the details of these three steps. For anesthesia checklists, in 2008 the American Society of Anesthesiologists provided general guidelines that should be checked before surgery, and institutions can implement the guidelines to tailor the checklist to their specific equipment and clinical setting.³

Proposed key questions

1. What is the evidence on the context and implementation of preoperative checklists in healthcare facilities?
2. What is the evidence on the adoption and diffusion of preoperative checklists in healthcare facilities?
3. What is the evidence on the effectiveness of preoperative anesthesia checklists in healthcare facilities?
4. What is the evidence on the context and implementation of preoperative anesthesia checklists in healthcare facilities?
5. What is the evidence on the adoption and diffusion of preoperative anesthesia checklists in healthcare facilities?

PICOTS Elements	Comments
Population	KQ1 and KQ2: Patients undergoing any surgery. KQ3, KQ4, and KQ5: Patients undergoing any surgery involving general anesthesia.
Intervention	Preoperative checklist, either electronic or hard-copy. KQ1 and KQ2: For a preoperative checklist addressing surgical safety in general, we examined in detail the World Health Organization Surgical Safety Checklist. For preoperative checklist specifically designed to implement the Universal Protocol and prevent wrong-site surgery, any checklist. KQ3, KQ4, and KQ5: For anesthesia, it must have been an equipment checklist prior to administering general anesthesia before surgery
Comparison	KQ1 and KQ2: No comparison required to be reported, but we extracted information on comparisons that were made. KQ3, KQ4, and KQ5: Not using a checklist, or a different checklist.
Outcomes	KQ1 and KQ2: No health outcomes necessary to be reported (because these questions do not involve effectiveness), but we extracted information on outcomes that were reported KQ3, KQ4, and KQ5: Rates of intraoperative awareness, any equipment complications, intraoperative patient complications, postoperative patient complications
Timing	Only examined postoperative events within one month of surgery, because later events are less likely to have been caused by the surgery itself.
Settings	Hospitals and surgical centers

Inclusion criteria:

General inclusion criteria: Full article published in a peer-reviewed journal, Abstracts will be excluded, English language publications only, published in 2000 or later, preoperative checklist (either electronic or hard-copy), surgery at either a hospital or a surgical center.

Inclusion criteria for Key Questions 1 and 2:

- Patients undergoing any surgery
- For preoperative checklists primarily designed to implement the Universal Protocol and prevent wrong-site surgery: At least 20,000 procedures. This number may change depending on the size of the literature that meets the inclusion criteria.
- For a preoperative checklist addressing surgical safety in general, we examined in detail the World Health Organization Surgical Safety Checklist.
- For preoperative checklist specifically designed to implement the Universal Protocol and prevent wrong-site surgery, any checklist.
- Any study design included, because these questions involve issues of implementation and adoption, which do not require a comparison set of procedures.

Inclusion criteria for Key Questions 3, 4, and 5:

- Patients undergoing any surgery involving general anesthesia
- At least 100 procedures. This number may change depending on the size of the literature that meets the inclusion criteria.
- Equipment checklist prior to administering general anesthesia before surgery
- Study must either compare the use of a checklist to not using a checklist, or study must compare checklists. We included any design that made such as comparison (e.g., before-after, interrupted time series, or time series with concurrent control group, etc).

- Reported at least one of the outcomes of interest (rates of intraoperative awareness, equipment complications, intraoperative patient complications, postoperative patient complications) within one month of the operation

References

1. Haynes AB, Weiser TG, Berry WR, et al. Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009;360(5):491-9. <http://content.nejm.org/cgi/content/full/NEJMsa0810119>. PMID: 19144931
2. Facts about the universal protocol for preventing wrong site, wrong procedure and wrong person surgery. Oakbrook Terrace, IL: The Joint Commission; 2004. www.jointcommission.org/PatientSafety/UniversalProtocol/up_facts.htm. Accessed January 9, 2008.
3. ASA Committee on Equipment and Facilities. 2008 recommendations for pre-anesthesia checkout procedures. Park Ridge (IL): American Society of Anesthesiologists; 2008.

Chapter 14. Use of Report Cards and Outcome Measurements To Improve the Safety of Surgical Care: American College of Surgeons National Quality Improvement Program (NEW)

SECTION A. Literature Search

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2000-11/26/2011

LANGUAGE:

English

SEARCH STRATEGY:

American College Surgeon* AND National Surgical Improvement Program

NUMBER OF RESULTS: 169

In addition to searching the published literature, this topic relied on evidence available on the American College of Surgeons NSQIP website at <http://www.acsnsqip.org/>. Interviews with leadership and administrators in ACS NSQIP were performed. Surgeon champions were questioned.

In addition to searching the published literature, this topic relied on evidence available on the American College of Surgeons NSQIP website at <http://www.acsnsqip.org/>.

SECTION B. Methods

Evidence from the literature and the ACS NSQIP website was reviewed by a general surgeon health services researcher with experience in systematic reviews. The synthesis was narrative.

Chapter 15. Prevention of Surgical Items Being Left Inside a Patient: Brief Update Review

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
Cochrane Library	Searched November 3, 2011	Wiley
ECRI Institute members website	Searched October 26, 2011	ECRI Institute
Institute for Healthcare Improvement	Searched October 26, 2011	
PSNet	Searched October 26, 2011	Agency for Healthcare Research and Quality
PubMed	Searched November 3, 2011	National Library of Medicine

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Non-journal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature as well as related citation searches using the Scopus database. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.) A number of organization websites were searched for relevant information, including: ECRI Institute members website, the Institute for Healthcare Improvement (ISI), and the Agency for Healthcare Research and Quality's Patient Safety Network (PSNet).

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in PubMed syntax. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree and Keywords

Conventions:

OVID

\$ = truncation character (wildcard)

exp = “explodes” controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary’s hierarchy)

.de. or

/ = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = publication type

[sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Foreign bodies	Foreign bodies[mh]	Foreign Gossypiboma “nothing left behind” Retained
Retained item		Body Bodies Instrument* Sponge* Tool*
Medical errors	Medical errors[mh]	Error* Medical “never event” Prevent* Surgical
Surgical	Surgical instrument[mh]	Surgery Surgical
Technology		“bar code” Bar-code count “RFID” Tag*

Embase/Medline/Premedline

English language, human, remove overlap

Set Number	Concept	Search statement
1	Foreign bodies	Foreign bodies[mh] OR ((foreign OR retained) AND (instrument* OR sponge* OR body OR bodies)) OR gossypiboma[tiab]
2	Surgery	Surgical[tiab] OR surgery[tiab]

Set Number	Concept	Search statement
3	Medical errors	Medical errors[mh] OR ((medical OR surgical) AND (error* OR "never event"))
4	Surgical tools	Surgical instruments[mh] OR (surgical AND (tool* OR instrument*))
5	Technology	RFID OR tag* OR "bar code" OR bar-code OR count
6	Term	"nothing left behind"
7	Combine	S1 AND S2 AND S3 AND S4
8	Combine	S1 AND S5
9	Combine for final set	S6 OR S7 OR S*
10	Apply date limit	2000-2011

Total Downloaded	Total Retrieved	Total Included
70	20	13

SECTION B. Methods

Titles and abstracts were reviewed by a health services research methodologist with experience in both systematic reviews and medical devices. Included studies were those most relevant to the risk and prevention of retained foreign objects as a result of surgery. We examined studies on manual counting, as well as those using various forms of radiofrequency identification. Potential barriers to implementation (e.g. user compliance) and the costs of various technologies were also assessed. Included studies were narratively summarized by the author.

Chapter 16. Operating Room Integration and Display Systems: Brief Review (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date Limits	Platform/Provider
PubMed	2000-November 28, 2011	National Library of Medicine
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	2000-November 29, 2011	EBSCOhost
ECRI Institute website	2000-November 29, 2011	ECRI Institute
Health Devices	2000-November 29, 2011	ECRI Institute

Name	Date Limits	Platform/Provider
Institute for Healthcare Improvement	2000-November 29, 2011	http://www.ihi.org
Joint Commission	2000-November 29, 2011	http://www.jointcommission.org/
Patient Safety Network	2000-November 30, 2011	Agency for Healthcare Research and Quality (AHRQ): http://psnet.ahrq.gov/
Pennsylvania Patient Safety Authority PASR (PA Safety Authority-patient safety reporting system)	2000-November 30, 2011	http://patientsafetyauthority.org/Pages/Default.aspx#
Google	2000-November 30, 2011	http://www.google.com

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in PubMed syntax. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), and Keywords

Conventions:

PubMed

- * = truncation character (wildcard)
- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract
- [ti] = keyword in title

Topic-Specific Search Terms

Concept	Controlled Vocabulary*	Keywords
Operating rooms	operating rooms[majr]	operating room/s operating suite/s surgery suite/s surgical suite/s OR/s C-suite/s hybrid operating suite/s supersuite/s super suite/s VIOR/s (visually integrated operating room) surgical field/s
Integration	operating room information systems[mh] systems integration[mh] video-assisted surgery[majr]	integration integrated central control centralized control centralised control common location single location plug and play router routing
Information itself		audio AV camera data EMR image/s imaging PACS picture archiving video
Transmission of information	computer communication networks[majr] monitoring, intraoperative/instrumentation[majr] videorecording[majr]	communication/s digital

Concept	Controlled Vocabulary*	Keywords
Display of information	data display[mj]	boom cart-mounted dashboard/s display/s flat panel high definition HD LCD/s monitor/s television/s touch screen/s touchscreen/s TV/s screen/s surgical display/s streaming video VCR wall-mounted workstation/s

*Note: none of the MeSH terms were specific enough to retrieve results relevant to the topic and were not incorporated into the main search strategy.

PubMed – main search

Set Number	Concept	Search Statement
1	Main concept	“integrated operating room”[tiab] OR “integrated operating rooms”[tiab]
2	Setting	operating rooms[mh] OR “operating room”[tiab] OR “operating rooms”[ti] OR “operating suite”[tiab] OR “operating suites”[tiab] OR “surgical suite”[tiab] OR “surgical suites”[tiab] OR “surgery suite”[tiab] OR “surgery suites”[tiab]
3	Descriptive concept	integrat*[ti]
4	Additional descriptive concepts	“central control”[tiab] OR “centralized control”[tiab] OR “centralised control”[tiab] OR dashboard*[tiab] OR digital[ti] OR display*[ti] OR “high definition”[tiab] OR PACS[tiab] OR “plug and play”[tiab] OR screen[ti] OR screens[ti] OR video[ti]
5	Combine sets	2 AND (3 OR 4)
6	Combine sets	1 OR 5*

*Note: no publication limits or safety concepts were applied to the final set of search results because there were few results.

PUBMED – ADDITIONAL TERMS THAT WERE BROWSED*

Set Number	Concept	Search Statement
1	Setting	C-suite OR C-suites OR hybrid operating OR supersuite OR super suite OR ORs “operating room” AND future VIOR*
2	Concepts	integrat*[tiab] central[ti] OR “central location” OR “common location” OR “single location” OR (visually[ti] AND integrated[tiab]) router*[tiab] OR routing[tiab] audio* OR AV camera*[ti] OR image[ti] OR images[ti] OR imaging[ti] OR “picture archiving” OR video*[ti] OR (visually[ti] AND integrated[tiab]) EMR[tiab] “cart mounted” OR “touch screen” OR “touch screens” OR touchscreen* OR workstation* boom* OR “flat panel” OR TV* OR television* OR “wall-mounted” OR HD OR LCD* OR VCR* OR streaming communication[ti] OR communications[ti] OR data[ti] OR “data integration”[tiab] OR “digital integration”[tiab] monitor[ti] OR monitors[ti] OR “surgical display” OR “surgical displays” OR (surgical[ti] AND display*[ti]) OR (“surgical field” AND display[tiab]) OR (“surgical field” AND monitor*[tiab])
3	Mesh concepts	Computer communication networks[mj] OR data display[mj] OR monitoring, intraoperative/instrumentation[mj] OR systems integration[mj] OR video-assisted surgery[mj] OR video recording[mj]

*Note: The terms in this table mainly yielded no results, irrelevant results, or large sets of results with few relevant. Some references were identified and kept during searches with these terms, but the terms were not useful enough to include in the main search strategy above.

CINAHL

Set Number	Concept	Search Statement
1	Setting	“operating room” OR “operating room”
2	Main concept	integrat*
3	Combine	1 AND 2

Total Downloaded	Total Retrieved	Total Included
140	44 instructions	18

SECTION B. Methods

Titles and abstracts were reviewed by a physician health services researcher with experience in systematic review. Only full published studies were considered for review (meeting abstracts were excluded). Only English-language publications were eligible for inclusion. For the effectiveness and harms of the PSP, we considered including studies of any design (e.g.,

randomized controlled trials, non-randomized controlled trials, prospective and retrospective observational studies, surveys) that may provide relevant data. For the implementation of the PSP, we considered including any qualitative or quantitative research that addressed the implementation issues. Included studies were narratively summarized by the author. As this PSP project team has agreed, we did not assess risk of bias of included individual studies or the overall strength of evidence for this brief PSP review.

Chapter 17. Use of Beta Blockers To Prevent Perioperative Cardiac Events: Brief Update Review

SECTION A. Literature Search

For this topic we did not do a formal literature search. Rather the principal meta-analyses and trials were already known to the authors as part of their clinical work. A “related articles” search was done on these to look for any additional relevant publications.

SECTION B. Methods

The meta-analyses, trials, and related articles search were reviewed by a physician health services researcher with experience in cardiovascular systematic reviews. The synthesis was narrative.

Chapter 18. Use of Real-Time Ultrasound Guidance During Central Line Insertion: Brief Update Review

SECTION A. Literature Search

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2000-12/15/2011

SEARCH #1:

ultrasound OR ultrasonograph*

AND

guided OR guidance OR ultrasound-guided OR doppler-guided OR ultrasound-assisted

AND

catheter* OR cannulat*

AND

vein OR veins OR venous OR vascular

MANUALLY FILTERED IN ENDNOTE FOR THE FOLLOWING JOURNALS:

JAMA

New England Journal of Medicine

British Medical Journal

Lancet

Annals of Internal Medicine

Critical Care Medicine

Journal of Clinical Monitoring

Anaesthesia
Circulation
Chest
Anesthesia & Analgesia
Annals of Emergency Medicine
Anesthesiology
Archives of Surgery

NUMBER OF RESULTS AFTER FILTERING: 92

=====
SEARCH #2 (RCT'S OR META-ANALYSES):
DATABASE SEARCHED & TIME PERIOD COVERED:
PubMed – 2000-12/16/2011

LANGUAGE:
English

SEARCH STRATEGY:
ultrasound OR ultrasonograph*
AND
guided OR guidance OR ultrasound-guided OR doppler-guided OR ultrasound-assisted
AND
catheter* OR cannulat*
AND
vein OR veins OR venous OR vascular
AND
randomized controlled trial* OR randomized controlled trial[pt] OR rct* OR double-blind* OR
single-blind* OR “double blind” OR “single blind” OR “systematic review” OR meta-analy* OR
metaanaly* OR meta analy* OR Meta-Analysis[pt]

NUMBER OF RESULTS: 93
NUMBER AFTER REMOVING REFERENCES FROM “SPECIFIED JOURNALS”
LIST: 74

=====
SEARCH #3
DATABASE SEARCHED & TIME PERIOD COVERED:
SCOPUS – 2000-12/16/2011

LANGUAGE:
English

SEARCH STRATEGY:

TITLE-ABS-KEY((ultrasound OR ultrasonograph*)
AND
guided OR guidance OR ultrasound-guided OR doppler-guided OR ultrasound-assisted
AND
TITLE-ABS-KEY-AUTH(catheter* OR cannulat*)
AND
vein OR veins OR venous OR vascular
AND
SUBJAREA(mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR
deci OR econ OR psyc OR soci)

MANUALLY FILTERED IN ENDNOTE FOR RCT'S OR META-ANALYSES
NUMBER OF RESULTS: 11

=====

SEARCH #4

DATABASE SEARCHED & TIME PERIOD COVERED:

Web of Science – 2000-12/16/2011

LANGUAGE:

English

SEARCH STRATEGY:

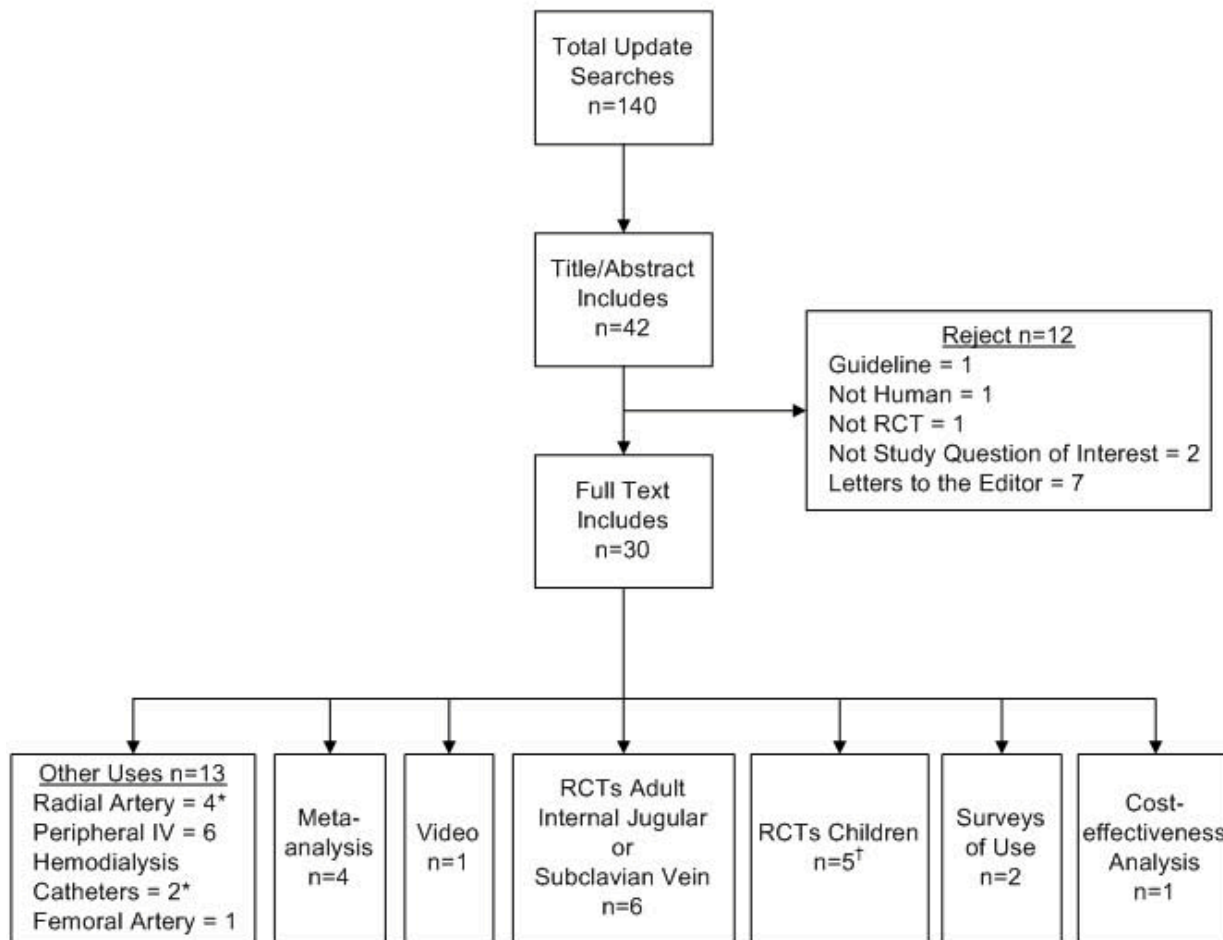
ultrasound OR ultrasonograph*
AND
guided OR guidance OR ultrasound-guided OR doppler-guided OR ultrasound-assisted
AND
catheter* OR cannulat*
AND
vein OR veins OR venous OR vascular

MANUALLY FILTERED IN ENDNOTE FOR RCT'S OR META-ANALYSES
NUMBER OF RESULTS: 12

B. Methods

Titles and abstracts were reviewed by a general internist with experience in systematic reviews (Figure 1). Relevant articles were narratively summarized. This summary was reviewed by the second author, a general internist experienced in the implementation and use of ultrasound for central-line placement, who suggested several additional references and described program implementation at one health care site.

Figure 1, Chapter 18. Literature flow diagram



* A meta-analysis is also included in these totals, hence numbers sum to more than the total.

† Three of these studies were also included in a meta-analysis on the topic.

Chapter 19. Preventing In-Facility Falls

SECTION A. Literature Search

DATABASE SEARCHED AND TIME PERIOD COVERED:

PubMed: 2005-8/1/2011

LANGUAGE:

English

SEARCH STRATEGY:

“Accidental Falls”[Mesh] OR “fallers”[tiab] OR “falls per”[tiab] OR “falls rate”[tiab] OR “falls incidence”[tiab] OR “falls prevention”[tiab] OR “fall prevention”[tiab] OR “prevention of falls”[tiab] OR “prevent falls”[tiab] OR “prevents falls”[tiab] OR “prevent patient falls”[tiab] OR “prevents patient falls”[tiab] OR “preventing fall”[tiab] OR “preventing falls”[tiab] OR “falls reduction”[tiab] OR “fall reduction”[tiab] OR “reduction of falls”[tiab] OR “reduce falls”[tiab] OR “reduces falls”[tiab] OR “reducing fall”[tiab] OR “reducing falls”[tiab] OR

“improve fall”[tiab] OR “improve falls”[tiab] OR “improves fall”[tiab] OR “improves falls”[tiab] OR “improving fall”[tiab] OR “improving falls”[tiab]

AND

hospital OR hospitals OR hospitali*

NOT

Publication Type:Meta-Analysis, Review

NUMBER OF RESULTS: 1841

DATABASE SEARCHED AND TIME PERIOD COVERED:

CINAHL: 2005-8/2/2011

SEARCH STRATEGY:

“Accidental Falls” OR “fallers” OR “falls per” OR “falls rate” OR “falls incidence” OR “falls prevention” OR “fall prevention” OR “prevention of falls” OR “prevent falls” OR “prevents falls” OR “prevent patient falls” OR “prevents patient falls” OR “preventing fall” OR “preventing falls” OR “falls reduction” OR “fall reduction” OR “reduction of falls” OR “reduce falls” OR “reduces falls” OR “reducing fall” OR “reducing falls” OR “improve fall” OR “improve falls” OR “improves fall” OR “improves falls” OR “improving fall” OR “improving falls”

AND

hospital OR hospitals OR hospitali*

NUMBER OF RESULTS: 876

NUMBER AFTER REMOVAL OF DUPLICATES: 524

DATABASE SEARCHED AND TIME PERIOD COVERED:

WEB OF SCIENCE – Science Citation Index, Social Science Citation Index, Arts & Humanities Index, Conference Proceedings Science Index, Conference Proceedings Social Science Index: 2005-8/5/2011

SEARCH STRATEGY:

Topic=(“Accidental Falls” OR “fallers” OR “falls per” OR “falls rate” OR “falls incidence” OR “falls prevention” OR “fall prevention” OR “prevention of falls” OR “prevent falls” OR “prevents falls” OR “prevent patient falls” OR “prevents patient falls” OR “preventing fall” OR “preventing falls” OR “falls reduction” OR “fall reduction” OR “reduction of falls” OR “reduce falls” OR “reduces falls” OR “reducing fall” OR “reducing falls” OR “improve fall” OR “improve falls” OR “improves fall” OR “improves falls” OR “improving fall” OR “improving falls”)

AND

Topic=(hospital OR hospitals OR hospitali*)

NUMBER OF RESULTS: 420

NUMBER AFTER REMOVAL OF DUPLICATES: 108

SECTION B. Methods

Articles identified by Hempel and colleagues using the above process were then reviewed by us using the following criteria:

- Acute care hospitals
- With large sample sizes (at least N=1,000)
- General population or older adult population

From the Prevention of Falls Newtork Europe (ProFANE) “Manual for the fall prevention classification system:” Domain 3: Components (Combination sub-section)¹

Combination
Most interventions fall under the following sub-domains (detailed under Domain 4: Descriptors of the intervention). Exercises (supervised and/or unsupervised) Medication (drug target) Surgery Management of urinary incontinence Fluid or nutrition therapy Psychological Environment/Assistive technology Social environment Knowledge/education interventions Other interventions/procedures Combination refers to how many sub-domains are delivered to the participants of an intervention, and importantly, the manner in which these sub-domains are combined.

¹ Lamb SE, Hauer K, Becker C. Manual for the fall prevention classification system. 2007. www.profane.eu.org/documents/Falls_Taxonomy.pdf.

Chapter 20. Preventing In-Facility Delirium

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date Limits	Platform/Provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	Searched June 10, 2011	EBSCOHost
Cochrane Library	Searched June 14, 2011	Wiley
EMBASE (Excerpta Medica)	1996 – August 23, 2011	OVID SP
MEDLINE	1996 – August 23, 2011	OVID SP
PreMEDLINE	1990 – August 23, 2011	OVID SP
PubMed	Searched August 17, 2011	National Library of Medicine

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase and Medline. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree and Keywords

Conventions:

OVID

- \$ = truncation character (wildcard)
- exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
- .de. or
- / = limit controlled vocabulary heading
- .fs. = floating subheading
- .hw. = limit to heading word
- .md. = type of methodology (PsycINFO)
- .mp. = combined search fields (default if no fields are specified)
- .pt. = publication type
- .ti. = limit to title
- .tw. = limit to title and abstract fields

PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Anesthesia Pre/Peri/Intra/Postoperative period Surgery	Analgesic agent/adverse drug reaction, drug interaction, drug toxicity, pharmacokinetics, pharmacology Analgesics, opioid/ae Exp analgesics/adverse effects, pharmacokinetics, poisoning, toxicity Exp perioperative care/ Exp Postoperative complication/ Postoperative care/	Anaesthe\$ Analgesic\$ Anesthe\$ Complicat\$ Opioid\$ Postop\$ Sedat\$
Disease/Condition	Delirium/ Delirium/et Delirium/pc	Acute confusional state Cause\$ Complicat\$ Control\$ Delirium Develop\$ Effect\$ etiology Event\$ Outcome\$ Prevent\$ Result\$ Sundown syndrome
Intervention program	Delirium/prevention and control Dt.fs. Tu.fs.	Approach\$ Barrier\$ barrier* Checklist\$ Collaborat\$ control Delirium Exercise\$ Families Family "hospital elder life" Implement\$ Initiative\$ Intervention\$ Monitor\$ movement non-pharma\$ non-pharmacolog\$ obstacle\$ occupational therapy Pharma Pharmacologic\$ Physical therap\$ plan Prevention Program\$ Project\$ prophylactic\$ protocol reduc\$ screen\$ sleep strateg\$ volunteer\$ walk*

Concept	Controlled Vocabulary	Keywords
Risk/Screening	Delirium/et Exp Risk/ or Risk Assessment/	Assess Assessment Checklist Examination Examine History Interview Predict Prediction Predictor Risk Survey
Setting	Intensive care units/	admission Hospital\$ Hospital-acquired iatrogenic Inpatient Intensive care "ICU" nosocomial patient

Embase/Medline/Premedline

English language, human, remove overlap

Set Number	Concept	Search Statement
1	Disease/Condition	*Delirium/
2		(deliriium or "sundown syndrome" or "acute confusional state").ti,ab.
3	Combine sets	1 or 2
4	Risk	exp risk/ or risk assessment/ or (epidemiology or etiology or prevention).fs. or (avoid\$ or caus\$ or risk\$ or predict\$ or prevent\$).ti,ab.
5	Risk of developing delirium	(delirium/et or (delirium and (cause\$ or result\$ or outcome\$ or complicat\$ or etiology or develop\$ or effect\$ or event\$)).ti,ab.)
6	Combine sets for risk of developing delirium	(3 AND 4) OR 5
7	Setting/Context	(hospital or hospitals or hospitaliz* or hospitalis* or inpatient\$ or iatrogenic or admission or admitted or "ICU" or "intensive care" or "post anesthesia" or "post anaesthesia" or "post surgery" or "post surgical" or postoperative or "post operative").ti.
8		exp hospitalization/ or exp intensive care units/
9	Combine sets for Setting	7 OR 8
10	Combine for final set of risk of developing delirium in hospital settings	6 AND 9
11	Postoperative complications	exp postoperative complication/ or (postop\$ adj2 complication\$).ti,ab.
12		exp perioperative care/ or (sedat\$ or analgesic\$ or aneste\$ or anaesthe\$ or opioid\$).ti,ab.
13		exp surgical procedures, operative/ae or (surgery or surgical or intraoperative or intra-operative).ti,ab.
14	Combine sets for Postoperative complications	11 OR 12 OR 13
15	Sedation	analgesics, opioid/ae
16		analgesic agent/ae, it, to, pk, pd [Adverse Drug Reaction, Drug Interaction, Drug Toxicity, Pharmacokinetics, Pharmacology]
17		exp Analgesics/ae, pk, po, to [Adverse Effects, Pharmacokinetics, Poisoning, Toxicity]

Set Number	Concept	Search Statement
18	Combine sets for Sedation	15 or 16 OR 17
19	Combine sets for Postoperative or Sedation Complications	14 OR 18
20	Combine sets for Postoperative or Sedation Complications and Risk of Delirium	19 AND 6
21	Disease/Condition prevention and control	*Delirium/pc or (delirium and (prevent\$ or control\$)).ti,ab.
22	Interventions	(interven\$ or initiative\$ or program\$ or project\$ or plan\$ or protocol\$ or monitor\$ or checklist\$ or collabor\$ or approach\$ or screen\$ or strateg\$).ti,ab.
23		(exercise\$ or walk or family or families or movement or non-pharma\$ or occupational therap\$ or physical therap\$ or sleep or hydrat\$ or volunteer\$).ti,ab. OR "hospital elder life".mp.
24		(pharma\$ or drug\$ or medication\$ or prophylactic\$ or therap\$).ti,ab. or dt.fs. or tu.fs.
25		program evaluation/ or program development/ or safety management/methods or models, organizational/ or clinical effectiveness/evaluation or quality assurance, health care/ or ((clinical or medical) adj (protocol* or checklist* or documentation*)).ti,ab.
26	Combine sets for Interventions	22 OR 23 OR 24 OR 25
27	Combine sets for Disease control and prevention and Interventions	21 AND 26
28	Incidence	exp incidence/ or (incidence or prevalence or rate or increase or decrease or reduc\$ or number).mp.
29	Barriers	(barrier\$ or obstacle\$ or resource\$ or cost\$ or time).ti,ab.
30	Combine sets for Barriers to Disease control and prevention and Interventions and Incidence of delirium	27 AND 28 AND 29
31	Combine Disease/Condition and Disease prevention and control	3 OR 21
32	Quality improvement hedge	(quality and improv\$ and intervention\$).mp.
33	Combine Disease and Quality Improvement hedge	31 AND 32
34	Combine final sets for review	10 OR 20 OR 30 OR 33
35	Limit	Limit 34 to yr="2000-2011"
36	Limit	Limit 35 to English language
37	Apply Systematic Review narrow hedge	36 AND ((research synthesis or pooled).mp. or systematic review/ or meta analysis/ or meta-analysis/ or ((evidence base\$ or methodol\$ or systematic or quantitative\$ or studies or search\$).mp. and (review/ or review.pt.)))
38	Remove duplicates	Remove duplicates from 37

Total Downloaded	Total Retrieved	Total Included
587	301	85

SECTION B. Methods

Inclusion/Exclusion Criteria

General criteria: Only full published studies were considered for review (meeting abstracts were excluded). Only English-language publications were eligible for inclusion.

Risk factors:

- Included RCTs comparing groups with different risk factors; also prospective and retrospective cohort studies that perform multivariate analyses of factors associated with incidence of delirium.
- Comparative studies must have at least 20 patients in each arm, while cohort studies must have at least 20 patients overall.

Effectiveness and harms:

- Included RCTs, controlled clinical trials (CCTs), interrupted time series, and controlled before-after studies (CBAs) where at least the after-intervention portion is prospective; CBAs are necessary to look at implementation (KQ6).
- Studies must have at least 20 patients in each arm.

Implementation and Context:

- Abstracted information on implementation and context from effectiveness studies, and descriptive studies of implementation with an associated effectiveness study
- Qualitative research studies addressing implementation of delirium prevention interventions
- Quantitative research studies on implementation of delirium prevention interventions

Chapter 21. Preventing In-Facility Pressure Ulcers

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date Limits	Platform/Provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	1981 – June 9, 2011	EBSCOHost
Cochrane Library	Searched June 22, 2011	Wiley
EMBASE (Excerpta Medica)	1996 –September 15, 2011	OVID SP
MEDLINE	1996 –September 15, 2011	OVID SP
PreMEDLINE	Searched August 16, 2011	OVID SP

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute’s collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE and MEDLINE. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree and Keywords

Conventions:

OVID

- \$ = truncation character (wildcard)
- exp = “explodes” controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary’s hierarchy)
- .de. or / = limit controlled vocabulary heading
- .fs. = floating subheading
- .hw. = limit to heading word
- .md. = type of methodology (PsycINFO)
- .mp. = combined search fields (default if no fields are specified)
- .pt. = publication type
- .ti. = limit to title
- .tw. = limit to title and abstract fields

PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Pressure ulcers	Pressure ulcer/ Skin ulcer/ or skin ulcers/ Decubitus/ or decubitus ulcer/	bed sore\$ bedsore\$ decubitus adj ulcer\$ pressure sore\$ Pressure ulcer\$ pressure ulcer\$ pressure wound\$ Skin ulcer\$ wound

Concept	Controlled Vocabulary	Keywords
Intervention program	clinical effectiveness/evaluation exp health care quality/ models, organizational/ program development/ program evaluation/ quality assurance, health care/ quality of health care or quality assurance, health care or quality indicators, health care or health plan implementation safety management/methods	Checklist checklist* Clinical checklist Clinical documentation clinical protocol Implement* implement* Initiative initiative* Intervention intervention Medical checklist* Medical documentation* Medical protocol* Program program* Protocol protocol quality and improvement and intervention\$ Standard standard* train* Training
Barriers	attitude of health personnel/ clinical competence/ education, medical/ health knowledge, attitudes, practice/ physician practice patterns/ staff, hospital/education	barrier\$ Barriers Compliance compliance\$ imped\$ (nurse\$ or physician\$ or staff or employee) and (educat\$ or train\$ or knowledge or attitude\$ or competen\$ or time) obstacle\$ outcome\$ Outcomes
Setting	exp health care organization/ exp health planning organizations/	alliance\$ coalition\$ collaborat\$ health care or healthcare medical health system\$ hospital\$ network\$
Effectiveness/Measure	Exp incidence/ Exp prevalence/ Exp vital statistics/	decrease incidence increase number prevalence rate

Embase/Medline/Premedline

English language, human, remove overlap

Set Number	Concept	Search Statement
1	Disease/Condition	*pressure ulcer/ or pressure ulcer*.ti,ab. or ((skin ulcers/ or skin ulcer/ and pressure.ti,ab.)
2		(exp decubitus/ or exp decubitus ulcer/) and skin.mp.
3		(pressure adj2 (sore\$ or ulcer\$ or wound\$)).ti,ab.
4		(bedsore\$ or (bed adj2 sore\$)).ti,ab.
5		(decubitus adj ulcer\$).ti,ab.
6	Combine sets for Disease	1 or 2 or 3 or 4 or 5
7	Intervention/Program Implementation/Quality improvement	program evaluation/ or program development/ or safety management/methods or models, organizational/ or clinical effectiveness/evaluation or quality assurance, health care/ or ((clinical or medical) adj (protocol* or checklist* or documentation*)).ti,ab.
8		(quality and improv\$ and intervention\$).mp.
9		(implement* or initiative* or program* or intervention or train* or checklist* or standard* or protocol).mp.
10		exp health care quality/ or (quality of health care or quality assurance,health care or quality indicators, health care or health plan implementation).sh.
11	Combine sets for Intervention/Program Implementation/Quality improvement	7 or 8 or 9 or 10
12	Obstacles/Barriers	attitude of health personnel/ or education, medical/ or staff, hospital/education or clinical competence/ or health knowledge, attitudes, practice/ or physician practice patterns/
13		(imped\$ or obstacle\$ or barrier\$ or outcome\$ or compliance\$ or ((nurse\$ or physician\$ or staff or employee) and (educat\$ or train\$ or knowledge or attitude\$ or competen\$ or time))).mp.
14	Combine sets for Obstacles	12 or 13
15	Context/Setting	(hospital\$ or hospital-acquired or inpatient\$ or patient\$ or acute care or long term care or long-term care).ti,ab.
16		exp health care organization/ or exp health planning organizations/ or ((hospital\$ or health system\$ or health care or healthcare or medical) and (collaborat\$ or alliance\$ or coalition\$ or network\$)).mp.
17	Combine sets for Setting	15 or 16
18	Combine Disease/Condition and Intervention/Program Implementation/Quality improvement	6 and 11
19	Combine Disease and Intervention/Program Implementation/Quality improvement	14 and 18
20	Combine Obstacles and Disease and Intervention/Program Implementation/Quality improvement and Setting	19 and 17
21	Remove duplicates	Remove duplicates from 20
22	Limit by date	Limit 21 to yr="2000-2011"
23	Incidence or prevalence	exp incidence/ or exp prevalence/ or (incidence or prevalence or rate or increase or decrease or number).mp.
24		exp Demography/sn [Statistics & Numerical Data]
25	Combine for Incidence or prevalence	23 or 24

Set Number	Concept	Search Statement
26	Combine Obstacles and Disease and Intervention/Program Implementation/Quality improvement and Setting and Incidence	22 and 25
27	Limit	Limit 26 to English language
28	Limit	Limit 27 to human
29	Combine Disease and Quality Improvement	6 and 8
30	Combine for final set	22 or 28 or 29
31	Limit	Limit 30 to yr="2000-2011"
32	Limit	Limit 31 to English language
33	Limit	Limit 32 to human

Total Downloaded	Total Retrieved	Total Included
454	87	47

CINAHL

Set Number	Concept	Search Statement	# Downloaded
S1	Disease/Condition	(MM "Pressure Ulcer") OR (MH "Pressure Ulcer Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 1 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 2 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 3 Care (Saba CCC)") OR (MH "Pressure Ulcer Stage 4 Care (Saba CCC)") OR (MH "Pressure Ulcer Care (Iowa NIC)") OR (MH "Pressure Ulcer Prevention (Iowa NIC)") OR TI pressure ulcers	
S2	Program	implement* OR program* OR initiative* OR protocol* OR checklist* OR train* OR standard*	
S3	Obstacles	Barrier* OR outcome* OR compliance*	
S4	Protocols/Guidelines	(MH "Nursing Protocols") OR (MH "Research Protocols") OR (MH "Protocols") OR (MH "Guideline Adherence") OR "protocol"	
S5	Combine Programs and Protocols	S2 OR S4	
S6	Combine Condition and Obstacles AND Programs or Protocols	S1 AND S3 AND S5	
S7	Limit	Limit S6 to 2000-2011	350
		From S7 keep	64

SECTION B. Methods

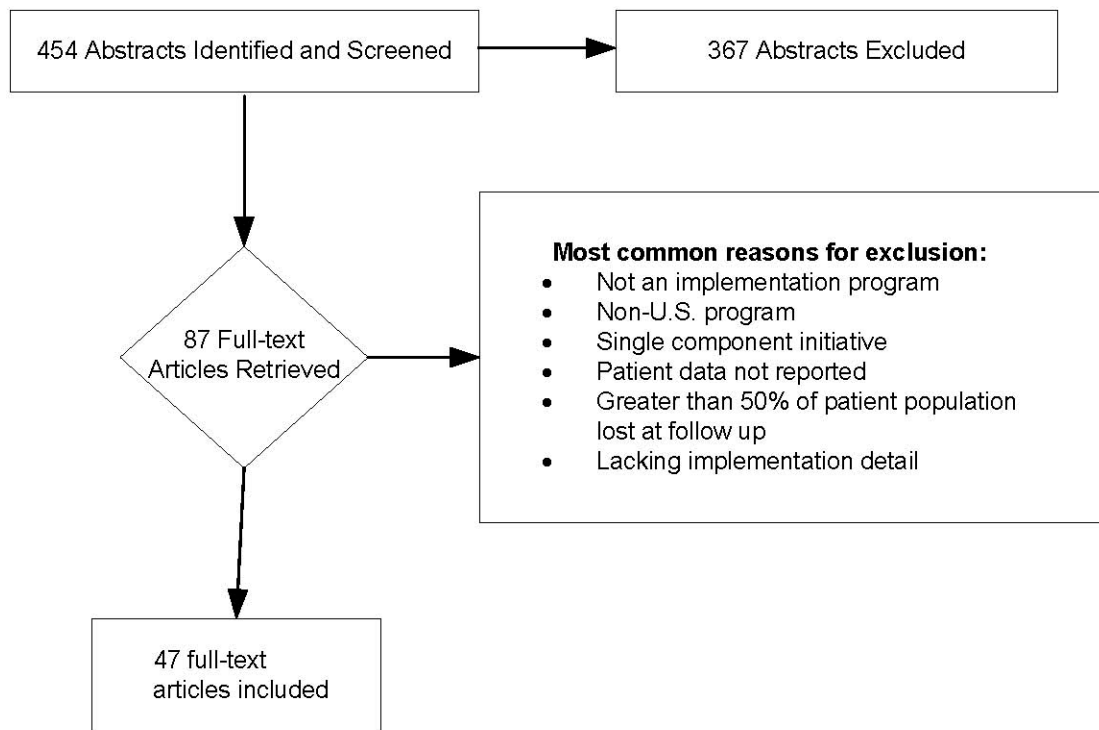
Inclusion criteria:

- Experimental research studies including randomized controlled trials, non-randomized controlled trials, pre-post studies (or before and after studies), and cohort studies that evaluated the implementation of a multicomponent pressure ulcer (PU) prevention programs
- Published post-2000 and conducted in the U.S.
- Study must report on PU rate (incidence/prevalence)
- Studies must report PU rate for at least 6 months post- implementation of prevention program

Exclusion criteria:

- Studies that did not report a baseline (pre-prevention program implementation) PU rate
- Studies with less than 50% of patient population at study end
- Studies focused on PU risk assessment or singular interventions that prevent PUs (e.g., special mattresses, skin care items, etc.). These topics are currently covered in a separate comparative effectiveness review.

Figure 1, Chapter 21. Study attrition diagram



Chapter 22. Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection (NEW)

SECTION A. Literature Search

Search for studies about cost

Database: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) <1948 to January Week 2 2010>
Search Strategy: yield through January 2010, updated October 2011

-
- 1 exp insulin/ (135826)
 - 2 exp hypoglycemic agents/ (159801)
 - 3 exp Blood Glucose/ (105380)
 - 4 (insulin or hypoglycemic agent\$ or hypoglycaemic agent\$ or glyceemic control or glycaemic control).mp. {mp=title, original title, abstract, name of substance word, subject heading word, unique identifier} (264080)
 - 5 1 or 2 or 3 or 4 (316621)
 - 6 Critical Illness/ (10449)
 - 7 critical care/ or intensive care/ (31575)
 - 8 exp Perioperative Care/ (65391)
 - 9 exp Postoperative Period/ (30372)
 - 10 ((critical\$ adj6 ill\$) or critical care or icu or intensive care or burn unit\$ or coronary care).mp. {mp=title, original title, abstract, name of substance word, subject heading word, unique identifier} (118455)

- 11 intensive care units/ or burn units/ or coronary care units/ or recovery room/ (31083)
- 12 postoperative complications/ or prosthesis-related infections/ or surgical wound dehiscence/ or surgical wound infection/ (269644)
- 13 (postoperative\$ or post operative\$).mp. {mp=title, original title, abstract, name of substance word, subject heading word, unique identifier} (501444)
- 14 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 (643228)
- 15 5 and 14 (6711)
- 16 randomized controlled trial.pt. (278973)
- 17 controlled clinical trial.pt. (79853)
- 18 randomized controlled trials.sh. (0)
- 19 random allocation.sh. (66268)
- 20 double blind method.sh. (103038)
- 21 single blind method.sh. (13368)
- 22 16 or 17 or 18 or 19 or 20 or 21 (416935)
- 23 (animals not human).sh. (4467853)
- 24 22 not 23 (374747)
- 25 clinical trial.pt. (452229)
- 26 exp clinical trials/ (0)
- 27 (clin\$ adj25 trial\$).ti,ab. (166370)
- 28 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab. (103187)
- 29 placebos.sh. (28486)
- 30 placebo\$.ti,ab. (118661)
- 31 random\$.ti,ab. (460194)
- 32 research design.sh. (57708)
- 33 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 (924508)
- 34 33 not 23 (807020)
- 35 34 or 24 (836845)
- 36 15 and 35 (1138)
- 37 exp Myocardial Infarction/ (124416)
- 38 exp Hospitalization/ (120073)
- 39 exp Inpatients/ (8203)
- 40 exp Cerebrovascular Accident/ (55676)
- 41 cerebrovascular disorders/ or brain ischemia/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ (120133)
- 42 exp myocardial revascularization/ or exp coronary artery bypass/ (64411)
- 43 37 or 40 or 41 or 42 (330035)
- 44 5 and 43 (4681)
- 45 35 and 44 (689)
- 46 45 not 36 (556)
- 47 38 or 39 (126877)
- 48 5 and 47 (1329)
- 49 35 and 48 (243)
- 50 49 not (36 or 46) (130)
- 51 exp Hypoglycemia/ci, ep, et {Chemically Induced, Epidemiology, Etiology} (9091)
- 52 1 or 2 or 4 (271238)
- 53 51 and 52 (5827)

- 54 14 and 53 (251)
- 55 43 and 53 (52)
- 56 47 and 53 (89)
- 57 54 or 55 or 56 (362)
- 58 57 not (36 or 46 or 49) (312)
- 59 exp Hypoglycemia/ (18273)
- 60 52 and 59 (10136)
- 61 14 and 60 (400)
- 62 43 and 60 (101)
- 63 47 and 60 (126)
- 64 61 or 62 or 63 (580)
- 65 64 not 57 (218)
- 66 65 not (36 or 46 or 49) (193)
- 67 exp "Costs and Cost Analysis"/ (145993)
- 68 15 and 67 (51)
- 69 exp Economics/ (413412)
- 70 ec.fs. (261917)
- 71 69 or 70 (488778)
- 72 15 and 71 (82)
- 73 72 not 68 (31)
- 74 from 73 keep 1-31 (31)

Search for trials

Database: Ovid MEDLINE(R) <1950 to November Week 2 2007>

- 1 exp insulin/ (130835)
- 2 exp hypoglycemic agents/ (151706)
- 3 exp Blood Glucose/ (98489)
- 4 (insulin or hypoglycemic agent\$ or hypoglycaemic agent\$ or glycemc control or glycaemic control).mp. {mp=title, original title, abstract, name of substance word, subject heading word} (243159)
- 5 1 or 2 or 3 or 4 (292506)
- 6 Critical Illness/ (8301)
- 7 critical care/ or intensive care/ (28092)
- 8 exp Perioperative Care/ (60582)
- 9 exp Postoperative Period/ (28181)
- 10 ((critical\$ adj6 ill\$) or critical care or icu or intensive care or burn unit\$ or coronary care).mp. {mp=title, original title, abstract, name of substance word, subject heading word} (103498)
- 11 intensive care units/ or burn units/ or coronary care units/ or recovery room/ (27247)
- 12 postoperative complications/ or prosthesis-related infections/ or surgical wound dehiscence/ or surgical wound infection/ (252519)
- 13 (postoperative\$ or post operative\$).mp. {mp=title, original title, abstract, name of substance word, subject heading word} (457854)
- 14 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 (582795)

15 5 and 14 (5822)
16 randomized controlled trial.pt. (246761)
17 controlled clinical trial.pt. (77022)
18 randomized controlled trials.sh. (52472)
19 random allocation.sh. (59778)
20 double blind method.sh. (94781)
21 single blind method.sh. (11591)
22 16 or 17 or 18 or 19 or 20 or 21 (418296)
23 (animals not human).sh. (4261058)
24 22 not 23 (382274)
25 clinical trial.pt. (444490)
26 exp clinical trials/ (199910)
27 (clin\$ adj25 trial\$.ti,ab. (139332)
28 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab. (94254)
29 placebos.sh. (26956)
30 placebo\$.ti,ab. (106977)
31 random\$.ti,ab. (394441)
32 research design.sh. (50582)
33 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 (887876)
34 33 not 23 (778635)
35 34 or 24 (798240)
36 15 and 35 (979)
37 exp Myocardial Infarction/ (115916)
38 exp Hospitalization/ (107713)
39 exp Inpatients/ (6673)
40 exp Cerebrovascular Accident/ (44100)
41 cerebrovascular disorders/ or brain ischemia/ or exp “intracranial embolism and thrombosis”/ or exp intracranial hemorrhages/ (112871)
42 exp myocardial revascularization/ or exp coronary artery bypass/ (56866)
43 37 or 40 or 41 or 42 (300510)
44 5 and 43 (4061)
45 35 and 44 (657)
46 45 not 36 (544)
47 38 or 39 (113294)
48 5 and 47 (1078)
49 35 and 48 (202)
50 49 not (36 or 46) (114)
51 exp Hypoglycemia/ci, ep, et {Chemically Induced, Epidemiology, Etiology} (8651)
52 1 or 2 or 4 (250082)
53 51 and 52 (5520)
54 14 and 53 (180)
55 43 and 53 (41)
56 47 and 53 (65)
57 54 or 55 or 56 (276)
58 57 not (36 or 46 or 49) (254)
59 exp Hypoglycemia/ (17277)

- 60 52 and 59 (9545)
- 61 14 and 60 (285)
- 62 43 and 60 (86)
- 63 47 and 60 (97)
- 64 61 or 62 or 63 (445)
- 65 64 not 57 (169)
- 66 65 not (36 or 46 or 49) (152)
- 67 limit 36 to english language (865)
- 68 limit 46 to english language (476)
- 69 limit 50 to english language (104)
- 70 limit 58 to english language (215)
- 71 limit 66 to english language (113)
- 72 from 67 keep 1-865 (865)
- 73 from 68 keep 1-476 (476)
- 74 from 69 keep 1-104 (104)
- 75 from 70 keep 1-215 (215)
- 76 from 71 keep 1-113 (113)

An additional search for adverse effects used the above strategy through line 71, followed by:

- 72 (ae or po or to).fs. (1254721)
- 73 exp Drug Toxicity/ (15829)
- 74 medical errors/ or medication errors/ (13158)
- 75 exp Drug Interactions/ (116890)
- 76 72 or 73 or 74 or 75 (1359022)
- 77 1 or 3 (186918)
- 78 6 or 7 or 8 or 9 or 11 or 12 (379861)
- 79 77 and 78 (2545)
- 80 76 and 79 (364)
- 81 limit 80 to english language (296)
- 82 limit 81 to humans (276)
- 83 15 and 76 (871)
- 84 limit 83 to english language (725)
- 85 limit 84 to humans (668)
- 86 85 not 82 (392)
- 87 from 82 keep 1-276 (276)
- 88 from 86 keep 1-392 (392)

Database: EBM Reviews - Database of Abstracts of Reviews of Effects <3rd Quarter 2008>

- 1 (insulin or hypoglycemic agent\$ or hypoglycaemic agent\$ or glyceemic control or glycaemic control).mp. {mp=title, full text, keywords} (163)
- 2 ((critical\$ adj6 ill\$) or critical care or icu or intensive care or burn unit\$ or coronary care).mp. {mp=title, full text, keywords} (327)
- 3 (postoperative\$ or post operative\$).mp. {mp=title, full text, keywords} (705)

- 4 2 or 3 (973)
- 5 1 and 4 (6)
- 6 from 5 keep 1-6 (6)

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <3rd Quarter 2008>

- 1 (insulin or hypoglycemic agent\$ or hypoglycaemic agent\$ or glyceic control or glycaemic control).mp. {mp=title, original title, abstract, mesh headings, heading words, keyword} (14093)
- 2 ((critical\$ adj6 ill\$) or critical care or icu or intensive care or burn unit\$ or coronary care).mp. {mp=title, original title, abstract, mesh headings, heading words, keyword} (6526)
- 3 (postoperative\$ or post operative\$).mp. {mp=title, original title, abstract, mesh headings, heading words, keyword} (36957)
- 4 2 or 3 (42208)
- 5 1 and 4 (541)
- 6 from 5 keep 1-541 (541)

SECTION B. Methods

Search strategy

We searched MEDLINE and the Cochrane Database of Systematic Reviews for literature published from database inception through January 2010 and obtained additional articles from consultation with experts and from reference lists of pertinent studies, reviews, and editorials. We updated this search for the purposes of this report in October 2011. Appendix Table 1 provides the search strategies in detail. We searched clinicaltrials.gov for information about unpublished studies. All citations were imported into an electronic database (EndNote X2, Thomson Reuters, New York, NY).

Study selection

Three investigators reviewed the abstracts of citations identified from literature searches. Full-text articles of potentially relevant abstracts were retrieved for further review. Eligible articles were published in English and provided primary data on the use of IIT in hospitalized patients. We excluded studies that evaluated fixed-dose insulin and glucose-insulin-potassium (GIK) infusions.

To evaluate the efficacy of and hypoglycemia risk associated with IIT in hospitalized patients, we considered randomized controlled trials that reported at least one of the following prespecified outcomes: mortality, cardiovascular events, congestive heart failure, disability, wound infection, sepsis, or renal failure requiring hemodialysis. We defined perioperative trials as those in which IIT was begun pre-, intra-, or immediately post-operatively and discontinued less than 24 hours post-operatively.

Because the safety of IIT may vary based on intervention and implementation characteristics, we evaluated hypoglycemia rates in controlled and uncontrolled studies of IIT protocols, even if they did not report other health outcomes (study selection details in Appendix Table 1).

To assess the risk of hypoglycemia associated with IIT, we included controlled and uncontrolled studies that evaluated IIT protocols in hospitalized patients, even if they did not report health outcomes. We excluded IIT studies that did not report rates of hypoglycemia [1-12]. In order to avoid studies with potential selection bias, we excluded prospective cohort studies in which patients were not consecutively enrolled or in which there was excessive loss to follow-up [12-21]. Because tight glycemic control strategies require personnel training and institutional acceptance, we excluded studies in which the intervention was evaluated over a short period of time (defined as 6 months or less) as we felt these studies were less likely to provide externally valid results [22-27].

Data extraction and quality assessment

From each study, we abstracted the following: study design, objectives, setting, demographics (sex, age, baseline morbidity), subject eligibility and exclusion criteria, number of subjects, years of enrollment, duration of follow-up, study and comparator interventions, method used to monitor blood glucose, target range for blood glucose control, outcomes measured, analytic method used, variables adjusted in the analysis, results of the study and mean blood glucose achieved in each group, information on concomitant therapy/nutrition, occurrence of hypoglycemia in each group, and any other adverse events.

The quality of each study was rated as good, fair, or poor based on U.S. Preventive Task Force Service criteria [28]. When reviewers disagreed about quality rating, consensus was reached through discussion with all authors.

Meta-analysis

We conducted meta-analyses using IIT studies identified in our original search through January 2010. Studies identified from the update search through October 2011 were described, but not included in these meta-analyses. The primary outcome of interest was short-term mortality, defined as mortality occurring within 28 days or during the ICU or hospital stay. If studies reported more than one of these outcomes, we preferentially used 28-day mortality for the analysis, followed by hospital- or ICU-mortality. We conducted a sensitivity analysis based on short-term mortality definition. Secondary outcomes included 90- or 180-day mortality, infection, length of stay, and hypoglycemia. For each outcome, we abstracted the number of events and total subjects from each treatment arm and obtained a pooled estimate of relative risk (RR) using a random effects model [29]. Statistical heterogeneity was assessed by Cochran's Q test and I^2 statistic [30]. All analyses were performed using Stata 10.0 (StataCorp, College Station, TX, 2007).

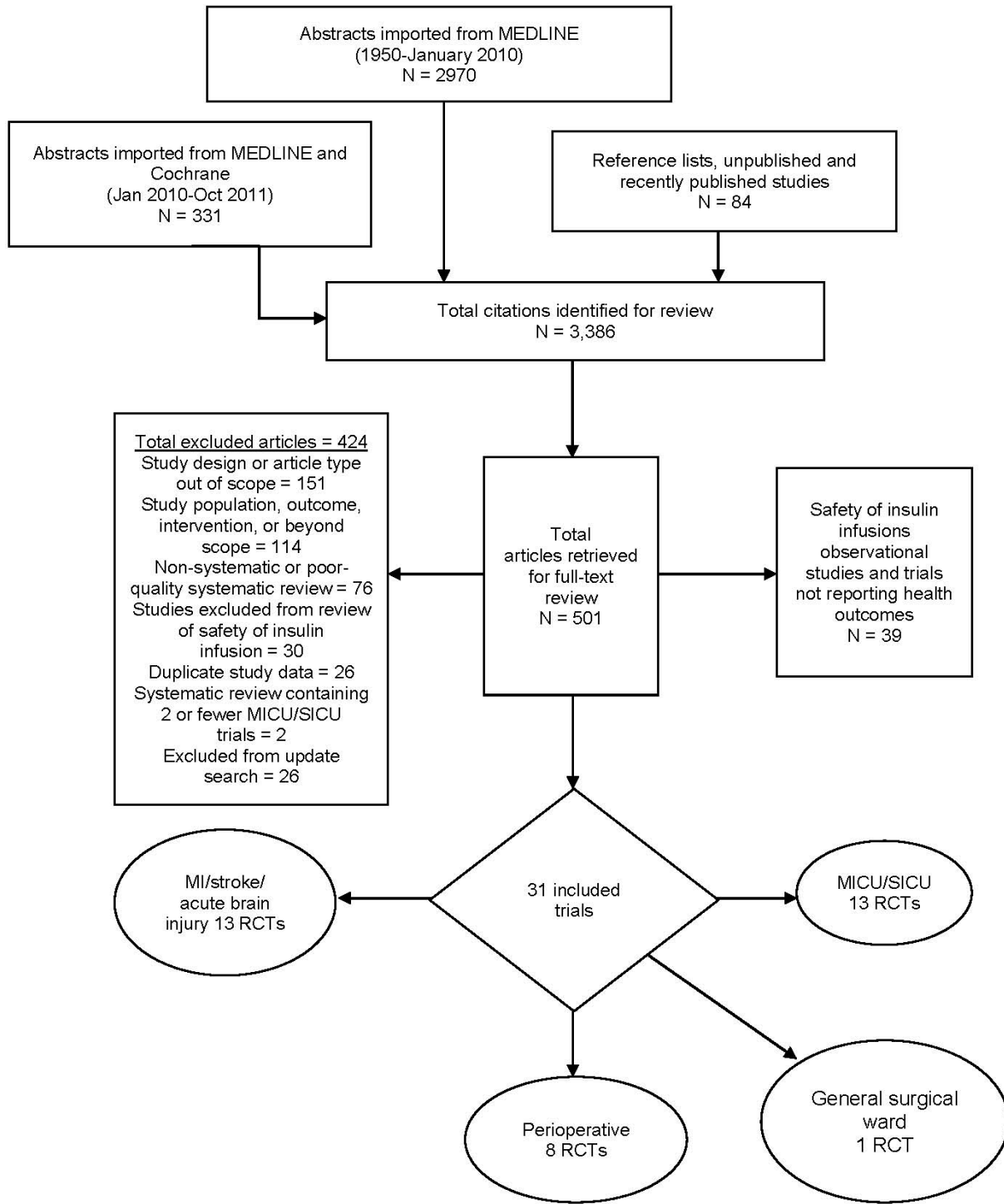
We conducted prespecified subgroup analyses comparing ICU with non-ICU studies, and sensitivity analyses on the following aspects: 1) the proportion of diabetic patients included, using 25% as a cut-point based on a natural division in the included studies; 2) mean blood

glucose achieved in the intervention group, using 6.7 mmol/L (120 mg/dL) as the cut-point since a lower threshold (6.1 mmol/L, 110 mg/dL) would have yielded only one study; and 3) study quality.

Study yield

From our initial search through January 2010, we identified 3,055 titles and abstracts of which 461 articles selected for full-text review. We included 31 trials conducted among critically ill patients, patients with acute MI or stroke, or perioperative patients. We also found 29 insulin protocol studies not reporting health outcomes. Our update search through October 2011 identified an additional 331 titles and abstracts of which 40 articles were selected for full-text review. We included 2 trials conducted in neurologic intensive care units, 1 trial in gastrectomy patients, and 1 trial of a subcutaneous insulin regimen in general surgical ward patients. We also found 10 insulin protocol studies not reporting health outcomes. The yield is summarized in Figure 1.

Figure 1, Chapter 22. Management of inpatient hyperglycemia literature flow



References

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Chapter 23. Interventions To Prevent Contrast-Induced Acute Kidney Injury

SECTION A. Literature Search

SEARCH METHODOLOGY

We conducted a structured search of PubMed using a search strategy developed by a medical librarian. The search strategy was last updated on December 6, 2011 and was as follows:

	Search string	Results
#1	((“contrast medium” OR “contrast media” OR “contrast dye” OR “radiographic contrast” OR “radiocontrast media” OR “radiocontrast medium” OR contrast agent*) AND (kidney diseases/ci OR kidney/ae OR kidney/de OR nephritis OR nephropath* OR nephrotox* OR renal insufficiencies[mh] OR renal insufficienc* OR diabetic nephropathies[mh] OR creatinine OR “kidney injury” OR “kidney dysfunction” OR “renal dysfunction”)) OR (“contrast induced” OR “contrast associated” AND (renal OR kidney OR nephropath* OR nephrotox*)) OR (contrast media/ae AND (kidney diseases[majr] OR kidney[majr] OR diabetic nephropathy[majr]))	5217
#2	#1 limited to Randomized Controlled Trials, English language, publication date since 1/1/2001	193
#3	#1 limited to Systematic Reviews, English language, publication date since 1/1/2001	53
#4	#3 limited to publication date since 1/1/2007	32

SECTION B. Methods

Based on the large number of systematic reviews identified by the above search, we opted to perform a systematic meta-review of the existing systematic reviews. We included only systematic reviews published since January 1, 2007. Two authors independently reviewed the 32 reviews identified through the PubMed search to identify systematic reviews and meta-analyses. All of the systematic reviews identified (N=20) were assessed for methodologic quality by two reviewers who independently completed the AMSTAR checklist. Disagreements in this process were resolved by consensus. The included systematic reviews were grouped according to the specific CI-AKI preventive intervention studied, and were summarized narratively.

Chapter 24. Rapid Response Systems (NEW)

SECTION A. Literature Search

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed: 2000-8/2/2011

LANGUAGE:

English

SEARCH STRATEGY:

“Hospital Rapid Response Team”[Mesh] OR “rapid response team” OR “rapid response teams” OR “rapid response system” OR “rapid response systems” OR “medical emergency team” OR “medical emergency teams” OR “critical care outreach team” OR “critical care outreach teams” OR “patient at-risk team” OR “patient at-risk teams” OR “patient at risk team” OR “patient at risk teams” OR “emergency medical team” OR “emergency medical teams”
AND
effectiv* OR implement* OR success* OR fail* OR utiliz* OR adopt*

OR

“patient care” AND team* AND (emergency OR emergencies OR rapid OR “critical care”)

AND

effectiv* OR implement* OR success* OR fail* OR utiliz* OR adopt*

NUMBER OF RESULTS: 1679

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

CINAHL: 2000-8/16/2011

SEARCH STRATEGY:

“rapid response team” OR “rapid response teams” OR “rapid response system” OR “rapid response systems” OR “medical emergency team” OR “medical emergency teams” OR “critical care outreach team” OR “critical care outreach teams” OR “patient at-risk team” OR “patient at-risk teams” OR “patient at risk team” OR “patient at risk teams” OR “emergency medical team” OR “emergency medical teams”

AND

effectiv* OR implement* OR success* OR fail* OR utiliz* OR adopt*

OR

“patient care” AND team* AND (emergency OR emergencies OR rapid OR “critical care”)

AND

effectiv* OR implement* OR success* OR fail* OR utiliz* OR adopt*

Search modes - Phrase Searching (Boolean)

NUMBER OF RESULTS: 333

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

EMBASE: 2000-11/4/2011

SEARCH STRATEGY:

‘rapid response team’/exp OR ‘rapid response team’ OR ‘rapid response teams’/exp OR ‘rapid response teams’ OR ‘rapid response system’/exp OR ‘rapid response system’ OR ‘rapid response systems’/exp OR ‘rapid response systems’ OR ‘medical emergency team’/exp OR ‘medical emergency team’ OR ‘medical emergency teams’/exp OR ‘medical emergency teams’ OR ‘critical care outreach team’ OR ‘critical care outreach teams’ OR ‘patient at-risk team’ OR ‘patient at-risk teams’ OR ‘patient at risk team’ OR ‘patient at risk teams’ OR ‘emergency medical team’ OR ‘emergency medical teams’ OR ((‘patient care’ NEAR/3 team*) AND (emergency OR emergencies OR rapid OR ‘critical care’))

AND

effectiv* OR implement* OR success* OR fail* OR utiliz* OR adopt*

NUMBER OF RESULTS: 594

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane: 2000-11/4/2011

SEARCH STRATEGY:

“rapid response team” OR “rapid response teams” OR “rapid response system” OR “rapid response systems” OR “medical emergency team” OR “medical emergency teams” OR “critical care outreach team” OR “critical care outreach teams” OR “patient at-risk team” OR “patient at-risk teams” OR “patient at risk team” OR “patient at risk teams” OR “emergency medical team” OR “emergency medical teams”:ti,ab,kw or “patient care” AND team* AND (emergency OR emergencies OR rapid OR “critical care”) :ti,ab,kw

NUMBER OF RESULTS: 72 (Syst Revs – 4, Other Revs – 7, Clin Trials – 55, Econ – 6)

SECTION B. Methods

PICOTS

Elements	
Population	Patients on general hospital wards - Adult and pediatric
Intervention	Rapid Response Systems
Comparator	Effectiveness: Usual practice Implementation: <ul style="list-style-type: none">- Technology/tools: criteria for activating team (extended vs restricted criteria), investment in human resources (team availability)- Staff selection/ training: Physician on team (MET model) vs. Nurse –led (RRT model); investment in team; education/training of team and floor staff- Identifying/addressing barriers/facilitators: Reluctance to call team, nursing workload, availability of team to respond
Outcomes	<ul style="list-style-type: none">• Mortality (total or preventable)• Incidence of cardio-respiratory arrest• Unanticipated intensive care unit admission
Timing	Before and after intervention
Settings	Hospitals

Inclusion/exclusion criteria:

Studies from all countries and languages were included

Effectiveness: Included all studies with a comparison group and at least some component of an RRS. Critical Care Outreach Team studies were included if they also included a pre-intensive care unit RRS component (general response to all ward patients). Effectiveness studies were only included after November 2008, the end date for a high-quality systematic review and meta-analysis.

Implementation: Included qualitative and quantitative studies addressing implementation.

Studies were defined as qualitative research studies if they used a formal qualitative methodology such as interviews, focus groups, or ethnography

Studies were defined as quantitative implementation studies if they evaluated the impact of a change or difference in implementation strategy on utilization of the RRS and/or patient outcomes.

Chapter 25. Medication Reconciliation Supported by Clinical Pharmacists (NEW)

SECTION A. Literature Search

A search strategy comprising multiple terms was developed by a library scientist with extensive experience in conducting systematic reviews in collaboration with a physician health services researcher also very experienced in literature searching and with content expertise in patient safety. As noted in the detailed description of the search, databases covered included MEDLINE, EMBASE, and the Cochrane library.

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to July 16, 2012>

- 1 ((reconcil* adj3 medicat*) or (med* reconcil* or medrec)).mp.
- 2 patient admission/ or patient discharge/ or patient readmission/ or patient transfer/ or Continuity of Patient Care/ or transition.ti.
- 3 Medication Errors/ or ((medication or discrepant* or discontinuit* or reconciliation).ti. or (medication adj8 discrepant*).ti,ab.)
- 4 (2 and 3) or 1
- 5 limit 4 to english

Embase <1980 to 2011 Week 18>

- 1 ((reconcil* adj3 medicat*) or (med* reconcil* or medrec)).mp.
- 2 Medication Errors/ or ((medication or discrepant* or discontinuit* or reconciliation).ti. or (medication adj8 discrepant*).ti,ab.)
- 3 hospital admission/ or hospital discharge/ or hospital readmission/ or patient transfer*.mp. or (continuity adj3 care).mp. or transition.ti.
- 4 1 or (3 and 2)
- 5 limit 4 to english

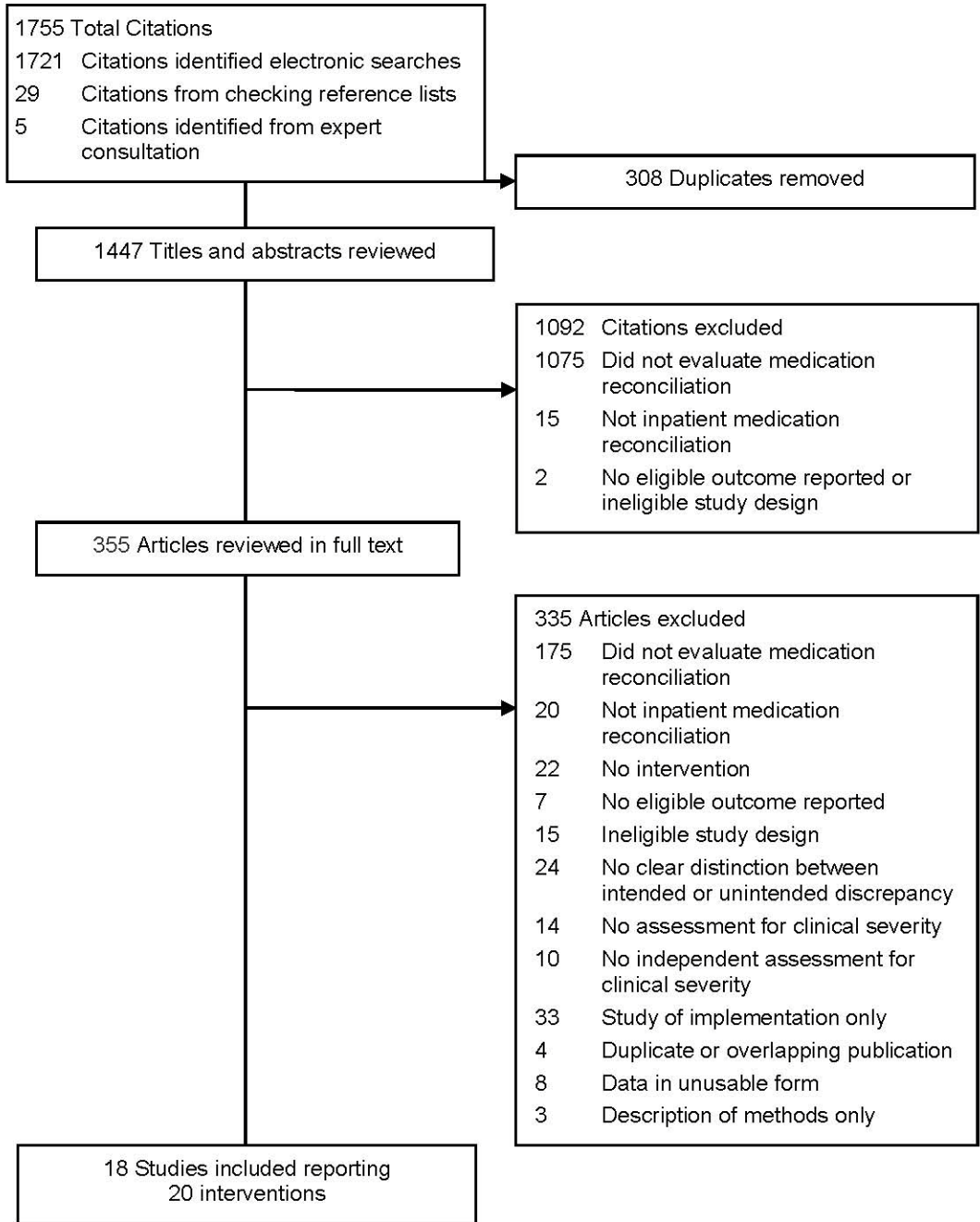
Cochrane CENTRAL (Central Register of ControlLed Trials) <June 2009>

- #1 (medication reconciliation):ti,ab,kw
- #2 "medication reconciliation":ti,ab,kw
- #3 (reconcil* near/3 medicat*):ti,ab,kw
- #4 (medrec):ti,ab,kw
- #5 (#1 OR #2 OR #3 OR #4)

SECTION B. Methods

Titles and abstracts were independently reviewed by 2 of 3 individuals, including a library scientist who has conducted numerous systematic reviews, a master's level research assistant with content experience in patient safety, a physician trainee with health services research

experience. Disagreements were resolved by discussion between reviewers as well as and consultation with a physician health services researcher with expertise in patient safety and extensive experience with systematic reviews.



Chapter 26. Identifying Patients at Risk for Suicide: Brief Review (NEW)

SECTION A. Literature Search

To conduct the review, we searched PubMed in October 2011 using major heading search terms Suicide, and Hospital or Inpatient or Safety Management, for English language articles published starting in the year 2000. We expanded the search using the PubMed “related citations” feature, and Google Scholar to search for citing articles of those retained for review; we identified additional relevant articles by reference mining. We also searched PSNet. Clinical trials, large observational studies, reviews, and reports on implementations were given priority. Systematic reviews were scored for methodologic quality using the 11-point AMSTAR scale; items rated Not Applicable were not counted towards either the score or the total.

SECTION B. Methods

Titles, abstracts and articles were reviewed by a psychiatrist health services researcher with extensive experience in systematic reviews, including a prior review of suicide prevention programs. The synthesis was narrative.

Chapter 27. Strategies To Prevent Stress-Related Gastrointestinal Bleeding (Stress Ulcer Prophylaxis): Brief Update Review

SECTION A. Literature Search

We searched PubMed for relevant articles using the search terms “stress ulcer” and “stress ulcer prophylaxis”, limited to systematic reviews published in the past 5 years. This search identified 19 articles

SECTION B. Methods

Articles identified using the above strategies were reviewed by two practicing hospitalists, one of whom has prior expertise in conducting and analyzing systematic reviews. The systematic reviews identified through this search form the basis of this review. These systematic reviews were summarized narratively, and their reference lists were reviewed by hand to identify other key articles on costs and implementation.

Chapter 28. Prevention of Venous Thromboembolism: Brief Update Review

SECTION A. Literature Search

For this topic we did not do a formal literature search, as the principal reviews and trials were already known to the authors as part of their quality improvement work where previous comprehensive searches had been performed to identify the most pertinent and up to date literature.

SECTION B. Methods

These reviews and studies were reviewed by a surgeon health services researcher with clinical and quality improvement experience with venous thromboembolism. The synthesis was narrative.

Chapter 29. Preventing Patient Death or Serious Injury Associated With Radiation Exposure from Fluoroscopy and Computed Tomography: Brief Review (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
ECRI Institute members website	Searched November 8, 2011	ECRI Institute
Institute for Healthcare Improvement	Searched November 14, 2011	
PSNet	Searched November 14, 2011	Agency for Healthcare Research and Quality
PubMed	Searched November 11, 2011	National Library of Medicine

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Non-journal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature as well as related citation searches using the Scopus database. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.) A number of organization websites were searched for relevant information, including: ECRI Institute members website, the Institute for Healthcare Improvement (ISI), and the Agency for Healthcare Research and Quality's Patient Safety Network (PSNet).

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in PubMed syntax. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH)

Conventions:

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

- [pt] = publication type
 [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
 [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
 [tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Adverse effects of radiation therapy	"radiation injuries/prevention and control"[majr] "radiation-protective agents"[majr] "radiation monitoring"[majr] "radiation dosage"[majr] "dose-response relationship, radiation"[majr] "radiation protection"[majr] "fluoroscopy/adverse effects"[majr] "radiography, interventional/adverse effects"[majr] "radiotherapy/adverse effects"[majr] radiation[majr] death[majr] mortality[majr] "wounds and injuries"[majr] burns[mesh] "skin transplantation"[mesh]	radiation fluoroscop* injuri* injury* death mortality injur* harm burn* skin graft skin transplant grade 3 grade 4
Programs	"outcome and process assessment (health care)"[majr] "safety management"[majr] "risk assessment"[majr] "secondary prevention"[mesh] "program development"[mesh] "program evaluation"[mesh] "health plan implementation"[mesh]	prevent* reduc* initiative* program* implement*
Study design	randomized controlled trial[pt] controlled clinical trial[pt] randomized controlled trials[mh] random allocation[mh] double-blind method[mh] single-blind method[mh] clinical trial[pt] clinical trials[mh] research design[mh:noexp] comparative study[pt] evaluation studies[pt] evaluation studies as topic[mh] follow-up studies[mh] prospective studies[mh] cross-over studies[mh] meta-analysis[mh] meta-analysis[pt] outcomes research[mh] multicenter study[pt]	clinical trial clinical trials comparative study comparative studies evaluation study evaluation studies

Pubmed

English language, human

Set Number	Concept	Search statement
1	Adverse effects of radiation therapy, controlled vocabulary only	"radiation injuries/prevention and control"[majr] OR "radiation-protective agents"[majr] OR "radiation monitoring"[majr] OR "radiation dosage"[majr] OR "dose-response relationship, radiation"[majr] OR "radiation protection"[majr] OR "fluoroscopy/adverse effects"[majr] OR "radiography, interventional/adverse effects"[majr] OR "radiotherapy/adverse effects"[majr]
2	Adverse effects of radiation therapy, controlled vocabulary and title/abstract	(radiation[majr] OR radiation[ti] OR fluoroscop*[ti]) AND (injur*[ti] OR injury*[ti] OR death[majr] OR death[ti] OR mortality[majr] OR mortality[ti] OR "wounds and injuries"[majr] OR injur*[ti] OR harm[ti] OR burns[mesh] OR burn*[ti] OR "skin transplantation"[mesh] OR "skin graft"[tiab] OR "skin transplant"[tiab] OR grade 3[tiab] OR grade 4[tiab])
3	Programs, preventive or assessment	"outcome and process assessment (health care)"[majr] OR "safety management"[majr] OR "risk assessment"[majr] OR prevent*[ti] OR reduc*[ti] OR "secondary prevention"[mesh] OR prevention[tiab] OR initiative*[tiab] OR "program development"[mesh] OR "program evaluation"[mesh] OR program*[tiab] OR "health plan implementation"[mesh] OR implement*[tiab]
4	Study design	randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies[pt] OR evaluation studies as topic[MH] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR meta-analysis[mh] OR meta-analysis[pt] OR outcomes research[mh] OR multicenter study[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] OR comparative study[tw] OR comparative studies[tw] OR evaluation study[tw] OR evaluation studies[tw]
5	Combine	(S1 OR S2) AND S3 AND S4
6	Apply date limit	2000-2011

Total Downloaded	Total Retrieved	Total Included
80	56	10

SECTION B. Methods

Titles and abstracts were reviewed by a health services research methodologist with experience in both systematic reviews and radiation therapy. Our research was limited to studies implementing practices (e.g., protocols, technical measures) to reduce radiation exposure to patients from fluoroscopy and computed tomography-guided diagnostic and interventional procedures. The focus was on studies published from 2005 to the present that compared outcomes (e.g., radiation dose, imaging time) following implementation of these practices compared to a control period when the technologies were not in place. Potential barriers to implementation, technical difficulty of practices and reported harms from patient safety practices were also assessed. Included studies were narratively summarized by the author.

Chapter 30. Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment: Brief Update Review

SECTION A. Literature Search

For this topic, since we had just completed a 2011 Agency for Healthcare Research and Quality systematic review on the topic of interventions to improve end-of-life care, we used syntheses and articles identified in this search, and did not conduct any additional literature searches.

SECTION B. Methods

Relevant reviews and studies were reviewed by a palliative care physician health services researcher with clinical and quality improvement experience with end-of-life care. The synthesis was narrative.

Chapter 31. Human Factors and Ergonomics

SECTION A and B. Literature Search and Methods

For this topic we determined that a systematic review of “Human Factors and Ergonomics” would be too diffuse to be useful to readers. Therefore this topic uses exemplars to illustrate different ways that human factors and ergonomics can be useful in patient safety.

Chapter 32. Promoting Engagement by Patients and Families To Reduce Adverse Events

SECTION A. Literature Search

SEARCH METHODOLOGIES

SEARCH #1:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2006-9/15/2011

LANGUAGE:

English

SEARCH STRATEGY:

“Physician–Patient Relations” OR “Nurse–Patient Relations” OR “Patient Participation” OR “Patient Education as Topic” OR “Social Responsibility” OR “Patient-Centered Care” OR “informed consent” OR “chronic disease”

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or “Cross Infection/prevention and control”

NUMBER OF RESULTS: 1673

SEARCH #2:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2006-9/15/2011

SEARCH STRATEGY:

Patient participation OR patient role OR patients role OR patient complain* OR patients complain*

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or “Cross Infection/prevention and control” OR safe* OR “medical error” OR “medical errors” OR mistake* OR “medication error” OR “medication errors”

AND

“patient participation”[All Fields]

NUMBER OF RESULTS: 4434

SEARCH #3:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2006-9/15/2011

SEARCH STRATEGY:

“Physician–Patient Relations” OR “Nurse–Patient Relations” OR “Patient Participation”[mh] OR “Patient Education as Topic” OR “informed consent” OR “patient reporting”[tiab] OR “patient reports”[tiab] OR “patients reporting”[tiab] OR “patients reports”[tiab] OR complain*[ti] OR patient participa* OR patients participa* OR “patient education”[tiab] OR “education of patients”[tiab]) OR “patient role” OR “patient’s role” OR “patients’ role*” OR “health literacy”

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or “Cross Infection/prevention and control” OR safe* OR “medical error” OR “medical errors” OR mistake* OR “medication error” OR “medication errors” OR adverse OR dangerous

AND

systematic[sb]

NUMBER OF RESULTS: 593

SEARCH #4:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2006-9/15/2011

SEARCH STRATEGY:

patient participation[mh] OR “patient participation”[tiab] OR “patient role” OR “patients role” OR patient complain* OR patients complain* OR “patient reporting”[tiab] OR “patient reports”[tiab] OR “patients reporting”[tiab] OR “patients reports”[tiab]

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or “Cross Infection/prevention and control” OR safe* OR “medical error” OR “medical errors” OR mistake* OR “medication error” OR “medication errors”

NUMBER OF RESULTS: 514

=====

SEARCH #5:

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane Database of Systematic Reviews – 2006-9/15/2011

SEARCH STRATEGY:

“Physician–Patient Relations” OR “Nurse–Patient Relations” OR “Patient Participation” OR “Patient Education” OR “informed consent” OR “patient reporting” OR “patient reports” OR “patients reporting” OR “patients reports” OR complain* OR patient participa* OR patients participa* OR “patient education” OR “education of patients” OR “patient role” OR “patient’s role” OR patients’ role* OR “health literacy” in Title, Abstract or Keywords

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or “Cross Infection/prevention and control” OR safe* OR “medical error” OR “medical errors” OR mistake* OR “medication error” OR “medication errors” OR adverse OR dangerous in Title, Abstract or Keywords

NUMBER OF RESULTS: 909

=====

SEARCH #6:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2006-9/19/2011

SEARCH STRATEGY:

“Physician–Patient Relations” OR “Nurse–Patient Relations” OR “Patient Participation” OR
“Patient Education as Topic” OR “Social Responsibility” OR “Patient-Centered Care” OR
“informed consent” OR “chronic disease”

AND

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical
Errors/prevention and control” or “Medical Errors/adverse effects” or “Safety Management” or
“Cross Infection/prevention and control”

NUMBER OF RESULTS: 2660

=====

SEARCH #7:

DATABASE SEARCHED & TIME PERIOD COVERED:

Medline on OVID – 2000-9/19/2011

SEARCH STRATEGY:

Physician Patient Relations/ OR Nurse Patient Relations/ OR Patient Participation/ OR Patient
Education as Topic/ or Social Responsibility.mp. OR Patient Centered Care/ OR informed
consent.mp. OR chronic disease\$.mp.

AND

(adverse event\$ OR iatrogenic disease OR medical adj error\$ OR safety adj2 manag\$ OR cross
adj2 Infection\$ adj2 prevent\$ OR adverse effect\$).mp. [mp=protocol supplementary concept,
rare disease supplementary concept, title, original title, abstract, name of substance word, subject
heading word, unique identifier]

NUMBER OF RESULTS: 1776

=====

SEARCH #8:

DATABASE SEARCHED & TIME PERIOD COVERED:

Medline on OVID – 2000-9/19/2011

SEARCH STRATEGY:

(Patient adj2 participa\$ or patient\$ adj5 role or patient adj5 complain4 or patient\$ adj3 involv\$
or patient\$ adj3 engag\$ or patient\$ adj3 report\$).mp.

AND

(adverse adj2 event\$).mp. or iatrogenic Disease/pc or Medical Errors/pc or Medical Errors/ae or
Cross Infection/pc or safe\$.mp. or unsaf\$.mp. or medical.mp. adj3 error\$.mp. or mistake\$.mp. or
medication.mp. adj3 error\$.mp.

NUMBER OF RESULTS: 532

=====

SEARCH #9:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – 2000-10/5/2011

SEARCH STRATEGY:

“adverse events” OR “Iatrogenic Disease/prevention and control” OR “Medical Errors/prevention and control” OR “medication errors/prevention and control” OR “Medical Errors/adverse effects” OR “Safety Management” OR “Cross Infection/prevention and control” OR “infection control”

AND

“Physician-Patient Relations” OR “Nurse-Patient Relations” OR “Patient Participation” OR “Patient Education as Topic” OR “Patient-Centered Care” OR “patient reporting” OR “patient-empowering” OR “patient empowerment” OR “patient partnership” OR “patient activation” or “patient self-effectiveness” or “patient involvement”

NUMBER OF RESULTS: 1499

=====

SEARCH #10:

DATABASE SEARCHED & TIME PERIOD COVERED:

CINAHL – 2000-10/24/2011

SEARCH STRATEGY:

(TI (Physician n3 Patient n3 relation*) OR (Nurse n3 Patient n3 relation*) OR Patient n3 Participat* OR Patient n3 Education OR “Patient-Centered Care” OR “patient reporting” OR patient n2 empower* OR patient n3 partner* OR “patient activation” OR “patient self-effectiveness” OR patient n3 involv*

OR AB (Physician n3 Patient n3 relation*) OR (Nurse n3 Patient n3 relation*) OR Patient n3 Participat* OR Patient n3 Education OR “Patient-Centered Care” OR “patient reporting” OR patient n2 empower* OR patient n3 partner* OR “patient activation” OR “patient self-effectiveness” OR patient n3 involv*

OR MW (Physician n3 Patient n3 relation*) OR (Nurse n3 Patient n3 relation*) OR Patient n3 Participat* OR Patient n3 Education OR “Patient-Centered Care” OR “patient reporting” OR patient n2 empower* OR patient n3 partner* OR “patient activation” OR “patient self-effectiveness” OR patient n3 involv*)

AND

‘adverse events’ OR ‘iatrogenic disease’ OR ‘medical errors’ OR ‘medication errors’ OR ‘medication error’ OR ‘medical error’ OR (‘cross infection’ AND prevent*) OR ‘safety management’ OR ‘infection control’

NUMBER OF RESULTS: 1283

=====

SEARCH #11:

DATABASE SEARCHED & TIME PERIOD COVERED:

Embase – 2000-10/27/2011

SEARCH STRATEGY:

‘physician-patient relations’ OR ‘nurse-patient relations’ OR ‘patient participation’ OR ‘patient education’ OR ‘patient-centered care’ OR ‘patient reporting’ OR ‘patient-empowering’ OR ‘patient empowerment’ OR ‘patient partnership’ OR ‘patient activation’ OR ‘patient self-effectiveness’ OR ‘patient involvement’ OR ‘doctor patient relation’

AND

‘adverse events’ OR ‘iatrogenic disease’ OR ‘medical errors’ OR ‘medication errors’ OR ‘medication error’ OR ‘medical error’ OR ‘cross infection’ AND prevent* OR ‘safety management’ OR ‘infection control’

NUMBER OF RESULTS: 2869

=====
SEARCH #12a:

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane Databases– 2000-11/9/2011

SEARCH STRATEGY:

“‘physician-patient relations’ OR ‘nurse-patient relations’ OR ‘patient participation’ OR ‘patient education’ OR ‘patient-centered care’ OR ‘patient reporting’ OR ‘patient-empowering’ OR ‘patient empowerment’ OR ‘patient partnership’ OR ‘patient activation’ OR ‘patient self-effectiveness’ OR ‘patient involvement’ OR ‘doctor patient relation’ OR ‘physician-patient relation’” in Title, Abstract or Keywords

AND

adverse OR iatrogenic OR error* OR harm* OR safe* OR (infection* AND prevent*) OR (infection* AND control*) in Title, Abstract or Keywords

NUMBER OF RESULTS: 7 (Cochrane Reviews [1] Other Reviews [0] | Clinical Trials [5] | Methods Studies [1] | Technology Assessments [0] | Economic Evaluations [0] Cochrane Groups [0])

=====
SEARCH #12b:

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane Databases– 2000-11/9/2011

SEARCH STRATEGY:

MeSH descriptor Physician-Patient Relations, this term only OR MeSH descriptor Patient Education as Topic, this term only OR MeSH descriptor Patient Participation explode all trees
AND

MeSH descriptor Safety Management, this term only OR drug toxicity OR MeSH descriptor Medical Errors explode all trees OR MeSH descriptor Infection explode all trees with qualifier: PC (Prevention & Control)

NUMBER OF RESULTS: 81 (Cochrane Reviews [5] | Other Reviews [4] | Clinical Trials [71] | Methods Studies [0] | Technology Assessments [0] | Economic Evaluations [1] | Cochrane Groups [0])

SECTION B. Methods

PICOTS

Elements	
Population	Patients in inpatient healthcare settings (adult and pediatric) and their family members
Intervention	Any intervention to encourage patient involvement in safety, including reporting adverse outcomes or errors
Comparator	Usual practice
Outcomes	Effectiveness of the intervention
Timing	Before and after the intervention
Settings	Hospitals

Inclusion/exclusion criteria:

- Only English-language studies from the US, UK, Canada, and Australia were included in the present review, due to potentially significantly different cultural issues in patient engagement in their health care outside of these countries, as well as potential differences in tools for promoting engagement.
- Included studies were required to focus on hospital care settings (e.g., intensive care units) – patient engagement in safety in the home setting would be difficult to differentiate from patient self-management of their medications and care, when providers are not present.
- Only systematic reviews focusing on effectiveness and prospective, controlled studies were included.

Chapter 33. Promoting a Culture of Safety

SECTION A. Literature Search

Search Methodology

PubMed:

Limit from 2000

Final Search Strategy:

“patient safety culture” OR “safety culture survey” OR “safety attitude questionnaire” OR “safety attitudes questionnaire” OR “safety attitude” OR “patient safety practice” OR (“Hospital Survey” AND “patient safety culture”) OR “Manchester Patient Safety Framework” OR (“Patient Safety Culture” AND survey) OR “patient safety climate” OR (“safety culture” OR “safety practice” OR “safety climate” OR “high reliability”)
AND

(rehabilitation OR snf OR “nursing home” OR “skilled nursing facility” OR hospital OR hospitals OR ICU OR intensive care unit OR “emergency room” OR attitude OR attitudes OR “assisted living” OR “long term care” OR resident OR residents OR “health center” OR

healthcare OR “health care” OR patients OR patient OR intervention OR improvement OR scale OR “primary care”)) OR “hospital patient climate safety scale” OR “culture of safety” OR “culture of trust” OR (culture[ti] reliability[ti])
Total Retrieved: 1637

Patient Safety Practices/Culture – PTN: HQ208-1000
search by J Larkin 9/19/2011

CINAHL:

Limit from 2000

Search Strategy:

“patient safety culture” OR “safety attitude questionnaire” OR “patient safety practice” OR “hospital survey on patient safety” OR “manchester patient safety framework” OR “hospital patient climate safety scale” OR “culture of safety” OR “culture of reliability” OR “culture of trust”

OR

(“safety culture” OR “safety practice” OR “safety climate” OR “high reliability”

AND

“skilled nursing facility” OR hospital OR hospitals OR ICU OR intensive care unit OR “emergency room” OR attitude OR attitudes OR “assisted living” OR “long term care” OR resident OR residents OR “health center” OR healthcare OR “health care” OR patients OR patient OR intervention OR improvement OR scale OR “primary care”)

802 results (NOT deduped with PubMed or any other database)

Results sent in .txt file(this is the generic bibliographic software file option) (unable to save to an .ris file from Ebsco)

PSC_Cinahl.txt

Patient Safety Practices/Culture – PTN: HQ208-1000
search by J Larkin 9/20/2011

Cochrane:

Limit from 2000

Search Strategy:

“patient safety culture” OR “safety attitude questionnaire” OR “patient safety practice” OR “hospital survey on patient safety” OR “manchester patient safety framework” OR “hospital patient climate safety scale” OR “culture of safety” OR “culture of reliability” OR “culture of trust”

OR

(“safety culture” OR “safety practice” OR “safety climate” OR “high reliability”

AND

“skilled nursing facility” OR hospital OR hospitals OR ICU OR intensive care unit OR “emergency room” OR attitude OR attitudes OR “assisted living” OR “long term care” OR

resident OR residents OR “health center” OR healthcare OR “health care” OR patients OR patient OR intervention OR improvement OR scale OR “primary care”)

51 results (NOT deduped with PubMed or any other database)
PSC_cochrane.ATXT

Patient Safety Practices/Culture – PTN: HQ208-1000
search by J Larkin 9/20/2011

embase Search:
Limit from 2000
no mapping or exploding of terms and unchecked “medline”
Search Strategy:

“patient safety culture” OR “safety attitude questionnaire” OR “patient safety practice” OR “hospital survey on patient safety” OR “manchester patient safety framework” OR “hospital patient climate safety scale” OR “culture of safety” OR “culture of reliability” OR “culture of trust”

OR

(“safety culture” OR “safety practice” OR “safety climate” OR “high reliability”

AND

“skilled nursing facility” OR hospital OR hospitals OR ICU OR intensive care unit OR “emergency room” OR attitude OR attitudes OR “assisted living” OR “long term care” OR resident OR residents OR “health center” OR healthcare OR “health care” OR patients OR patient OR intervention OR improvement OR scale OR “primary care”)

1352 results (NOT deduped with PubMed or any other database)

In this instance, the combination of terms and this database in general tend to produce higher numbers of results. I do believe there will be a decent amount of overlap with the other databases though.

PSC_embase.ris

Patient Safety Practices/Culture – PTN: HQ208-1000
search by J Larkin 9/19/2011

PsycInfo Search:
Limit from 2000
Search Strategy:

“patient safety culture” OR “safety attitude questionnaire” OR “patient safety practice” OR “hospital survey on patient safety” OR “manchester patient safety framework” OR “hospital patient climate safety scale” OR “culture of safety” OR “culture of reliability” OR “culture of trust”

OR

(“safety culture” OR “safety practice” OR “safety climate” OR “high reliability”

AND

“skilled nursing facility” OR hospital OR hospitals OR ICU OR intensive care unit OR “emergency room” OR attitude OR attitudes OR “assisted living” OR “long term care” OR resident OR residents OR “health center” OR healthcare OR “health care” OR patients OR patient OR intervention OR improvement OR scale OR “primary care”)

727 results (NOT deduped with PubMed or any other database)

Results sent in .txt file(this is the generic bibliographic software file option) (unable to save to an .ris file from Ebsco)

PSC_Psycinfo.txt

SECTION B. Methods

PICOTS

Elements	
Population	Patients in inpatient healthcare settings Adult and pediatric
Intervention	Promoting a culture of safety
Comparator	Usual practice
Outcomes	Overall <ul style="list-style-type: none"> - Change in patient safety culture/climate - Clinical indicators of safety/harm where available
Timing	Before and after the intervention
Settings	Hospitals

Inclusion/exclusion criteria:

-Only English-language studies from the US, UK, Canada, and Australia were included in the present review. While there are a growing number of studies that have translated English-language surveys of culture into other languages, there is still limited evidence that construct validity of such measures is comparable across samples.

-Included studies were required to focus on in-patient units within hospital care settings (e.g., intensive care units). Studies in the operating room, radiology, and other non-inpatient units were not included in this review.

- Included studies had to report on measures of culture over at least two points in time.

- Included studies were also required to use a psychometrically valid measure of safety culture that is present in the peer-reviewed literature. As a guideline, studies that utilized one of the following measures of patient safety culture were included: hospital survey on patient safety culture (HSOPSC) / HSOPS, Hospital Survey on Patient Safety Patient Safety Climate/ patient safety climate in health care organizations (PSCHO), Safety Climate Survey (SCS) Safety Attitudes Questionnaire (SAQ) Hospital safety climate scale (HSC) Operating Room Management Attitudes Questionnaire (ORMAQ) Hospital Survey on Patient Safety Stanford/PSCI Culture Survey Safety Climate Scale MSSA, Medication Safety Self Assessment HTSSCS, Hospital Transfusion Service Safety Culture Survey Manchester Patient Safety Framework.

- Interventions had to target practicing health care professionals or para-professionals. Studies examining PSPs aimed at medical or nursing students, or otherwise including only education outside of a clinical setting, were not included.

- The stated purpose of the PSP described had to specifically include aims “to improve culture”.

-Studies specifically targeting patient safety culture were included. Studies of other types of culture (e.g., general organizational culture) were not included.
-Only prospective studies were included.

Chapter 34. Effect of Nurse-to-Patient Staffing Ratios on Patient Morbidity and Mortality

SECTION A. Literature Search

DATABASE SEARCHED & TIME PERIOD COVERED:

Web of Science – 2007-9/12/2012

SEARCH STRATEGY:

“Forward searches” on the following 4 source publications:

Kane RL, Shamliyan T, Mueller C, Duval S, Wilt TJ.

“Nursing Staffing and Quality of Patient Care,” *Evid Rep Technol Assess.* 2007 Mar;(151):1-115.

NUMBER OF RESULTS: 78

Robert L. Kane, MD,* Tatyana A. Shamliyan, Christine Mueller, Sue Duval, and Timothy J. Wilt

“The Association of Registered Nurse Staffing Levels and Patient Outcomes: Systematic Review and Meta-Analysis,” *Medical Care* 2007 Dec;45(12):1195-1204.

NUMBER OF RESULTS: 149

Aiken LH, Clarke SP, Cheung RB, Sloane DM, Silber JH.

“Educational levels of hospital nurses and surgical patient mortality.” *JAMA.* 2003 Sep 24;290(12):1617-23.

NUMBER OF RESULTS: 337

Needleman J, Buerhaus P, Mattke S, Stewart M, Zelevinsky K.

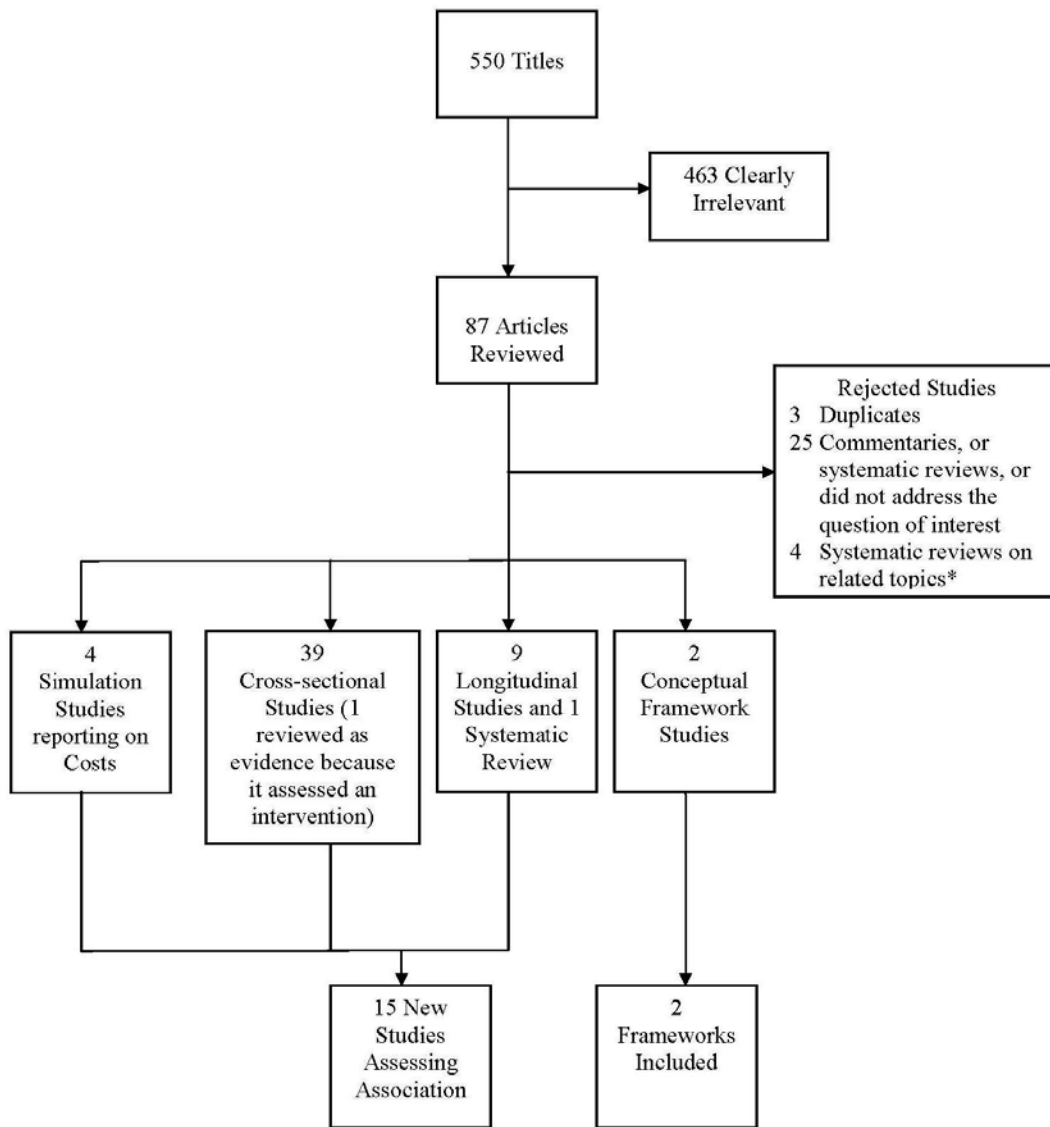
“Nurse-staffing levels and the quality of care in hospitals.” *N Engl J Med.* 2002 May 30;346(22):1715-22.

NUMBER OF RESULTS: 131

TOTAL NUMBER AFTER REMOVAL OF DUPLICATES: 546

SECTION B. Methods

Figure 1, Chapter 34. Literature flow diagram



*¹⁻⁴The figure shows the flow of articles through the review process. With one exception we did not include any additional cross-sectional studies of association. The one exception is detailed in the text.

References

1. Stone PW, Pogorzelska M, Kunches L, et al. Hospital staffing and health care-associated infections: A systematic review of the literature. *Clinical Infectious Diseases*. 2008;47(7):937-44.WOS:000259038400015
2. Cummings GG, MacGregor T, Davey M, et al. Leadership styles and outcome patterns for the nursing workforce and work environment: A systematic review. *International Journal of Nursing Studies*. 2010;47(3):363-85.WOS:000275611400012
3. Butler M, Collins R, Drennan J, et al. Hospital nurse staffing models and patient and staff-related outcomes. *Cochrane Database of Systematic Reviews*. 2011;(7).WOS:000292554300006
4. Flynn M, McKeown M. Nurse staffing levels revisited: a consideration of key issues in nurse staffing levels and skill mix research. *Journal of Nursing Management*. 2009;17(6):759-66.WOS:000283227200011.

Chapter 35. Patient Safety Practices Targeted at Diagnostic Errors (NEW)

SECTION A. Literature Search

We designed a four-pronged literature search strategy to identify a broad range of interventional studies with implications for errors in clinical diagnosis. In the first mechanism of our overall strategy, we utilized the Agency for Healthcare Research and Quality’s Patient Safety Network (PSNet, see *psnet.ahrq.gov*). The PSNet website contains regularly-updated resources related to patient safety, and therefore, the PSNet online database was searched for articles classified under the safety target “diagnostic error.” We used articles from this search in the final review, and also to test search terms for the PubMed MEDLINE database search. In the second search mechanism, we hand-screened two previous systematic reviews^{1,2} related to diagnostic errors, and adapted their search strategies for our review. In the third mechanism, a structured search was built to identify published literature indexed to the PubMed MEDLINE database (see Table 1). In the fourth mechanism, we reviewed reference lists of articles flagged in the earlier search phases for the purpose of identifying further eligible studies.

During the first review phase, every article identified through the first three mechanisms (n = 1,389) was screened by two independent reviewers who recommended the study for inclusion or exclusion based upon title and abstract (if available). To make these recommendations, reviewers excluded those studies that: (1) did not contain an intervention component, (2) contained an intervention component unrelated to diagnostic errors, or (3) did not report patient-related outcomes. Discrepancies between reviewer’s recommendations in this phase were evaluated by the entire team until a consensus was achieved. Articles that met our inclusion criteria proceeded to the second review phase, a full text review (n = 269). During the full text review, our final inclusion criteria required that studies reported: (1) results from an intervention related to diagnostic errors, and (2) relevant patient outcomes, or proxy measures of patient outcomes, indicating that (3) the study was conducted with real patients. Again, two independent reviewers evaluated full-text articles and recommended them for inclusion in the final report. The fourth search mechanism—the references review—was conducted by one researcher who screened 2,332 article titles. For all relevant articles, the abstracts were reviewed (n = 115) using the same inclusion criteria as above. Once an abstract was considered relevant, it entered data abstraction review by two separate reviewers. Discrepancies between reviewer recommendations in the second full-text phase were again addressed by the team consensus method. Studies that met the all aforementioned requirements in the second phase were included within the chapter (n = 91). Data were then abstracted from the final set of articles by two independent abstractors, and discrepancies in the data abstraction phase were evaluated by the team consensus method.

Figure 2 summarizes details number of studies identified initially by the four search mechanisms, and the number of included and excluded studies from each review phase.

Search Limitation: Due to the variety of potential topics related to diagnostic errors, the search strategy was built to identify a broad base of literature addressing potential contributors to errors across clinical domains and care settings. However, the current strategy did not include additional searches to directly target interventional types with lower yields as might be expected

if focusing on a specific clinical specialty or care setting. For example, the major subheading search for “Delayed Diagnosis” in MEDLINE would likely capture studies with a primary focus related to the current review, but may not capture a study primarily focusing on particular clinical processes such as x-ray review for injuries. The extensive number of possible search terminology combinations using specific clinical domains (e.g., “radiology”), care settings (e.g., “critical care”), and intervention types (e.g., “double review”) where diagnostic errors may occur was beyond the scope of the current review. However, with our extensive reference review we expect that our included studies represent at a minimum a reasonable probe of the literature for certain clinical specialties, care settings, and intervention types likely to be of importance to reducing diagnostic errors (e.g., evaluations of an additional reviewer of radiology reports added to the diagnostic pathway; laboratory-focused interventions).

Table 1, Chapter 35. MEDLINE search strategy

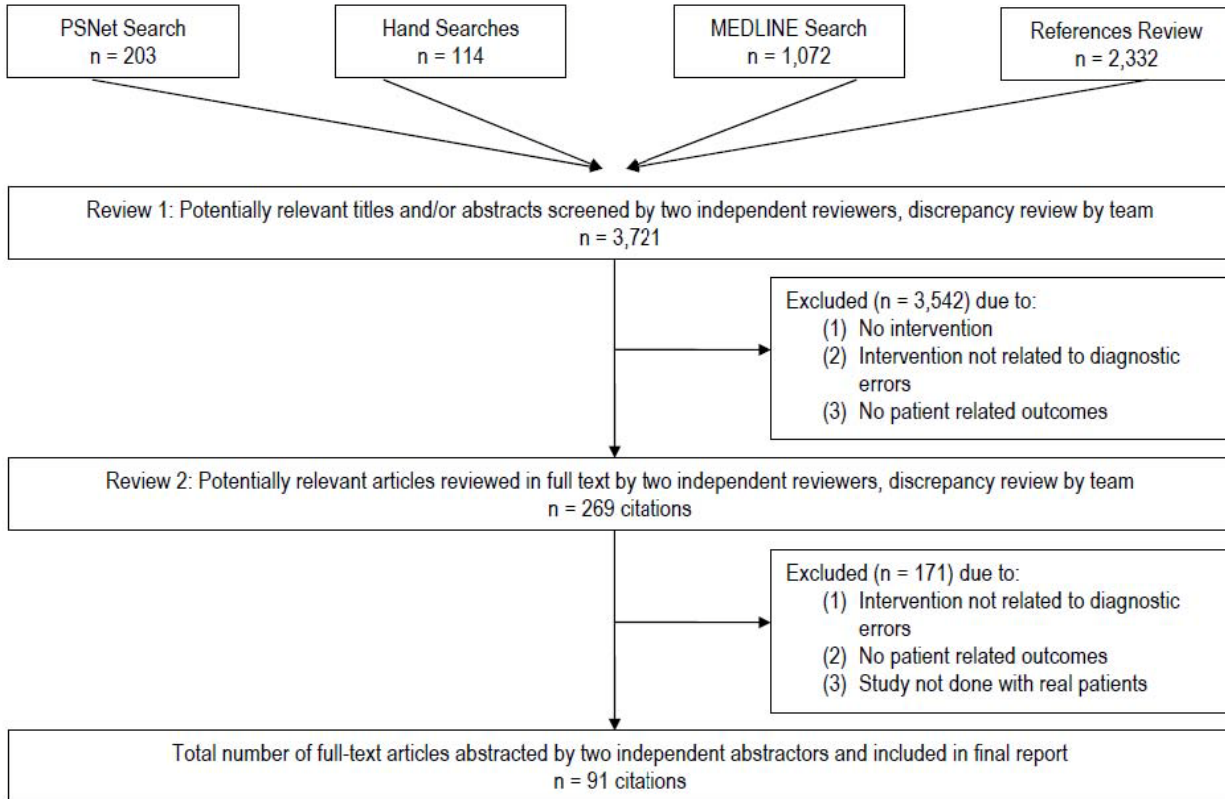
The final search was performed on October 10, 2011. The search was conducted using PubMed MEDLINE and was limited to English language publications.
The following two search strategies were used in conjunction with one another to identify articles with diagnostic error reduction interventions published between 1980 and 2011.
<i>Search Strategy A:</i> (((“Diagnostic Errors”[Majr] OR “Delayed Diagnosis”[Majr])) AND (interven*[tiab] OR intervention studies[mh] OR model*[ti] OR strateg* OR improv*[ti] OR implementation*[tiab] OR practices OR random* OR controlled clinical trial[pt] OR program[tiab] OR programs[tiab] OR programme[tiab] OR programmes[tiab] OR (program evaluation[mh] AND treatment outcome[mh]) OR systematic review*)
<i>Search Strategy B:</i> (((“Diagnostic Errors”[Majr] OR “Delayed Diagnosis”[Majr])) AND (“Affect”[Mesh] OR “Clinical Competence”[Mesh] OR “Communication”[Mesh] OR “Continuity of Patient Care”[Mesh] OR “Decision Making”[Mesh] OR “Decision Making, Organizational”[Mesh] OR “Decision Support Systems, Clinical”[Mesh] OR “Decision Support Techniques”[Mesh] OR “Human Engineering”[Mesh] OR “Judgment”[Mesh] OR “Medical Informatics”[Mesh] OR “Medical Records Systems, Computerized”[Mesh] OR “Mental Recall”[Mesh] OR “Organizational Culture”[Mesh] OR “Patient Access to Records”[Mesh] OR “Patient Participation”[Mesh] OR “Feedback”[Mesh] OR “Forms and Records Control/standards”[Mesh] OR “Guidelines as Topic”[Mesh] OR “Health Knowledge, Attitudes, Practice”[Mesh] OR “Health Literacy”[Mesh] OR “Health Records, Personal”[Mesh] OR “Physician-Patient Relations”[Mesh] OR “Physician’s Practice Patterns”[Mesh] OR “Problem Solving”[Mesh] OR “Professional-Patient Relations”[Mesh] OR “Reminder Systems”[Mesh] OR “Systems Analysis”[Mesh] OR “Time Factors”[Mesh] OR “Truth Disclosure”[Mesh] OR “Knowledge Bases”[Mesh] OR “cognitive error” OR “bias” OR “metacognition”)
Search Strategy B replicates that used by Singh et al ² , though for a wider date range. Citations from their search dates (2000-2009) were removed from both Search A and B, so as not to duplicate their work.

References

1. Ioannidis JP, Lau J. Evidence on interventions to reduce medical errors: an overview and recommendations for future research. *J Gen Intern Med.* 2001;16(5):325-34.11359552
2. Singh H, Graber ML, Kissam SM, et al. System-related interventions to reduce diagnostic errors: a narrative review. *BMJ Qual Saf.* 2012;21(2):160-70.22129930

SECTION B. Methods

Figure 2, Chapter 35. Diagnostic errors systematic review flow chart



Chapter 36. Monitoring Patient Safety Problems (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
EMBASE (Excerpta Medica)	1996 –September 21, 2011	OID SP
MEDLINE	1996 –September 21, 2011	OID SP
PreMEDLINE	Searched September 22, 2011	PubMed
PSNet	Searched September 13, 2011	AHRQ

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute’s collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE and MEDLINE.

Medical Subject Headings (MeSH), Emtree and Keywords

Conventions:

OVID

- \$ = truncation character (wildcard)
- exp = “explodes” controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary’s hierarchy)
- .de. or / = limit controlled vocabulary heading
- .fs. = floating subheading
- .hw. = limit to heading word
- .md. = type of methodology (PsycINFO)
- .mp. = combined search fields (default if no fields are specified)
- .pt. = publication type
- .ti. = limit to title
- .tw. = limit to title and abstract fields

PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = publication type
- [sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Adverse events	ae.fs. Adverse outcome/ exp Cross infection/ Hospital infection/ iatrogenic disease/ exp Medical errors/	Administration Adverse events Diagnostic Error\$ iatrogenic Medical Medication Nosocomial
Chart review	Concurrent review/ Documentation/ Drug utilization review/ Medical audit/ Medical records/ Medical record review/	Chart review Case finding Computerized surveillance
Patient safety	Patient safety/ Safety/ Safety management	Patient safety Patient Safety Organization PSO

Concept	Controlled Vocabulary	Keywords
Reporting Systems	Medline/Embase Adverse drug reaction reporting systems/ Population surveillance/ exp Product surveillance, postmarketing/ exp Postmarketing surveillance/ Sentinel surveillance/	
	PSNet Error reporting Government reporting Institutional reporting Reporting	
Trigger tools	Medline/Embase Electronic medical record/ Hospital information systems/	Automated Automatic Computer-based detection Data mining Electronic adj2 screen\$ Surveillance Trigger tool\$
	PSNet Computerized adverse event detection Electronic health records	

Embase/Medline/Premedline

English language, human, remove overlap

Set Number	Concept	Search statement
1	Adverse events	Ae.fs. or exp cross infection/ or iatrogenic disease/ or exp medical errors/ or adverse outcome/ or hospital infection/ or iatrogenic disease/
2		iatrogenic or nosocomial or (hospital adj acquired) or ((medical or medication or diagnostic or administration) adj2 error\$)
3	Combine sets	1 or 2
4	Direct observation	Direct observation or (executive adj walk\$)
5	Chart review	Chart review or chart\$.ti. or case finding
6		Concurrent review/ or documentation or drug utilization review/ or medical audit/ or medical records/ or medical record review/ or utilization review/
7	Combine sets – chart review	5 or 6
8	Trigger tools	(electronic medical record/ or hospital information systems/) and (data mining or automated or automatic or surveillance)
9		Electronic adj2 screen\$
10		Computer-based detection
11		Trigger tool\$
12	Combine sets	8 or 9 or 10 or 11
13	Combine sets – trigger tools	3 and (4 or 7 or 12)

Patient Safety Net (PSNET)

Set Number	Concept	Search statement	# downloaded
		<i>Browsed categories:</i> Computerized adverse event detection Governmental reporting Institutional reporting Non-governmental reporting Patient safety indicators	

Total Downloaded	Total Retrieved	Total Included
250	176	

SECTION B. Methods

Inclusion/Exclusion Criteria

Healthcare organizations have been using a wide array of methods to detect patient safety problems. These methods include incident reporting, direct observation of patient care, chart review, analysis of malpractice claims, patient complaints and reports to risk management, executive walk rounds, trigger-tool use, patient interviews, morbidity and mortality conferences, autopsy, and clinical surveillance. Many of these methods (e.g., trigger tools) can be further categorized by the targeted problems (e.g., medication-related medical errors or iatrogenic infections), tools, algorithms, and data source used. Given the limited time frame for this review, we focus this chapter on general approaches to detecting patient safety problems that involve using multiple methods (e.g., incident reporting, executive walk rounds, clinical surveillance, chart review, and trigger tools) to collect data. We primarily reviewed studies that compared the utilities of different methods, because we believe that understanding the strengths and weaknesses of different methods is most relevant to decision makers who need to form an effective strategy for monitoring patient safety problems for their organizations. Comparison studies that used one method (e.g., chart review) as a gold standard to validate another method (e.g., incident reporting) were not included for this chapter, because, in essence, these studies still focused on one individual method (i.e., the method being validated).

Only full published studies were considered for review (meeting abstracts were excluded). Only English-language publications were eligible for inclusion. For the effectiveness and harms of the PSP, we considered including studies of any design (e.g., systematic reviews, randomized controlled trials, non-randomized controlled trials, prospective and retrospective observational studies, surveys) that may provide relevant data. For the implementation and context of the PSP, we primarily abstracted data from the effectiveness or safety studies being reviewed.

Risk of Bias and Strength of Evidence

We did not assess the risk of bias of the included studies or the overall strength of evidence. The body of evidence consists of one systematic review and several studies that compared the types and numbers of patient safety problems identified using different methods. No adequately

validated tool is available for assessing this type of comparison studies or for assessing the overall strength of evidence that mixes such comparison studies with a systematic review.

Chapter 37. Interventions To Improve Care Transitions at Hospital Discharge (NEW)

SECTION A. Literature Search

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed: 1990-7/29/2011

LANGUAGE: English

SEARCH #1:

transitional care OR readmission OR readmit* OR patient discharg* OR (length of stay[mh] AND discharge plan*) OR (emergency service,hospital[mh] OR emergency service*[tiab] OR emergency room*) AND (discharg* OR home visits[mh] OR home visit*[tiab] OR house calls[mh] OR house call*)

AND

interven*[ti] OR intervention studies[mh] OR model*[ti] OR strateg* OR improv*[ti] OR practices OR random*

NUMBER OF RESULTS: 3540

SEARCH #2:

“transitional care” OR care transition* OR patient discharge[mh] OR patient discharge[tiab] OR discharge plan*[tiab] OR hospital discharg*[tiab] OR patient readmission[mh] OR readmission[tiab] OR readmit*[tiab] OR rehospital*[tiab]

OR

(emergency service*[tiab] OR emergency room* OR emergency service, hospital[mh]) AND (post-discharg* OR postdischarg* OR home visit[mh] OR home visit*[tiab] OR house calls[mh] OR house call*[tiab])

AND

home OR homes OR continuity of patient care OR “continuity of care” OR outpatient* OR ambulatory care OR self care[mh] OR “multidisciplinary care”

AND

systematic OR observation* OR prospective OR retrospective OR cohort OR intervention stud* OR evaluation stud* OR comparative stud* OR design* OR model[tiab] OR models[tiab] OR program[tiab] OR programs[tiab] OR program evaluation[mh] OR ((single OR double OR triple OR treble) AND (blind* OR mask*)) OR random*

NUMBER OF RESULTS: 5160

=====

DATABASE SEARCHED & TIME PERIOD COVERED:
Cochrane Central Register of Controlled Trials – 1990-8/12/2011

LANGUAGE:
English

SEARCH STRATEGY:

(transitional care OR readmission OR readmit* OR patient discharg*):ti,ab,kw or (length of stay OR “length-of-stay”) AND discharge plan*:ti,ab,kw or (emergency service,hospital OR emergency service* OR emergency room*):ti,ab,kw
AND
(discharg* OR home visits OR home visit* OR house calls OR house call*):ti,ab,kw
AND
(interven* OR model* OR strateg* OR improv* OR practices OR random*):ti,ab,kw
AND
home OR house

NUMBER OF RESULTS: 1030
NUMBER AFTER REMOVAL OF DUPLICATES: 620

=====
DATABASE SEARCHED & TIME PERIOD COVERED:
EconLit – 1990-8/15//2011

LANGUAGE:
English

SEARCH STRATEGY:
EconLit – 1990-8/15/2011

SEARCH STRATEGY:

transitional care OR readmission OR readmit* OR patient discharg* OR ((length of stay OR “length-of-stay”) AND discharge plan*) OR emergency service,hospital OR emergency service* OR emergency room*
AND
discharg* OR home visits OR home visit* OR house calls OR house call*

OR

readmit* OR readmission* OR rehospitali* OR re-hospitali*
AND
home OR house

NUMBER OF RESULTS: 48
NUMBER AFTER REMOVAL OF DUPLICATES: 38

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

PsycINFO – 1990-8/15/2011

SEARCH STRATEGY:

transitional care OR readmission OR readmit* OR patient discharg* OR ((length of stay OR “length-of-stay”) AND discharge plan*) OR emergency service,hospital OR emergency service* OR emergency room*

AND

discharg* OR home visits OR home visit* OR house calls OR house call*

AND

home OR house

Search modes - Phrase Searching (Boolean)

OR

“transitional care”

OR

readmit* OR readmission* OR rehospitali* OR re-hospitali*

AND

home OR house

NUMBER OF RESULTS: 617

NUMBER AFTER REMOVAL OF DUPLICATES: 407

=====

DATABASE SEARCHED & TIME PERIOD COVERED:

Embase – 1990-9/12/2011

LANGUAGE:

English

SEARCH STRATEGIES:

SEARCH #1 (S. Rennke Strategy)

‘transitional care’ OR care NEAR/3 transition* OR discharge NEAR/3 plan* OR patient NEAR/3 discharg* AND [humans]/lim AND [english]/lim AND [1990-2012]/py 8,919 View | Edit

#1transitional AND care OR care AND transition* OR transition* AND in AND care OR transition* OR discharge AND plan* OR patient AND discharg*

AND

readmi* OR rehospital* OR (avoid* OR reduc* AND admission*) OR medical NEAR/2 error* OR medical NEAR/2 mistake* OR medication NEAR/2 error* OR adverse NEAR/2 event* OR 'continuity of patient care' OR home NEAR/2 visit* OR house NEAR/2 call* OR aftercare OR team*

AND

interven* OR model*:ti OR strateg* OR improv*:ti OR implement* OR practices OR random* OR 'controlled clinical trial' OR 'controlled clinical trials' OR program OR programs OR programme OR programmes OR ('program evaluation' AND outcome*) OR systematic NEAR/2 review*

AND

human

SEARCH #2 (Revision 1):

'transitional care' OR rehospitali* OR discharge NEAR/2 plan* OR (emergency NEAR/2 service* OR emergency NEAR/2 room* AND 'hospital readmission') OR (medical NEAR/2 error* OR medical NEAR/2 mistake* OR medication NEAR/2 error* OR adverse NEAR/2 event* OR 'patient care team'/exp OR 'patient care team' OR 'patient care teams' OR multidisciplinary NEAR/2 team* AND hospital NEAR/2 readmi*)

AND

readmi* OR patient NEAR/2 discharg* OR (avoid* OR reduc* AND admission*) OR 'continuity of care' OR 'continuity of patient care' OR home NEAR/2 visit* OR house NEAR/2 call* OR aftercare

AND

interven* OR model*:ti OR strateg* OR improv*:ti OR implement* OR practices OR random* OR clinical NEAR/2 trial* OR (program* NEAR/2 evaluation* AND treatment NEAR/2 outcome*) OR systematic NEAR/2 review*

SEARCH #3 (Revision 2):

'transitional care' OR rehospitali* OR (discharge NEAR/2 plan* OR emergency NEAR/2 service* OR emergency NEAR/2 room* OR medical NEAR/2 error* OR medical NEAR/2 mistake* OR medication NEAR/2 error* OR adverse NEAR/2 event* OR 'patient care team'/exp OR 'patient care team' OR 'patient care teams' OR multidisciplinary NEAR/2 team* AND readmi*)

AND

readmi* OR postdischarge OR 'post-discharge' OR patient NEAR/2 discharg* OR (avoid* OR reduc* AND (admission* OR admit*)) OR 'continuity of care' OR 'continuity of patient care' OR home NEAR/2 visit* OR house NEAR/2 call* OR aftercare

AND

interven* OR model*:ti OR strateg* OR improv*:ti OR implement* OR practices OR random* OR clinical NEAR/2 trial* OR (program* NEAR/2 evaluation* AND treatment NEAR/2 outcome*) OR systematic NEAR/2 review*

ALL THREE SEARCHES WERE COMBINED ("OR'ED TOGETHER) & DUPLICATES WERE REMOVED

TOTAL NUMBER OF RESULTS: 1427

=====

DATABASE SEARCHED & TIME PERIOD COVERED:
CINAHL – 1990-9/12/2011

LANGUAGE:
English

SEARCH STRATEGY:

transitional care OR care transition* OR rehospital* OR discharge plan* OR “patient care team”
OR “multidisciplinary team” OR ((emergency service, hospital OR emergency service* OR
emergency room*) AND readmi*) OR medical error OR medical errors OR medical mistake*
OR medication errors OR adverse event*

AND

postdischarge OR “post-discharge” OR readmi* OR patient discharg* OR “continuity of patient
care” OR “continuity of care” OR “home visits” OR “home visit” OR “house calls” OR “house
call” OR aftercare OR ((avoid* OR reduc*) AND (admit* OR admission))

AND

interven* OR strateg* OR implement* OR practices OR random* OR “controlled clinical trial”
OR “controlled clinical trials” OR program* OR systematic review* OR (“program evaluation”
AND outcome*) OR TI (model* OR improv*)

NUMBER OF RESULTS: 1235

NUMBER OF RESULTS AFTER REMOVING DUPLICATES: 588

SECTION B. Methods

Figure 1, Chapter 37. Theoretical model for the effectiveness of patient safety practices for transitional care

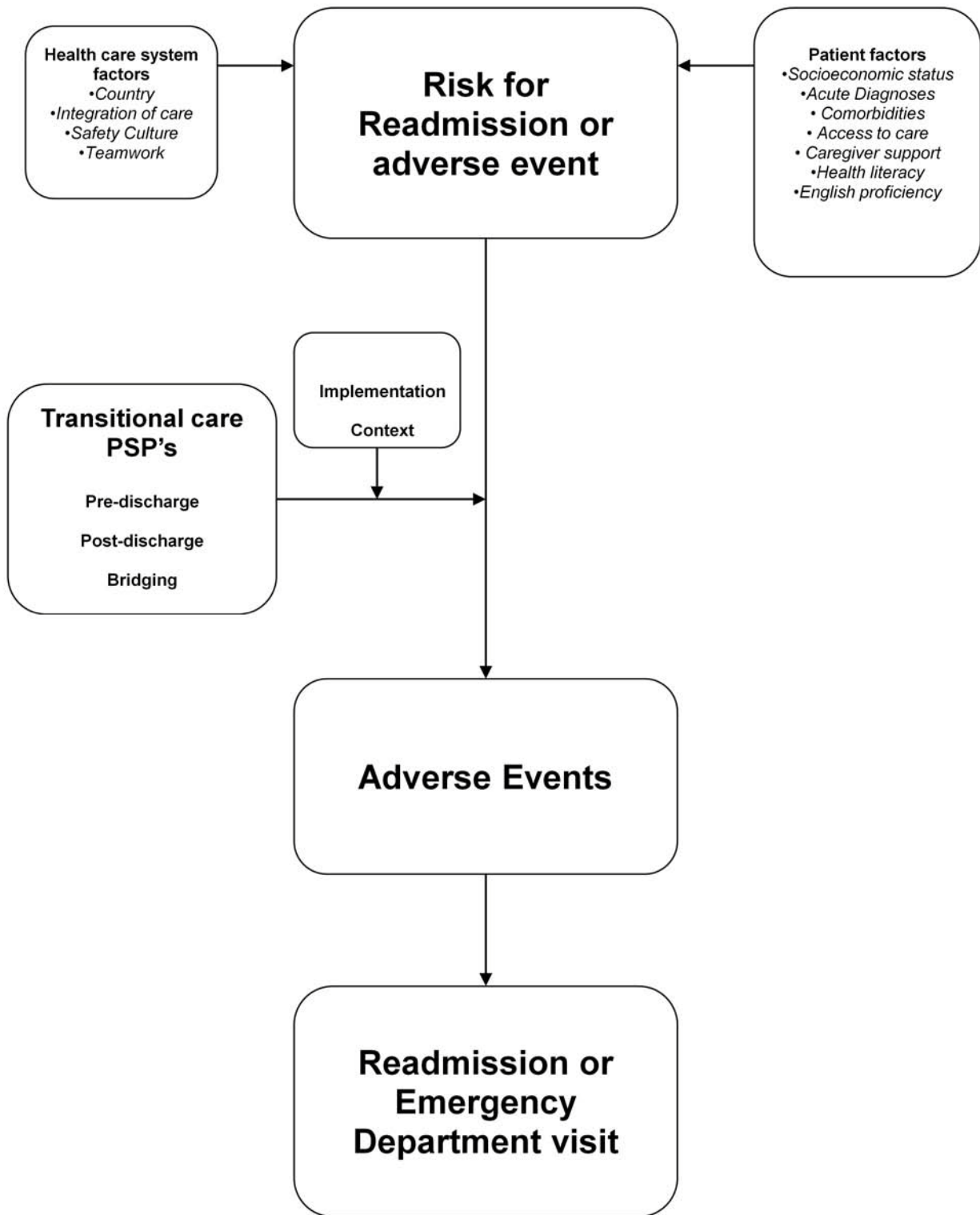
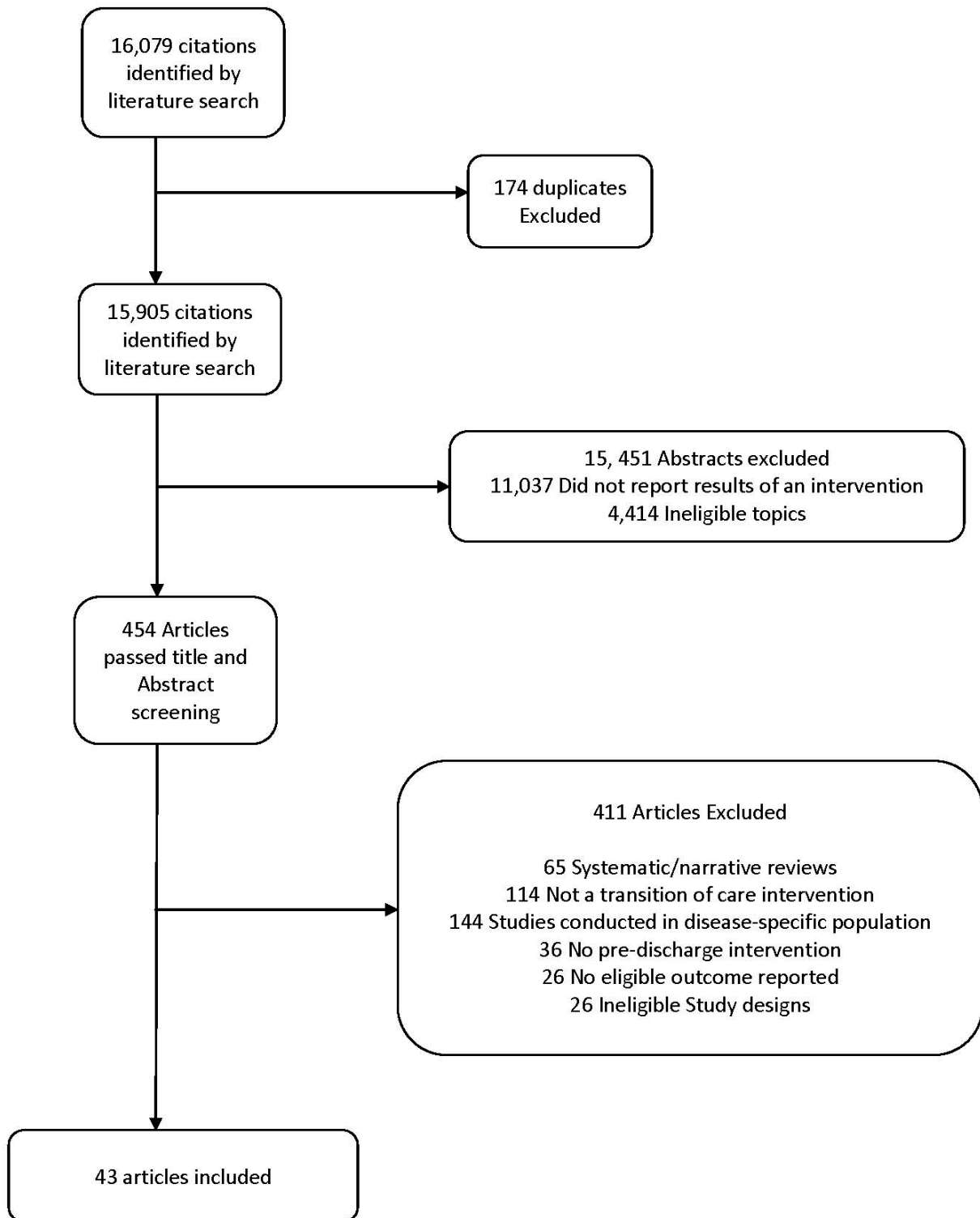


Figure 2, Chapter 37. Trial flow diagram



Chapter 38. Use of Simulation Exercises in Patient Safety Efforts

SECTION A. Literature Search

Search Strategies and Citation Results

PubMed Search Strategies

The first PubMed search, run November 14, 2011, yielded 42 titles. Full-text copies of 31 articles (74%) were reviewed, of which none reported T2 or T3 outcomes. Six articles from this search were included in the chapter at the recommendation of experts or to provide supplemental information about simulation. The first strategy was:

```
((("patient simulation"[all fields] OR "patient simulator"[all fields]) AND ("safety"[all fields] OR "accident prevention"[mesh])) AND (Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Practice Guideline[ptyp] OR Randomized Controlled Trial[ptyp])) OR ("Models, Theoretical"[Mesh] AND "accident prevention"[mesh] AND Meta-Analysis[ptyp]))
```

The second PubMed search, run November 15, 2011, yielded 304 titles. Full-text copies of 64 articles (21%) were reviewed, of which 11 studies reported T2 or T3 outcomes that were included in the review. Three additional articles from this search were included in the chapter to provide supplemental information about simulation. The second strategy was:

```
((("patient simulation"[all fields] OR "patient simulator"[all fields]) AND (Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Practice Guideline[ptyp] OR Randomized Controlled Trial[ptyp])) OR ("Models, Theoretical"[Mesh] AND "accident prevention"[mesh] AND Meta-Analysis[ptyp]))
```

The third PubMed search, run November 29, 2011, yielded 142 titles. Full-text copies of 12 articles (8%) were reviewed, of which 4 studies reported T2 or T3 outcomes and were included in the chapter. One additional article from this search was included to provide supplemental information about simulation. The third strategy was:

```
(("Health Care Category"[Mesh])) AND (simulation[All Fields]) AND (Meta-Analysis[ptyp])
```

Cochrane Library Databases Search Strategies

The Cochrane Database of Systematic Reviews was searched November 16, 2011 for "*simulat**" in title, abstract, or keyword fields. This search yielded 17 results, of which full-text copies of 6 articles (35%) were reviewed. Two of these studies reported T2 or T3 outcomes in combinations with T1 outcomes and were included in the review of empirical literature. A third study was included for an example of other uses of simulation that were not a focus of the current review.

The Cochrane Central Register of Clinical Trials was searched November 16, 2011 for "*simulat**" and "*safe**" across any field. This search yielded 328 results, of which full-text copies

of 66 articles (20%) were reviewed. Thirteen of these studies reported T2 or T3 outcomes and were included for review of empirical literature.

Other Literature Capture Methods

Secondary or “chain-method” literature prompted full-text review of an additional 15 empirical articles, 13 of which are presented in the empirical review. This search method also resulted in 16 articles that were used to provide supplemental information about simulation. Experts recommended an additional 22 articles, all of which are presented in the review. Many of these articles included important theoretical work or important resources for those looking to implement simulation. Experts also recommended important T1 studies for inclusion in the review (n = 9).

Literature Totals

The empirical literature search resulted in 833 titles, of which 174 (21%) were reviewed in full-text for inclusion in the review. The final reference list in *Simulation and Patient Safety* was ultimately comprised of 45% (n = 40) literature directly captured by database searches, 32% secondary literature (n = 27), and 25% literature recommended by practitioners with expertise in simulation (n = 25). Eight additional articles served an explanatory function (e.g., clinical rationale for placing a central venous catheter), and these articles were retrieved from free-text searches in PubMed and Google Scholar.

SECTION B. Methods

The methodology for identifying empirical literature in this review involved three primary mechanisms. In the first mechanism, structured search strategies for PubMed and the Cochrane Library Databases provided the initial capture of simulation references. These searches were limited to meta-analyses or systematic reviews, and to studies that were empirical in nature. Theoretical pieces and commentary publications were not excluded in these search strategies, but these publication types were not a focus of this mechanism to capture literature. The search strategies were limited to general terminology (e.g., “simulation”) rather than specific terms that might be required if one wished to perform a systematic review of simulation practices. Specific simulation search terms might include the clinical specialty under investigation (e.g., “anesthesiology”), the procedure under investigation (e.g., “laparoscopic cholecystectomy”), the purpose of the simulation (e.g., “curriculum”), or the fidelity and specific simulation exercise (e.g., “mannequin”). Due to the brief nature of the current review, and to the extensive possible combinations of these specific terms, this search mechanism identified literature through general terms rather than exhaust these combinations. In the second mechanism, practitioners with expertise in simulation were asked to provide recommendations on seminal work in simulation, current key articles, empirical research on simulation and patient safety, areas of focus most pertinent to implementing simulation, and guidance in terms of implementing simulation. Secondary or “chain-method” capture of references provided the third mechanism to inform this review. That is, reference lists in articles captured from the first two mechanisms provided additional literature. Specifics and resulting citations are provided below on each of these search mechanisms.

Empirical articles were held to a translational science paradigm for inclusion. Articles were given priority if they reported outcomes from care provided to actual patients, or from actual care system interventions. In terms of translational science, these are “T2” or “T3” simulation studies, respectively. Due to the nature of simulation, selected studies that did not report outcomes from care provided to actual patients (i.e., “T1” or “within the lab” studies) were included if experts recommended their inclusion to adequately represent the applications of simulation. All efforts were made to remain inclusive across clinical specialties, no preference was assigned to specific procedures or care practices. There is a section on central venous catheter placement that provided an “in-depth” look at simulation to improve patient safety. This literature was selected for in-depth presentation because (1) as a specific topic it had the greatest number of articles captured in our review with outcomes reported at both the T2 and T3 level, and (2) this particular line of research included analyses of costs for those looking to implement simulation.

Chapter 39. Obtaining Informed Consent From Patients: Brief Update Review

SECTION A. Literature Search

Pubmed was searched for review articles with the MeSH term of “Informed Consent” that were published since 2001. This was supplemented with a Google search for “informed consent and patient safety”, “informed consent and health literacy”, “simplified informed consent”; “written educational materials and informed consent”, “decision aids and informed consent” “informed consent and reading comprehension” “informed consent and Limited English Proficiency”, “informed consent and patient comprehension”, “informed consent and teach back”, “informed consent and structured interview, “informed consent and computer” and “video informed consent”. Forward citation searches using Google Scholar were also done for included original studies. A search on PSNet was also performed.

SECTION B. Methods

Titles and abstracts were reviewed by a physician health services researcher with expertise in informed consent. Inclusion criteria were informed consent in a clinical setting; articles about informed consent in the research setting were excluded. The citations from relevant reviews were searched for original studies, and full text articles of potentially relevant original studies were reviewed. The synthesis of included studies was narrative.

Chapter 40. Team Training in Health Care: Brief Update Review

SECTION A. Literature Search

Given the presence of recent reports and systematic reviews in this area, we did not conduct a systematic literature search for this topic. Key information was compiled from previous reports and from articles identified by experts in this area.

SECTION B. Methods

Systematic reviews and articles were abstracted by health services researchers with expertise in the topic area, and the results were narratively synthesized.

Chapter 41. Computerized Provider Order Entry With Clinical Decision Support Systems: Brief Update Review

SECTION A. Literature Search

We searched the specialized database AHRQ Patient Safety Net (PSNet) using the search terms “computerized provider order entry”, “computerized physician order entry”, “clinician decision support systems”, “clinical decision support systems”, “electronic medical records”, and “health information technology”. We also manually reviewed the reference lists of the articles identified through this search.

SECTION B. Methods

We evaluated the effectiveness of this PSP by identifying and narratively summarizing the systematic reviews of this topic that have been published since 2007, as well as identifying and summarizing additional original research studies that were published in 2011 (and thus are too recent to have been included in systematic reviews). Data regarding cost, implementation issues, and potential for harm associated with this PSP were summarized narratively.

Chapter 42. Tubing Misconnections: Brief Review (NEW)

SECTION A. Literature Search

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/providers
PubMed	2005 – November 9, 2011	www.pubmed.gov
ECRI Institute: <ul style="list-style-type: none">• <i>Clinical Risk Management</i>• <i>Health Devices Alerts</i>• <i>Health Devices</i>• <i>Healthcare Risk Control</i>• <i>Health Technology Assessment Information Service</i>• <i>Operating Room Risk Management</i>	2005 – November 9, 2011	www.ecri.org

PUBMED – English language, human

Set Number	Concept	Search statement
1	Tubing misconnections	Equipment design[mh] OR equipment safety[mh]
2		#1 AND (tube* OR tubing OR catheter*)
3		#2 AND (connector* OR connection* OR misconnect*)
4		Misconnections[ti]
5		(luer*[tw] OR tubing[tw]) AND misconnection*
6		#2 OR #3 OR #4 OR #5
7	Reviewed related citations for PMIDs	16610452 17090266 18491692 16739386

ECRI Institute Resources

Set Number	Concept	Search statement
1	Tubing Misconnections	Misconnection OR connectors
2	Relevant UMDNS codes	17-501 Intravenous Line Connectors OR 11-726 Fittings/Adapters OR 16-795 Fittings/Adapters, Pin-indexed OR 11-729 Fittings/Adapters, Luer
3	Combine sets	1 OR 2

Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Sites viewed for this topic include:

- Joint Commission – www.jointcommission.org
- U.S. Food and Drug Administration – www.fda.gov
- Pennsylvania Patient Safety Authority – www.patientsafetyauthority.org
- PSNet- www.psnet.ahrq.gov

SECTION B. Methods

Titles and abstracts were reviewed by a health services research methodologist with experience in both systematic reviews and medical devices. Included studies consisted of guidance documents and clinical studies that discussed engineering controls and work practice changes to prevent tubing misconnections. Potential barriers to implementation, and reported benefits and harms from the patient safety practices were also assessed. Included guidance documents and studies were narratively summarized by the author.

Chapter 43. Limiting Individual Provider’s Hours of Service: Brief Update Review

SECTION A. Literature Search

We searched the specialized database AHRQ Patient Safety Net (PSNet) using the search terms “work hours”, “duty hours”, “hours of service”, “fatigue”, “sleep deprivation”, and “burnout”, and manually reviewed the reference lists of the articles and reports identified through this search.

SECTION B. Methods

We evaluated the effectiveness of this PSP by identifying and narratively summarizing the systematic reviews and original research studies of this topic that have been published since 2004. Data regarding cost, implementation issues, and potential for harm of this PSP were also summarized narratively.

Appendix D. Supplementary Evidence Tables

Evidence Tables for Chapter 3. High-Alert Drugs: Patient Safety Practices for Intravenous Anticoagulants

Table 1, Chapter 3. Evidence table

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Baird, 2001 ¹	A single protocol for heparin administration was developed by a team of doctors, nurses and a pharmacist.	Pre-post 58 patients on 5 physician-specific protocols; 10 patients on new protocols.	Not reported	large tertiary care hospital-intensive care units, 115 beds	Leadership : Protocol development team	None.	Received optimal bolus dose Results: 5 (8.6%) pre vs: 10 (90%) post Statistics: NR Mean time to anticoagulation Results: 34 hrs vs 63 +- 49 hours Statistics: NR	Not reported	Not reported	
Fanikos, 2007 ²	Smart pump; drug library with point-of-care decision support for high or low infusion rates; can infusing 4 drugs simultaneously; programmable hard drug alerts smart infusion device with a hospital-determined drug library and software	Pre-post 7,395 medication alerts from a possible 14,012 administered heparin doses in 3,674 patients	Not reported	Brigham and Women's Hospital	Implementation tools : Est. hard limits for rates outside the defined guardrails & soft-limits for anticoagulants	None stated.	Results: Anticoagulation medication errors: 49 before; 48 after Statistics: NS	Not reported	Not reported	Results post implementation only: Prevented 10-fold overdose in 40 patients; 100-fold overdose in 40 patients; and >100-fold overdose in 10 patients; similar results for under doses; heparin was #4 most common drug generating alerts
Fraipont, 2003 ³	Nurse-directed weight-based nomogram	Pre-post 19 nomogram, 19 not	Not reported	8-bed Intensive care unit in 635-bed university hospital in Belgium	Implementation tools : Raschke nomogram		Time to therapeutic anticoagulation: 13.5 hours standard vs 9.5 hours nomogram, NS Complications: 2 standard vs 1 nomogram, NS	Not reported	Not reported	

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Oyen, 2005 ⁴	Computerized nomogram for acute coronary syndromes	Pre-post 419 nomogram, 98 comparison	Logic model	Cardiovascular services (88 beds) at a 1300-bed teaching hospital	Implementation tools: Dosing based on US organization guidelines	Not described	Percentage aPTT in goal range Results: 44% nomogram vs 27% not Statistic: p<0.01 Time to goal aPTT Result: 0.42 days nomogram, 1.6 days not Statistic: p<0.01	Not reported	Not reported	Complications not reported; discussion that on prior paper nomogram, clinicians deviated over 50% of the time by adjusting doses; program provided feedback and performed calculations; computerization allowed individualized protocol for acute coronary syndromes
Prusch, 2011 ⁵	Intelligent infusion devices (IIDs), bar-code-assisted medication administration system, and electronic medication administration record system-integrated to populate provider-ordered, pharmacist-validated infusion parameters on IIDs IV interoperability	Pre-post 16,533 opportunities pre and 16,833 opportunities post-implementation	Model for how IID works	538-bed community teaching hospital - expanded to all units	Organizational characteristics : multidisciplinary team and relationship with BCMA and IID vendors to develop interoperability between systems Leadership : Executive sponsorship, Direction and support of pharmacy and therapeutics committee Implementation tools : Nurse education	preparation, pilot, validation, and expansion; extensive software design and testing before introduction to patient care	Telemetry drug library monthly compliance Results: 56.5 pre to 72.1 post Statistics: p<0.001 Number of telemetry manual pump edits Results: 56.9 to 14.7 Statistics: p<0.001	Not reported	Not reported	similar decrease in medical-surgical drug library results; reduction in monthly reported intravenous heparin errors (28 to 17, NS); cost: 24.8% reduction (23.4 sec onds) in the mean nursing time for pump programming; 90% compliance

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Toth, 2002 ⁶	Weight-based nomogram for heparin dosing in TIA and/or stroke.	RCT 206 patients	Not reported	Neurology ward, Canada			<p>Results: Total complications: 9 pre (8.5%) vs 2 post (2%) Statistics: p=0.04</p> <p>Supratherapeutic aPTT Results: 1.1 nomogram vs. 1.6 no nomogram Statistics: p=0.01</p> <p>Time to therapeutic-range aPTT Results: 13 nomogram, 18 no nomogram Statistics: p<0.01</p>	Not reported	Not reported	Doctor completed nomogram; bolus provided if indicated. Initial heparin found by nomogram. Nurses changed heparin from aPTT results by following nomogram. Also, significantly fewer calls to house staff and mistakes made in nomogram group. Time to discontinue heparin: 4 ±0.2.8 vs. 4.6±3.8; P=0.33; 94% of staff preferred use of nomogram
Zimmermann, 2003 ⁷	Weight-based heparin nomogram for patients with acute coronary syndromes	Pre-post 84 patients weight-based, 89 patients in non-weight-based	Not reported	Public hospital		Weight-based nomogram was based on other nomograms in literature; dosage based on absolute weight. Weight and aPTT determined later adjustment in infusion rate.	<p>Results: Time to first therapeutic aPTT: Nomogram median 8.75 vs >24 hours Statistics: (p<0.001)</p> <p>Mean number of aPTT determinations Results: 3.62(.85) (no nomogram) vs 4.15 (.83) (nomogram) Statistics: (p=0.002)</p> <p>Major hemorrhagic events Results: 4 (4.5%) non-weight-based, vs 2 (2.4%) weight-based, NS</p>	Not reported	Not reported	Adherence to nomograms was "good" (not described in detail)

References

1. Baird RW. Quality improvement efforts in the intensive care unit: development of a new heparin protocol. *Proc (Bayl Univ Med Cent)* 2001; 14(3):294-6; discussion 296-8.
2. Fanikos J, Fiumara K, Baroletti S et al. Impact of smart infusion technology on administration of anticoagulants (unfractionated Heparin, Argatroban, Lepirudin, and Bivalirudin). *Am J Cardiol* 2007; 99(7):1002-5.
3. Fraipont V, Lambermont B, Moonen M, D’Orio V. *Annales Francaises d’Anesthesie et de Reanimation: Comparison of a nurse-directed weight-based heparin nomogram with standard empirical doctor-based heparin dosage.* 2003; 22:591-4.
4. Oyen LJ, Nishimura RA, Ou NN, Armon JJ, Zhou M. Effectiveness of a computerized system for intravenous heparin administration: using information technology to improve patient care and patient safety. *Am Heart Hosp J* 2005; 3(2):75-81.
5. Prusch AE, Suess TM, Paoletti RD, Olin ST, Watts SD. Integrating technology to improve medication administration. *Am J Health Syst Pharm* 2011; 68(9):835-42.
6. Toth C, Voll C. Validation of a weight-based nomogram for the use of intravenous heparin in transient ischemic attack or stroke. *Stroke* 2002; 33(3):670-4.
7. Zimmermann AT, Jeffries WS, McElroy H, Horowitz JD. Utility of a weight-based heparin nomogram for patients with acute coronary syndromes. *Intern Med J* 2003; 33(1-2):18-25.

Evidence Tables for Chapter 4. The Clinical Pharmacist’s Role in Preventing Adverse Drug Events: Brief Update Review

This brief review had no additional evidence tables. There is one table in the text.

Evidence Tables for Chapter 5. The Joint Commission’s “Do Not Use” List: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 6. Smart Pumps and Other Protocols for Infusion Pumps: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 7. Barrier Precautions, Patient Isolation, and Routine Surveillance for the Prevention of Healthcare-Associated Infections: Brief Update Review

Table 1, Chapter 7. Evidence table

	Reference	Study Population/Setting	Summary/Main Contribution
Systematic literature review	McGinle KL, 2008(33)	Systematic literature review evaluated studies assessing the use of active surveillance to reduce MRSA-related morbidity, mortality and costs	The investigators did not identify any randomized, controlled trials. They reviewed 16 observational studies and 4 economic analyses. Only 2 studies included control groups. None of the studies were of good quality. Thirteen studies reported decreases in the incidence of MRSA infections associated with the use of active surveillance Existing evidence may favor the use of active surveillance, but the evidence was of poor quality and the investigators could not make definitive recommendations.
Systematic literature review	Backman C, 2011(35)	Systematic literature review evaluated articles published on infection prevention and control programs for multidrug-resistant organisms in acute care hospitals	32 articles were assessed, of which 53% used surveillance; 75% implemented infection control precautions to prevent transmission; 22% introduced environmental measures; 28% used patient decolonization; 56% had an administrative measure as an intervention; 63% had education and training of healthcare personnel; and 25% had judicious use of antimicrobial agents. Although the evidence of the relationship between infection prevention and multidrug-resistant infection rates was weak; the overall evidence supported use of multiple interventions to <u>reduce the rates of multidrug-resistant organisms</u>
Systematic literature review	Cooper BS, 2003(10)	Systematic literature review assessed the quality of the literature regarding the effectiveness of different isolation policies and screening practices in reducing the incidence of MRSA colonization and infection among hospitalized patients.	46 studies were evaluated, of which 18 assessed isolation, 9 assessed cohorting nurses, and 19 assessed other isolation policies. Few were planned prospective studies and all but one included multiple interventions. Investigators for most studies did not consider potential confounders, implement measures to prevent bias, or use appropriate statistical analysis. The studies were limited by major methodological weaknesses and inadequate reporting. Thus, Cooper et al, could not exclude plausible alternative explanations for the decreased incidence of MRSA acquisition. The investigators conducting the metaanalysis did not identify any well-designed studies that allowed them to assess the role of isolation measures alone.

	Reference	Study Population/Setting	Summary/Main Contribution
Active Surveillance	Robicsek A, 2008(36)	In a 3-hospital, 850-bed organization with approximately 40,000 admissions each year, a 3-phase quasi-experimental study compared: Phase 1: Baseline, Phase 2: Universal surveillance for MRSA among all patients admitted to the ICU and contact isolation for patients who carried MRSA, Phase 3: Universal surveillance for MRSA among all patients admitted to the hospital and contact isolation plus decolonization for patients who carried MRSA.	The absolute change between baseline and ICU surveillance was -1.5 infections per 10,000 patient-days ($p = 0.15$), and the absolute change between baseline and universal surveillance of all patients admitted to the hospital was -5.0 infections per 10,000 patient-days ($p < 0.01$) The investigators concluded that universal surveillance for MRSA of all patients on admission was associated with a reduction in MRSA infections during admission and within 30 days after discharge.
Active Surveillance	Jain R, 2011(24)	The investigators implemented an "MRSA bundle," including active surveillance and contact isolation for MRSA in 153 acute care Veterans Affairs hospitals nationwide to decrease healthcare-associated MRSA.	After the VA system implemented the bundle, the rates of healthcare-associated MRSA decreased by 45% in the non-ICUs and 62% in the ICUs compared with baseline rates ($p < 0.001$ for trend).
Active Surveillance	Harbarth S, 2008(37)	21,754 surgical ICU patients admitted to a Swiss teaching hospital were included in a crossover study comparing rapid screening on admission to detect MRSA colonization plus standard infection control measures vs standard infection control measures alone.	During the intervention periods, 1.11 patients per 1,000 patient-days acquired healthcare-associated MRSA compared with 0.91 per 1,000 patient-days during the control periods (adjusted incidence rate ratio=1.20; 95% CI: 0.85,1.69; $p = 0.29$). Universal, rapid MRSA screening on admission was not associated with decreased rates of healthcare-associated MRSA among patients admitted to a surgical department where MRSA carriage was endemic but where rates of healthcare-associated MRSA was relatively low.
Active Surveillance	Huskins WC, 2011(13)	This cluster-randomized trial included 5,434 admissions to 10 intervention ICUs, and 3,705 admissions to 8 control ICUs. Intervention ICUs performed surveillance for MRSA and VRE colonization and expanded use of barrier precautions. Control ICUs continued to use existing practice.	The mean (\pm standard error) ICU-level incidence of events of colonization or infection with MRSA or VRE per 1,000 patient-days at risk, adjusted for baseline incidence, did not differ significantly between the intervention and control ICUs (40.4 ± 3.3 and 35.6 ± 3.7 in the two groups, respectively; $p = 0.35$). Surveillance for MRSA and VRE colonization and expanded use of barrier precautions did not reduce transmission of MRSA or VRE. However, the results may have been affected by suboptimal adherence to standard precautions.
Active Surveillance	Siddiqui AH, 2002 (70)	Four time periods (pre-active surveillance, first period of active surveillance for VRE, period without active surveillance, and second period of active surveillance for VRE) were compared to determine the effect of active surveillance for VRE in two ICUs.	Incidence of VRE decreased during the periods of active surveillance demonstrating reductions in VRE ranging from 32% to 64%.

	Reference	Study Population/Setting	Summary/Main Contribution
Active Surveillance	Price CS, 2003(71)	This quasi-experimental study compared hospital A, which did not routinely screen for VRE colonization, to hospital B, which actively screened high-risk patients for VRE and placed VRE colonized or infected patients under contact isolation. High-risk patients were those admitted to the hematology-oncology, transplant, or intensive care units	When the analysis was corrected for patient-days, the rate of VRE bacteremia was 2.1-fold higher in hospital A compared to hospital B. The majority of VRE isolates in hospital A were clonally related.
Isolation of high-risk patients	Matsushima A, 2011(52)	This single ICU, quasi-experimental study to assessed an intervention where all intubated patients were placed under pre-emptive contact precautions. In the first phase of the study (415 patients), active surveillance for MRSA was performed at ICU admission and weekly with contact precautions for MRSA positive patients. In the second phase of the study (1280 patients), active surveillance and contact precautions for MRSA remained, however all intubated patients were also placed on contact precautions.	This study found a decrease in healthcare-associated MRSA infections for both intubated patients (p=0.02) and in all ICU patients (p<0.05) in the second phase of the study.
Universal Glove	Bearman G, 2007 (49)	6 month, single ICU study in which phase 1 (3 months) consisted of VRE and MRSA surveillance cultures on admission and every 4 days with contact precautions for patients colonized or infected with VRE or MRSA; and phase 2 (3 months) consisted of universal gloving only. In phase 1 there were 1090 patient-days and in phase 2 there were 1377 patient-days.	No difference was seen in VRE or MRSA acquisition in the 2 study phases. The total nosocomial infection rate was higher in phase 2 compared to phase 1.
Universal Glove	Bearman G, 2010 (50)	12 month single ICU study in which phase 1 (6 months) consisted of VRE and MRSA surveillance cultures on admission and every 4 days with contact precautions for patients colonized or infected with VRE or MRSA; and phase 2 (6 months) consisted of universal gloving and staff education. In phase 1 there were 3,486 patient days and in phase 2 there were 2,946 patient days.	No difference was seen in VRE or MRSA acquisition in the 2 study phases.

	Reference	Study Population/Setting	Summary/Main Contribution
Universal Gown and Glove	Wright MO, 2004 (50)	A single ICU, quasi-experimental study in which phase 1 assessed active surveillance and contact precautions for MRSA and VRE while phase 2 included active surveillance for MRSA and VRE but also implemented a bundle to stop a multidrug-resistant <i>Acinetobacter baumannii</i> outbreak. The bundle included contact isolation for all patients in the ICU regardless of culture positivity, supervised terminal cleaning, education sessions, and ban on artificial fingernails.	The intervention bundle controlled the outbreak of multidrug-resistant <i>Acinetobacter baumannii</i> . In addition, the bundle in phase 2 led to a decrease in MRSA acquisition from 14% to 10% (p=0.5), and VRE acquisition from 21% to 9% (p=0.05)

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Evidence Tables for Chapter 8. Interventions To Improve Hand Hygiene Compliance: Brief Update Review

This brief review had no additional evidence tables

Evidence Tables for Chapter 9. Reducing Unnecessary Urinary Catheter Use and Other Strategies To Prevent Catheter-Associated Urinary Tract Infection: Brief Update Review

Table 1, Chapter 9. Characteristics of studies with interventions to avoid unnecessary urinary catheter use

Study (Country)	Study Design	Population, Total N	Interventions to avoid unnecessary catheter PLACEMENT	Interventions to prompt REMOVAL of unnecessary catheters	Other Interventions
Apisarntharak et al, 2007 ¹ (Thailand)	Pre-Post	All Inpatients, N=2412 patients	None	Reminder: Nurse-generated daily bedside verbal reminders to encourage physicians to remove unnecessary UC.	None
Bruminhent et al, 2010 ² (USA)	Pre-Post	Med-Surg: Ward + ICU, N=400 patients	None	Reminder: Sticker applied to medical record to remind physicians to discontinue unnecessary UCs.	None
Cornia et al, 2003 ³ (USA)	Non-randomized crossover trial	Medical (non-ICU), N=70 patients	Computerized UC order required selection of an appropriate UC indication	Stop order: Computer-generated stop order for physicians to discontinue/renew UC order 72 hours after placement.	UC care education
Crouzet et al, 2007 ⁴ (France)	Pre-Post	All Inpatients, N=234 patients	None	Reminder: Daily reminders from nurses to physicians to remove unnecessary UC \geq 4 days after insertion.	None
Dumigan et al, 1998 ⁵ (USA)	Pre-Post	ICU: Med-Surg, N=27103 patient-days	Guideline for appropriate UC indications	Stop order, nurse-empowered: Daily use of UC indication protocol by nurse empowered to remove UC no longer meeting criteria without requesting physician order.	UC care education
Elpern et al, 2009 ⁶ (USA)	Pre-Post	ICU: Medical, N=337 patients	Appropriate indications for UC insertion were emphasized, and list of inappropriate reasons to insert was provided.	Reminder: Daily review by nurses for UC indication to make recommendations for removal; removal required physician order.	None
Fakih et al, 2008 ⁷ (USA)	Pre-Post with concurrent controls	Med-Surg (non-ICU) N=3736 intervention patient-days, and 4041 control patient-days	None	Reminder: Nurse generated reminder to physician to remove UC when no appropriate indication.	None

Study (Country)	Study Design	Population, Total N	Interventions to avoid unnecessary catheter PLACEMENT	Interventions to prompt REMOVAL of unnecessary catheters	Other Interventions
Fakih et al, 2010 ⁸ (USA)	Pre-Post	ED, N=322 patients had UCs placed, of 2517 ED patients in sample	Institutional guidelines for appropriate UC placement, ED physician education regarding UC utilization	None	None
Fakih et al, 2012 ⁹ (USA)	Pre-Post	Statewide, N=163 inpatient units in 71 hospitals	Education intervention to promote adherence to appropriate UC indications	None	None
Fuchs et al, 2011 ¹⁰ (USA)	Pre-Post	ICU: Med-Surg, N=not provided	Urinary retention protocol, including use of bladder scanner Procedure-specific protocols for appropriate indications for UC placement	Stop order: Daily checklist for evaluating UCs; when not indicated, physician order was requested for removal. Stop order: Procedure-specific protocols for UC removal.	None
Gokula et al, 2007 ¹¹ (USA)	Pre-Post	ED, N=200 patients with UCs placed in ED	UC indication checklist attached to UC kits	None	None
Gotelli et al, 2008 ¹² (USA)	Pre-Post	Medical (not ICU), N=not provided	None	Stop order, nurse-empowered: Nurses were empowered to assess UC need by protocol and remove if not indicated.	None
Huang et al, 2004 ¹³ (Taiwan)	Pre-Post	ICU: Med-Surg, N=6297 patients	None	Reminder: Nurse generated daily reminder to physician to remove unnecessary UC 5 days after insertion.	None
Jain et al, 2006 ¹⁴ (USA)	Pre-Post	ICU: Med-Surg, N=13471 catheter-days	None	Reminder: Daily use of checklist in multidisciplinary rounds to determine if UC still indicated, then nurse contacted physician for order to removal UC if no longer indicated.	Bladder Bundle: UC care steps, selected use of silver-alloy UC.
Knoll et al, 2011 ¹⁵ (USA)	Pre-Post	All Inpatients, N=112,140 patient-days	Education interventions about an approved hospital list of UC indications Computer UC order template with indication	Stop order: Computerized order for UC with indications and 72 h default stop date. Reminder: ICU daily checklist for UC necessity.	Bundle: UC care education, dedicated UC nurse.
Loeb et al, 2008 ¹⁶ (Canada)	RCT	Medical (non-ICU), N=692 patients	None	Stop order, nurse-empowered: Pre-written in chart for nurses empowered to discontinue UC based on criteria without an additional physician order.	None

Study (Country)	Study Design	Population, Total N	Interventions to avoid unnecessary catheter PLACEMENT	Interventions to prompt REMOVAL of unnecessary catheters	Other Interventions
Murphy et al, 2007 ¹⁷ (USA)	Pre-Post	Not explained, N=Not provided	None	Reminder: Foley bag sticker with time/date of insertion to remind to nurse to notify physician when Foley in place >48h in order to request removal.	UC care education
Patrizzi et al, 2009 ¹⁸ (USA)	Pre-Post	ED, N=Not provided	Computerized ED UC order with indications, UC alternatives promoted, urinary retention protocol with bladder scanner use	None	None
Reilly et al, 2008 ¹⁹ (USA)	Pre-Post	ICU: Med-Surg, N=207 patients	Developed criteria for appropriate UC placement in ICU, implemented with educational interventions regarding UC indications, and urinary retention protocol	Reminder: Daily use of checklist of appropriate UC indications by nurse, reminding nurse to contact physician to recommend UC removal.	UC care education
Robinson et al, 2007 ²⁰ (USA)	Pre-Post	Med-Surg (non-ICU), N=69 patients		Stop order: Nurse identified patients without appropriate indications, then requested removal order from physicians	None
Rothfield et al, 2010 ²¹ (USA)	Pre-Post	Medical ICU step-down unit, N=99 patients	Developed list of appropriate indications for which UCs could be requested by nurses	Stop order: Nurses asked physicians for order to remove UCs when not indicated.	None
Saint et al, 2005 ²² (USA)	Pre-Post with concurrent nonequivalent controls	Intervention Group: Medical, Control Group: Surgery. N=3027 patients	None	Reminder: Study nurse generated sticker placed in chart reminding physician to generate stop order after 48 hours of UC use if no longer needed	None
Schultz et al, 2011 ²³ (USA)	Pre-Post	ICU: unclear type, N=Not provided	Urinary retention protocol, including use of bladder scanner	Stop order, nurse-empowered: Nurses were empowered to insert and remove UCs by protocol.	None
Seguin et al, 2010 ²⁴ (France)	Pre-Post	ICU: Surgical, N=1271 patients	None	Stop order: Daily assessment required by physicians to assess if UC is needed or not; when categorized as not indicated, then removed by nurses.	None

Study (Country)	Study Design	Population, Total N	Interventions to avoid unnecessary catheter PLACEMENT	Interventions to prompt REMOVAL of unnecessary catheters	Other Interventions
Stephan et al, 2006 ²⁵ (Switzerland)	Pre-Post with concurrent nonequivalent controls	Surgery: Ward+ICU <u>Intervention:</u> Orthopedic, N=539 <u>Control:</u> Abdominal, N=489	UC placement restrictions, urinary retention protocol	Stop order: Pre-operative written order to remove UC on post-operative day 1 or 2, depending on surgery.	UC care education
Topal et al, 2005 ²⁶ (USA)	Pre-Post	Medical (non-ICU), N = 245 patients	Urinary retention protocol including bladder scanner	Stop order: Computerized order entry system order to prompt physicians to remove/re-order UC if placed in ED or in place >48 hours. Stop order, nurse-empowered: Nurses were also empowered to remove UCs no longer needed by protocol criteria.	UC care education
van den Broek et al, 2011 ²⁷ (The Netherlands)	Pre-Post	All Inpatients, in 5 hospitals. N=2943 patients	Bladder scanner protocol in 2 hospitals	Intervention varied by hospital: Reminders: Used by 4 hospitals, placed in patient's record. Stop order: Fixed order for removal, employed by 1 hospital.	Specially trained UC nurse
Voss, 2009 ²⁸ (USA)	Pre-Post	Medical (non-ICU), N=187 patients age 65 or older	None	Stop order, nurse-empowered: Daily assessment by nurse for UC indications, with authority for nurse to remove if not indicated.	None
Weitzel, 2008 ²⁹ (USA)	Pre-Post	Medical (unclear if ICU), N=50 patients	None	Reminder: Daily use of protocol by nurse to review if UC still indicated, unclear if protocol allowed for UC removal without physician order.	None
Wenger, 2010 ³⁰ (USA)	Pre-Post	All Inpatients, N=Not provided	None	Stop order, nurse-empowered: Daily assessment by nurse of UC necessity, with authority to remove if not indicated.	UC care education, silver-alloy UC

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Evidence Tables for Chapter 10. Prevention of Central Line-Associated Bloodstream Infections: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 11. Ventilator-Associated Pneumonia: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 12. Interventions to Allow the Reuse of Single-Use Devices: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 13. Preoperative Checklists and Anesthesia Checklists

Table 1, Chapter 13. Studies of the World Health Organization surgical safety checklist at other locations

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context
Sewell 2011 ¹	2008 WHO surgical checklist, unmodified	Before and after study, comparing pre-training period to post-training	“The underlying philosophy of the checklist is that a true team approach with good communication between operating room team members is safer and more efficient than a hierarchical system that relies on individuals”	A U.K. hospital, orthopedic operations. 28% of operations were urgent, and 77% involved general anesthesia	Pre-training period Feb-May 2009 (480 operations). During this period: Correct checklist use 8%, and 47% thought it improved team communication Pre-training staff perceptions: 55% thought it caused an unnecessary time delay, 28% thought it improves patient safety, 47% thought it improves team communication and teamwork, 64% would want the checklist used if they were having an operation
Helmio 2011 ²	2008 WHO surgical checklist. No specialty-related changes, but some “minor changes.” Checklist included in publication; modifications did not exclude any items	Before and after study	“The idea of the checklist is to be an add-on security tool for the defined safety standard”	Finland, otorhinolaryngology-head and neck surgery ORs. 747 operations in the two month study periods combined. All subgroups of otorhinolaryngology-head and neck surgery were included.	One-month pre-implementation period in May 2009 (304 operations). 17% were urgent operations. 24% were on children. 16% were local anesthesia. Before implementation: Knowledge of OR-teams’ names and roles ranged from 61 % to 92%. Discussing risks was 24%. Postop instructions recorded 74%-84%. Successful communication 79%-93%.
Conley 2011 ³	2008 WHO surgical checklist, unmodified	Case series	None explicitly stated.	Five Washington state hospitals. Two hospitals had <10 ORs, one had 10-20, and two had >20. Two urban, two suburban, and one rural.	Nothing reported about pre-existing safety culture. The Vice President for Patient Safety at the Washington State Hospital Association provided “significant assistance.” Checklist introduction Dec 2008 to Jan 2009. Interviews conducted Sept - Dec 2009. One of the five hospitals had a recent wrong-site incision that motivated surgical staff and “opened people’s eyes to the need for ongoing patient safety efforts”
Bell 2010 ^{4,5}	2008 WHO checklist adapted different for different surgical specialties. Checklist not included in publication.	Case series	“Without a doubt, the checklist works best when all staff members are engaged”	Large two-hospital Trust in the U.K. with 10,000 staff and 850,000 patients annually.	Nothing about pre-existing safety culture. To prepare for the checklist, they set up a Patient Safety Working Group

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context
Sparkes 2010 ⁶	2008 WHO checklist locally adapted. Checklist included in publication; modifications did not exclude any items	Case series	Discussed various ways a checklist could enhance safety, including teamwork and effective communication	Teaching hospital in the U.K. with 29 ORs in five locations performing specialized complex surgery	NR
Royal Bolton 2010 ⁷	2008 WHO checklist, unmodified. Local adaptation of it was considered but ultimately not done.	Case series	Improve patient safety by enhancing teamwork and communication	Trust in the U.K. with eight ORs	Prior to the checklist, the trust already had a core group of patient safety experts assembled; this group met to discuss how to introduce the checklist. They examined the previous year's 41 safety incidents and all were "found to be avoidable had the checklist been in use"
Vats 2010 ⁸	2008 WHO surgical checklist adapted for England and Wales. Checklist included in publication; modifications did not exclude any items	Case series	"...the checklist ensures that critical tasks are carried out and that the team is adequately prepared for the operation"	U.K. academic hospital	Nothing reported about pre-existing safety culture. Piloted March-Sept 2008 at a London hospital in 58% of operations (424/729) among the two ORs selected (one for trauma/orthopedics OR, the other for GI/GYN).
Kearns 2011 ⁹	WHO surgical checklist, version NR. Some obstetric-specific checks had been added, but the list of revisions was not reported. Checklist not included in publication.	Before and after study	"Checklists may be used to improve patient safety by ensuring that all elements of a practice are instituted for each new clinical event."	U.K. study in obstetrics ORs. Tertiary referral obstetric center with ~6,400 deliveries per year.	Before introducing the checklist, they measured staff attitudes, preserving respondent anonymity: 30% "felt familiar" with others in the OR 81% felt communication could improve 85% felt that in elective cases the checklist would be useful 53% felt that in emergency cases the checklist would be inconvenient

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context
Norton 2010 ¹⁰	2008 WHO checklist modified for pediatric operations and also to meet the 2009 Joint Commission Universal Protocol. Checklist included in publication. Removed the following three items from the WHO checklist: pulse oximetry, difficult airway, anticipated blood loss	Case series	Checklist can help to reduce breakdowns in communication, ineffective teamwork, and lack of compliance with process measures	Children's hospital in the US performing numerous types of pediatric surgery	At this hospital they had been building a quality infrastructure for five years prior, and had already implemented the Universal Protocol.

Note: NR=Not reported; Int=Intervention; OR=Operating room; GI=Gastrointestinal; GYN=Gynecology

Table 2, Chapter 13. Implementation findings in studies of the World Health Organization surgical safety checklist at other locations

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Sewell 2011 ¹	Checklist forms placed in ORs, compulsory training video detailing correct and incorrect uses of the checklist, emphasis placed on all team members being responsible. Active discouragement of a simple tickbox approach. Checklist training was not associated with reductions in any complications or mortality	Training phase first (unreported duration). Post-training period June-Oct 2009 (485 operations). Correct checklist use 97%. 2 minutes. 20% thought it caused an unnecessary time delay.	"The initial implementation of the checklist was met with resistance by some operating room team members as there was a belief that many of the points were already in practice."	77% thought it improved team communication, 68% thought it improves patient safety, 80% would want the checklist used if they were having an operation	Early complications 8.5% before checklist training and 7.6% after. Mortality 1.9% before checklist training and 1.6% after. Lower respiratory tract infections 2.1% before checklist training and 2.5% after. Surgical site infection 4.4% before checklist training and 3.5% after. Unplanned return to OR 1.0% before checklist training and 1.0% after.

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Helmio 2011 ²	Training involved a presentation from an outside expert and three 45 minute lectures. Specific guidelines were in the OR, and short instructions on the back of the checklist.	One-month implementation period in Sept 2009 (443 operations).	"Use of the checklist improved verification of patient identity, but this was still inadequate." "Our study confirms that the surgical checklist fits well into otolaryngology." "We recommend the use of this checklist in all operations"	"...overall, the operating room personnel were supportive." Anesthesiologists' knowledge about patients had improved as compared to the pre-implementation period. Preoperative check of anesthesia equipment increased from 71% to 84%. After implementation, staff were more likely to accurately report patient identity, procedure, and operative side. After implementation, there was improvement in: Knowledge of OR-teams' names and roles ranged from 81 % to 94%. Discussing risks was 38%. Postop instructions recorded 86%. Successful communication 87%-96%.	NR

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Conley 2011 ³	NR	Duration of rollout: <2 months at three hospitals, >6 months at two hospitals.	The key is whether the local champion can "persuasively explain why and adaptively show how to use the checklist." Implementation was incomplete at three hospitals: One cancelled attempts to implement the checklist due to "fear of insurmountable resistance and poor interdisciplinary communication" Another cancelled attempts because they were unable to move beyond pilot testing. The third had less effective implementation because of a laissez-faire leadership style; no training; staff understood neither why nor how the checklist could be implemented	Interviews conducted, but no quantitative summary of opinions provided. Three hospitals were discussed in detail.	NR
Bell 2010 ^{4,5}	Training provided to prevent "teething problems." Instead of requiring paperwork, they used in each OR an A3 board (a drawing board about 14x20 inches) that was color-coded to aid completion. Publicity campaign in both hospitals.	Piloted the checklist at one of the two hospitals first.	"To implement the checklist effectively, it was essential to engage all staff to ensure the theatre team worked together." "Working with individuals to identify any gaps or issues with implementation." Currently it is "being used as standard throughout theatres"	"Communication and staff morale have definitely improved since the checklist was implemented."	NR

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Sparkes 2010 ⁶	"Extensive educational support and training"	3 month pilot, during which changes to the checklist were made. After the pilot, and training, the checklist was introduced to all 29 ORs in Nov 2009.	Even though people agreed with the checklist in theory, it was difficult to change attitudes and behaviors, particularly the senior team. The checklist was required to be signed by team members, and "This had led to the fear that legal colleagues will apportion blame to those who have signed the checklist when complications occur."	Before checklist introduction: "Although all found the checklist to be useful, many senior clinicians felt that such communication already took place informally, and that more paperwork would not add to safety." Audit of 250 cases in Feb 2010 found that team briefings occurred in 77% and time outs in 86%.	NR
Royal Bolton 2010 ⁷	Drop-in educational sessions which involve 120 participants	May and June of 2009 were spent getting the word out about plans to start using the checklist. Piloted first for one month in two of the Trust's hospitals in 62 operations. Sept 2009 was the trust-wide launch of the checklist. "Every Trust is different but implementing the checklist across the trust rather than a prolonged pilot period." Within the first week 33% of operations employed the checklist. By one month it was at 72%. Currently all eight ORs use it.	"The importance of communicating with and involving people beyond this core group was recognised straight away." "Essentially it is all about changing the culture, which can be a long process, but it's well worth it."	"The feedback we received from staff was very positive. Most people were keen to introduce the checklist as quickly as possible."	One-month pilot identified nine potential incidents that were avoided as a result of the checklist.

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Vats 2010 ⁸	Limited time given to training.	Checklist accelerated with use. Large variability in how the checklist was used: sometimes incompletely, hurried, dismissive replies, and without some key participants. Compliance was initially good, then fell when the research team was absent, and so the team had to re-enter ORs to encourage greater use. Compliance ranged from 42% to 80% in the six month period.	Need a local champion as well as local organizational leadership. Importance of being able to modify to fit local needs, for example there was no need to check pulse oximetry because it is already used always.	Anesthetists and nurses were "largely supportive." Some surgeons were "not very enthusiastic." Awkward self-introductions, takes time to achieve comfort, Steep interpersonal hierarchy, ID the patient BEFORE draping, not after. Complaints about duplication; perhaps a revised checklist could have less duplication	"At our hospital, we found no significant change in overall morbidity or mortality, which were already very low, after the introduction of the checklist. However, there was a noticeable improvement in safety processes such as timely use of prophylactic antibiotics, which rose from 57% to 77% of operations after the checklist was introduced."
Kearns 2011 ⁹	Training, humorous posters provided, and "all staff empowered to remind the team to perform the checklist if it was forgotten."	Compliance with the preoperative part of the checklist was 61% after three months and 80% after one year. Compliance with the postoperative part of the checklist was 68% after three months and 85% after one year.	Authors cited four contributors to success: allocation of responsibilities, local champion, sense of ownership by team members, and ongoing staff consultation.	Staff attitudes three months after checklist introduction: 50% now "felt familiar" with others in the OR. 70% felt communication had improved. 80% felt that in elective cases the checklist was useful. 30% felt that in emergency cases the checklist was inconvenient. Fifty-eight patients were asked whether they noticed the operating team performing a series of checks before the operation, and 75% said they did, and another 19% remembered it after being prompted. Of the combined 94%, they all disagreed with the idea that the checks would make them worried, and 93% said they were reassuring.	NR

Author/Year	Training	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Norton 2010 ¹⁰	3x5 foot posters in each OR. Launch involved formal letter to staff, electronic training application, multiple in-service training sessions, and mention in hospital newsletter	December 2008 pilot test in six pediatric surgical services (general, neuro, orthopedic, otolaryngology, plastic surgery, and urology). Feb 2009 pilot test on the revised procedures, and more minor edits were made. "Go-live" date April 1, 2009 in all of the hospital's ORs. Surgical chiefs were local champions, and one nurse champion was paired with each surgeon champion. They divided the responsibility for leading the Time Out phase among all team members, and identified key speaking points. Compliance at ORs improved over time during this period from July 2009 to Feb 2010.	"Use of the Pediatric Surgical Safety Checklist encourages multidisciplinary teamwork and has brought increased communication to our ORs and in other areas."	Dec 2008 pilot test of 30 procedures had 80-90% compliance, with "overwhelmingly positive" feedback. "Team members have expressed satisfaction with the flow and content of the checklist".	Checklist caught one near miss during sign in (site not marked), several near missed during time out, (antibiotics not given, problems with consent forms, site marking not visible after draping, missing equipment), and sign out (one team realized a patient needed straight catheterization, and reviewing procedure name helped nurse documentation, one specimen was incorrectly labeled).

Notes: NR=Not reported; Int=Intervention; OR=Operating room; GI=Gastrointestinal; GYN=Gynecology

Table 3, Chapter 13. Studies of wrong-site-surgery checklists implementing the universal protocol

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context	Implementation Details
Garnerin et al. 2008 ¹¹	Verification protocol for checking patient identity and the site of surgery	Case series	“...the prevention of wrong patients and wrong site surgery, not to mention accountability, demanded an intervention aimed at improving the way both patient identity and site of surgery checks were performed, while acquiring the ability to identify and correct deficiencies”	Swiss anaesthesiology service located within a 1200 bed university hospital	Prior to introduction of the checklist, all patients were required to wear ID bracelets, and the operative site had to be signed by the surgeon. Anesthesiologists were made aware that they were being monitored.	Verification protocol developed by an interdisciplinary team. It required patients to state their identity, comparing the statement to the ID bracelet, OR schedule, and medical record. Similar types of checks for correct site of surgery. Nine consecutive months of data were obtained (October 2003 to June 2004), and later three subsequent months (October 2004, March 2005, and October 2005). Compared to the first three months of implementation, the next three months saw better compliance in checking patient identify (63% up to 81%), complete compliance with identity checks (10% up to 38%), proportion of surgical site checks performed (77% up to 93%), and complete compliance with surgical site checks (32% up to 52%). Compliance was stable in subsequent periods. Authors attributed the improvements to increased use of wristbands upon admission into the OR, the switch from to using an open-ended questioning format, and the use of three different sources for verification. Barriers included 1) surgeons saying they already knew that patients or the surgical site was obvious, and 2) the failure to develop the protocol with the input of ALL surgical services

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context	Implementation Details
Nilsson et al. 2010 ¹²	Preoperative "time-out" checklist	Questionnaire after implementation	None explicitly stated	Two Swedish hospitals, bed sizes not reported	In the autumn of 2007, there were two incidents of wrong-side surgery at these hospitals, and a root-causes analysis suggested that a time-out procedure might help. The checklist was pre-approved by the heads of the operating and anesthesia departments.	Implementation began in December 2007. Checklist was a shared responsibility of the OR team. One year later, a questionnaire was sent to all 704 surgeons, anesthesiologists, operation nurses, anesthetic nurses, and nurse assistants, soliciting their opinions about the new time-out checklist. Of the 331 responders, 93% felt that the checklist contributes to increased patient safety (either "without a doubt," or "probably"). When asked about eight specific components of the time-out checklists, the percentage of respondents who felt the component was "very important" varied widely, from a low of 14% for the introduction of team members to highs of over 80% for patient identity, correct procedure, and correct side. Regarding the sign-out, 91% felt that the item involving the count of surgical instruments and sponges was very important.

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Safety Context	Implementation Details
Owers et al. 2010 ¹³	Correct site surgery checklist incorporate into an existing preoperative checklist	Case series	None explicitly stated	English children's hospital, bed size not reported	A preoperative checklist already existed at this facility; they added a correct site surgery component	Five people were required to sign the documentation: marking surgeon, operating surgeon, ward nurse, scrub nurse, and anesthetist. Two audit cycles: once in 2006 (sooner after implementation) and once in 2008 (two years later). Comparing 2008 to 2006, correct completion of the eight items was not at all improved for four items (ward nurse signed, operating surgeon signed, scrub nurse, signed, and operating department practitioner signed) but was improved for the other four (mark site documented, no mark required documented, entries legible, and marking surgeon signed). "The lack of documentation, of course, may not reflect that the new guidance and processes are not being followed, but rather that the documentation is regarded as a low priority part of the process."
Anonymous 2007 ¹¹	Checklist to implement the Universal Protocol, tailored to this hospital's preferences and procedures	Case series	Stated that the checklist provides cues for staff when preparing for a procedure.	Hospital in North Carolina, bed size not reported	Before this checklist, they were using a "cumbersome form" to document their compliance with the Universal Protocol.	Original checklist in 2005, minor revisions for 2006. Demonstrated the checklist during educational staff meetings, and new staff were given a primer. Staff gave positive comments that they no longer had to remember everything. The completed checklist is kept as part of the medical record.

Notes: NS=Not stated; Int=Intervention

Table 4, Chapter 13. Studies of anesthesia equipment checklist implementation

Author/Year	Study Design	Description of Organization	Study Phases and Checklist Fidelity	Reasons for Success or Failure	Opinions, Knowledge and Behavior	Health Outcomes
Thomassen et al. 2010 ¹⁴	Case Study	Anaesthesia and intensive care department of a 1,100-bed tertiary teaching hospital	Developed 26-item checklist after review of adverse events, PubMed review of literature, and expert panel discussions. Modified Delphi technique used. Checklist used on 502 patients.	Emphasized avoiding checklist fatigue. Process was supervised by participating senior clinician; researchers were also present. 85 checklists identified one or more missing items (17%).	There was a low compliance (61%) during the testing period; a few persons in leading positions discouraged use of checklists.	Median checklist completion time was 88.5 seconds; did not substantially increase pre-induction time.
Thomassen et al. 2010 ¹⁵	Case Study	Anaesthesia and intensive care department of a 1,100-bed tertiary teaching hospital	Follow up study from Thomassen et al. 2010 ¹⁵ Focus group interviews were conducted after previous study was completed.	Checklist improved confidence in unfamiliar contexts. It revealed insufficient equipment standardization.	Checklists could divert attention away from the patient. Senior consultants were both skeptical and supportive.	N/A

Notes: NS=not stated; Int=Intervention

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Evidence Tables for Chapter 14. Use of Report Cards and Outcome Measurements To Improve the Safety of Surgical Care: American College of Surgeons National Quality Improvement Program (NEW)

This review had no additional evidence tables. There is one evidence table in the text.

Evidence Tables for Chapter 15. Prevention of Surgical Items Being Left Inside A Patient: Brief Update Review

This review had no additional evidence tables.

Evidence Tables for Chapter 16. Operating Room Integration and Display Systems: Brief Review (NEW)

This review had no additional evidence tables.

Evidence Tables for Chapter 17. Use of Beta Blockers To Prevent Perioperative Cardiac Events: Brief Update Review

This review had no additional evidence tables.

Evidence Tables for Chapter 18. Use of Real-Time Ultrasound Guidance During Central Line Insertion: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 19. Preventing In-Facility Falls

This topic modifies an evidence table from an existing systematic review, and therefore some of the columns and entries are different than our normal format.

Table 1, Chapter 19. Evidence table adapted from Oliver and colleagues

References	Study Design	Setting	Participants	Individualized/ Use of Risk Score	Assessment/ Intervention Performed By	Discipline involved in intervention
Ang et al, 2011 ^{1*}	RCT	8 medical wards in an acute care hospital in Singapore	1822 newly admitted patients who were age 21 or older, and scored 5 or above on fall risk model were randomized.	Yes/Local	Research Staff	Nursing
Barker et al, 2009 ²	Before-and-after study	Small acute hospital in Australia	271,095 patients admitted over 3 years before, and 6 years after intervention	Yes/Local ¹	Ward Staff	Nursing
Barry et al, 2001 ³	Before-and-after study	Small long-stay and rehabilitation hospital in Ireland	All patients admitted to 95 beds for 1 year preintervention and 2 years postintervention	Yes/Local	Ward Staff	Multi
Brandis, 1999 ⁴	Before-and-after study	An acute hospital in Australia (including pediatric wards)	All patients admitted to 500 beds for 1 year preintervention and second year postintervention (no data provided for first year of intervention)	No/No	Ward Staff	Nursing
Cumming et al, 2008 ⁵	Cluster RCT	24 acute and rehabilitation elderly care wards in 12 Australian hospitals	3999 patients admitted during the 3-month study period on each ward	Yes/No	Research Staff/Ward Staff	Nursing and Physiotherapy

* New studies added from update search

¹ While based on STRATIFY, extensive changes were made.

References	Study Design	Setting	Participants	Individualized/ Use of Risk Score	Assessment/ Intervention Performed By	Discipline involved in intervention
<i>Dykes et al, 2010^{6*}</i>	Cluster RCT	8 medical units in 4 urban United States hospitals	All patients admitted or transferred to units over 6 month study period	Yes/Local	Research Staff/ Ward Staff	Multi
Fonda et al, 2006 ⁷	Before-and-after study	Four elderly acute and rehabilitation wards in an Australian acute hospital	All admitted patients (1905 before, 2056 after) over 1 year before, 2 years after	Yes/Local	Ward Staff	Multi
Grenier-Sennelier et al, 2002 ⁸	Before-and-after study	A 400-bed rehabilitation hospital in France	All admitted patients over 2 years before and 2 years after (ca 800 admissions per year)	Yes/Local	Ward Staff	Nursing
Haines et al, 2004 ⁹	RCT	Three subacute wards within an Australian rehabilitation and elderly care hospital	626 patients consenting to randomization drawn from 1040 consecutive admissions	Yes/No	Ward Staff/ Research Staff	Physiotherapy and Occupational Therapy
Healey et al, 2004 ¹⁰	Cluster RCT	Four acute and 4 rehabilitation wards in one acute and 2 rehabilitation hospitals in the UK	All admitted patients over 1 year (3386 patients)	Yes/No	Ward Staff	Multi
Koh et al, 2009 ¹¹	Cluster RCT	Two acute hospitals in Singapore	All admissions during 1 year before and 6 months after	Yes/Local	Ward Staff	Nursing
Krauss et al, 2008 ¹²	Before-and-after study with contemporaneous cohort	General medical wards in an acute academic hospital	All admissions during 9 months before and 9 months after period (N not given)	Yes/No	Ward Staff	Nursing

References	Study Design	Setting	Participants	Individualized/ Use of Risk Score	Assessment/ Intervention Performed By	Discipline involved in intervention
Mitchell et al, 1996 ^{13*}	Before-and-after	The intervention took place in a 32 bed medical ward serving both acute and subacute patients with high acuity needs, which was compared to fall rates in the entire 225 bed acute care teaching hospital in Australia prior to the pilot.	All admissions in the hospital for 6 months prior to the pilot compared to 6 months in the pilot ward after implementation.	Yes/Local	Ward Staff	Nursing
Oliver et al, 2002 ¹⁴	Before-and-after study measure	An elderly medical unit within an acute hospital in England	3200 patients admitted annually; data collected for 1 year preintervention and 1 year postintervention	Yes/STRATIFY	Ward Staff	Multi
Schwendimann et al, 2006 ¹⁵	Before-and-after study	Internal medicine, geriatric and surgical wards in a 300-bed Swiss acute hospital	All admissions (34,972) over an 18-month before and 42-month after period	Yes/Local	Ward Staff	Multi
Stenvall et al, 2007 ¹⁶	RCT	Orthogeriatric ward (intervention) and orthopedic ward and geriatric ward (control) in a Swedish acute hospital	199 consecutively admitted patients with femoral neck fracture consenting to randomization ² and without complex needs	Yes/No	Research and ward staff	Multi
Uden et al, 1999 ¹⁷	Before-and-after study	A geriatric department in an acute hospital in Sweden	47 randomly selected patients from the year before intervention, all 332 admitted patients in the intervention year	Yes/No	Ward Staff	Nursing

² There were apparently no ward capacity issues as there is no mention of any patients not being admitted to the ward to which they were randomized.

References	Study Design	Setting	Participants	Individualized/ Use of Risk Score	Assessment/ Intervention Performed By	Discipline involved in intervention
Van der Helm et al, 2006 ³¹⁸	Before-and-after study	One internal medicine ward and one neurology ward within an acute hospital in the Netherlands	All admitted patients (2670) during a 6-month before and 18-month after period	No/Local	Ward Staff	Nursing
Vassallo et al, 2004 ¹⁹	Cohort Study ⁴	Three rehabilitation wards within a UK rehabilitation hospital	825 patients (the first 275 patients to be admitted to each of the 2 control and 1 intervention wards)	Yes/Downton	Ward Staff	Multi
Von Renteln-Kruse and Krause, 2007 ²⁰	Before-and-after study	Elderly acute and rehabilitation wards in an acute hospital in Germany	4272 patients admitted in a 23-months ⁵ before period, 2982 admitted in a 16-month after period	Yes/STRATIFY	Ward Staff	Multi
Williams et al, 2007 ^{21*}	Before-and-after study	Three medical wards (72 beds total) and a 17 bed geriatric evaluation management unit in a 755 bed metropolitan tertiary care teaching hospital in Australia	1,357 patients admitted during the 6 month study period were compared to aggregate hospital fall rates over the same period a year earlier.	Yes/Local	Ward Staff	Multi

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³ Note that the investigators describe the “before” period as a pilot study, but actually appear to be describing the falls rate and practice before the intervention, that is, a baseline rather than the piloting of the intervention.

⁴ Although the investigators refer to the study as quasi-randomized and Oliver et al (2007)¹ refer to it as a cluster RCT, it appears the intervention ward was selected (not randomized) on the basis of being the ward where the researchers worked, and the quasi-randomization relates only to the fact that patients would be allocated from a waiting list to whichever ward was the first to have an empty bed. The study also refers to “matching” patients, but this appears to be comparison of the cohorts for differences rather than matching at individual patient level.

⁵ A separate publication (von Renteln-Kruse and Krause, 2004) describes a review of reported falls from January 2000 to December 2002 when 5946 patients were admitted of whom 1015 were fallers and who had 1596 falls. This suggests that the proportion of fallers had been reducing substantially year-on-year even before the intervention was introduced (ie, 17% [1015/5946] of patients fell before intervention in 2000–2002, 14% [611/4272] of patients fell before intervention in 2003–2004, and 11% [330/2982] of patients fell after intervention in 2005–early 2006).

Table 2, Chapter 19. Stenvall et al. 2007, Main content of the postoperative program and differences between the two groups: teamwork²⁰

	Intervention group	Control group
Teamwork	Team included registered nurses (RN), licensed practical nurses (LPN), physiotherapists (PT), occupational therapists (OT), dietician, and geriatricians. Close cooperation between orthopedic surgeons and geriatricians in the medical care of the patients	No corresponding teamwork at the orthopedic unit.

Table 3, Chapter 19. Implementation studies evidence table

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
Browne et al., 2004 ²²	A new tool, the ADAPT Fall Assessment Tool, was developed, piloted, and implemented as a redesign for the existing fall prevention program. The tool automatically calculates a fall risk score from nurse shift assessments and produces a score and categorical recommendation. The 4 categories were disorientation, activity, postmedication, and toileting precautions, and each had a corresponding protocol and suggested interventions of care.	Descriptive with summative evaluation N=6402 inpatient and observation records reviewed from all adult medical-surgical units, all intensive care, rehabilitation, skilled nursing, and psychiatric units.	Redesign process looked for “current recommendations in the literature” for fall risk factors. This included 4 authors. The tool of one of these authors, Hendrich, was used to validate the ADAPT tool.	The Methodist Healthcare System (MHS) of San Antonio used the Meditech Clinical Documentation Module for electronic health records. This system includes 7 inpatient facilities that deliver full pediatric, adult, rehabilitation, maternal-child, and psychiatric services.	Context: 7 years of effort had failed to produce appreciable decreases in falls on injury. A fall committee identified reasons that might undermine fall prevention efforts. <ul style="list-style-type: none"> Missed partial or incorrect documentation of fall events (missed opportunities) Overidentification of fall risk patients with 60% of case plans listing a fall risk problem. Committee Goals: To develop: a computerized documentation to promote reassessment; an evidence-based risk assessment tool; a tailored intervention program; and a system for integrating information into documentation and communication. Considerations: “Complete, consistent, and accurate fall risk reassessment by nursing staff was essential to success of the project.” Pilot: Once the tool was developed, it was piloted and validated. The results were presented to the MHS Falls Committee, who gave permission for automated implementation system-wide. Education: “fall and restraint fairs” at the time of implementation served to educate nurses about the redesigned program. Iterative change: <ul style="list-style-type: none"> Nurse dissatisfaction with fall risk appearing in a list of acute care problems led to ongoing evaluation of where best to 		“Fall assessment documentation compliance on admission and daily increased to 100% for all units in all hospitals.” Fall rates decreased from 3.41 to 3.21 per 1000 adjusted patient days. Injuries per 100 falls decreased from 1.44 to 0.95.

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
					<p>place the fall risk items.</p> <ul style="list-style-type: none"> Certain units with specific issues (short-stay areas with less routine review, specialty units with at-risk and actual fall discrepancies) have resulted in special work teams tasked with customizing fall prevention program to their unique challenges. “One size fits all” where all patients get the same set of interventions 		
Capan et al., 2007 ²³	<p>A new fall risk assessment tool was developed to evaluate 7 risk factors every 12 hours for all patients. All significant risk patients received a wrist band, door sign, written guide, hip protectors, and orthostatic hypotension assessment. Specific risk factors (unsteady gait, disorientation, toileting issues, medication issues), have additional tailored interventions.</p> <p>Additionally, care coordination rounds had an interdisciplinary team meet to</p>	<p>Time series design</p> <p>No sample size given</p>	<p>“a literature search looking at best practices and reviewing existing fall risk assessment tools”</p>	<p>Franklin Square Hospital Center, a 357 bed acute care hospital in Baltimore, MD, is part of the MedStar Health System, which is a community-based network of 7 hospitals in the Baltimore-Washington Area.</p>	<p>There was an external pressure to improve, since this hospital had higher fall rate than benchmark from the Maryland Hospital Assoc. Quality Indicator Project (MHA QI). The existing fall risk tool was not identifying high risk patients.</p> <p>A root cause analysis of one year’s data found that, as opposed to the prior assumption that most fallers were confused, 70% of fallers were not confused. This meant the hospitals existing falls risk assessment tool was not identifying the majority of the patients who fell.</p> <p>The intervention and implementation were guided by a multidisciplinary team.</p> <p>A pilot test was performed in a unit with high fall rate and readiness for change indication. Staff was involved in choosing equipment. An internal financial incentive was used; a contest for gift cards was introduced for the first 25 staff documenting a prevented fall. Unit champions were considered key to the acceptance and needed to be passionate mentors; when nurses were only partially</p>		<p>In pilot, the fall rate declined from 1.17 to 0.45 per 100 patient days over a year.</p> <p>In full implementation, the rate dropped from 0.45 to 0.32 per 100 patient days, below the benchmark target of 0.35. Severity of injury has also declined, and declines have continued, with the fall rate cut in half over two years.</p>

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
	discuss total plan of care for each patient on the unit.				using the tool, champions' analysis of fall incidents helped build value and falls rate declined. Expansion: Initially planned for one unit at a time, increasing fall rates led to immediate hospital-wide implementation. Extensive education efforts included in-servicing and scheduled classes, with 95% of staff completing education prior to implementation.		
Dempsey, 2004 ²⁴	A new "injury risk assessment form" was used to match individual risk factors to interventions, educational materials, and illuminated graphics at patient's bedside.	Pre-post study of implementation in 1995-1996, follow up assessment in 2001.	The falls intervention was devised "using the literature and the collective experience of the clinicians." No other details are given.	"A regional teaching hospital" In Australia.	Compliance with the intervention was monitored. Compliance was 88% and was on a downward trend at the 2001 assessment (no data given). No change in staffing, but occupancy rates rose over time and could be related to decline of effectiveness. No significant differences in case mix.	A possible reason for the increase in falls was increased reporting and not an increase in falls.	After an initial reduction in falls, in 1995-1996, beginning in 1998 falls reporting began to increase until they exceeded pre 1995 levels. The researcher concluded that falling compliance associated with increased occupancy was partly causative for the decline in effectiveness of the program.
Gutierrez, 2008 ²⁵	A specific specialty adult focused environment (SAFE) unit as a part of the definitive observation unit. The SAFE unit had 3 rooms with 2 beds each, staffed by 2 RNs and 1 technical partner. Fall protocol order sets, post fall order	Time series design Total number of patients not responding	A literature review was performed to identify potentially promising interventions. Values of physicians, and nursing staff were solicited to assess the potential intervention components.	Scripps Mercy Hospital in San Diego California No other information provided	<ol style="list-style-type: none"> 1. Assess values of staff and available resources. 2. Identify clinical champions 3. Develop an "Elevator Speech" to motivate nurses. <ul style="list-style-type: none"> • Our project goal is to improve the patient care quality by preventing inpatient falls. • Our patient population is more educated about healthcare quality and is seeking the highest-quality care available. • Nurses play a primary role in 		This project found a lower rate of falls (p-37/1000 patient days) 3-6 months after the intervention compared to the 9 months prior (3.0, 4.18, and 4.87 falls/1000 patient days).

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
	sets, quiet zones, use of recliners in the hallways, low beds with internal alarms, keeping doors open and curtains back, and nurses use of portable computers for documentation within sight of patients.				<p>preventing falls.</p> <ul style="list-style-type: none"> • We want to be able to advise to the public that we have the highest-quality nursing care available in California; to this end, we must reduce patient falls. • Historically, the DOU floor has exceeded minimum acceptable fall occurrence standards as benchmarked by CalNOC. • If provided enough resources and staff and nursing is practiced according to evidence, we can likely minimize falls and the related negative outcomes. • We wish to prove that we can reduce our fall rates by eliminating practice barriers in our existing nursing-centered multidisciplinary fall prevention plan. • Our project goal is to identify and eliminate practice barriers within our existing evidence-based fall prevention protocol, improve its effectiveness, and thereby reduce falls and improve our quality of patient care. • We think that we can reduce our fall rates dramatically by being more vigilant about a good fall prevention plan; for instance, toileting our high-risk patients per protocol. • “I know it sounds simple, but these strategies have been used in other hospitals and they are known to work.” <p>4. One champion for day and one for night shift came to ensure compliance with protocol for a total of 192 hours.</p> <p>5. “Champions=Change”, the belief that champions change not only the</p>		

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
					<p>practice but also the culture.</p> <p>6. The process is slow.</p> <p>7. Leadership support, staff involvement, time, money, and energy are needed.</p> <p>8. A “no blame” culture for fall reporting.</p>		
Kolin et al., 2010 ²⁶	<p>Fall risk assessments were completed on admission, at least every 24 hours, and after certain trigger events. At-risk patients receive visual identification (arm band, door sign, etc.)</p> <p>A new tool was developed and implemented. Depending on the number of questions on which a patient screened positive, levels of interventions were applied.</p> <p>“Lightning Rounds,” which focused on a “vital few” patients, were implemented hourly.</p> <p>A standard post-fall form was adopted.</p> <p>New patient educational materials were developed, and</p>	Time series; data presented on fall rates and injury rates for a year preceding implementation, as well as for the intervention year in the UPMC system overall, as well as for one specific units.	A fall literature review was conducted on multiple databases (CINAHL, Medline, Cochrane) and categorized into levels of evidence. Evidence was then synthesized to determine components for inclusion in a multifactorial intervention.	University of Pittsburgh Medical Center (UPMC) has 19 acute care facilities in Western Pennsylvania.	<p>UPMC leadership formed a system-wide team, including expert members and the paper authors, to prioritize falls, identify best practices, compare UPMC strengths and weaknesses, and determine a model for implementation. The team had regular ongoing meetings beyond the duration of the project.</p> <p>Data on the overall fall and injury rates were collected and compared to benchmarks, which was then presented to leadership.</p> <p>A survey was then taken at each facility, which revealed variability of compliance with risk reassessment, type of post-fall follow-up for, and patient assessment form.</p> <p>Team members participated in falls education, and then held a rapid improvement event, where experts were divided amongst groups to address 5 specific issues: assessment and reassessment, prevention equipment and interventions, hospital environment, staff and patient/family education, and post-fall follow-up. The first group tested and compared different tools in a convenience sample before developing their own assessment tool.</p> <p>A comprehensive education for the nursing staff was provided before the implementation of the new tool.</p>		

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
	environmental modification recommendations were proposed.				Not all facilities use electronic medical records, so roll-out was staggered between those with and without EMRs. Those with EMRs began working to connect the records to the event reporting system.		
McCollam, 1995 ²⁷	<p>The Morse Fall Scale (MFS) was adopted.</p> <p>Nursing staff were trained using a video and instructions for scoring the scale. Their understanding was then checked using an evaluation.</p> <p>Patients scoring 45 or above received nursing implementations.</p>	<p>Descriptive quantitative</p> <p>Data provided on fall rates, compliance and tool reliability</p>	<p>“a careful review of research-based falls literature...found only one falls assessment instrument that met [our criteria].” The identified scale is the MFS.</p>	<p>Veterans Affairs Medical Center, Portland, Oregon</p>	<p>Research in Practice Committee led effort.</p> <p>The MFS was pilot for 3 months on the hospital’s 40-bed Cardiology General Medicine Unit to determine if: 1. Patients were accurately identified as at risk; 2. Nurses could use it reliably; 3. MFS was practical for routine clinical use. At the end of data collection, a staff nurse survey was used to evaluate aims 2 and 3.</p> <p>Before this, near falls had not been part of the reporting.</p> <p>Problems identified during the pilot included inconsistent and incomplete reassessment, identification of secondary diagnoses, and score consistencies between shifts. Cut-off score was adjusted from 45 to 55.</p> <p>Full implementation included approval from Nursing Administration, inclusion of the scale in admission forms, and staff education.</p> <p>Although instrument completion compliance ranged from 75 to 85%, care plans or interventions for fall prevention were only in the 50-58% range. This could be due to a lack of knowledge or skepticism about the program.</p> <p>Strategies needed to maintain MFS use,</p>		<p>In the year after MFS implementation, reported falls had risen 24%, and serious injuries had decreased 175%.</p>

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
					strengthen interventions for at-risk patients, and assigning responsibilities for follow-up program monitoring and evaluation.		
Neily, 2005 ²⁸	Collaborative breakthrough series (BTS); the intervention includes signs to identify high risk patients, toileting interventions, use of hip pads, environmental rounds, staff education, and post-fall assessment.	Pre-post study with summary evaluation exploring the influence of context on effectiveness. Number of patients not reported.	The intervention implementation was based on the collaborative breakthrough series.	32 Veterans Affairs facilities (a mix of acute and long term care facilities). State veterans homes and one private long term care facility.	In 4 sites where the intervention was spread, leadership support was cited as one of the strongest factors for continued change. Root cause analysis and a multidisciplinary approach were also cited as important risk factors. Leadership support, teamwork skills correlated with one-year high team performance. At the one year follow up, high performing sites, compared to low performing sites, reported higher agreement with questions about the presence of useful information systems, the sites gained and exchanged overall value, teamwork skills, and leadership support.		The primary effectiveness assessment of the intervention was a decrease in major injury rate of 62%.
O'Connell, 2001 ²⁹	Assess fall risk using standardized scale; patients at high risk of falling identified with stickers and wristbands; "standard fall prevention measures could be implemented for this group of patients"	Pre-post test with summative evaluation Study sample N-1065 patients, 2 wards in an acute care hospital. No other patient data provided	Literature review to assess potentially effective interventions. No additional specification.	Acute care hospital in Australia; no details except mean length of stay = 34 days	The authors themselves identified these themes. <i>Confounding Contextual Issues:</i> Hiring freeze during the middle of the study period meant staff vacancies could not be filled. Concurrent implementation of a program to increase physical activity led to feelings by staff of being overwhelmed by the requirements of two projects, and lost motivation. Implied was the notion that a project "driven by middle management" would receive less support. Concurrent implementation of another falls prevention program by the occupational therapy department may also have contributed to confusion. <i>Difficulties with the fall prevention program:</i> The risk assessment instrument identified about 75% of patients as high	<i>Methodological barriers:</i> Initial attempt to design evaluation as RCT, then controlled before-and-after, left evaluation team discouraged that pre-post study was the only feasible design.	In this study, no statistically significant benefit of the program was observed.

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
					risk. Consequently most patients had stickers and bracelets. But 70% of falls occurred in patients who were not classified as high risk. This may have undermined staff confidence in the intervention and that the program “lost some of its significance.” No or limited ability to audit whether standard fall prevention measures were being done. Some staff said they were already doing everything to prevent falls and this new program did not add anything new to this.		
Rauch et al., 2009 ³⁰	<p>The Schmid Risk Assessment tool was used to identify at-risk patients. Depending on specific risk factors, multiple interventions were specified, including a general intervention and interventions tailored for specific risk factors like medications or altered mobility.</p> <p>Visual identifiers were used in the general intervention, with a daily list of at-risk patients, arm bands, and door signs.</p> <p>A postfall protocol was developed and introduced.</p>	Time series, data provided about fall rates and compliance	<p>Ishikawa case and effect chart and root cause analysis process</p> <p>Plan-Do-Study-Act (PDSA) performance improvement model was used throughout the implementation process.</p>	University Medical Center at Princeton	<p>The project began with a current practice evaluation based on the Ishikawa methods, and uncovered improvement opportunities including communication, care-planning and assessment, equipment, education, process and staffing.</p> <p>Leadership hired the Hill-Rom Clinical Excellence team as an outside consultant with experience and expertise. All levels of leadership were engaged and accepted ownership of the process.</p> <p>“...it is imperative to obtain frontline staff input and feedback to ensure that successful change management occurs in the clinical arena.”</p> <p>Policy was reviewed and rewritten to include specific intervention components, including a valid assessment tool, assessment frequency, etc.</p> <p>A multidisciplinary fall team including managers and frontline staff identified the Schmid Risk Assessment Tool for use in the intervention.</p> <p>The tool was first piloted in a unit with high fall risk and willing staff. Originally</p>		<p>The rate of falls with injury in the pilot unit decreased from 43% to 14% over the year.</p> <p>Staff compliance is steadily improving.</p>

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
					<p>planned for 30 days, the pilot was extended another 30 days to incorporate changes and solidify the process before full roll-out. Significant changes were made, including activity distribution between shifts, additional staffing, and ongoing education and communication.</p> <p>Weekly teleconferences between consultants and key hospital members, as well as monthly fall team meetings support the ongoing status of the implementation.</p> <p>After 8 weeks of fine tuning, there was an incremental roll out in the rest of the hospital.</p> <p>Routine monitoring of staff compliance and understanding was measured using the GAP analysis tool.</p> <p>The program was well received by the staff.</p>		
Semin-Goossens, 2003 ³¹	A guideline developed by an internal project team of 11, with 4 nurses from each ward, that focused on identifying patients, at increased risk on the basis of 3 main risk factors and then for patients at increased risk doing one or more of: moving bed to lowest position; raising side rails; noting the increased risk in	Longitudinal time series study sample N=2670 patients. No other patient data provided.	The intervention used Grol's 5 step implementation model: 1) develop and change protocol; 2) identify obstacles to change; 3) link intervention to obstacles; 4) develop and plan; and 5) evaluate the process. The implementation was a "bottom up" approach with input from ward nurses at every step of the way and attention paid to attractiveness of the educational materials	Acute care hospitals in the Netherlands, 2 "voluntary cooperating" wards. A 32 bed neurology ward with 33 nurses and 850 admissions/ year. A 32 bed internal medicine ward with 34 nurses and 1500 admissions/year. Overall, the hospital has 1000 beds and is a teaching hospital. The motive for the intervention was the high number of falls reported to the Incident Reporting Committee.	<p>The investigators judged nurses may have been resistant to the idea that falls could be predicted and prevented. On the neurology ward, nurses stated it was "simply impossible" to prevent falls. Falling was considered to be an inevitable part of aging. These "feelings of helplessness" did not change during the intervention. The authors speculate that an important aspect of success is changing the attitude of nurses. The authors conclude with three things they would do differently:</p> <ul style="list-style-type: none"> • Get more buy-in from floor nurses and not just the head nurse • Assess the prior experience with implementation of practice guidelines 	Nurses found filling out falls incident report forms troublesome.	In this study, no statistically significant benefit of the program was observed.

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
	the nursing file; informing patients and relatives about the measures; putting the call bell within reach; and a restraining waist belt could be used. Additionally, efforts were made to reduce environmental hazards.		and feedback on fall rates. An organizational plan to use stickers to identify high risk patients was abandoned because nurses judged them stigmatizing with little evidence of effectiveness.	A previous fall prevention program failed. The belief was that the implementation was simplistic.	<ul style="list-style-type: none"> Get more organizational buy-in in order to create an environment in which it is easier to implement change. Attempt to involve medical chiefs and nurse managers. 		
Weinberg et al., 2011 ³²	<p>Fall prevention initiative (FPI) included:</p> <p>1. Monthly Fall reviews were attended by unit managers, staff involved in patient care, and the FPI co-chairs.</p> <p>2. Patient care staff and managers were made more accountable for breaches, and a fall index report by unit, as well as daily rounds, were instituted.</p> <p>3. Policy changes included: Formalized use of bed alarms; improved fall documentation; medication restrictions; fall risk</p>	<p>Time series design.</p> <p>All beds were included in analysis, 714 beds in hospital.</p>	<p>“The FPI was related to adaptive and business management models used in industries... that cannot permit failures. These models institutionalize continuous quality improvement and evidence-based strategies for implementing cultural change through modification of system failures, leadership support, communication, clear goals for each member, lateral accountability and cooperation, and correction of system failures.”</p> <p>The normal accident theory and high-reliability theory, which emphasize</p>	<p>Staten Island University Hospital has two campuses and 714 beds. Services include medical/surgical, pediatric, maternity, behavioral sciences and physical rehabilitation.</p>	<p>“Adaptive challenges,” including poor institutional prioritization and poor compliance with existing protocols, were identified. Prior to the FPI, reactions to falls rates included policy and procedure changes that failed to reduce incidence.</p> <p>Two events provided motivation for the intervention: the highest recorded fall rate at the hospital and the introduction of fall prevention as a National Patient Safety Goal.</p> <p>Hospital leadership initiated the effort and prioritized falls, forming a multidisciplinary hospital falls committee to review fall-related policy breaches. Committee attendance was mandated.</p> <p>FPI provided “forum for staff to define and solve problems, encouraged collaborations between units, and the sharing of best practices.”</p> <p>FPI co-chairs evaluated cultural factors, and found that although existing protocols followed best practices, low prioritization of falls, superficial fall analysis, and lack of accountability all</p>		<p>After four years, yearly inpatient fall rates decreased by 63.9% (p<.0001).</p> <p>Documentation of injury level increased and minor and moderate fall-related injuries decreased, all statistically significant.</p>

Author/ Year	Description of Fall program	Study Design	Theory or Logic Model?	Description of Organization	Implementation Themes – focus on association with effectiveness	Additional themes	Comments
	and postfall assessments.		documentation and the role of a just culture, were also utilized.		<p>decreased protocol success.</p> <p>Initial reviews revealed partial or superficial compliance, highlighting compliance as a main issue for effective prevention.</p> <p>Most protocols and policies stayed from before FPI, the biggest change was culture. “as the initiative processed, the culture of the hospital appeared to change to one in which, rather than being burdensome, fall prevention engendered pride and enthusiasm...”</p>		

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Evidence Tables for Chapter 20. Preventing In-Facility Delirium

Table 1, Chapter 20. Risk factors for delirium

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Slor et al. 2011 ³ The Netherlands	Secondary analysis of RCT 526 patients	Adults aged 70 years or older undergoing acute or elective hip surgery, without delirium at admission (or profound dementia precluding communication)	Academic hospital (915 beds)	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria and Confusion Assessment Measure (CAM)	Univariate analyses followed by multivariable logistic regression; factors controlled for include age, APACHE II score, MMSE score, Snellen test score, benzodiazepines, anticholinergics, opioids, type of anesthesia	No significant risk factors for delirium were identified.	None	High
Burkhardt et al. 2010 ⁴ Switzerland	Cohort study (post-hoc analysis of RCT) 113 patients	Adults aged 65 years or older undergoing cardiac surgery with cardio- pulmonary bypass (CPB); patients with Mini-Mental State Exam (MMSE) score <15/30 were excluded	Academic hospital	CAM	Univariate and multivariable logistic regression with stepwise backward elimination; factors adjusted for include C-reactive protein (CRP), intraoperative fentanyl, and duration of mechanical ventilation	Multivariable logistic regression analyses: <u>Maximum value of C-reactive protein measured post-op:</u> OR: 1.1 (95% CI: 1.01-1.16) P = 0.02 <u>Fentanyl intraoperatively:</u> OR: 4.9 (95% CI: 1.72-13.8) P = 0.003 <u>Duration of mechanical ventilation:</u> OR: 1.1 (95% CI: 1.04-1.21) P = 0.004	Fentanyl amount, duration of mechanical ventilation	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Hudetz et al. 2010 ⁵ USA	Prospective cohort study 40 patients	Adult males aged 55 years or older scheduled for elective CABG and/or valve replacement/ repair procedures with CPB. Patients with prior documented cognitive deficits or vascular dementia were excluded.	Veterans Affairs (VA) medical center	Intensive Care Delirium Screening Checklist (ICDSC)	Univariate and multiple logistic regression; factors adjusted for include psychosocial variables (dispositional optimism, perceived social support, perceived stress level, and depression)	Incidence of post-op delirium within 5 days of surgery was reduced by: <u>dispositional optimism:</u> OR: 0.57 (95% CI: 0.35-0.92) p<0.02	None	Moderate
Kazmierski et al. 2010 ⁶ Poland	Prospective cohort study 563 patients	Adult patients admitted for cardiac surgery with cardiopulmonary bypass; patients with preop dementia were excluded.	Academic hospital	DSM-IV criteria	Univariate analyses followed by multivariate backward stepwise logistic regression; factors adjusted for include age, MMSE score, major depression, anemia, atrial fibrillation (AF), intubation time, and pO ₂ level.	Risk factors for delirium: <u>Age ≥65 years:</u> OR: 4.23 (95% CI: 2.24-7.96) <u>MMSE <25:</u> OR: 6.14 (95% CI: 3.31-11.39) <u>Intubation >24 hr:</u> OR 5.29 (95% CI: 2.14-13.06) <u>pO₂ <60 mmHg:</u> OR: 3.24 (95% CI: 1.77-5.94) <u>Major depression:</u> OR: 4.69 (95% CI 1.84-11.93) <u>Anemia:</u> OR: 4.77 (95% CI: 1.35-16.82) <u>AF:</u> OR: 3.67 (95% CI: 1.40-9.60)	Cognitive impairment, depression, anemia, and AF could be treated prior to surgery	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Koebrugge et al. 2010 ⁷ The Netherlands	Retrospective cohort study 107 patients	Patients aged 65 years or older undergoing aortoiliac surgery; patients with Alzheimer's disease or dementia were excluded.	Suburban teaching hospital	DSM-IV criteria	Univariate and multivariate step forward logistic regression; factors adjusted for include age and urgency of surgery (emergency vs. elective)	Post-op delirium: <u>Age ≥70 years:</u> OR: 7.7 (95% CI: 1.9-30.4) P<0.01 <u>Emergency (vs. elective) surgery:</u> OR: 5.3 (95% CI: 1.3-21.2) P<0.01	None	High
Lin et al. 2010 ⁸ USA	Retrospective cohort study 26,057,988 hospitalizations	Hospitalizations recorded in the National Inpatient Sample (NIS) for DRG categories pneumonia, orthopedic surgery of the lower extremity, congestive heart failure, and urinary tract/ kidney infections	NIS database from 1998-2005	ICD-9 codes for delirium with dementia, drug-induced delirium, and non-dementia, non-drug (NDND) delirium	Multivariate stepwise forward logistic regression; factors adjusted for include age, gender, logarithm base e, length of stay, payor, DRG, cerebrovascular disease, dementia, adverse drug effect, sodium imbalance, volume depletion, anemia, atrial fibrillation, respiratory intervention, and diabetes mellitus	<u>Dementia-associated delirium:</u> Age, logarithm base e, length of stay, cerebrovascular disease, dementia, adverse drug effect, sodium imbalance, volume depletion, atrial fibrillation were all significant risk factors for delirium. Female gender, Medicaid as payor, congestive heart failure DRG, pneumonia DRG, anemia, and diabetes were associated with significantly lower risk of delirium. <u>Drug-induced delirium:</u> Age, logarithm base e, length of stay, cerebrovascular disease, orthopedic DRG, dementia, adverse drug effect, were all significant risk factors for delirium. Female gender, Medicaid as payor, congestive heart failure	Sodium imbalance, volume depletion, atrial fibrillation, and anemia	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
						<p>DRG, pneumonia DRG, sodium imbalance, anemia, and diabetes were associated with significantly lower risk of delirium.</p> <p><u>Non-dementia, non-drug delirium:</u> Age, logarithm base e, length of stay, cerebrovascular disease, adverse drug effect, sodium imbalance, volume depletion, atrial fibrillation, and respiratory intervention were all significant risk factors for delirium.</p> <p>Female gender, Medicaid as payor, orthopedic DRG, congestive heart failure DRG, pneumonia DRG, anemia, and diabetes were associated with significantly lower risk of delirium.</p>		
Lin et al. 2010 ⁹ USA	Retrospective cohort study 1,968,527 hospitalizations	Acute care hospitalizations (for pneumonia, lower extremity orthopedic surgery, congestive heart failure [CHF], and kidney/urinary tract infection [UTI]) of patients aged 18 years or older in New York	De-identified inpatient data obtained from the New York State Dept of Health Statewide Planning for Research Cooperative System (SPARCS) database	ICD-9 codes used to identify delirium cases; original diagnostic criteria not reported	Forward stepwise logistic regression; factors adjusted for include comorbidities, DRG categories, adverse drug effects (ADEs), dementia, mechanical ventilation/ventilator assistance, gender, age (in decade), year of discharge, Caucasian ethnicity, Medicaid reimburse-	<p>Any delirium after admission: <u>Decade of age:</u> OR: 1.53 (95% CI: 1.49-1.58) <u>Female:</u> OR: 0.70 (95% CI: 0.66-0.75) <u>Caucasian:</u> OR: 1.45 (95% CI: 1.29-1.62) <u>Elective admission:</u> OR: 0.87 (95% CI: 0.80-0.94)</p>	None	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
		State (1998-2007).			ment, and elective admission status	<p>Medicaid: OR: 0.74 (95% CI: 0.66-0.82)</p> <p><u>CHF DRG:</u> OR: 0.76 (95% CI: 0.64-0.89)</p> <p><u>Lower extremity orthopedic surgery DRGs:</u> OR: 7.36 (95% CI: 6.38-8.50)</p> <p><u>Any ADE:</u> OR: 22.19 (95% CI: 20.72-23.76)</p> <p><u>Dementia:</u> OR: 1.26 (95% CI: 1.12-1.41)</p> <p><u>Respiratory intervention:</u> OR: 1.96 (95% CI: 1.62-2.36)</p> <p><u>Cerebrovascular disease:</u> OR: 1.18 (95% CI: 1.01-1.39)</p> <p><u>Atrial fibrillation:</u> OR: 1.24 (95% CI: 1.15-1.34)</p> <p><u>Diabetes mellitus:</u> OR: 1.14 (95% CI: 1.06-1.23)</p> <p><u>Volume depletion:</u> OR: 1.41 (95% CI: 1.28-1.57)</p> <p><u>Anemia:</u> OR: 1.15 (95% CI: 1.05-1.25)</p> <p><u>Hyponatremia:</u> OR: 1.42 (95% CI: 1.25-1.60)</p>		

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Radtke et al. 2010 ¹⁰ Germany	Cohort study 910 patients	Patients received elective general anesthesia and were observed in recovery room and hospital ward on first postoperative day	Academic hospital	Nursing delirium screening scale (Nu-DESC)	Univariate and multivariate logistic regression with delirium as the response. Regression analyses were supplemented with a feature selection process using backward elimination. Factors adjusted for include age, gender, duration of surgery, site, intraop opioids, anesthetic, preop fasting (solids and fluids)	Multiple logistic regression analyses: Longer preoperative fluid fasting time (>6 hr) was the only significant risk factor for delirium in both the recovery room (OR: 2.69, 95% CI: 1.38-5.24) and the ward (OR: 10.57, 95% CI: 1.42-78.62). Older age (OR: 1.02, 95% CI: 1.01-1.03) and surgical site (intraabdominal or intrathoracic vs. other sites) (OR: 1.83, 95% CI: 1.09-3.07) were significant risk factors in the recovery room. Intraoperative opioid choice (fentanyl vs. remifentanyl) was a significant risk factor in the ward (OR: 2.27, 95% CI: 1.01-5.06).	Preoperative fluid fasting time, choice of intraoperative opioid	Moderate
Rigney 2010 ¹¹ USA	Prospective cohort study 44 patients	Patients aged 65 or older who spoke and understood English; Patients with prevalent delirium or moderate to severe cognitive dysfunction were excluded.	Academic hospital (365 beds)	CAM	Univariate and bivariate analyses followed by logistic regression; factors adjusted for include total allostatic load (AL) scores, primary mediators score, secondary outcomes score, and individual AL parameters	Primary mediators score was the only significant factor predicting delirium.	None	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Sieber et al. 2010 ¹² USA	Double-blind randomized controlled trial (RCT) 114 patients	Patients aged 65 or older undergoing hip fracture repair under spinal anesthesia with propofol sedation; patients with “mental... barriers that would preclude data collection” were excluded.	Academic medical center	CAM	Univariate and multivariate regression; factors adjusted for include deep sedation, dementia, units of packed erythrocytes transfused, and admission to the ICU	Multivariate regression significant risk factors: <u>Deep sedation:</u> OR: 2.69 (95% CI: 1.04-6.93) p = 0.04 <u>preoperative dementia:</u> OR: 3.97 (95% CI: 1.54-10.2) p = 0.004), <u>units of packed erythrocytes transfused:</u> OR: 1.62 (95% CI: 1.10-2.38) p = 0.01), and <u>admission to the ICU:</u> OR: 3.69 (95% CI: 1.17-11.7) p = 0.02).	Sedation	Moderate
Bo et al. 2009 ¹³ Italy	Prospective cohort study 252 patients	Patients aged ≥70 years admitted from emergency dept (ED) to an acute geriatric ward (AGW) or an acute general medical ward (AGMW); patients with delirium during ED stay or at ward entry were excluded.	Academic hospital	CAM	Univariate analyses, then multivariate forward stepwise modeling of variables associated with incident delirium; factors adjusted for include APACHE II score, SPMSQ score, stressful events, AGW hospitalization (vs. AGMW hospitalization)	Risk of incident delirium: <u>APACHE II:</u> RR: 1.30 (95% CI: 1.11-1.51) P = 0.001 <u>SPMSQ:</u> RR: 2.06 (95% CI: 1.62-2.64) P<0.001 <u>Stressful events:</u> RR: 3.36 (95% CI: 2.86-5.44) P = 0.001 <u>AGW hospitalization:</u> RR: 0.04 (95% CI: 0.01-0.21) P<0.001	More patients can be admitted to AGW vs. AGMW, some stressful events might be reduced	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Greene et al. 2009 ¹⁴ USA	Prospective cohort study 100 patients	Patients aged 50 years or older admitted for major elective noncardiac surgery with at least a 2-day postop stay	Academic medical center	CAM	Bivariate analyses then multivariate analysis: factors adjusted for include Geriatric Depression Score-Short Form, Trails B time, Digit Symbol Test, and Symbol Search Test	<u>Geriatric Depression Score-Short Form:</u> OR per unit: 1.53 (95% CI: 1.22-2.05) P = 0.0001); <u>Trails B time:</u> OR: 1.02 (95% CI: 1.01-1.04)	Depression	Moderate
Hattori et al. 2009 ¹⁵ Japan	Prospective cohort study 160 patients	Patients aged ≥75 years admitted for abdominal surgery, vascular surgery, or orthopedic surgery (all non-emergency); patients with severe dementia were excluded.	4 hospitals (1 academic), bed size ranged from 300 to 887	NEECHAM Confusion Scale	Univariate and multivariate analyses; factors adjusted for include age, gender, department, anesthesia, MMSE, and preop NEECHAM score	Risk of postop delirium: <u>Age >80 years:</u> OR: 3.14 (95% CI: 1.35-7.26) <u>Male:</u> OR: 2.86 (95% CI: 1.09-7.47) <u>Preop MMSE <25:</u> OR: 3.96 (95% CI: 1.52-10.39) <u>Preop NEECHAM <27:</u> OR: 5.33 (95% CI: 1.84-15.31)	None	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Katznelson et al. 2009 ¹⁶ Canada	Prospective cohort study 1,059 patients	Patients undergoing cardiac surgery with CPB	Academic hospital	CAM-ICU	Univariate analysis then multivariate logistic regression with backward and stepwise selection; factors adjusted for include older age, gender, preop depression, preop renal dysfunction, hypertension, peripheral vascular disease, New York Heart Association (NYHA) class >2, preop anemia, diabetes, preop history of cerebrovascular accident/TIA, prolonged CPB, intraop anemia and hyperglycemia, complex cardiac surgery, perioperative intraortic balloon pump support, and massive blood transfusion	Risk of postop delirium: <u>Red blood cell transfusion (>5 units):</u> OR: 3.29 (95% CI: 2.09-5.19) <u>Perioperative intraaortic balloon pump support:</u> OR: 3.84 (95% CI: 1.72-8.56) <u>Preop depression:</u> OR: 3.06 (95% CI: 1.36-6.90) <u>Preop creatinine ≥150 mM:</u> OR: 2.96 (95% CI: 1.9-4.63) <u>Age ≥60 years:</u> OR: 2.47 (95% CI: 1.43-4.23) <u>Combined CABG and valvular surgery:</u> OR: 1.86 (95% CI: 1.16-2.98) <u>Preop administration of statins:</u> OR: 0.54 (95% CI: 0.35-0.84)	Preop administration of statins, preop depression, preop creatinine	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Maldonado et al. 2009 ¹⁷ USA	RCT 118 patients were randomized to three different sedatives	Patients aged 18-90 years admitted to the ICU following elective cardiac surgery. Patients with prior diagnosis of dementia were excluded.	Academic medical center and a VA medical center	DSM-IV criteria applied by a neuro-psychiatrist	Univariate followed by multiple logistic regression; factors adjusted for include age, gender, ASA class, baseline MMSE score, Midazolam (vs. Dexmedetomidine), and Propofol (vs. Dexmedetomidine)	Post-op sedation: <u>Midazolam vs. Dexmedetomidine:</u> OR: 28.6 (95% CI: 3.7-262.5) p = 0.01 <u>propofol vs. dexmedetomidine:</u> OR: 29.6 (95% CI: 4.8-280.6) p = 0.01 <u>Age (increasing 10 years):</u> OR: 1.3 (95% CI: 1.1-1.5) p = 0.01	Post-op sedation	High
Pisani et al. 2009 ¹⁸ USA	Prospective cohort study 304 patients	Patients aged ≥60 years admitted to ICU	Academic hospital (900 beds, with 14-bed ICU)	CAM-ICU	Bivariate analyses, then multivariate forward selection regression of variables associated with delirium (P<0.20); factors adjusted for include benzodiazepine or opioid use, Haloperidol use, steroid use, ADL impairment, history of depression, dementia, ICU diagnosis of respiratory disease, APACHE II score (minus Glasgow Coma Scale), Alanine aminotransferase level, intubated during ICU stay, restraint use during ICU stay	<u>Benzodiazepine or opioid use:</u> Rate Ratio: 1.64 (95% CI: 1.27-2.10) <u>Dementia:</u> Rate Ratio: 1.19 (95% CI: 1.07-1.33) <u>Haloperidol:</u> Rate Ratio: 1.35 (95% CI: 1.21-1.50) <u>APACHE II score:</u> Rate Ratio:1.01 (95% CI: 1.00-1.02) Other models showed: Benzodiazepines or opioids are a significant risk for delirium when dementia is absent, but not when it is present. Haloperidol is a significant risk for delirium when dementia is absent, but not when it is present.	Medication use	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Rudolph et al. 2009 ¹⁹ USA	Prospective cohort study 122 patients (derivation set), 109 patients (validation set)	Patients aged ≥60 years who underwent cardiac surgery under general anesthesia; patients with delirium prior to surgery were excluded.	Two academic medical centers and a VA hospital	CAM	Multivariate modeling with bootstrap resampling was used to develop a prediction rule.	Mini mental state examination (MMSE) ≤23, prior stroke/TIA, abnormal albumin, and geriatric depression scale >4 were included in the prediction rule. Both cohorts showed increasing risk of delirium with increasing risk score (C-statistic = 0.74).	Depression, cognitive impairment, abnormal albumin	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Smith et al. 2009 ²⁰ USA	Retrospective cohort study 998 patients	Adults aged ≥18 years undergoing non-cardiac surgery, with a minimum of 2 days inpatient stay. Patients with history of dementia or MMSE score ≤23 were excluded.	Academic hospital	Retrospective chart review and/or CAM	General linear modeling and logistic regression with all covariates entered simultaneously. Factors adjusted for include age, years of education, Charlson comorbidity scale, alcohol consumption (drinks per week), pain, and depressive symptoms	After adjustment for <u>covariates, older age:</u> OR: 1.85 (95% CI: 1.11-3.09) P = 0.019 <u>greater medical comorbidities:</u> OR: 1.38 (95% CI: 1.02-1.86) P = 0.036) <u>higher levels of depressive symptoms:</u> OR: 1.37 (95% CI: 1.00-1.88) P = 0.049 and <u>poorer executive function:</u> OR: 1.23 (95% CI: 1.06-1.43) P = 0.007 continued to predict postoperative delirium. <u>In a post-hoc multivariate analysis, Stroop task was the only index of executive function that predicted postoperative delirium:</u> OR: 1.56 (95% CI: 1.14-2.14) P = 0.006	Depressive symptoms are modifiable with treatment	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Van Rompaey et al. 2009 ²¹ Belgium	Prospective cohort study 523 patients	Patients aged ≥18 years were in the ICU for at least 24 hours.	One academic hospital, one private hospital, and two community hospitals	Neelon and Champagne Confusion Scale	Univariate logistic regression followed by multivariate forward conditional regression analysis; factors adjusted for include daily alcohol use, cognitive impairment, admission for internal medicine, psychoactive medication, endotracheal tube or tracheostomy, more than 3 perfusions, isolation, no visible daylight, and no visit	<u>Daily use of more than 3 units of alcohol:</u> OR: 3.23 (95% CI: 1.30-7.98) <u>predisposing cognitive impairment:</u> OR: 2.41 (95% CI: 1.21-4.79) <u>admission for internal medicine:</u> OR: 4.01 (95% CI: 1.46-11.01) <u>psychoactive medication:</u> OR: 3.34 95% CI: 1.50-11.23 <u>endotracheal tube or tracheostomy:</u> OR: 8.07 (95% CI: 1.18-55.06) <u>more than 3 perfusions:</u> OR: 2.74 (95% CI: 1.07-7.05) <u>isolation:</u> OR: 2.89 (95% CI: 1.00-8.36) <u>no visible daylight:</u> OR: 2.39 (95% CI: 1.28-4.45) <u>and no visit:</u> OR: 3.73 (95% CI: 1.75-7.93)	Alcohol intake, psychoactive medication dose, isolation, daylight, allowing visitors	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Vidan et al. 2009 ²² Spain	Controlled clinical trial 542 patients	Patients aged ≥70 years admitted to the geriatric acute care unit and two internal medicine wards. Patients had to be free of delirium yet have risk factors for delirium at time of admission.	Academic hospital	CAM	Logistic regression with adjustment for confounders; these included age (per decade), dementia, baseline ADL independence, in-hospital stay (per day), intervention group	<u>Dementia:</u> OR: 2.14 (95% CI: 1.15-3.99) P = 0.02 <u>Baseline ADL independence:</u> OR: 0.78 (95% CI: 0.69-0.89) P = 0.001 <u>In-hospital stay (per day):</u> OR: 1.02 (95% CI: 1.00-1.05) P = 0.05 <u>Intervention group:</u> OR: 0.43 (95% CI: 0.24-0.77) P = 0.005	Intervention	Moderate
Voyer et al. 2009 ²³ Canada	Cross- sectional study 155 patients	Patients aged ≥65 years with a prior diagnosis of dementia	Three long- term care (LTC) facilities and one LTC unit of a large regional hospital	CAM	Bivariate analyses then multivariate regression; factors adjusted for include age, severity of dementia, and risk factor scores	<u>Severity of dementia:</u> OR: 1.04 (95% CI: 1.02-1.06) <u>risk factor scores:</u> OR: 1.67 (95% CI: 1.11-2.51) Risk factor scores based on number of predisposing factors for each patient.	Dehydration, fever, number of medications, depression were modifiable factors associated with higher risk scores	Moderate
Koster et al. 2008 ²⁴ The Netherlands	Prospective cohort study 112 patients	Patients aged ≥45 years who underwent elective cardiac surgery (with or without CPB). Patients with preop delirium were excluded.	Hospital	DSM-IV criteria	Univariate and multivariate analysis; factors adjusted for include age, type of operation, anxiety score, disturbed sodium/potassium, diabetes mellitus, use of CPB, and EuroSCORE	<u>EuroSCORE:</u> OR: 1.12 (95% CI: 1.05-1.19) P = 0.001 <u>Electrolytes disturbance:</u> OR: 3.29 (95% CI: 1.16-9.34) P = 0.025	Electrolytes disturbance	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Lin et al. 2008 ²⁵ Taiwan	Prospective cohort study 151 patients	Mechanically- ventilated adult patients admitted to ICU; delirium assessed for first 5 days; history of dementia was an exclusion criterion	Academic medical center	CAM-ICU	Univariate analyses, then multivariate stepwise regression using selected variables (P<0.1); factors adjusted for include diabetes mellitus, sepsis, and hypoalbuminemia	Sepsis: OR: 3.65 (95% CI: 1.03-12.90) Hypoalbuminemia: OR: 5.94 (95% CI: 1.23-28.77) Note: Medications were not associated with delirium in univariate analyses.	None	Moderate
Oh et al. 2008 ²⁶ Korea	Retrospective cohort study 224	All patients aged ≥70 years who had undergone neurosurgery during a 2-year period	Academic medical center	MMSE and CAM	Univariate analyses followed by multivariate regression of significant factors; factors adjusted for include prior dementia/ delirium, abnormal preop serum glucose, diabetes, local or regional anesthesia, duration of surgery, recovery room stay, VAS score (>6.8), and analgesics usage	Multivariate model risk factors: <u>Previous dementia/delirium:</u> OR: 630.4 (95% CI: 289.2-852.4) P<0.0001 <u>Pre-existent diabetes:</u> OR: 1.47 (95% CI: 1.17-2.45) P = 0.012 <u>Local or regional anesthesia:</u> OR: 2.21 (95% CI: 1.34-3.47) P<0.001 <u>VAS score (>6.8):</u> OR: 1.99 (95% CI: 1.45-4.16) P<0.001 <u>Analgesics usage:</u> OR: 1.38 (95% CI: 1.06-2.14) P = 0.038	Preop serum glucose, type of anesthesia, analgesics usage	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Redelmeier et al. 2008 ²⁷ Canada	Retrospective cohort study 284,158 patients	All patients aged ≥65 years who underwent elective surgery	Database representing all Ontario hospitals	ICD codes used to identify cases	Multivariable logistic regression; factors adjusted for include age, sex, neuropsychiatric drug, type of surgery, duration of surgery	<u>Age (per year increase):</u> OR: 1.09 (95% CI: 1.09-1.10) <u>Sex (male vs. female):</u> OR: 1.71 (95% CI: 1.59-1.86) <u>Cholinesterase inhibitor:</u> OR: 3.99 (95% CI: 2.26-7.05) <u>Antipsychotic:</u> OR: 1.57 (95% CI: 1.26-1.95) <u>Antidepressant:</u> OR: 2.01 (95% CI: 1.75-2.25) <u>Benzodiazepine:</u> OR: 1.40 (95% CI: 1.28-1.53) <u>Thoracic surgery:</u> OR: 1.54 (95% CI: 1.29-1.84) <u>Neurosurgery:</u> OR: 1.22 (95% CI: 1.00-1.49) <u>Vascular surgery:</u> OR: 1.20 (95% CI: 1.06-1.36) <u>Musculoskeletal surgery:</u> OR: 1.19 (95% CI: 1.08-1.31) <u>Lower urologic and gynecologic:</u> OR: 0.55 (95% CI: 0.48-0.62) <u>Breast and skin surgery:</u> OR: 0.46 (95% CI: 0.36-0.59) <u>External head and neck surgery:</u> OR: 0.39	Neuropsychiatric drug use	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
						(95% CI: 0.30-0.50) <u>Ophthalmologic surgery:</u> OR: 0.08 (95% CI: 0.05-0.13) <u>Duration of surgery (per 30 min increase):</u> OR: 1.20 (95% CI: 1.19-1.21)		
Inouye et al. 2007 ²⁸ USA	Prospective cohort study 491 patients (development cohort) 469 patients (validation cohort)	Patients aged ≥70 years admitted to 6 general medicine units at an academic hospital	Academic medical center	CAM	Bivariable analyses then multivariate model; factors adjusted for include dementia, vision impairment, activities of daily living impairment, Charlson score, and restraint use during delirium	<u>Dementia:</u> OR: 2.3 (95% CI: 1.4-3.7) <u>vision impairment:</u> OR: 2.1 (95% CI: 1.3-3.2) <u>activities of daily living impairment:</u> OR: 1.7 (95% CI: 1.2-3.0) <u>Charlson score ≥4:</u> OR: 1.7 (95% CI: 1.1-2.6) <u>restraint use during delirium:</u> OR: 3.2 (95% CI: 1.9-5.2)	Restraint use, vision impairment, functional impairment	Moderate
Ely et al. 2007 ²⁹ USA	Prospective cohort study 53 patients	Patients aged ≥18 years admitted to the ICU for >24 hrs	Community teaching hospital (541 beds)	CAM-ICU (intensive care unit)	Ordinal logistic regression (dependent variable was delirium days); factors adjusted for include APOE4, age, APACHE II score, coma days, sepsis/ARDS/ pneumonia, and Lorazepam total dose	<u>APOE4:</u> OR: 7.32 (95% CI: 1.82-29.5) P = 0.005 <u>Coma days, quintiles:</u> OR: 1.32 (95% CI: 1.08-1.60) P = 0.006	None	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Leung et al. 2007 ³⁰ USA	Prospective cohort study 203 patients	Patients aged ≥65 years scheduled for major noncardiac surgery requiring anesthesia	Academic medical center	CAM	Univariate analysis then multivariate logistic regression with the most promising factors (APOE, age, history of CNS disorders, education, pain, ADLs, alcohol intake, cognitive status, GDS score)	Risk factors for delirium: <u>APOE (with e4 vs. without e4):</u> OR: 3.64 (95% CI: 1.51-8.77) <u>Age:</u> OR: 1.08 (95% CI: 1.00-1.16) <u>History of CNS disorders (yes vs. no):</u> OR: 3.42 (95% CI: 1.44-8.09)	None	High
Ouimet et al. 2007 ³¹ Canada	Prospective cohort study 203 patients	Patients age ≥18 years admitted for more than 24 hr to an ICU	Academic hospital	Intensive care delirium screening checklist (ICDSC)	Univariate then multivariate stepwise logistic regression on selected variables; factors adjusted for included age, hypertension, tobacco consumption, alcohol consumption, APACHE II score, epidural catheter use, opiate dose, benzodiazepine dose, propofol dose, indomethacin dose, coma, anxiety, and pain	<u>Hypertension:</u> OR: 1.88 (95% CI: 1.3-2.6) <u>Alcoholism:</u> OR: 2.03 (95% CI: 1.26-3.25) <u>APACHE II score:</u> OR: 1.05 (95% CI: 1.03-1.07) <u>Coma:</u> OR: 3.71 (95% CI: 2.32-5.9) <u>Anxiety:</u> OR: 1.8 (95% CI: 1.04-3.37)	These factors are difficult to modify in the short term in an ICU environment.	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Pisani et al. 2007 ³² USA	Prospective cohort study 304 patients	Patients ≥60 years old admitted to ICU for at least 24 hrs	Academic hospital (900 beds, with 14-bed ICU)	CAM-ICU	Univariate analysis then multivariate modeling; factors adjusted for include alcohol, Medicaid status, race, history of depression, medication use, dementia, APACHE II score, admitting diagnosis, admitting laboratory variables, and admitting physiologic variables	<u>Dementia by I/QCODE >3.3:</u> OR: 6.3 (95% CI: 2.9-13.8) <u>Benzodiazepines before ICU admission:</u> OR: 3.4 (95% CI: 1.6-7.0) <u>Creatinine >2 mg/dL:</u> OR: 2.1 (95% CI: 1.1-4.0) <u>Arterial pH <7.35:</u> OR: 2.1 (95% CI: 1.1-3.9)	Benzodiazepine use, creatinine level, and arterial pH are modifiable	Moderate
Rudolph et al. 2007 ³³ USA	Prospective cohort study 1,218 patients	Patients aged ≥60 years undergoing noncardiac surgery. Patients with dementia were excluded.	13 hospitals in 8 countries (Denmark, France, Germany, the UK, Greece, the Netherlands, Spain, and the USA)	DSM-III criteria	Bivariate analyses, then stepwise backward and forward proportional hazard regression models using the most promising variables; factors adjusted for included age, gender (male), cognitive performance, tobacco exposure, diabetes, prior myocardial infarction (MI), and vascular surgery	<u>Vascular risk factors (tobacco exposure and vascular surgery):</u> Rate Ratio: 3.2 (95% CI: 2.1-4.9) <u>Mildly impaired cognitive performance:</u> Rate Ratio: 2.2 (95% CI: 1.4-2.7) <u>Age (per year):</u> Rate Ratio: 1.1 (95% CI: 1.0-1.1)	Cognitive deficit might be treatable prior to surgery	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Veliz-Reissmuller et al. 2007 ³⁴ Sweden	Prospective cohort study 107 patients	Patients aged ≥60 years scheduled for CABG, valve surgery or combined procedures; none had dementia	Academic hospital	CAM	Univariate analysis then logistic regression of significant variables; factors adjusted for include age, alcohol consumption, memory complaints, CABG-valve vs. CABG, valve vs. CABG, MMSE score	<u>Memory complaints:</u> OR: 3.37 (95% CI: 1.0-11.5) <u>Valve vs. CABG:</u> OR: 3.90 (95% CI: 1.0-15.8) <u>MMSE score (≤28 preop):</u> OR: 11.3 (95% CI: 2.7-47.7)	Cognitive deficit may be treatable prior to surgery	High
Beaussier et al. 2006 ³⁵ France	Double-blind RCT 59 patients	Patients aged >70 years undergoing surgical resection of cancer of the left colon or rectum; patients with preoperative mental dysfunction were excluded.	Academic hospital	CAM	Comparison of randomized group outcomes, no adjustment for other factors. General anesthesia for colon resection; pre-op intrathecal morphine (0.3 mg) + postop patient-controlled (PCA) intravenous morphine vs. PCA alone	No significant difference in delirium incidence was found between the two groups.	None, since neither intervention showed a difference	Moderate
Furlaneto and Garcez-Leme 2006 ³⁶ Brazil	Prospective cohort study 103 patients	Patients aged ≥65 years admitted to the geriatric orthopedic ward for hip fracture (almost all underwent surgery)	Academic medical center	CAM	Univariate regression prior to logistic regression modeling; factors adjusted for include mental assessment factors (MMSE, clock drawing, blessed), ADL and length of hospital stay	<u>Cognitive deficit:</u> OR: 3.04 (95% CI: 1.24-7.41)	Cognitive deficit may be treatable	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Goldenberg et al. 2006 ³⁷ USA	Prospective cohort study 77 patients	Patients aged >65 years admitted for hip surgery; patients with existing delirium were excluded	Community teaching hospital	CAM	Univariate logistic analysis identified 12 factors as predictors; these were included in a multivariate logistic regression analysis (age, morbidity index, Hct, Alb, MMSE score, set test score, ADL score, dementia, skilled nursing facility (SNF) residence, multiple medications, CNS medications and abnormal laboratory values)	Risk factors for delirium: <u>Multiple medications:</u> OR: 33.6 (95% CI: 1.9-591.6) <u>Set test score <20:</u> OR: 13.1 (95% CI: 2.1-82.7) <u>MMSE score <24:</u> OR: 6.9 (95% CI: 1.2-39.5) <u>Albumin <3.5 g/dl:</u> OR: 6.1 (95% CI: 1.2-39.5)	Multiple medications and cognitive impairment, but there may not be time before surgery to modify these factors	Moderate
Kazmierski et al. 2006 ³⁸ Poland	Prospective cohort study 260 patients	All patients received cardiac surgery; patients with preop delirium or dementia were excluded	Academic hospital	DSM-IV criteria	Univariate analyses, then significant variables added to multivariate regression model (backward stepwise procedure); factors adjusted for include MMSE score, AF, peripheral vascular disease, major depression, cerebrovascular disease, and age	Risk factors for delirium: <u>MMSE ≤24:</u> OR: 10.2 (95% CI: 3.7-28.6) <u>AF:</u> OR: 7.2 (95% CI: 2.3-22.7) <u>Peripheral vascular disease:</u> OR: 6.4 (95% CI: 1.9-21.6) <u>Major depression:</u> OR: 6.3 (95% CI: 1.4-29.7) <u>Age ≥65 years:</u> OR: 4.0 (95% CI: 1.5-10.4)	Depression, cognitive impairment, AF can be treated prior to surgery	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Leung et al. 2006 ³⁹ USA	Blind RCT 228 patients	Patients aged ≥65 years undergoing non-cardiac surgery requiring general anesthesia, expected to remain in the hospital ≥48 hr	Academic hospital	CAM	Bivariate analyses then multivariate logistic regression analysis with variables associated with delirium (P≥0.20); factors adjusted for include age, anesthetic type (N2O vs. oxygen), dependence on performing ≥1 IADL, Postop analgesia (PCA vs. oral opioids), benzodiazepine use on POD 1 or POD 2	<u>Age:</u> OR: 1.07 (95% CI: 1.02-1.26) <u>Dependence on performing ≥1 IADL:</u> OR: 1.54 (95% CI: 1.01-2.35) <u>Postop analgesia (PCA vs. oral opioids):</u> OR: 3.75 (95% CI: 1.27-11.01) <u>Benzodiazepine use on POD 1 or POD 2:</u> OR: 2.29 (95% CI: 1.21-4.36)	Postop analgesia, benzodiazepine use	Moderate
Pandharipande et al. 2006 ⁴⁰ USA	Prospective cohort study 198 patients	All adult mechanically- ventilated patients admitted to ICU; patients with preop neurological diseases that would confound delirium diagnosis were excluded.	Academic medical center	CAM-ICU and Richmond Agitation Sedation Scale (RASS)	Multivariable analysis of sedative and analgesic medications as risk factors for delirium in a Markov model; factors adjusted for include age, gender, visual and hearing deficits, dementia, depression, severity of illness, sepsis, neurologic disease, hematocrit, daily serum glucose level, lorazepam, midazolam, fentanyl, morphine, and propofol	Risk factors for delirium: <u>Lorazepam:</u> OR: 1.2 (95% CI: 1.1-1.4) P = 0.003 No other sedative or analgesic showed a statistically significant risk for delirium.	Use of lorazepam (alternative medications can be substituted)	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Ranhoff et al. 2006 ⁴¹ Italy	Prospective cohort study 401 patients	Patients ≥60 years of age admitted to a sub-intensive care unit for elderly patients (SICU)	General hospital	CAM	Bivariate analysis then multiple logistic regression of variables with p<0.05 in bivariate analysis; factors adjusted for include heavy alcohol use, fitted bladder catheter, number of drugs, visual problems, Acute Physiology Score (APS), Age, S-albumin, dementia	<u>Heavy alcohol use:</u> OR: 6.1 (95% CI: 1.8-19.6) <u>Fitted bladder catheter:</u> OR: 2.7 (95% CI: 1.4-4.9) <u>Max no. of drugs (7+):</u> OR: 1.9 (95% CI: 1.1-3.2) <u>Disabled:</u> OR: 2.5 (95% CI: 1.3-4.7) <u>Probably demented:</u> OR: 11.5 (95% CI: 6.1-20.1)	Use of bladder catheters and no. of drugs	Moderate
Sheng et al. 2006 ⁴² Australia	Prospective cohort study 156 patients	Stroke patients aged ≥65 years recruited over 1 year	Academic teaching hospital (450 beds)	DSM-IV criteria	Binary logistic regression then multiple logistic regression analyses using significant variables; factors adjusted for include age, dementia prestroke, hemorrhagic stroke, metabolic factor, able to lift both arms, Glasgow coma scale score <15, neglect, dysphasia, vision field loss, urinary tract infection, urinary incontinence, fecal incontinence, systolic blood pressure, diastolic blood pressure, and one or more metabolic factors	<u>Age:</u> OR: 1.1 (95% CI: 1.0-1.2) <u>Dementia prestroke:</u> OR: 5.7 (95% CI: 1.3-24.9) <u>Hemorrhagic stroke:</u> OR: 3.7 (95% CI: 1.2-11.6) <u>Metabolic factor:</u> OR: 6.1 (95% CI: 1.9-20.2) <u>Able to lift both arms:</u> OR: 0.3 (95% CI: 0.1-0.9) <u>Glasgow coma scale score:</u> OR: 10 (95% CI: 3.7-26.7)	None	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Korevaar et al. 2005 ⁴³ The Netherlands	Prospective cohort study 126 patients	All patients >65 years and acutely admitted	Academic medical center	CAM	Univariate and multivariate logistic regression analysis; factors adjusted for include cognitive impairment, Katz ADL, Urea, and leucocytes	Risk factors for delirium: <u>Cognitive impairment:</u> adjusted hazard ratio: 9.48 (95% CI: 2.27-39.54) <u>Katz ADL 5-6:</u> 8.14 (95% CI: 1.08-61.31) <u>Katz ADL ≥7:</u> 14.13 (95% CI: 2.26-88.24) <u>Urea:</u> 1.10 (95% CI: 1.02-1.18) <u>Leucocytes(10⁹/L):</u> 0.87 (95% CI: 0.79-0.97)	Cognitive impairment	Moderate
Shulman et al. 2005 ⁴⁴ Canada	Retrospective cohort study 10,230 patients	All patients >65 years who were newly dispensed 1 of 3 drugs: lithium, valproate, or benztropine	4 administra- tive databases covering all hospitals in Ontario	Not reported	Cox proportional hazards regression, adjusted for lithium, valproate, benztropine, age, sex, comorbidity, visual impairment, and hearing impairment	<u>Benztropine (vs. lithium):</u> hazard ratio: 1.88 (95% CI: 1.35-2.62)	Benztropine use	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Yildizeli et al. 2005 ⁴⁵ Turkey	Retrospective cohort study 432 patients	Patients aged ≥18 years admitted for major elective or urgent thoracic surgery	Academic hospital	DSM-IV criteria	Univariate analyses, then multivariate stepwise logistic regression; factors adjusted for include age, gender, chronic disease, alcohol abuse, psychiatric problems, diabetes, cerebrovascular disease, chemotherapy usage, operation due to malignancy, urgent operation, respiratory insufficiency, markedly abnormal serum chemistry values, operation time, length of hospital stays, length of intensive care unit stays, sleep deprivation, hypertension, infection, blood transfusion, use of various drugs, immobilization	<u>Markedly abnormal serum chemistry values:</u> OR: 3.01 p = 0.038 <u>Sleep deprivation:</u> OR: 5.64 p = 0.05 <u>Age:</u> OR: 1.04 p = 0.03 <u>Operation time:</u> OR: 1.29 p = 0.04	Sleep deprivation, abnormal serum chemistry	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Bucerius et al. 2004 ⁴⁶ Germany	Retrospective cohort study 16,184 patients	All patients receiving cardiac surgery	Academic hospital	Physician diagnosis based on American Psychiatric Association (APA) guidelines	Univariate analyses, then significant variables added to multivariate regression model (backward stepwise procedure); factors adjusted for include age, beating-heart surgery, atrial fibrillation, cerebrovascular disease, diabetes, peripheral vascular disease, LVEF, preop cardiogenic shock, urgent operation, operating time, intraop hemofiltration, and RBC transfusion	Risk factors for delirium: <u>Cerebrovascular disease:</u> OR: 2.15 (95% CI: 1.69-2.72) <u>Atrial fibrillation:</u> OR: 1.36 (95% CI: 1.14-1.62) <u>Diabetes:</u> OR: 1.31 (95% CI: 1.16-1.49) <u>Peripheral vascular disease:</u> OR: 1.34 (95% CI: 1.17-1.53) <u>LVEF ≤30%:</u> 1.30 (95% CI: 1.09-1.49) <u>Preop cardiogenic shock:</u> OR: 1.23 (95% CI: 1.05-1.45) <u>Urgent operation:</u> OR: 1.17 (95% CI: 1.02-1.34) <u>Operating time ≥3 hr:</u> OR: 1.26 (95% CI: 1.01-1.45) <u>Intraop hemofiltration:</u> OR: 1.26 (95% CI: 1.06-1.49) <u>RBC transfusion ≥2000 ml:</u> OR: 3.15 (95% CI: 2.71-3.65) Lower risk of delirium: <u>Beating-heart surgery:</u> OR: 0.47 (95% CI: 0.32-0.69) YOUNGER AGE: Age <50 years:	Type of surgery (if patient is candidate for beating-heart surgery); AF can be treated prior to surgery	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
						OR: 0.22 (95% CI: 0.15-0.31) <u>Age ≥50 and <60 years:</u> OR: 0.34 (95% CI: 0.27-0.43) <u>Age ≥60 and <70 years:</u> OR: 0.6 (95% CI: 0.52-0.68)		
Caeiro et al. 2004 ⁴⁷ Portugal	Prospective cohort study 218 patients	Consecutive acute stroke patients admitted to stroke unit	Academic hospital with 12-bed stroke unit	Delirium Rating Scale (DRS) score ≥10 and fulfilled DSM-IV-TR criteria	Univariate and multivariate analysis with stepwise logistic regression	Non-neuroleptics anticholinergics (ACH) during hospitalization, medical complications, ACH taken before stroke, and intracerebral hemorrhage (ICH) all remained in the final regression model.	Use of ACH medications	High
Santos et al. 2004 ⁴⁸ Brazil	Prospective cohort study 220 patients	Patients aged ≥60 years admitted for nonemergency CABG; patients with severe cognitive deficits were excluded.	Academic tertiary referral hospital	DSM-IV criteria	3 multivariate analyses: (1) preop variables; (2) preop and intraop variables; (3) preop, intraop, and postop variables); factors adjusted for include age, blood urea, cardiothoracic index, hypertension, smoking, blood replacement, AF, pneumonia, blood balance 2 nd postop day	<u>Age:</u> OR: 1.1 (95% CI: 1.01-1.19) <u>Blood urea:</u> OR: 1.03 (95% CI: 1.01-1.05) <u>Cardiothoracic index:</u> OR: 3.38 (95% CI: 1.39-8.25) <u>Hypertension:</u> OR: 3.55 (95% CI: 1.25-10.14) <u>Smoking:</u> OR: 4.19 (95% CI: 1.35-13.05) <u>AF:</u> OR: 2.62 (95% CI: 1.05-6.58) <u>U:</u> OR: 6.36 (95% CI: 1.24-32.71)	Blood urea, hypertension and AF are potentially modifiable prior to nonemergency surgery	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Bohner et al. 2003 ⁴⁹ Germany	Prospective cohort study 153 patients	Patients undergoing elective arterial surgery with an expected time of ≥90 minutes	Academic hospital	DSM-IV criteria plus DRS score ≥12 points	Univariate then stepwise multivariate analysis, which adjusted for age, depression, major amputation, supraortic occlusive disease, body length, cognitive impairment (MMSE), colloid infusion, minimal potassium level, hypercholesterinemia	Risk factors for delirium: <u>No history of supraortic occlusive disease:</u> OR: 6.73 P = 0.001 <u>History of major amputation:</u> OR: 24.4 P = 0.001 <u>No history of hypercholesterinemia:</u> OR: 5.51 P = 0.001 <u>Age >64 years:</u> OR: 3.03 P = 0.018 <u>Body length <170 cm:</u> OR: 3.95 P = 0.004 <u>MMSE <25 points:</u> OR: 28.0 P = 0.001 <u>Intraop colloid infusion >800 ml:</u> OR: 2.62 P = 0.035 <u>Intraop minimal potassium <3.4 mmol/L:</u> OR: 3.18 P = 0.021	Intraop colloid infusion, intraop minimal potassium; cognitive impairment can be treated prior to surgery	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Centorrino et al. 2003 ⁵⁰ USA	Retrospective cohort study 139 patients	Consecutive adult hospitalized patients given clozapine	Academic hospital	Investigator consensus based on signs and symptoms in medical chart, and rated by consensus on a 3-point severity scale (mild, moderate, severe)	Bivariate analysis followed by multivariate logistic regression of factors with associations with delirium ($p \leq 0.10$); factors adjusted for include anticholinergic meds, clinical responder, age, hospitalized ≥ 20 days, antipsychotic meds, CNS agent, anticonvulsants, any mood stabilizer, clozapine dose >250 mg/day, tricyclic antidepressants, benzodiazepines, serotonin reuptake inhibitors, women, lithium, any antidepressant	<u>Any centrally active anticholinergic:</u> X ² = 9.69 p = 0.002 <u>Age ≥ 39 years:</u> X ² = 5.69 p = 0.017	Anticholinergic exposure	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Morrison et al. 2003 ⁵¹ USA	Prospective cohort study 541 patients	Patients admitted for hip fracture without evidence of delirium	4 metropolitan hospitals	CAM	Univariate analyses then multivariate logistic regression; factors adjusted for included age, gender, residence, cognitive impairment, FIM score, RAND score, abnormal BP, abnormal heart rhythm, chest pain, heart failure, medical complication, morphine, meperidine	Risk factors for delirium: <u>Cognitive impairment:</u> OR: 3.6 (95% CI: 1.8-7.2) <u>Abnormal BP:</u> OR: 2.3 (95% CI: 1.2-4.7) <u>Heart failure:</u> OR: 2.9 (95% CI: 1.6-5.3) <u>Parenteral morphine sulfate equivalents/d <10 mg:</u> OR: 5.4 (95% CI: 2.4-12.3) <u>Received meperidine:</u> OR: 2.4 (95% CI: 1.3-4.5)	Morphine dose, meperidine use; cognitive impairment can be treated prior to surgery	Moderate
Zakriya et al. 2002 ⁵² USA	Prospective cohort study 168 patients	Patients admitted for hip fracture service (age 50-98); patients with pre- existing delirium or dementia were excluded.	Academic hospital	CAM	Univariate analyses then multiple logistic regression of variables with P≤0.1 from univariate; factors adjusted for include normal white blood cell count, abnormal serum sodium, ASA class, history of congestive heart failure, history of AF, history of peripheral vascular disease	<u>Normal white blood cell count:</u> OR: 2.2 (95% CI: 1.2-4.1) <u>Abnormal serum sodium:</u> OR: 2.4 (95% CI: 1.1-5.3) <u>ASA class >II:</u> OR: 11.3 (95% CI: 2.6-49.2)	Abnormal serum sodium and white blood cell count	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Agostini et al. 2001 ⁵³ USA	Prospective cohort study 426 patients	Patients aged ≥70 years with no baseline delirium admitted to general medical service (non-ICU); profound dementia precluding verbal communication was an exclusion criterion.	Academic hospital (900 beds)	CAM	Logistic regression model adjusted for baseline delirium risk, gender, and age	<u>Diphenhydramine:</u> OR: 2.3 (95% CI: 1.4-3.6)	Diphenhydramine	Moderate
Andersson et al. 2001 ⁵⁴ Sweden	Prospective cohort study 457 patients	Patients aged ≥65 years referred for orthopedic surgery (hip fracture or elective coxarthros or gonarthros surgery)	Hospital	Modified Organic Brain Syndrome (OBS) Score; also considered DSM-IV criteria	Multiple regression, stepwise model; factors adjusted for included gender, age, vision, hearing, reason for hospital admission, number of other diseases, postop complications, bladder catheter, preop medical treatment, anesthesia time and method, loss of blood during surgery, time from admission to surgery, surgery time, time of admission, marital status, cohabitation, type of housing	Risk of developing delirium: <u>Four or more physical diseases:</u> Exp (B): 15.94 (95% CI: 4.60-55.31) <u>Reason for admission:</u> Exp (B): 4.74 (95% CI: 1.76-12.80) <u>Impaired vision:</u> Exp (B): 4.52 (95% CI: 2.27-8.98) <u>Preop medical treatment:</u> Exp (B): 2.66 (95% CI: 1.26-5.62) <u>Anesthesia time:</u> Exp (B): 1.82 (95% CI: 1.31-2.53) <u>OBS-score on admission:</u> Exp (B): 1.28 (95% CI: 1.06-1.54) <u>Age:</u> Exp (B): 1.10 (95% CI: 1.04-1.15)	Impaired vision, anesthesia time, possibly preop medical treatment; cognitive impairment can be treated prior to surgery	Moderate

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
Dubois et al. 2001 ⁵⁵ Canada	Prospective cohort study 418 patients	Consecutive patients aged ≥18 years admitted for >24 hrs to the ICU	Academic hospital with 16-bed medical and surgical ICU	Intensive care delirium screening checklist	Univariate analyses then multivariate analysis using the 5 best factors (morphine, use of epidural, smoking history, bilirubin level, hypertension) Univariate non- significant factors: COPD, alcohol abuse, sodium level, glucose level, lorazepam, rooms without windows, rooms with windows	Risk of developing delirium: <u>Hypertension:</u> OR: 2.6 (95% CI: 1.14-5.72) <u>Bilirubin level (% days abnormal):</u> OR: 1.2 (95% CI: 1.03-1.40) <u>Use of Epidural:</u> OR: 3.5 (95% CI: 1.20-10.39) <u>Morphine (mean daily dose):</u> 0.01-7.1 mg: OR: 7.8 (1.76-34.4) 7.2-18.6 mg: OR: 9.2 (2.17-39.0) 18.7-331.6 mg: OR: 6.0 (1.41-25.4)	Hypertension, bilirubin level, use of epidural, morphine dose	High

Author/Year/ Country	Study Design	Patient Population	Description of Organization	Diagnosis of Delirium	Type of Analysis and factors adjusted for	Risk Factors	Modifiable risk factors	Overall risk of bias
McCusker et al. 2001 ⁵⁶ Canada	Retrospective cohort study 444 patients (326 with delirium, 118 without)	Patients ≥65 years admitted from ED to medical services; 59.5% had dementia.	Primary acute care general hospital	CAM	Multivariable analyses of variance; factors adjusted for include age, delirium index score, comorbidity, length of follow-up, dementia, study group, prevalent delirium, visual or hearing impairment, number of room changes, hospital unit, in isolation, stimulation level, not in the same room, in a single room, physical restraint, medical restraint, surroundings not well-lit, surroundings noisy/quiet, radio/TV on, clock/watch absent, calendar absent, no personal possessions, not wearing glasses, not using hearing aids, family absent	Final model for prediction of delirium severity: <u>Delirium index score:</u> Beta: 0.54 ±0.03, (P<0.01) <u>Dementia:</u> Beta: 1.09 ±0.28, (P<0.01) <u>Number of room changes:</u> Beta: 0.40 ±0.16, (P = 0.01) <u>ICU vs. medical:</u> Beta: 4.62 ±0.60, (P<0.01) <u>Physical restraint:</u> Beta: 1.21 ±0.17, (P<0.01) <u>Medical restraint:</u> Beta: 0.42 ±0.19, (P = 0.02) <u>Not wearing glasses:</u> Beta: 0.81 ±0.19 (P<0.01)	Room changes, physical and medical restraint, glasses	Moderate
Christe et al. 2000 ⁵⁷ Switzerland	Double-blind RCT 65 patients	Consecutive geriatric inpatients requiring upper gastrointestinal endoscopy	Academic geriatric hospital (304 beds)	MMSE decrease of 3 points or more	Univariate analyses then multivariate stepwise forward and backward logistic regressions; factors adjusted for were not stated	<u>Basal MMSE <21:</u> OR: 6.4 (95% CI: 1.1-37.3)	None	High

Table 2, Chapter 20. Delirium prevention—multi-component interventions

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Inpatient hospital care									
Allen et al. 2011 ⁵⁸ USA	System-wide quality improvement (QI) project to prevent delirium in hospitalized patients	Prospective controlled before-after (CBA) study 199 patients	Not reported	<p><u>External:</u> None mentioned</p> <p><u>Organizational Characteristics:</u> 6 community hospitals (part of Summa Health System), over 2,000 licensed beds. Acute Care for Elders (ACE) unit had prior experience using delirium prevention guidelines.</p> <p><u>Teamwork:</u> Multidisciplinary delirium workgroup with physicians and ACE nurses, director of hospital quality. Nurse quality management and leadership, clinical informatics nurses, geriatric pharmacy, and geriatric medicine fellows.</p> <p><u>Leadership:</u> 3 of the authors led the pilot in the ACE unit.</p> <p><u>Culture:</u> Statement that Summa Health System “maintains a strong commitment to patient safety and quality”</p> <p><u>Implementation tools:</u></p>	First obtained stakeholder agreement, then multidisciplinary workgroup devised strategy and carried out the pilot project. It involved education of ACE unit staff on delirium screening, prevention and treatment protocols that were then implemented.	Delirium incidence decreased from 8.8% in pre-implementation group to 7.2% in implementation group (not statistically significant). Mean length of stay decreased from 7.6 days to 4 days (difference 3.6 days, 95% CI: 0.66 to 6.49 days).	No harms reported for intervention. Deaths, ICI transfers, and 30-day readmissions all decreased in intervention group.	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
				Staff education and training, use of audit and feedback					
Black et al. 2011 ⁵⁹ Northern Ireland	Nurse-facilitated family participation	Prospective CBA study 170 patients aged ≥18 years admitted to a general intensive care unit (ICU)	Neuman's system model for nursing interventions	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Inner city public hospital with 7-bedded general ICU <u>Teamwork:</u> Researchers, nurses, and family members work together. <u>Leadership:</u> Researchers (Director of School of Nursing and Emeritus Professor of Nursing) <u>Culture:</u> Not reported <u>Implementation tools:</u> Researcher or nurse provides family members with an information booklet describing how to prevent delirium; they also provide verbal and printed introduction to the study and booklet.	Nurses gave family members the information booklet at admission to the unit; researcher provided explanation of the study and booklet on Day 1; from Day 2 to transfer to ward, nurses facilitated family access to patient, and families implemented the booklet's advice.	Incident delirium: <u>Intervention:</u> 25/87 (29%) <u>Control:</u> 64/83 (77%) OR = 0.12 (95% CI: 0.06-0.24) P<0.0001 Authors also state "there were no significant differences in mean scores between groups."	Not reported	Not reported	High
Chen et al. 2011 ⁶⁰ Taiwan	Modified Hospital Elder Life Program (HELP); modified to include 3 shared risk	CBA study (historical control) 189 patients aged ≥65 years admitted to a	Prior evidence suggests the HELP model can prevent and reduce older patients' post-surgical	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Urban medical hospital (2,200 beds, 36-bed	The trained HELP nurse helped (sometimes with family members) mobilize patients and simultaneously engaged them in	Delirium at discharge: <u>HELP:</u> 0/102 (0%) <u>Control:</u> 12/77 (15.6%) OR = 0.03	Not reported	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	factors (functional, nutritional, and cognitive status) targeted by 3 modified HELP protocols (early mobilization, nutritional assistance, and therapeutic cognitive activities)	gastro-intestinal ward for elective surgery, with expected length of stay >6 days	functional decline. The authors' earlier work suggests that 3 key elements are the most relevant for surgical patients and those were used in this study.	gastrointestinal ward) <u>Leadership:</u> Researchers designed program and led the study <u>Teamwork:</u> Not reported <u>Culture:</u> Not reported <u>Implementation tools:</u> A full-time trained HELP nurse, blinded to the study hypothesis and not an outcomes assessor, implemented the program.	cognitive activities (such as discussing things that interested the patient); the nurse also provided nutritional assistance (oral care, assisted feeding if necessary).	(95% CI: 0.001-0.44) P<0.001			
Rubin et al. 2011 ⁶¹ USA	Hospital Elder Life Program (HELP)	CBA study (historical control) Thousands of patients (aged ≥70 years) from 2002 to 2008	HELP provides skilled interdisciplinary staff and trained volunteers to conduct intervention protocols targeted toward 6 delirium risk factors: orientation, therapeutic activities, early mobilization, vision and hearing protocols, oral volume repletion, and sleep enhancement; it has been	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Community teaching hospital (500 beds) <u>Leadership:</u> The project director was primarily responsible for implementation <u>Teamwork:</u> Interdisciplinary staff and trained volunteers <u>Culture:</u> Not reported <u>Implementation tools:</u> Volunteers were trained by staff; some received additional training by speech therapists and	HELP was first implemented in one 40-bed medical unit in 2002; by 2008 it had spread to 6 units with a total of 184 beds; The project director initially worked with hospital leadership to determine metrics for measuring success; initial success in the proposed metrics was demonstrated, so the hospital agreed to continue funding and allowed expansion to additional units; before starting in a new unit, the project	Delirium rate: <u>Pre-HELP (2001):</u> 41% <u>HELP (2002):</u> 26% <u>HELP (2005):</u> 16% <u>HELP (2008):</u> 18% Nurse satisfaction: Nurses and nurses aides reported benefit and satisfaction with HELP and agreed with a questionnaire item that their job was "more satisfying due to HELP."	Not reported	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
			shown to be effective for delirium prevention.	physical therapists	director solicited input from each nursing unit director; the project director worked with the Chief Nursing Director to identify subsequent units to target; as patient volume increased, paid HELP staff and volunteers were added; one Elder Life Specialist became the lead volunteer coordinator; weekly meetings of staff were held to maintain quality and document modifications to the original HELP protocols				
Inouye et al. 2003 ⁶² , 1999 ⁶³ USA	HELP for prevention of delirium in elderly patients	Prospective matched CBA study 852 patients at least 70 years old admitted to general medicine floor (later study included 422 patients from the HELP arm of the study)	Delirium has been associated with several risk factors; the HELP targets 6 of these risk factors (cognitive impairment, sleep deprivation, immobility, visual impairment, hearing	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Urban teaching hospital (900 beds) <u>Teamwork:</u> Interdisciplinary team including a geriatric nurse-specialist, two Elder Life specialists, a certified therapeutic-recreation specialist, a physical therapy consultant, a geriatrician, and	With oversight by a geriatric nurse specialist and geriatrician, the Elder Life specialists implemented 6 interventions: orientation, therapeutic activities, mobility, sleep, hearing or vision, and volume repletion (for dehydration); they were assisted by trained volunteers;	In the earlier publication, incident delirium was significantly lower in the intervention group vs. the usual care group (9.9% vs. 15%, OR: 0.60 (95% CI: 0.39–0.92); P = 0.02	Not reported	High patient adherence to individual interventions significantly reduced incident delirium rates. Adherence (each 1 point increase): OR: 0.69 (95% CI: 0.56-0.87) P = 0.001	Moderate

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
			impairment, and dehydration)	trained volunteers. <u>Leadership:</u> Not reported <u>Culture:</u> Not reported <u>Implementation tools:</u> All staff and volunteers underwent quarterly standardization to ensure consistent application of all intervention protocols	all patients were assigned orientation, therapeutic activities, and mobility; other protocols were targeted to a subgroup of patients with the identified risk factor.				
Bjorkelund et al. 2010 ⁶⁴ Sweden	Multifactorial intervention including pre-hospital and perioperative treatment and care of patients with hip fracture. Components include supplemental oxygen 3-4l/min, IV fluid supplementation and extra nutrition, increased monitoring of vital physiological parameters, adequate pain relief, avoid delay in transfer logistics, daily	Prospective CBA study 263 patients aged ≥65 years with hip fracture	Authors cite prior multifactorial intervention studies; they added pre-hospital component because prior studies have identified preop risk factors for delirium	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic hospital, also pre-hospital ambulance care <u>Leadership:</u> Researchers were in charge <u>Teamwork:</u> Nurses and orthopedic surgeons were part of the team <u>Culture:</u> Not reported <u>Implementation tools:</u> Two of the authors were in charge of implementation	Patients underwent pre-hospital care, nurse assessment immediately after admission, orthopedic surgeon assessment 30 min before referral to X-ray department, then transfer to orthopedic ward, then surgery for hip fracture with general or spinal anesthesia. Delirium was assessed by researchers within 4 hrs of admission and 8 hr after the end of anesthesia.	Post-op delirium: <u>Intervention:</u> 28/131 (21.4%) <u>Control:</u> 44/132 (33.3%) OR = 0.54 (0.31-0.95) P = 0.03	Any complications: <u>Intervention:</u> 66/131 (50.4%) <u>Control:</u> 70/132 (53.0%) P = 0.67	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	delirium screening using Organic Brain Syndrome (OBS) scale, avoid poly-pharmacy, and perioperative/ anesthetic period protocol								
Needham et al. 2010 ⁶⁵ USA	Structured quality improvement (QI) model with components including: understanding the problem within the larger healthcare system, creating a multi-disciplinary improvement team, enlisting all stakeholders to identify barriers to change and appropriate solutions, and creating a change in practice through engagement, education, execution, and	CBA study (historical control) 57 patients with acute respiratory failure	The QI model was based on a “4 Es” model (engage, educate, execute, and evaluate). Previous studies have shown that early physical medicine and rehabilitation (PM&R) in the ICU provides benefits for critically ill patients, and the QI model applied this evidence to patients in the medical ICU (MICU).	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic hospital with 16-bed MICU <u>Leadership:</u> The lead author was the project leader. Researchers were in charge <u>Teamwork:</u> A multidisciplinary QI team with representatives from each relevant clinician group in the MICU and PM&R <u>Culture:</u> Not reported <u>Implementation tools:</u> Education and training of nurses, physical therapists, occupational therapists, and respiratory therapists to obtain specific skills related to rehab of mechanically	Standardized MICU admission modified to change default activity from “bed rest” to “as tolerated;” change in sedation practice from continuous intravenous infusions to “as needed” bolus doses; establishing guidelines for PT and OT consultation; developing safety-related guidelines for PM&R-related consultation; including a full-time PT and OT and a part-time rehab assistant; consulting a physiatrist; and increasing consultations to neurologists for MICU patients with severe or prolonged	Incident delirium: <u>QI period:</u> 125/482 (28%) MICU patient days <u>Pre-QI period:</u> 107/312 (36%) MICU patient days P = 0.003	Unexpected events: <u>QI period:</u> 4 cases of rectal or feeding tube removal, without any significant complications <u>Pre-QI period:</u> No unexpected events P>0.99	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	evaluation			ventilated patients.	muscle weakness.				
Vidan et al. 2009 ²² Spain	Education measures and specific actions in 7 risk areas (orientation, sensory impairment, sleep, mobilization, hydration, nutrition, drug use), with daily monitoring of adherence	Controlled clinical trial 542 patients aged ≥70 years admitted to a geriatric acute care unit and two internal medicine wards	Authors discuss the HELP program as inspiration, but the new protocol was designed to be implemented in daily practice without extra staff (unlike HELP).	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic hospital <u>Leadership:</u> A specialist geriatric nurse coordinated the intervention and monitored adherence. <u>Teamwork:</u> A multidisciplinary QI team including geriatricians, residents and nurses who worked in the geriatric ward. <u>Culture:</u> Not reported <u>Implementation tools:</u> Educational program aimed at changing the patient care approach of geriatric ward staff.	Intervention implemented within first 24 hours of admission to geriatric ward by geriatricians, residents, and nurses. A specialist geriatric nurse coordinated the intervention and monitored adherence.	New delirium episodes: <u>Intervention:</u> 20/170 (11.7%) <u>Usual care:</u> 69/372 (18.5%) OR = 0.59 (95% CI: 0.34-1.00) P = 0.05	Not reported	Not reported	High
Harari et al. 2007 ⁶⁶ U.K.	Proactive care of older people undergoing surgery (POPS); multidisciplinary preoperative comprehensive geriatric assessment (CGA) service with post-operative	CBA study (historical control) 108 patients aged ≥65 years undergoing elective surgery	The authors hypothesized that preoperative CGA "incorporating prediction of adverse outcomes combined with targeted interventions, would reduce	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Urban teaching hospital <u>Leadership:</u> Not reported <u>Teamwork:</u> A multidisciplinary QI team including a consultant geriatrician,	The multidisciplinary QI team implemented POPS. Most patients received pre-op home visits from occupational therapist and physiotherapy. Social worker provided inputs if needed. Patients were educated in	Post-op delirium: <u>POPS:</u> 3/54 (5.6%) <u>Pre-POPS:</u> 10/54 (18.5%) OR = 0.26 (0.07-1.00) P = 0.036	Only reported complications were related to surgery, not POPS	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	follow-through		post-operative complications and hence length of stay (LOS) in older people undergoing elective surgery.” This strategy did not target delirium alone, but any factor that might contribute to complications or longer LOS.	nurse specialist in older people, occupational therapist, physiotherapist and social worker <u>Culture:</u> Not reported <u>Implementation tools:</u> Geriatrician and nurse provided staff education in post-op early detection and treatment of medical complications, early mobilization, pain management, bowel-bladder function, nutrition and discharge planning.	optimizing post-op recovery. The geriatrician and nurse reviewed patients in surgical wards and provided staff education in post-op early detection and treatment of medical complications, early mobilization, pain management, bowel-bladder function, nutrition and discharge planning. Follow-up therapy home visits were provided to those with functional difficulties, and outpatient clinical review in those with ongoing medical problems.				
Lundstrom et al. 2007 ⁶⁷ Sweden	Postoperative multifactorial intervention to reduce delirium and improve outcomes in patients with femoral neck fractures	Randomized controlled trial (RCT) 199 patients aged ≥70 years with femoral neck fractures	Not reported	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic hospital with 24-bed geriatric unit (used only for intervention group) <u>Leadership:</u> Not reported <u>Teamwork:</u> A multidisciplinary team including RNs, LPNs, registered physiotherapists,	After education, all team members (except dietician) assessed each patient, usually within 24 hours after admission; team planning of individual rehab performed twice a week; assessment of patients with delirium for precipitating factors; prevention and	Post-op delirium: <u>Intervention:</u> 56/102 (54.9%) <u>Control:</u> 73/97 (75.3%) OR = 0.40 (0.22-0.73) p = 0.003 Days with post-op delirium: <u>Intervention:</u> 5.0 ±7.1 days <u>Control:</u> 10.2±13.3 days, p = 0.009	Not reported	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
				registered occupational therapists, a dietician and geriatricians <u>Culture:</u> Not reported <u>Implementation tools:</u> All nursing and medical staff members attended a 4-day course in caring, rehabilitation, teamwork, and medical knowledge.	treatment of complications (infection, anemia, embolism); assessment of bowel/bladder function; treatment of sleep apnea; prevention and treatment of decubitus ulcers; prevention and treatment of post-op pain; ensure oxygen saturation during first post-op day; measure blood pressure for first 2 post-op days; ensure adequate nutrition; mobilization within first post-op day; and secondary prevention of falls and fractures.				
Lundstrom et al. 2005 ⁶⁸ Sweden	Education program and reorganization of nursing and medical care	Quasi-RCT 400 patients aged ≥70 years admitted to two wards (intervention and usual care)	Not reported	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic hospital <u>Leadership:</u> Two of the authors were the leaders of the program <u>Teamwork:</u> A multidisciplinary team including all staff in the intervention ward <u>Culture:</u>	All nursing and medical staff members attended a 2-day course focusing on dementia and delirium in geriatric patients. Staff were also trained in the caregiver-patient interaction. Nursing care was reorganized to support individualized care,	Prevalent delirium within 24 hrs of admission: <u>Intervention:</u> 63/200 (31.5%) <u>Control:</u> 62/200 (31%) P = 0.91 Delirium on Day 7: <u>Intervention:</u> 19/63 (30.2%) <u>Control:</u> 37/62 (59.7%) OR = 0.29 (0.14-0.61) P = 0.001	No harms related to intervention were reported	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
				Not reported <u>Implementation tools:</u> All nursing and medical staff members attended a 2-day course focusing on dementia and delirium in geriatric patients. Staff were also trained in the caregiver-patient interaction.	and nursing staff received guidance once a month by a supervisor observing a nursing action.				
Tabet et al. 2005 ⁶⁹ ; 2006 ⁷⁰ U.K.	Educational package for medical and nursing staff to reduce incidence of delirium in hospitalized elderly patients; a control ward did not receive the educational package and performed usual practice.	CBA study (concurrent control) 250 patients aged ≥70 years admitted to two acute admission wards	The authors cite prior studies of educational programs directed at staff that have influenced nursing practice in relation to mental health issues in elderly people.	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Two acute admission wards in an inner-city teaching hospital <u>Teamwork:</u> Geriatric psychiatrist educated staff, who altered their practice based on the education. <u>Leadership:</u> The lead investigator (a geriatric psychiatrist) supervised the project. <u>Culture:</u> Not reported <u>Implementation tools:</u> Education program on delirium for staff with follow-up sessions delivered by geriatric psychiatrist	The educational package, which highlighted delirium risk factors, was delivered on site and at various times to ensure all staff were involved. There was an initial 1 hr formal presentation, written information on guidelines for delirium prevention and management, and regular follow-up meetings to reinforce learning; researchers did not intervene in day-to-day management or provide specific advice pertaining to specific patients.	Point prevalence of delirium: <u>Intervention ward:</u> 12/122 (9.8%) <u>Usual care ward:</u> 25/128 (19.5%) OR: 0.45 (95% CI: 0.21-0.94, P<0.05)	Not reported	The educational package was found to more effectively prevent delirium in men (OR: 0.17, 95% CI: 0.05-0.65) than in women (OR: 1.04, 95% CI: 0.38-2.81).	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Wong et al. 2005 ⁷¹ Australia	Delirium education for hospital staff plus recommendations by geriatric registrar for up to 10 possible targeted intervention strategies to prevent delirium after hip fracture	CBA study (historical control) 99 patients aged >50 years with hip fracture admitted to a general orthopedic unit	This strategy had been successfully used at a U.S. hospital in a previously-published study; targeted recommendations include regulation of bladder and bowel function, early detection/treatment of major complications, correction of fluid and electrolyte imbalance, discontinuation of unnecessary medications, provision of oxygen, severe pain treatment, agitated delirium treatment, use of appropriate environmental stimuli, adequate nutritional intake, and early mobilization and rehabilitation.	<u>External:</u> None mentioned <u>Organizational</u> <u>Characteristics:</u> Urban teaching hospital (460 beds) <u>Teamwork:</u> Multidisciplinary committee with medical, nursing, and allied health members of the orthopedic, geriatric, and anesthetic depts. <u>Leadership:</u> The lead investigator supervised the project. <u>Culture:</u> Not reported <u>Implementation tools:</u> The leader educated frontline staff (interns, ward nurses, and allied health staff) on delirium every 10 weeks	The lead investigator educated staff, supervised data collection and assessed patients; the project team met fortnightly to supervise the program; the intervention was implemented over a 3-month period; the major barrier was a high turnover of nursing staff that was partly overcome by the nurse manager of the orthopedic unit ensuring that all nursing staff attended the tutorials and received education about the use of the CAM.	Incident delirium: <u>Intervention:</u> 9/71 (12.7%) <u>Pre-intervention:</u> 10/28 (37.5%) OR = 0.26 (95% CI: 0.09-0.74) P = 0.012	None reported	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Marcantonio et al. 2001 ⁷² USA	Proactive geriatrics consultation with target recommendations based on a structured protocol for patients after hip fracture (target recommendations same as in Wong et al. 2005)	Single-blind RCT 126 patients aged ≥65 years admitted emergently for surgical repair of hip fracture	Not clearly stated, other than that geriatrics consultation is easily implementable and that a targeted, proactive strategy with intervention on defined outcomes has shown effectiveness, although it is not clear whether it has shown prior effectiveness in delirium prevention.	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> Academic tertiary medical center <u>Teamwork:</u> Geriatrician and orthopedics team worked together <u>Leadership:</u> Not reported <u>Culture:</u> Not reported <u>Implementation tools:</u> Not reported	A geriatrician evaluated patients preoperatively or within 24 hours postop, performed daily visits for duration of hospitalization and made targeted recommendations. The orthopedics team (surgeons and nurses) implemented the recommendations (adherence rate: 77%). The usual care group received management by the orthopedics team, including internal medicine or geriatric consults on a reactive rather than proactive basis.	Post-op delirium: <u>Consult:</u> 20/62 (32%) <u>Usual care:</u> 32/64 (50%) P = 0.04 However, when adjusted for baseline imbalances the effect size was no longer statistically significant: OR: 0.6 (95% CI: 0.3-1.3) No significant between-group difference in days of delirium per episode	None reported	Consultation showed a trend toward being more effective among patients without prefracture dementia or ADL impairment, but the differences were not statistically significant	Moderate
Long-term care									
Lapane et al. 2011 ⁷³ USA	Pharmacist-led Geriatric Risk Assessment MedGuide (GRAM) reports and automated monitoring plans focusing on medication monitoring phase to prevent potential	<u>Quasi-RCT:</u> 3,202 patients (2003) 3,321 patients (2004) 25 nursing homes were randomized to receive intervention or control	GRAM was designed to assist healthcare professionals with expertise in geriatric pharmacotherapy in problem identification when evaluating complex medication	<u>External:</u> None mentioned <u>Organizational Characteristics:</u> 25 nursing homes (each with 50 or more geriatric beds). All nursing homes had stable contracts with Omnicare and had few short stay residents <u>Teamwork:</u> Pharmacists shared	After training in 2003, GRAM database for falls and delirium was integrated in January 2004 into the pharmacies' commercial pharmacy software system for the intervention homes. Reports were generated on medications that	Potential delirium indicator: <u>In home 2003/04:</u> Adjusted hazard ratio: 0.93 (0.80-1.09) <u>New admits 2004:</u> Adjusted hazard ratio: 0.42 (0.35-0.52)	No significant difference between groups for potential adverse-event related hospitalization, falls, or death	Not reported	High

Author/Year	Description of PSP	Study Design and Patients	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	adverse drug events (falls and delirium) in nursing homes		regimens of older adults to identify, resolve, and prevent medication-related problems, aid in evaluation of medications as a cause or aggravating factor contributing to an older adult's physical, cognitive, or functional decline, and facilitate incorporation of medication monitoring information into the older adult's plan of care.	reports with facility nurses. <u>Leadership:</u> Consultant pharmacists <u>Culture:</u> Not reported <u>Implementation tools:</u> The ASCP Foundation developed and delivered in-service programs for nursing staff and consultant pharmacists. Two of the authors were instructors.	contribute to falls and delirium, as well as medication monitoring care plans and flow records. Facility nurses received reports within 24 h of admission for new admissions; consultant pharmacists did on-site reviews of drug regimens for each resident once every 30 days.				

Table 3, Chapter 20. Delirium prevention—single interventions

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Inpatient hospital care									
Al-Aama et al. 2010 ⁷⁴ Canada	Low dose melatonin for patients with hip fracture	Double-blind RCT 145 patients aged ≥65 years admitted to internal medicine service	The article cites a theory that delirium may be related to abnormal tryptophan metabolism, which can be regulated by melatonin supplementation	Internal medicine service in a tertiary care center	Study medication was administered (in double-blind fashion) daily between 1,800 and 2,400 h depending upon patient availability and medication administration schedules for up to 14 days	Incidence of delirium: <u>Melatonin:</u> 2/56 (3.6%) <u>Placebo:</u> 10/52 (19.2%) RR = 0.19 (95% CI: 0.04-0.81) P<0.02	2/61 patients on melatonin had side effects of nightmares or hallucinations	Not applicable	Moderate
Larsen et al. 2010 ⁷⁵ USA	Atypical antipsychotic Perioperative olanzapine (5 mg orally before and after surgery) or placebo to prevent postop delirium in elderly patients after joint replacement surgery	Double-blind RCT 400 patients aged ≥65 years undergoing elective knee or hip replacement surgery	Olanzapine is an antipsychotic with some prior evidence of efficacy for delirium treatment and prevention.	Academic hospital	Perioperative olanzapine (5 mg orally) or placebo was administered before and after surgery by nurses not involved in ongoing care of the patients.	Incidence of delirium: <u>Olanzapine:</u> 28 (14.3%) <u>Placebo:</u> 82 (40.2%) RR = 0.36 (95% CI: 0.24-0.52) P<0.0001 The difference was also significant in separate subgroups (knee replacement, hip replacement)	Severity of delirium was greater in the olanzapine group (DRS-R-98 score: 16.44 vs. 14.5, p = 0.02), and lasted longer (2.2 vs. 1.6 days, p = 0.02). Medical complications did not differ significantly between groups.	Not applicable	Moderate

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Prakanrattana and Prapaitrakool 2007 ⁷⁶ Thailand	Atypical antipsychotic Risperidone (1 mg) or placebo taken orally (sublingually) a single time following cardiac surgery	Double-blind RCT 126 patients aged >40 years undergoing elective cardiac surgery	Risperidone is an antipsychotic with some previous evidence of efficacy for treatment of delirium	Academic hospital	Risperidone (1 mg orally) or placebo was given by nurses when patients began to wake in the ICU	Post-op delirium: <u>Risperidone:</u> 7/63 (11.1%) <u>Placebo:</u> 20/63 (31.7%) RR = 0.35 (95% CI: 0.16-0.77) P = 0.009	None reported (post-op complications did not differ significantly between groups)	Not applicable	Low
Sieber et al. 2010 ¹² USA	Light propofol sedation during hip repair surgery	Double-blind RCT 114 patients aged ≥65 years undergoing hip fracture repair	The authors hypothesized that minimizing sedation depth during spinal anesthesia for hip fracture repair in elderly patients could decrease the occurrence of postop delirium	Academic medical center	Implemented by anesthesiologists during surgery.	Post-op delirium: <u>Light sedation:</u> 11/57 (19%) <u>Deep sedation:</u> 23/57 (40%) RR = 0.48 (95% CI: 0.26-0.89) P = 0.02	Complication rates were similar in both groups. <u>Light sedation:</u> 26/57 (46%) <u>Deep sedation:</u> 30/57 (53%) p = 0.57	Not applicable	Moderate
Maldonado et al. 2009 ¹⁷ USA	Different types of post-op sedation after cardiac surgery	RCT 118 patients aged ≥18 years undergoing elective cardiac valve surgery	The authors hypothesized that dexmedetomidine may be associated with a lower incidence of delirium due to its pharmacologic properties	Academic medical center	Implemented in the ICU following cardiac surgery. Patients were randomized to three different sedatives.	Post-op delirium (Intention-to-treat): <u>Dexmedetomidine:</u> 4/40 (10%) <u>Propofol:</u> 16/36 (44%) <u>Midazolam:</u> 17/40 (44%) p<0.001 Per protocol analysis also significantly different (p<0.001)	Not reported	Not applicable	High
Shehabi et al. 2009 ⁷⁷ Australia	Sedation Dexmedetomidine vs.	Double-blind RCT 306	Dexmedetomidine is a selective and	Two tertiary referral academic	Study drug infusion began at 3 ml/h within 1 h of	Incident Delirium: <u>Dexmedetomidine:</u> 13/152 (8.6%)	Bradycardia occurred more often in	Not applicable	Moderate

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
	morphine, effect on prevalence of delirium in patients at least 60 years old after cardiac surgery	patients aged ≥60 years undergoing cardiac surgery	potent α2 adrenergic receptor agonist. In theory, it's specificity may provide an advantage for delirium prevention compared to other post-surgical sedatives or analgesics	hospitals	admission to the ICU; dexmedetomidine dose was 0.1-0.7 µg/kg; morphine dose was 10-70 µg/kg; a propofol infusion and/or boluses were given if deemed necessary for rapid control of hypertensive episodes or unplanned awakening; open label morphine was allowed in the dexmed group to achieve equivalent analgesia, and propofol was allowed in the morphine arm to maintain equivalent sedation; drug infusion was continued until removal of chest drains when patient was ready for discharge from ICU, or for up to 48 h of mechanical ventilation.	<p><u>Morphine:</u> 22/147 (15%) <u>Rate Ratio:</u> 0.57 (95% CI: 0.26-1.1), P = 0.09</p> <p>Duration of delirium, median: <u>Dexmedetomidine:</u> 2 days <u>Morphine:</u> 5 days (95% CI: 1.1-6.7) P = 0.03</p>	<p>Dex group (16.5%) than in the Morphine group (6.1%) P = 0.006 Systolic hypotension occurred more often in Morphine group (38.1%) compared to Dex group (23%) P = 0.006</p>		

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Hudetz et al. 2009 ⁷⁸ USA	Anesthetic (NMDA receptor antagonist) Ketamine during anesthetic induction in older patients undergoing cardiac surgery with CPB.	RCT 58 patients aged ≥55 years undergoing cardiac surgery with CPB.	Citing prior evidence that ketamine may have neuro-protective effects, the authors hypothesized that a single dose of ketamine during anesthetic induction would attenuate postop delirium in older patients undergoing cardiac surgery with CPB.	Veterans Affairs medical center	Ketamine (0.5 mg/kg) or placebo was administered intravenously during anesthetic induction for cardiac surgery.	Post-op delirium: <u>Ketamine:</u> 1/29 (3.4%) <u>Placebo:</u> 9/29 (31%) RR = 0.11 (95% CI: 0.02-0.81) P = 0.01	Not reported	Not applicable	Moderate
Mouzopoulos et al. 2009 ⁷⁹ Greece	Local anesthetic Fascia iliac block prophylaxis (via Bupivacaine) for hip fracture patients	RCT 207 patients aged ≥70 years admitted for hip fracture	The authors cite prior studies suggesting that hip fracture patients are at increased risk of delirium due to severe pain; therefore, a fascia iliac block might prevent delirium by preventing severe pain.	Hospital (type not reported) (980 beds)	Bupivacaine was injected on admission (in blinded fashion) and repeated daily every 24 h until delirium occurrence or hip surgery; 24 hr after surgery it was re-administered and repeated daily until delirium occurrence or discharge.	Incident delirium: <u>Prophylaxis:</u> 10.8% (11/102) <u>Placebo:</u> 23.8% (25/105) OR = 0.45 (95% CI: 0.23-0.87)	No complications other than 3 local hematomas at injection site which resolved spontaneously	Not applicable	Moderate

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Gamberini et al. 2009 ⁸⁰ Switzerland	Acetylcholinesterase inhibitor Rivastigmine administered every 8 hrs from night before surgery until 6th postop day in a high-risk group of elderly patients undergoing elective cardiac surgery with CPB	Double-blind RCT 120 patients aged ≥65 years undergoing elective cardiac surgery with CPB	Based on prior studies suggesting cholinesterase inhibitors can successfully treat delirium, the authors hypothesized that short-term administration of oral rivastigmine would reduce the incidence of postop delirium in a high-risk group of elderly patients undergoing elective cardiac surgery with CPB	Academic hospital	Rivastigmine administered every 8 hrs as a colorless odorless solution from night before surgery until 6 th postop day	Incident delirium as assessed by CAM: <u>Rivastigmine:</u> 18/56 (32%) <u>Placebo:</u> 17/57 (30%) RR = 1.12 (95% CI: 0.50-2.48) P = 0.80	No significant between-group difference for any adverse events.	Not applicable	Low

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Liptzin et al. 2005 ⁸¹ USA	Acetylcholinesterase inhibitor Donepezil (given at 5 mg/day) or placebo for 14 days preop and 14 days postop in patients undergoing total joint replacement (knee or hip)	Double-blind RCT 80 patients aged ≥50 years undergoing knee or joint replacement	Donepezil is a cholinesterase inhibitor (disruption in cholinergic transmission is thought to be in causal pathway of delirium)	Academic medical center	Each patient was evaluated before surgery then given either Donepezil (given at 5 mg/day) or placebo for 14 days preop and 14 days postop	Post-op delirium: <u>Donepezil:</u> 8/39 (20.5%) <u>Control:</u> 7/41 (17.1%) Rate Ratio = 1.2 (95% CI: 0.6-2.6) P = 0.69	Not reported	Not applicable	Moderate

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
McCaffrey et al. 2006 ⁸² USA	Music therapy (musical selection with bedside CD turned on 1-3 times/day + standard postop care from anesthesia awakening time until discharged) for patients undergoing hip or knee surgery	RCT (music therapy + usual care vs. usual care alone) 124 patients aged ≥65 years undergoing elective hip or knee surgery	Prior studies have shown evidence that music can improve cognition and calm agitated patients	Large tertiary care center	Nurses blinded to room designation made room assignments. Various CDs were available in the music therapy rooms. Music was played when patients were awakening from anesthesia. CD was set to play for 1 hour 4 times daily. Also, nurses were asked to turn on the music each time they entered the room, and family members and patients were instructed how to use the CD player. Research assistants checked that CD players were working and that the music and timing of play suited patient preferences.	Patients who experienced acute confusion: <u>Music therapy:</u> 2/62 (3.2%) <u>Usual care:</u> 36/62 (58.1%) RR = 0.06 (95% CI: 0.01-0.22) P<0.0001	None reported	Not applicable	High

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
McCaffrey and Locsin 2004 ⁸³ USA	Music therapy (musical selection with bedside CD turned on 1-3 times/day + standard postop care from anesthesia awakening time until discharged) for patients undergoing elective hip and knee surgery	RCT (music therapy + usual care vs. usual care alone) 66 patients aged ≥65 years undergoing elective hip or knee surgery	Prior studies have shown evidence that music can improve cognition and calm agitated patients	Large tertiary care center	Nurses blinded to room designation made room assignments. Various CDs were available in the music therapy rooms. Music was played when patients were awakening from anesthesia. CD was set to play for 1 hour 3 times daily. Also, nurses were asked to turn on the music each time they entered the room, and family members and patients were instructed how to use the CD player. Research assistants checked that CD players were working and that the music and timing of play suited patient preferences.	Significantly fewer patients in the music therapy group had episodes of confusion and delirium (F = 19.568, P = 0.001)	None reported	Not applicable	High

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Kalisvaart et al. 2005 ⁸⁴ The Netherlands	Typical antipsychotic Haloperidol or placebo (0.5 mg 3 times daily) was started on admission and continued until 3 days postop to prevent delirium after hip surgery	Double-blind RCT 430 patients aged ≥70 years undergoing hip surgery	Haloperidol is a dopamine antagonist which can enhance acetylcholine release. Since delirium is highly associated with cholinergic deficiency, the authors hypothesized that haloperidol may have an indirect beneficial effect on delirium.	Teaching hospital	Haloperidol (0.5 mg 3 times daily) or placebo was started on admission and continued until 3 days after surgery. Experienced geriatric nurses and geriatricians provided proactive geriatric consultation (based on a structured multimodal protocol) to all patients.	Post-op delirium: <u>Haloperidol:</u> 32/212 (15.1%) <u>Placebo:</u> 36/218 (16.5%) RR = 0.91 (95% CI 0.59-1.42) P = 0.69 Duration of delirium (days): <u>Haloperidol:</u> 5.4±4.9 <u>Placebo:</u> 11.8±7.5 P<0.001	No drug-related side effects were reported	Not applicable	Moderate
Aizawa et al. 2002 ⁸⁵ Japan	Benzo-diazepines Diazepam + flunitrazepam drip infusion and pethidine drip infusion for first 3 days (day of operation and first 2 postop days) in patients undergoing gastrointestinal surgery	RCT (delirium-free protocol [DFP] vs. non-DFP) 40 patients aged >70 years undergoing gastrointestinal surgery	Sleep-wake cycle disorders have been reported to be associated with postop delirium, so medications that target sleep cycle disorders might prevent delirium	A city hospital, no other details provided	Diazepam (0.1 mg/kg intramuscular) + flunitrazepam (0.04 mg/kg drip infusion) and pethidine (1 mg/kg drip infusion) at specific times during first 3 days (day of operation and first 2 postop days)	Incidence of post-op delirium: <u>DFP:</u> 1/20 (5%) <u>Non-DFP:</u> 7/20 (35%) P = 0.023	DFP was reported to cause "morning lethargy" in 8/20 patients (40%). No other side effects were reported.	Not applicable	High

Author/Year	Description of PSP	Study Design and patients	Theory or Logic Model	Description of Organization	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Overall Risk of Bias
Long-term care									
Mentes and Culp 2003 ⁸⁶ USA	Hydration (individually calculated fluid intake goal) over an 8-week period in nursing home residents aged ≥65 years	Quasi-RCT (randomization by coin toss of different participating facilities) 49 participants aged ≥65 years	Prior studies have shown that chronic under-hydration may lead to delirium and other adverse events	2 Veteran's Administration (VA), 2 community nursing homes	All RNs responsible for coordinating implementation at their site received intensive training on intervention/ usual care implementation. The project director made weekly visits to each site to ensure that the protocol was being implemented. RNs were responsible for most implementation details with assistance from NAs. NAs were responsible for providing fluids for participants.	Episodes of acute confusion: <u>Treatment:</u> 0/25 (0%) <u>Control:</u> 2/24 (8.2%) P = not significant	None reported	Not clear, but the possibility was raised that control group staff might have altered their standard hydration practices due to awareness of research staff data collection.	High
Moretti et al. 2004 ⁸⁷ Italy	Rivastigmine (3-6 mg/day) for 2 years in patients with vascular dementia	RCT (Rivastigmine vs. cardio-aspirin) 246 patients aged 68-85 years with vascular dementia	Delirium in patients with vascular dementia might be due to lack of acetylcholine in the brain. Rivastigmine is an anti-cholinesterase inhibitor	Academic hospital	Rivastigmine (3-6 mg/day) or aspirin (100 mg/day) for 2 years in patients with vascular dementia	Patients with episodes of delirium during follow-up: <u>Rivastigmine:</u> 46/115 (40%) <u>Cardioaspirin:</u> 71/115 (62%) RR = 0.65 (95% CI: 0.50-0.85) P<0.001 Mean duration of delirium: <u>Rivastigmine:</u> 4 ±1.71 days <u>Cardioaspirin:</u> 7.86 ±2.73 days P<0.01	Not reported	Not applicable	High

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Evidence Tables for Chapter 21. Preventing In-Facility Pressure Ulcers

Table 1, Chapter 21. Multi-component pressure ulcer prevention initiatives conducted in acute care settings in the United States

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Lynch and Vickery 2010 ^{1a}	Zero-tolerance philosophy <u>Target safety problem:</u> PU <u>Key elements:</u> Multidisciplinary team; educate staff/resident/family, streamline documentation, wound-care workshops, case studies, setting goals, identify and address barriers	Pre-post	NS	166-bed acute rehabilitation	<u>External:</u> New CMS reimbursement <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> After reviewing 2007 data on PUs, the team was dismayed at the number of misidentification of PUs at admission; skin assessments incomplete and inconclusive; incorrect staging; incorrect documentation (e.g., document denuded skin as PU); documentation fragmented; definition of thorough skin assessment; inconsistent documentation of interventions; incorrectly transcribing interventions to appropriate documentation. <u>Implementation tools:</u> <ul style="list-style-type: none"> • Interdisciplinary team • Education at orientation, annually, and one-on-one, via web • Documentation streamlined to 1 form • Wound care workshops for nurses at orientation; after 2 months • Report cards 	<u>Length:</u> 1 year <u>Process:</u> Multidisciplinary team reviews current processes of care and finds errors with assessment and documentation; education of staff is quickly put in place; staff is encouraged to report HAPUs and view as an opportunity to learn; rate goals are set for hospital and by unit; report cards are posted so units can track their progress. <u>Successes:</u> Due to streamlining documentation, timely and accurate completion of documentation increases from 60% to 90% in 90 days; patients on a neurobehavioral stroke unit did not develop PU <u>Barriers:</u> Patients dissatisfied with off-loading boots <u>Addressing Barriers:</u> Trial initiated to evaluate use of pillow; leads to improved outcomes <u>Sustainability:</u> Quarterly newsletter attached to paychecks	<u>PU Rates:</u> Pre: 2.8% Post: 0.48% (-82.8%)	NS

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Young et al. 2010 ^{2a}	Clinician-led task force leads prevention initiatives <u>Target safety problem:</u> PU <u>Key elements:</u> Clinician-led task force; skin champions; adoption of Save our Skin logo; education/training; revise policies and procedures based on CPGs; integrate new documentation and assessment tools	Pre-post	Shared governance approach (decisions made at point of care)	540-bed acute care facility (3 campuses) in Indiana	<u>External:</u> NS <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> A clinician-led skin care team replaces administration-led <u>Implementation tools:</u> <ul style="list-style-type: none"> • Save our Skin (SOS) logo adopted and appears on educational forms and t-shirts worn during audits and educational in-services • Laminated SOS logo tool placed on doors of patients at-risk • Revise online policies and procedures; 1 new policy remains • Adopt Braden Scale (electronically) • Body map assessment tool • Mandatory training includes presentation of case studies • Educational brochure for residents and families • Feedback on educational presentations • Updating of core orientation, uploaded to hospital Web site • Posters depicting PU rates, examples of new forms, and revised policies/procedures 	<u>Length:</u> 2 years <u>Process:</u> Members of clinician-led task force include director of Clinical Care and Oncology Nursing Services, manager of Wound Care Institute, and nursing representatives from 15 hospital units; task force members appoint skin champions from each unit; champions invited to join team; task force members join subcommittees of choice to develop logo, policy and procedures and other program components; after comparing practices to CPGs 7 existing policies are combined into 1; manager of the Wound Care Institute works with the Director of Informatics on revising online policies and procedures; monthly quality audits <u>Successes:</u> Revised policies reduced from 7 to 1; documentation of skin care reduced from 8 to 3 <u>Barriers:</u> Time constraints, insufficient computer resources, competing goals <u>Addressing Barriers:</u> Clinicians were allocated 4 paid hours to carry out responsibilities; web access to library resources were	<u>Incidence:</u> <u>Pre:</u> Campus 1: 12.5% Campus 2: 8.7% Campus 3: NR <u>Post:</u> Campus 1: 9.1% Campus 2: 2.8% Campus 3: NR	NS

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
					<ul style="list-style-type: none"> placed on each unit Hospital-wide standardizing of patient-turning schedules Flip-chart algorithm placed bedside to differentiate between old and new skin care products Audit tool 	<p>added to intranet; <u>Sustainability:</u></p> <ul style="list-style-type: none"> RNs and LPNs must demonstrate competency annually Monthly updates provided via intranet to nursing personnel by unit champions/ team members; includes product changes 		
Bales et al. 2009 ³	<p>Implementation of evidenced-based prevention strategies <u>Target safety problem:</u> PU <u>Key elements:</u> Increase hours of certified wound, ostomy and continence nurses (CWOCNs) to full-time to provide 24-hour support to staff, provide mandatory education and resources for staging and treating wounds, increase wound monitoring and reporting efforts, purchase pressure-redistribution beds, add musical alarms to remind nurses to turn patients, and identify at-risk surgical patients.</p>	Time series	NS	300-bed community hospital, USA	<p><u>External:</u> To comply with principles of the Magnet program, which validates excellence in nursing practices <u>Organizational Characteristics:</u> Magnet hospital that serves mostly adult and geriatric patients <u>Teamwork, Leadership, Culture:</u> Decentralized decision-making in which shared decision-making is encouraged prevails, feedback and participation of all staff is actively encouraged <u>Implementation tools:</u> CWOCNs, computers to aid in staging wounds and treatment information, and external alarms to remind nurses to turn patients</p>	<p><u>Length:</u> 1 year <u>Process:</u></p> <ul style="list-style-type: none"> 24-hour support provided by CWOCNs Mandatory education Strict oversight of monitoring and reporting Periodical motivational campaigns that included staff and unit incentives. <p><u>Successes:</u></p> <ul style="list-style-type: none"> Patients received optimal care Institution avoided the cost of treating stage 3 or 4 ulcers <p><u>Barriers:</u> Staff motivation and lack of proper reporting and documentation</p> <p><u>Addressing Barriers:</u> Monthly to quarterly campaigns are launched to maintain staff motivation. Nursing units that had zero-hospital acquired PUs are recognized and awarded</p>	<p><u>Hospital acquired prevalence rates:</u> Pre: 4.20% Post: 0%</p>	The hospital's managerial style encouraged staff involvement in decision-making about the process of developing a program and the leadership team gave strong support to the program and promoted it to both other leaders in the team and hospital staff.

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						<p>during campaigns. <u>Sustainability:</u> Success requires awareness of key management skills and priorities, such as strong leadership, involvement of staff in decision-making and a desire to foster interdisciplinary relationships.</p>		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Chicano & Droishagen, 2009 ⁴	Implement strategies to lower the incidence of hospital-acquired pressure ulcers <u>Target safety problem:</u> PU <u>Key elements:</u> Developed a protocol for assessment and documentation of wounds, implemented procedures for CWOCN to work with staff and patients to initiate appropriate treatment, implemented the Braden Scale for Pressure Sore Risk, conducted a literature review on the use of thromboembolic device stockings and compression devices and revised practice standards for use of devices based on findings of review	Time series	NS	25-bed intermediate care unit in the United States	<u>External:</u> Quarterly HAPU data indicate increased prevalence <u>Organizational</u> <u>Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> The care unit supported a self-governing nursing council. <u>Implementation tools:</u> Survey to identify practices regarding skin assessment, documentation, and nursing intervention and opportunities for education, CWOCNs, and Braden Scale	<u>Length:</u> 23 months <u>Process:</u> Phase 1 took 5 months and involved developing protocols and procedures to assess and treat wounds; Phase 2 took 3 months to complete and involved educating staff and implementing the Braden Scale, Phase 3 took 15 months to complete and involved a literature review and revision of practice standards on use of compression devices. <u>Successes:</u> Staff participation in survey, continued adherence to implemented prevention practices, development of educational materials, and staff acceptance of shared governance <u>Barriers:</u> Engaging staff as council members in the planning and implementation of the project. <u>Addressing Barriers:</u> Updating staff of progress and continual encouragement to participate from other council members <u>Sustainability:</u> Commitment and diligence from the quality improvement team and self-governance council.	<u>Hospital acquired incidence rate:</u> <u>Pre:</u> 6 occurrences during a 12 month period, 5 during subsequent 5 months <u>Post:</u> 1 occurrence within 12 months following implementation, 0 at latest assessment covering 2 month period.	“Commitment and diligence from the quality improvement team and from the members of the staff’s self-governance councils played a significant factor in achieving our goal of reducing HAPU prevalence in our intermediate care unit.”

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Walsh et al. 2009 ^{5a}	Implementation of evidence-based practices <u>Target Safety problem:</u> PU Key elements: revision of skin management program; use of CPGs; educating clinician/nurse; multidisciplinary team; add certified WOCN to management; replace risk assessment tool; replace wound care products	Time series	NS	1 acute care facility in northwest CT <u>Bed size:</u> 371	<u>External:</u> CMS <u>Organizational Characteristics:</u> Regional medical center and community teaching hospital; primary provider for 350,000 <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> <ul style="list-style-type: none"> • Add WOCN nurse to team • Rely on EBPs (AHRQ CPGs, IHI, WOCN Society) • Rely on The National Database of Nursing Quality Indicators' PU presentation for re-education on wound etiology and staging • Clinician and staff education (computer-based and classroom presentations) • Replace risk assessment tool with Braden Scale • Update skin management policies/procedures • Assessed wound care products • Multidisciplinary team • Alert system (POA sticker) • Visual turning clocks, laminated pocket cards including CPG information • Bed surface algorithms 	<u>Length:</u> 18 months <u>Process:</u> Clinical education relies on 6 essential elements of prevention; in 2007, Braden scale risk assessment tool replaces current un-validated tool form (not research based); each unit assigns an interdisciplinary team; purchases of new beds, stretchers and curtains followed by new skin lotion and incontinence care products <u>Successes:</u> Reduction in prevalence; increased focused communication among patient caregivers; buy-in from clinicians improves behavior <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> "Remains current regarding initiatives for improved patient safety, changes in regulatory mandates, and changes in EBP."	<u>Prevalence:</u> <u>Baseline:</u> 12.8% <u>Post-implementation:</u> 0.6%	NS

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
					<ul style="list-style-type: none"> • Illustrative wound reference guides with recommended treatment modalities • Standardize wound care products 			
Dibsie, L. 2008 ^b	<p>Implementation of evidence-based protocol and practices for preventing and treating PUs</p> <p><u>Target safety problem:</u> PU</p> <p><u>Key elements:</u> Development of protocol for monitoring, preventing, and treating PUs based on recent evidence, standardization of all products related to prevention and treatment of PUs, and education for nurses on the protocol and use of products.</p>	Time series	NS	4 adult critical care units (54 beds total) at 2 academic medical centers in the United States	<p><u>External:</u> Two significant events occurred and there was an overall lack of reporting and communication of issues related to skin breakdown (specifics of events not reported)</p> <p><u>Organizational Characteristics:</u> NS</p> <p><u>Teamwork, Leadership, Culture:</u> NS</p> <p><u>Implementation tools:</u> Staff nurse skin committee and skin champions</p>	<p><u>Length:</u> >1 year</p> <p><u>Process:</u> Change began with becoming educated about current practices and equipment in wound care. Once educated, the nursing skin committee began purchasing equipment, developing procedures for monitoring and documenting skin breakdown, and educating staff on monitoring, reporting, and treating PUs.</p> <p><u>Successes:</u> Decrease in the rate of hospital-acquired stage 2 or greater pressure ulcers.</p> <p><u>Barriers:</u></p> <ul style="list-style-type: none"> • Coordinating efforts between 2 sites • Coordinating and identifying skin committee members and staff champions • Scheduling staff education • Continuation of efforts • Cost of purchasing new equipment <p><u>Addressing Barriers:</u> Communication, active involvement of clinical managerial leaders, and</p>	<p><u>Surgical ICU acquired:</u> Pre: 6.1% Post: 6.1%</p> <p><u>Facility-wide overall rate:</u> Pre:4.2% Post: 3.2%</p>	“The changes in the climate and practice related to skin care and prevention of breakdown are the direct result of nursing taking ownership of their practice with the support of nursing leaders at all levels.”

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						constant education support. <u>Sustainability:</u> Organization commitment remains strong and next steps for success, such as developing aggressive indicators of success and having staff identify practice issues are in the works.		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
McInerney, J. 2008 ⁷	To implement multiple strategies for decreasing the prevalence of hospital-acquired PUs <u>Target safety problem:</u> PU <u>Key elements:</u> Electronic medical records, risk assessment measures, pressure relief measures (new equipment and personnel augmentation, and interdisciplinary team to develop protocols.	Time series	NS	Two-hospital system with 548 beds in United States; 548 bed; non-profit	<u>External:</u> NS <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> WOCN oversaw implementation of strategies.	<u>Length:</u> 18 months to implement program; follow-up reported for over 5 years <u>Process:</u> <ul style="list-style-type: none"> • Electronic medical records (EMRs) to assess and document skin care needs. • Risk assessment measures (e.g., Braden Scale) • Automated consults and orders through EMRs • Pressure relief measures • Staff education • Hiring of second WOCN <u>Successes:</u> Reduction in PUs, cost savings and elimination of pain and suffering for the patients <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> NS	Hospital acquired prevalence rates: <u>Pre:</u> 12.8% all PUs; 6.7% PUs on heel. <u>Post (4.5 years after implementation):</u> 1.9% all PUs; 1.1% PUs on heel.	"With the assistance of the automated consults and orders, the addition of another WOC nurse, the appropriate equipment, the interdisciplinary task force, continuing education, and monitoring, the hospital system was able to reduce the hospital-acquired pressure ulcer prevalence rate by 81%, and the rate for heel ulcers alone was reduced by 90%." <u>Estimated annual cost savings:</u> \$11,466,000

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Ballard et al. 2007 ⁸	<p>Implementation of multiple strategies in an intensive care unit (ICU) to reduce the rate of PUs</p> <p><u>Target safety problem:</u> PU</p> <p><u>Key elements:</u> Strategies included: restructured risk assessment and documentation, translated numeric data into easy-to-understand graphs of PU rates, increased staff awareness, implemented “turn rounds,” increased prevalence assessments and redesigned “skin team,” used evidence-based practices for monitoring and treating PUs, and created an access database to track weekly prevalence</p>	Time series	NS	Two-unit ICU with a total of 44 beds located in two separate geographical locations in the United States.	<p><u>External:</u> Joining the National Database of Nursing Quality Indicators (NDNQI) and realizing that ICU had high prevalence of PUs.</p> <p><u>Organizational Characteristics:</u> NS</p> <p><u>Teamwork, Leadership, Culture:</u> Primary nursing model</p> <p><u>Implementation tools:</u> CWOCN conducted a needs assessment, creation of user friendly reports to show rate of PUs, posted data of PU rates for staff to see, skin teams (consisted of nursing staff who performed weekly prevalence assessments and provided education), and Access database</p>	<p><u>Length:</u> 1 year</p> <p><u>Process:</u> Conducted needs assessment to identify areas of weakness in identifying, monitoring, treating, and reporting PUs; made revisions to protocol based on results of needs assessment; created user friendly reports to display PU rates; increased staff awareness through displaying PU rates and providing education; implemented “turn rounds” every two hours; redesigned skin team, implemented evidence-based practices to assess risk and monitor PUs, and implemented Access database to track PUs.</p> <p><u>Successes:</u> Reduction in rate of PUs and improved patient outcomes.</p> <p><u>Barriers:</u> NS</p> <p><u>Addressing Barriers:</u> NS</p> <p><u>Sustainability:</u> Staff commitment to implementing strategies and maintaining quality care.</p>	<p><u>Hospital acquired incidence rate:</u> NS</p> <p><u>Hospital acquired prevalence rates:</u> Pre: 34% Post: 8.0%</p>	Utilizing benchmark data helped the ICU focus on pressure ulcer prevention, which led to improved patient outcomes.

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Catania et al. 2007 ⁹	Design and implementation of the Pressure Ulcer Prevention Protocol Interventions (PUPPI): a nursing initiative to prevent PUs <u>Target safety problem:</u> PU <u>Key elements:</u> The PUPPI involves assessing risk and nutritional status, providing skin care, documenting, and giving referrals as needed.	Time series	NS	All 5 inpatient units in one hospital in the United States. Units included 2 medical units, 2 surgical units, and one critical care unit.	<u>External:</u> 2 stage IV ulcer identified; evidence from the NDNQI survey that the prevalence of PUs in the hospital in the study exceeded the national benchmark by close to 50%. <u>Organizational Characteristics:</u> Dedicated cancer hospital <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Quality improvement team that consisted of a quality manager, nursing director, certified nurse aids (CNSs), nursing staff developmental specialists, and an enterostomal therapy nurse to develop and implement protocol.	<u>Length:</u> 6-months to implement; follow-up data reported for 18 months <u>Process:</u> Initial efforts started in 2003 and involved having clinical nurse specialists assess patient risk using the Braden Scale. These efforts led to the development of a quality-improvement team in 2004 and the development of the PUPPIs. The PUPPI was implemented in September 2004 and included a systematic process for monitoring and educating staff. <u>Successes:</u> Reduction in rates of PUs <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> Proactive nursing staff who have adopted initiatives in protocol into their daily routine.	<u>Hospital acquired incidence rate:</u> NS <u>Hospital acquired prevalence rates:</u> <u>Pre:</u> 11.11% all ulcers; 6.67% hospital acquired <u>Post:</u> 4.08% all ulcers; 1.36% hospital acquired	"While the unit CNSs have championed this process and continue to monitor the program, it has been the nursing staff who have embraced evidence-based nursing practice and brought it to the bedside by adopting the initiative into daily practice."

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LeMaster, K. 2007 ¹⁰	Pressure Ulcer Prevention Project implemented on targeted units—pulmonary unit and oncology unit <u>Target safety problem:</u> PU <u>Key elements:</u> Turning at-risk patients every two hours minimally, placing a pressure-reducing overlay on the bed of every patient at risk, and elevating bony prominences at risk	Time series	NS	Pulmonary and oncology unit of the largest hospital campus within one healthy system; a 502-bed hospital in the United States.	<u>External:</u> Selection of study units was based on unit having a higher hospital-acquired PU rate than the NDNQI database mean for similar units and having higher hour-of-care ratios than the NDNQI mean for similar units. <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Manual containing information about wounds and wound care, instructions on the use of the Braden Scale to assess risk for developing PUs, patient turn schedule, and cues to use as reminders to turn patients.	<u>Length:</u> Summer 2004–April 2005 <u>Process:</u> The first phase of implementation involved assessing and establishing baseline knowledge of unit staff nurses for assessing risk. Staff then identified resources and studied the manual. Nursing staff began assessing and documenting risk and implementing other aspects of the protocol (placing pressure-reducing overlay on bed). A CNS provided consultation and oversight throughout implementation period. <u>Successes:</u> Reduction of PUs in targeted units and successful duplication of intervention in other medical units. <u>Barriers:</u> Braden scores were not documented at 100% per policy. Patients were missed because of failure in communication between two different electronic documentation systems. <u>Addressing Barriers:</u> Barrier to be eliminated with transition to a single, universal electronic record system within hospital. <u>Sustainability:</u> Manual and cues to help maintain consistent and complete practice patterns.	<u>Hospital acquired incidence rate:</u> NS <u>Hospital acquired prevalence rates:</u> Pre Pulmonary Unit: 9.0% Post Pulmonary Unit: 0.0% Pre Oncology Unit: 12.0% Post Oncology Unit: 0.0%	NS

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Courtney et al. 2006 ¹¹	To develop and implement Save Our Skin program to reduce the rate of PUs <u>Target safety problem:</u> PU <u>Key elements:</u> Updating pressure-relieving mattress, introducing skin breakdown prevention protocols, clarifying staff roles and responsibilities (introduced a skin champion), and improving measurement a communication of PU performance data	Time series	Used procedures of the Six Sigma method, a data-focused, decision-making process that utilizes a five phase process called DMAIC: Defining the problem, Measuring the performance, Analyzing the problem, Improving the situation, and Initiating change.	710-licensed bed, multisite, not-for-profit facility that serves a 37-county area; is Magnet designated	<u>External:</u> Results using the Nursing Care Quality Initiative guidelines that revealed high prevalence of PUs (13%) and lack of documentation and management. Revitalized interest in treatment and prevention shown by American Nurses Association and AHRQ in developing new guidelines. <u>Organizational Characteristics:</u> Magnet designated hospital <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Implemented guidelines for the prevention and management of PUs from the Wound, Ostomy, and Continence Nurses Society and assessed risk using the Braden Scale.	<u>Length:</u> Follow-up 3 years <u>Process:</u> Adopted Six Sigma procedures, assessed potential causes of high incidence of PUs and lack of staff coordination and management of PUs, and introduction of solutions: staff training and awareness, development and implementation of Skin Breakdown Prevention protocol, replacement of pressure mattresses, designation of Skin champion, clarification of staff roles, and implementing monitoring procedures <u>Successes:</u> Reduced incidence of PUs and cost savings <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> Defining staff responsibilities, monitoring performance, using data to inform staff performance, and making data public	<u>Hospital acquired incidence rate:</u> <u>Pre:</u> 9.4% <u>Post:</u> 1 st quarter implementation 3.1%; last follow-up 1.8% <u>Hospital acquired prevalence rates:</u> NS	This project refocused efforts on traditional direct nursing care and problem solving procedures from the Six Sigma method to implement the Save Our Skin program.
Gibbons et al. 2006 ¹²	To develop and implement best practice guidelines, known as the SKIN bundle (Surfaces, Keep the patient turning, Incontinence management,	Time series	NS	Large 528-bed hospital, part of nation's largest Catholic and non-profit health system	<u>External:</u> Development of the SKIN bundle is part of the Ascension Health Care system's initiative to reduce/eliminate preventable hospital-related injuries and deaths. <u>Organizational</u>	<u>Length:</u> 10 months to implement; follow-up 2 years <u>Process:</u> Began with engaging leadership, forming an interdisciplinary team, and providing "protected" time to	<u>Hospital acquired incidence rate:</u> <u>Pre:</u> 5.7% <u>Post:</u> 0.448 No new Stage III or IV HAPU	Of eight priorities identified for action by Ascension Health; St. Vincent's Medical Center was

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	<p>Nutrition) to prevent PUs <u>Target safety problem:</u> PU <u>Key elements:</u> Developed a synergistic group of interventions that includes appropriate surface selection (e.g., pressure mattress), regular turning of patients, incontinence management, nutrition and hydration, ongoing monitoring and staff training.</p>				<p><u>Characteristics:</u> Faith-based, non-profit hospital <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Regular assessment and documentation on flow sheets, skin risk alert reminders, weekly team meetings, and ongoing performance monitoring and reporting.</p>	<p>work on project. The project moved toward identifying best practices, assessing current practices, and developing the SKIN bundle. Lastly, the project involved educating staff and piloting the SKIN bundle. <u>Successes:</u> 90% reduction in incidence of PUs. <u>Barriers:</u> Educating staff, communication, motivation, and hard- to-treat patients (patients whose treatment involves hours of sitting or lying down, such as radiology or dialysis) <u>Addressing Barriers:</u> Keep educational offerings basic, short and focused, and available at multiple times; make sure key staff organizing initiative have good communication skills and plan for times and methods of communication, celebrate successes and provide tangible incentives, make a plan for hard-to-treat patients. <u>Sustainability:</u> Being open to suggestions from staff, continually focusing on education, monitoring outcomes, and promoting free exchange of information.</p>	<p>occurred between August 2004 and February 2006</p>	<p>selected to develop the PU process. The hospital leadership “welcomed the opportunity to develop this nursing-driven program as a means of establishing pride in professional nursing practice.” 67 acute care facilities in the Ascension health system agreed to implement the SKIN bundle plus “common measures of quality and performance.”</p>

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Hiser, et al. 2006 ¹³	To implement a team approach to performance improvement and develop an education plan for clinical staff to better prevent and treat PUs <u>Target safety problem:</u> PU <u>Key elements:</u> Education, policy changes, development of evidence-based protocols, cost improvement strategies, implementing new support surfaces, and improved reporting and monitoring through quarterly prevalence studies and improved risk assessment using the Braden scale.	Time series	NS	580-bed regional medical facility in the U.S.	<u>External:</u> NS <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Created a Wound Care Team that consisted of CWOCNs and an advanced registered nurse practitioner to implement changes and educate staff; replaced the Norton Scale with the Braden scale to assess risk.	<u>Length:</u> 2 years follow-up. <u>Process:</u> Implementation started with a review of the literature of best practices for prevention and treatment of PUs. <u>Successes:</u> Reduced prevalence of PUs and annual cost savings. <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> Ongoing education and newsletters reporting progress and positive feedback to staff.	<u>Hospital acquired prevalence rates:</u> Pre: 9.2% Post: 6.6% (measured at 2 years follow-up)	NS

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Lyder et al. 2004 ¹⁴	To implement a multihospital collaboration to increase the identification of patients at high risk of PUs and to promote the use of preventive measures among hospitalized Medicare patients <u>Target safety problem:</u> PU <u>Key elements:</u> Increase in the following: tracking of PUs, performance and documentation of risk assessment, use of prevention protocol (includes education and oversight of staff), scheduled repositioning, use of pressure-reducing devices, nutritional consults, and accuracy of staging.	Pre-post	Plan-Do-Study-Act (PDSA)	17 hospitals ranging from 200 to 800 beds with 9 located in urban and 8 in rural settings in the U.S.	<u>External:</u> In response to Centers for Medicare & Medicaid Services charge to improve quality of care to Medicare patients. <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> Hospitals needed to develop a team approach to implementing changes. <u>Implementation tools:</u> Qualidigm, the Connecticut QIO, Computerized charting system for tracking PUs, creation of skin care task force, and pocket-sized wound staging card.	<u>Length:</u> 9 months implementation, 2 years follow-up. <u>Process:</u> The PDSA framework involved 1) identifying problem to be changed and designing an intervention; 2) implementing this intervention; 3) evaluating the impact of the intervention, and implementing what was learned from evaluation. <u>Successes:</u> Significant increases in identifying high-risk patients, repositioning bed and chair bound patients, use of nutritional consults, and staging of acquired Stage II or greater PUs. <u>Barriers:</u> View that PU prevention was a nursing issue. <u>Addressing Barriers:</u> Re-educating various disciplines about their role in PU prevention <u>Sustainability:</u> Hospitals found that the most sustainable interventions were institutionalized, such as change in pressure-relieving mattress. Interventions that depended more on sufficient staff such as turn schedules were less sustainable.	<u>Hospital acquired incidence rate:</u> No statistically significant change from baseline to follow-up (20.6 to 20.8, p = 0.90) <u>Hospital acquired prevalence rates:</u> NS Decrease in median length of hospital stay (8.0 days to 7.0 days, p = 0.05)	“Focusing pressure ulcer prediction and prevention programs on the nursing staff is limited insofar as effective pressure ulcer prevention requires a multidisciplinary effort. The PDSA model assists hospitals in working in multidisciplinary teams and places the onus for improvement on the team rather than on a particular discipline.”

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Stier et al. 2004 ¹⁵	To implement a system wide multidisciplinary skin care initiative to standardize care to reduce the incidence and severity of PUs <u>Target safety problem:</u> PU <u>Key elements:</u> The project involved standardization of risk assessment methods, delineating timeframes for patient assessment, and reassessment, developing a uniform skin care formulary, negotiating a system-wide contract for therapeutic support surfaces, and providing staff education.	Time series	NS	A large not-for-profit health care system in the U.S. with over 5,600 beds and more than 33,000 employees. The system is composed of 18 hospitals, 4 skilled nursing facilities, 1 certified home health agency, and 2 hospice agencies. The focus of current study is on implementing skin care initiatives in acute care hospitals.	<u>External:</u> NS <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> Implemented Braden scale to standardize risk assessment	<u>Length:</u> 2 years follow-up <u>Process:</u> Convened a multidisciplinary team of experts to develop an implementation plan. The first initiative implemented was the Braden scale of risk assessment. The second was working closely with Materials Support Services to develop a formulary for skin care products. The final steps involved staff education and implementing quality control measures. <u>Successes:</u> Reduction in the inpatient incidence of PUs. <u>Barriers:</u> NS <u>Addressing Barriers:</u> NS <u>Sustainability:</u> Valid and reliable measurement system that allows for ongoing assessment and evaluation of performance and ongoing education.	<u>Hospital acquired incidence rate:</u> Pre: 2.2% Post: 1.3%	"A standardized approach to patient assessment/re-assessment through the use of evidence-based guidelines and educational programs led to a common understanding of pressure ulcer management, improved communication among care providers, and sustained improvement in patient outcomes."

^a Not included in the Soban 2009 review¹⁶

CMS: Centers for Medicare and Medicaid Services

CNS: Clinical nurse specialist

CPG: Clinical practice guidelines

CWOCN: Certified Wound, Ostomy, and Continence Nurse

DMAIC: Defining, measuring, analyzing, improving, initiating change

EBP: Evidence-based practice

EMR: Electronic medical record

HAPU: Hospital-acquired pressure ulcer

ICU: Intensive care unit

IHI: Institute for Healthcare Improvement

LPN: Licensed practical nurse

MICU: Medical intensive care unit
NDNQI: National Database of Nursing Quality Indicators
NR: Not reported
NS: Not stated
PDSA: Plan-Do-Study-Act
POA: Present on admission
PSP: Patient safety practices
PU: Pressure ulcer
PUPPI: Pressure Ulcer Prevention Protocol Intervention
QIO: Quality Improvement Organization
RN: Registered nurse
SKIN: Surfaces, KeeP the patient turning, Incontinence management, Nutrition
SOS: Save our skin
WOC: Wound, ostomy and continence
WOCN: Wound, Ostomy and Continence Nurses Society

Table 2, Chapter 21. Multi-component pressure ulcer prevention initiatives conducted in long-term care settings in the United States

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Horn et al. 2010 ¹⁷	Real-Time Program (renamed On-Time Quality Improvement for Long Term Care [On-Time]) <u>Target safety problem:</u> PU <u>Key elements:</u> CNA assist in redesigning documentation to include core data elements to help identify high-risk patients; facilitators provide feedback on weekly clinical decision-making reports; staff educated on QI methods and smooth integration of these CNA documentation and clinical reports into day-to-day flow	Time series	Based on best practices from AHRQ and AMDA guidelines, and findings from the National Pressure Ulcer Long-term Care Study (NPULS)	11 not-for-profit facilities in 7 states Bed size: 44–432 beds 1–3 highest-risk units per facility participated	<u>External:</u> AHRQ funded <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> <ul style="list-style-type: none"> CNA documentation processes and timely reports to identify patients at risk A project leader (e.g., DON) and ongoing team identified Educate staff on QI methods and use of documentation forms and reports 	<u>Length:</u> 9 months <u>Process:</u> Facilitators work with a multidisciplinary team from each facility. Redesigned CNA documentation incorporating “core data elements” including nutrition and incontinence variables. CNA’s coached to improve documentation. Sites fax scannable forms to project office. Clinical reports returned within 24 hours and displayed. Feedback includes inconsistencies and completeness of CNA documentation per unit/unit over time/shift. After reviewing with CNAs, need for additional education noted. Conference calls (bi-weekly), all-facility meetings (every 6 months) and on-site	<u>CMS HRPrU QM prior to implementation (k = 7):</u> 13.0% <u>CMS HRPrU QM 12 months after implementation (k = 7):</u> 8.7% <u>HRPrU QM % change (5 facilities using ≥2 reports)</u> -25% to -82.4% <u>High Risk PrU QM % change (2 facilities using 1 report)</u> +8.3%, +14.3% Average number of in-house acquired PU (all stages) per facility pre-implementation vs post-implementation: 12.1 to 4.6 (62% reduction) Average number of CNA documentation forms reduced by 53.2%.	Facility “B” which had the highest reduction in PU (-82.4%) was the only facility that: <ul style="list-style-type: none"> had 100% participation of residents (n = 75) Facility “B” was 1 of 3 facilities who incorporated all 4 clinical reports for care planning. Two facilities with the lowest reduction in PUs did not involve a multidisciplinary team.

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<p>meetings were scheduled with facilitators, project leaders and frontline staff.</p> <p><u>Successes:</u> CNA's widely accept revised forms and increase productivity. Documentation completeness rates increase from 80%–90% to mid-90%.</p> <p><u>Barriers:</u> EMR system used by 1 facility could only export data elements and create 1 report Issues raised with preparing the CNA documentation</p> <ul style="list-style-type: none"> • forms needing the resident's study ID number and • faxing forms for report generation <p>Staff turnover especially by DON slowed project momentum.</p> <p><u>Addressing Barriers:</u></p> <ul style="list-style-type: none"> • Add new CNA documentation process into orientation programs 		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<ul style="list-style-type: none"> Phase in use of documentation. Develop a strong multidisciplinary team to lead improvement efforts and not rely on one project leader. <p><u>Sustainability:</u> “HIT needed to capture CNA documentation and generate reports.” “Managing the manual data collection, faxing forms to the project office and creating clinical reports for distribution back to the facilities on a weekly basis could not be maintained over the long term for many facilities.” Program expanded throughout the U.S.</p>		
Rantz et al. 2010 ¹⁸	Bedside EMR (OEMR, Irvine, CA) and statewide on-site clinical consultation services (QIPMO – Quality Improvement Program for Missouri) <u>Target safety</u>	RCT 4-group comparison Group 1: EMR plus consult Group 2: EMR Group 3: Consult Group 4: Control	NS	18 facilities in 3 U.S. states Group 1: 4 facilities Bed size range, 98–240, total 668 Group 2: 4 facilities Bed size range, 105–218, total 635 Group 3:	<u>External:</u> CMS funds OEMR hardware, software and ongoing tech support <u>Organizational Characteristics:</u> Mix of for-profit, not-for-profit, and governmental facilities <u>Teamwork, Leadership, Culture:</u> NS	<u>Length:</u> 2 years <u>Process:</u> <ul style="list-style-type: none"> Project coordinator works with OEMR staff Staff works with QIPMO nurses at least monthly QIPMO nurses encourage staff to focus on 	Relative improvement in high risk pressure sores (negative scores indicate improvement) <u>12 months</u> Group 1: -53% Group 2: -12% Group 3: -5% Group 4: +435% <u>24 months</u> Group 1: -3%	“Total costs for the 3-year evaluation for the groups of facilities implementing technology increased \$15.11 (12.5%) for Group 1 and \$16.89 (9.6%) for Group 2, while those for the comparison groups did not.”

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
	<p><u>problem:</u> Comprehensive</p> <p><u>Key elements:</u> Mandatory OEMR training, QIPMO nurses</p>			<p>5 facilities Bed size range, 90–123, total 543 Group 4: 5 facilities Bed size range, 120–310, total 890 Group 1, 3, 4 from Missouri Group 2: Other States</p>	<p><u>Implementation tools:</u></p> <ul style="list-style-type: none"> • Project coordinator assigned at intervention facility • QIPMO nurses 	<p>clinical care and improving care systems to be enabled by OEMR</p> <p><u>Successes:</u> Group 1, 2 and 3 showed improvements at 12 months; Group 1 and 2 sustained at 24 months</p> <p><u>Barriers:</u> NS</p> <p><u>Addressing Barriers:</u> NS</p> <p><u>Sustainability:</u> Improvement sustained during Year 2 for Group 1 and 2</p>	<p>Group 2: -8% Group 3: +59% Group 4: +105%</p>	<p>“Cost increases were most likely attributable to the cost of technology, maintaining and supporting the technology, and on-going staff training to use the EMR and not increase direct care staffing or turnover.”</p>

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Milne et al. 2009 ¹⁹	LTACH care process improvement <u>Target safety problem:</u> PU <u>Key elements:</u> Nursing association consults; team training; improve assessment and documentation methods; EMR revised; formal and informal staff education; wound care product reviews	Time series	Failure mode and effects analysis*	Long-term acute care facility in CT Bed size, 108	<u>External:</u> NS <u>Organizational Characteristics:</u> Above average PU prevalence <u>Teamwork, Leadership, Culture:</u> <ul style="list-style-type: none"> Faulty EMR Inconsistent use of EMR by clinicians Deficient risk assessment documentation <u>Implementation tools:</u> <ul style="list-style-type: none"> Training by nursing association APN appointed in-house leader APN and nursing supervisor become WCC Team clinicians trained in prevalence data collection EMR revised; PUSH tool added Staff educated via formal clinical rounds, interactive sessions and one-on-one bedside sessions Immediate feedback given on training 	<u>Length:</u> 13 months <u>facility wide Process:</u> <ul style="list-style-type: none"> Roles for new skin team members defined Team meets weekly to review “failure modes” and develop new care processes Revamping of policies and procedures after review of CPGs Wound care product reviews <u>Successes:</u> PU reduced to <3% on two units due to increased monitoring of modified nasal cannula (pulmonary unit) and increased attentiveness to heel offloading, support surfaces and proper positioning (SCI/trauma unit); of the 396 charts reviewed, <1% had missing data; staging and wound etiology were consistently determined by wound team in greater than 90% of	Mean facility-acquired PU prevalence: <ul style="list-style-type: none"> Pre: 41% Post: 4.2% Pulmonary-focused unit: <ul style="list-style-type: none"> Pre: 25% Post: <3% SCI/trauma unit: <ul style="list-style-type: none"> Pre: 33.8% Post: 2.9% 	Data on PU prevention implementation in a LTACH is sparse. Two LTACH units however were able to reduce PUs to <3% due to “increased diligence” by the team. The authors noted an “increased collaboration among disciplines with regard to wound prevention and treatment as well as a tendency for early intervention when wounds are newly discovered.”

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<p>cases (based on a review of 45 patient charts)</p> <p><u>Barriers:</u> Rates climbed once strict monitoring was leveled off</p> <p><u>Addressing</u> <u>Barriers:</u> Increase in unit presence, chart monitoring, feedback to staff, and biweekly prevalence rounds</p> <p><u>Sustainability:</u></p> <ul style="list-style-type: none"> • CWCN certification of 2 team members provide in-house expertise • Monthly review of documentation and PU prevention interventions • Early intervention 		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Tippet A. 2009 ²⁰	Physician consultant leads deficient nursing home to zero facility-acquired PUs <u>Target safety problem:</u> PU <u>Key elements:</u> Physician wound consultant, multidisciplinary team, education, weekly informal feedback, wound care protocols based on AHRQ CPG, wound coordinator sustains program	Time series	Based on AHRQ CPG	Midwest skilled facility Bed size: 151	<u>External:</u> G-level citation (actual harm deficiency) and state survey deficiencies <u>Organizational Characteristics:</u> NS <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> <ul style="list-style-type: none"> Physician consultant Multi-disciplinary team Braden Scale, AHRQ CPG Incentive programs Informal feedback Simplified wound care formulary Equipment evaluation (Delphi process used to evaluate products) 	<u>Length:</u> 6 years <u>Process:</u> <ul style="list-style-type: none"> Physician consultant educates staff and conducts yearly follow-up training (all mandatory) Team forms goals and meets weekly Select members conduct wound rounds Follow-up training through in services, and yearly follow-up Nursing supervisors conduct one-on-one with staff and weekly informal feedback Preventive care plans created Protocols discussed in classes, become part of routine shift reporting and charting All nursing staff made accountable for care and reporting <u>Successes:</u> Goal of zero facility	Average pre-initiative incidence: 5.19% Average post-initiative incidence: 0.73% (p<0.0001) 4 year post-initiative incidence: 0.06% (p<0.0001)	Estimated cost savings per PU/per month: \$1,617 Monthly savings: \$10,187 Yearly savings: >\$122,000

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<p>acquired ulcers reached after 6 months Facility citation free "Accolades from surveyors for wound program" Judged competitions between floors promote teamwork and buy-in <u>Barriers:</u> NS <u>Addressing</u> <u>Barriers:</u> NS <u>Sustainability:</u> Wound care coordinator position established to supervise, train, provide clinical support and track wounds. Permanent decline after 6 months through study end</p>		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Rosen et al. 2006 ²¹	Ability, Incentives, and Management feedback (AIM system) <u>Target safety problem:</u> PU <u>Key elements:</u> Staff ability enhancement (skin care training, use of penlights and TAP card), real-time management feedback, financial incentives	Longitudinal time series study; four 12-week periods (baseline assessment, intervention, and two post-intervention periods)	NS	Not-for-profit nursing home in U.S. Bed size, 136	<u>External:</u> AHRQ funded <u>Organizational Characteristics:</u> Received multiple Department of Health citations due to persistently high PU rates <u>Teamwork, Leadership, Culture:</u> Lack of management to oversee earlier processes <u>Implementation tools:</u> <ul style="list-style-type: none"> • Research team contacts administrators responsible for overseeing implementation. • Mandatory “skin care” training (a 40-minute computer-based, interactive-video education program). • Penlights • Caregivers wear plastic TAP (turn and position card) to remind all hospital personnel the direction residents should 	<u>Length:</u> 48 weeks <u>Process:</u> One skin care nurse assessed patients upon admission or notification by staff of any skin changes. During the post-intervention periods, no weekly reports were provided to the administrators, no established targets or goals were established, and there were no financial incentives offered to staff. Only 3 of 29 new hires completed training. <u>Sustainability:</u> The intervention was not sustained over the two post-intervention periods however Rosen et al. indicated that a highly motivated administrator could have maintained the 3 program components.	Significant reduction in emergence of stage 1–4 PUs Pre-intervention: 28.3% Intervention: 9.3% (z[I] = 2.64, p<0.001) <u>Total ulcers Stage 1 and beyond</u> Pre-intervention (n = 134): 38% (28.3) Intervention (n = 107): 10% (9.3) Post-Intervention I: 19% (17.7) Post-Intervention II: 19% (17.7) <u>Total ulcers Stage 2 and beyond</u> Pre-intervention: 31% (23.1) Intervention: 10% (9.3) Post-Intervention I: 15% (14.0) Post-Intervention II: 17% (15.9)	With a mean cost of \$2700 of treating a single stage II PU, [26] reducing the incidence of these ulcers by approximately 15 over 12 weeks yields a potential savings of more than \$40,000 while distributing less than \$10,000 as incentives. This does not take into consideration the added savings in fewer personal injury lawsuits. The primary management feedback tool was adherence to the mandated training (not emergence of a new PU). Additional real-time feedback was provided to staff in the form of a visual “thermometer” of PU occurrences each week. All a nonfinancial incentive, it served as a supplementary motivating factor as the incidence of PUs was visually perceived as declining.

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
					<p>be facing every 2 hours.</p> <ul style="list-style-type: none"> • Administrators receive a weekly report of staff that had completed training. • A graphic “thermometer” of PU incidence was also updated weekly and displayed in the staff lounge. • Each staff member received \$75 if the PU incidence was below target goal (incidence <3%) set by administration. • Staff reprimanded for non-completion. • Staff terminated for not completing training during extension period. 			

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
Abel et al. 2005 ²²	<p>Process of care system changes in collaboration with a state QIO</p> <p><u>Target safety problem:</u> PUs</p> <p><u>Key elements:</u> Collaborative with a state QIO, intervention tool kit, nurses aid and licensed staff training</p>	Pre-post	NS	<p>20 facilities in Texas</p> <p>Average residents: 100</p> <p>Average Medicare beds: 15</p>	<p><u>External:</u> Identified from 143 Medicare-certified skilled nursing facilities as having high rates of PUs and a high volume of residents receiving preventive care</p> <p><u>Organizational Characteristics:</u> Selected due to accessibility to state QIO (Texas Medical Foundation [TMF])</p> <p><u>Teamwork, Leadership, Culture:</u> NS</p> <p><u>Implementation tools:</u></p> <ul style="list-style-type: none"> • TMF provides tools <ul style="list-style-type: none"> ○ Nurses Station Reference Cards ○ Pocket Assessment Card ○ Mobility Program ○ Fax Communication Form ○ Care Planning Tool ○ Resident Patient and Family Education Brochure <p>Tool kit components based on information</p>	<p><u>Length:</u> 2 years</p> <p><u>Process:</u></p> <ul style="list-style-type: none"> • Monthly onsite visits by TMF • Tools modified • Periodic progress assessment <p><u>Successes:</u></p> <ul style="list-style-type: none"> • Performance significantly improved on 8 of 12 QIs • Management maintains autonomy which promoted “continued commitment and a sense of ownership” <p><u>Barriers:</u></p> <ul style="list-style-type: none"> • Staff resistance • “Staff turnover and variation in new staff orientation often contributed to clinical or operational practices that were inconsistent with their protocol requirements.” • Incomplete risk assessments • Monitoring systems not appropriately used 	<p>Incidence rate: Pre: 13.6% Post: 10.0%</p> <p>Significant improvements in 8 QIs (baseline vs. re-measurement):</p> <ul style="list-style-type: none"> • Proportion of residents with appropriate risk assessment completed within 2 days of admission (2.2% vs. 15.3%; p<0.0001) • Proportion of high-risk residents with appropriate care plan for ALL selected triggers for high-risk residents (10.1% vs. 21.8%; p<0.0001) • Proportion of high-risk residents whose care reflects the triggered care plan interventions (2.0% vs. 9.8%; p<0.0001) • Proportion of residents with PUs that receive weekly skin 	<p>“Although there are areas for improvement, the implementation of process of care system changes by NHs in a collaborative relationship with a QIO may yield improvements in measures of patient outcomes (e.g., PU incidence).”</p> <p>Abel et al. also indicated that the 10 facilities with the highest [QI] scores at re-measurement showed a trend toward a lower [PU] incidence rates than the 10 facilities with the lowest [QI] indicator scores at re-measurement (S = 125.5, p = 0.07).</p> <p>Facilities with the highest QI scores versus facilities with the lowest QI scores (baseline vs. re-measurement; PU incidence rate, %):</p> <p>High scoring group: 12.3% vs. 7.7%</p> <p>Low scoring group: 14.8% vs. 12.2%</p> <p>Facilities with the</p>

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
					<p>from the AHRQ CPGs, Rhode Island Quality Partners, and regulatory requirements (federal and state)</p> <ul style="list-style-type: none"> • Nursing staff internally responsible • TMF externally responsible • QA committee 	<ul style="list-style-type: none"> • Documented risk factors not acted upon <p><u>Addressing</u> <u>Barriers:</u> Monthly visits by TMF and improving performance <u>Sustainability:</u> NS</p>	<p>assessments (12.6% vs. 32.8%; p<0.0001)</p> <ul style="list-style-type: none"> • Proportion of facility-acquired and community-acquired PUs with appropriate ulcer description within 24 hours of ulcer recognition (53.5% vs. 68.9%; p = 0.035) • Proportion of residents with PUs and mobility issues using a pressure relief mattress/overlay (50.7 vs. 76.7; p<0.0001) • Proportion of residents identified as high risk (as per MDS) using a pressure relief mattress/overlay (33.0% vs. 53.4%; p = 0.003) • Proportion of residents whose treatment orders and care plan interventions for PUs reflect facility wound 	<p>greatest improvement versus facilities with the least improvement in QI scores (baseline vs. re-measurement; PU incidence rate, %): High scoring group: 13.1% vs. 7.1% Low scoring group: 14.0% vs. 12.8%</p>

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
							care protocol (1.3% vs. 4.9%; p = 0.0505)	
Rantz et al. 2001 ²³	Statewide implementation of Show-Me QI report <u>Target safety problem:</u> Comprehensive <u>Key elements:</u> Workshops, Minimum Data Set (MDS) Quality Indicator (QI) feedback reports, clinical consultation	RCT Group 1: Workshop plus feedback reports Group 2: Workshop, feedback reports and clinical consult Group 3: Control	NS	87 nursing homes in Missouri Bed size: 1–60: 10 61–120: 52 120+: 25	<u>External: NS</u> <u>Organizational Characteristics:</u> Adequate experience with transmitting MDS data electronically <u>Teamwork, Leadership, Culture:</u> NS <u>Implementation tools:</u> <ul style="list-style-type: none"> Educational workshop RAI manual RAPs CPG (AHRQs) Comparative feedback Show-Me QI report (quarterly) GCNS consult 	<u>Length:</u> 1 year <u>Process:</u> <ul style="list-style-type: none"> “Core group” receives Show-Me QI report in workshop; subsequent quarterly reports sent to administrator and DON GCNS help interpret report, assess resident problems, and document care 15 facilities (Group 2) had ≥1 on-site visits and GCNS calls 18 facilities (Group 2) had only 1 call and limited GCNS calls 13 quality indicator outcome measures were evaluated <u>Successes:</u> Reduction in pressure ulcers (overall and low-risk) for residents in facilities using GCNS <u>Barriers:</u>	<u>Secondary regression analysis:</u> MDS QI 29 Pressure Ulcers (overall): Case mix: 0.156 Time Pre-Post: 0.240 Intervention: 0.026 Group X Time: 0.085 (p≤0.10) MDS QI 29lr Pressure ulcers low risk: Case mix: 0.417 Time Pre-Post: 0.037 Intervention: 0.064 Group X Time: 0.057 (p≤0.10)	A subset of Group 2 nursing homes that were intensely involved with the intervention showed improvement in MDS QI scores for five outcome measures including MDS QI 29 (pressure ulcers). “Nursing homes that did have continuous quality improvement systems in place were often part of larger health care systems that have ongoing support from a quality improvement expert.”

Author/ Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<ul style="list-style-type: none"> • Short staff • Staff turnover especially nurse RAI coordinator • “Taking care themselves” • Cancelled site visit at last minute • Additional time needed to correct inaccurate MDS assessments • Teams “mired in the MDS assessment process and coding issues” • Difficulty convincing staff to use continuous QI principles <p><u>Addressing Barriers:</u></p> <ul style="list-style-type: none"> • Stronger incentives to use GCNS • GCNS more local • More flexible site visit times • Extend time to implement change • Use teams to address problems • Post accomplishments 		

Author/Year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Influence of Contexts on Outcomes
						<ul style="list-style-type: none"> Multiple nurses responsible for RAI process Use of quality manager on staff to support care delivery improvements Leadership buy in to QI Sustainability: NS		
Ryden et al. 2000 ²⁴	Protocol implementation by APNs <u>Target safety problem:</u> Comprehensive <u>Key elements:</u> APNs assist staff to implement care plan; APNs provide direct care to residents	Controlled before-and-after APN treatment (2 facilities) vs. usual care (1 facility)	Havelock's (1974) model of effective research utilization	3 privately-owned facilities located in suburban Minneapolis-St. Paul area; certified for Medicare	<u>External:</u> NS <u>Organizational Characteristics:</u> APNs work with head nurse who works with physician or GNP <u>Teamwork,</u> <u>Leadership, Culture:</u> NS <u>Implementation tools:</u> <ul style="list-style-type: none"> AHRQ CPG Staff education Work with nursing assistants APNs participate in conferences and wound care rounds 	<u>Length:</u> 6 months <u>Process:</u> <ul style="list-style-type: none"> RAs assess risk/collect data 2 APNs reassess risk, analyze data (10 hrs/week per facility) APNs meet with residents 15-30 min/wk <u>Successes:</u> 6 months of APN treatment significantly improved 3 of 4 clinical problems compare to usual care <u>Barriers:</u> <ul style="list-style-type: none"> High turnover of unlicensed staff <u>Addressing Barriers:</u> NS <u>Sustainability:</u> A wound care committee was established at 1 facility.	<u>APN Treatment</u> (n = 86) Pre: 19.8 Post: 3.5 $\chi^2 = 3.01(1)$, $p = 0.04$, one-tailed <u>Usual Care</u> (n = 111) Pre: 17.3 Post: 10.0	"The relatively short time (10 hr per week in each nursing home) and the high turnover rates of unlicensed staff (range of 11%-45%) reduced opportunities for each APN to establish relationships with staff."

APNs: Advanced practice gerontological nurses
CMS: Centers for Medicare and Medicaid
CPG: Clinical practice guidelines
DON: Director of Nursing
EMR: Electronic medical record
GCNS: Gerontological clinical nurse specialist
GNP: General nurse practitioner
GP: General Practitioner
HRPrU: High-risk PU quality measure
Int: Intervention
LPN: Licensed practical nurses
LTACH: Long-term acute care hospital
NS: Not stated
PT: Physical therapist
PU: Pressure ulcer
QI: Quality indicator
QM: Quality measure
RA: Resident assistants
RAI: Resident assessment instrument
RAP RAI: Resident assessment protocols
RCT: Randomized controlled trial
SCI: Spinal cord injury
WCC: Wound Care Certified

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Evidence Tables for Chapter 22. Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection (NEW)

Table 1, Chapter 22. Large trials (n > 500) evaluating the health outcome effects of IIT

Patient population Single or multi-center Country	Implementation/ Context	Diabetes mellitus (%)	Glucose target, T v C (mg/dL)	Inpatient BG achieved, T v C (mg/dL)	Mortality and T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate T v C, RR (95%CI)	Other reported outcomes* T v C	Quality
SICU Single center Belgium ¹⁰	Insulin protocol was developed and use overseen by study investigators.	13	80-110 v 180-200	103 v 153† (p<0.001)	ICU mortality 4.6 v 8% (p=0.005 unadjusted) RR 0.42 (95% CI 0.22-0.62); Hospital mortality: 7.2 v 10.9% (p=0.01) RR 0.66; 95% CI 0.48-0.92	<40, 5 v 0.76%, RR 6.65 (2.83-15.62)	Renal replacement 4.8 v 8.2% (p=0.007) Sepsis 4.2 v 7.8% (p=0.0003)	Fair
Neurosurgical ICU Single center Italy ⁵⁸	Efforts made to limit nursing turnover. New nursing staff worked with experienced staff.	NR	80-110 v 180-200	92 v 143‡ (p<0.001)	6-month mortality: 74.0 v 72.0% (p=0.82)	<50, 93.8 v 62.8%, p<0.001	Sepsis 2.9 v 3.3% (p=NS) Long-term disability: 40.2 v 41.1% (p=0.98)	Fair
MICU Single center Belgium ⁵⁹	Study conducted in a hospital that had already conducted similar IIT study in SICU patients. Authors note the nurse:bed ratio of 2.5 was not changed for study.	16	80-110 v 180-200	111 v 153† (p<0.001)	ICU mortality: 24.2 v 26.8% (p=0.31) Hospital mortality: 37.3 v 40.0% (p=0.33) RR 0.93; 95% CI 0.81-1.08 90d mortality: 35.9 v 37.7% (p=0.53)	<40, 18.7 v 3.1%	Infection 0.7 vs 0.8% (p=NS) Renal replacement 20.8 v 22.7% (p=0.50)	MICU Single center Belgium ⁵⁹

Patient population Single or multi-center Country	Implementation/ Context	Diabetes mellitus (%)	Glucose target, T v C (mg/dL)	Inpatient BG achieved, T v C (mg/dL)	Mortality and T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate T v C, RR (95%CI)	Other reported outcomes* T v C	Quality
MICU Multicenter Germany ²⁰	No details provided	30	80-110 v 180-200	112 v 151† (p<0.001)	28d mortality: 24.7 v 26% (p=0.74) RR 0.95, 95% CI 0.70-1.28 90d mortality: 39.7 v 35.4% (p=0.31)	<40, 17 v 4.1% RR 4.11 (95% CI 2.21-7.63)	Renal replacement 27.5 v 22.5% (p=0.001)	MICU Multicenter Germany ²⁰
MICU/SICU Multicenter Europe ⁶⁰	Characteristics from each study site were reported. Median nurse:bed ratio was 2. ICUs ranged widely in size, patient volume, and number of glucometers per ICU.	17 T, 22 C (p=0.031)	80-110 v 140-180	117 v 144‡ (p<0.001)	ICU mortality: 17.2 v 15.3% (p=0.41) Hospital mortality: 23.3 v 19.4% (p=0.11) 28d mortality: 18.7 v 15.3% (p=0.14)	< 40, 8.7 v 2.7%	Renal replacement (patient days) 519 v 523 (p=0.75)	Fair
MICU/SICU Single center Saudi Arabia ¹⁸	24/7 ICU coverage by intensivists. Protocol designed by multidisciplinary team at study site. Physicians and nurses attended training sessions before and during study.	32 T, 48 C (p<0.001)	80-110 v 180-200	115 v 171‡ (p<0.001)	ICU mortality: 13.5 v 17.1% (p=0.70) RR□ 1.09 (0.70-1.72) Hospital mortality: 27.1 v 32.3% (p=0.19) RR□ 0.84 (0.64-1.09)	< 40, 28.6 v 3.1%, p < 0.001	Renal replacement 11.7 v 12.1% (p=0.89)¶ Sepsis 36.9 v 40.9% (p=0.35)	Fair
MICU/SICU Single center Colombia ⁵³	Three month staff training period before study.	13 T, 12 C (p=NS)	80-110 v 180-200	120 v 149‡ (p,0.001)	ICU mortality: 33.1 v 31.2%; RR 1.06 (0.82-1.37) 28d mortality: 36.6 v 32.4%; RR 1.1 (0.85- 1.42)	<40, 8.3 v 0.8%	Infection 27.2 v 33.2% (p=NS) Renal replacement 10.8 v 13% (p=0.45)	Fair

Patient population Single or multi-center Country	Implementation/ Context	Diabetes mellitus (%)	Glucose target, T v C (mg/dL)	Inpatient BG achieved, T v C (mg/dL)	Mortality and T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate T v C, RR (95%CI)	Other reported outcomes* T v C	Quality
MICU/SICU Multicenter International ⁵⁴	Pre-trial pilot studies carried out to test/improve insulin protocol. Final computerized insulin protocol algorithm accessible to study sites through a central Web site. No clear explicit training prior to study.	20	80-108 v <180	115 v 144§ (p<0.001)	28d mortality: 22.3 v 20.8% (p=0.17) RR 1.09 (0.96-1.23) 90d mortality: 27.5 v 24.9% (p=0.02) RR 1.14 (1.02-1.28)	<40, 6.8 v 0.5% OR 14.7 (9.0-25.9)	Renal replacement 15.4 v 14.5% (p=0.34) Sepsis 12.8 v 12.4% (p=0.57)	Fair
Acute MI Multicenter CCU Sweden ⁶¹	No details provided	39	126-198 v NR	24 hours: T: 172.8 (59.4) C: 210.6 (73.8) p < .001	3 month mortality: 12.4% v 15.6%, p = NS 1 year mortality: 18.6% v 26.1 %, RR 0.69; 95% CI 0.49-0.96	<54, 15.0 v 0% (p < .001)		Fair
Acute MI Multicenter Europe ⁶²	No details provided	77 established DM; 23 new DM of < 1y	group 1 and 2: 126-180 group 3: NR	24 hours: group 1: 163.8 (54.0), group 2: 163.8 (50.4), group 3: 180.0 (64.8) p = .0001	Adjusted 2- year mortality: Group 1 v 3 = 1.19 (0.86 - 1.64) Group 2 v 3 = 1.23 (0.89 - 1.69)	< 54, Gr 1 v Gr2 v Gr3: 12.7 v 9.6 v 1.0		Poor

Patient population Single or multi-center Country	Implementation/ Context	Diabetes mellitus (%)	Glucose target, T v C (mg/dL)	Inpatient BG achieved, T v C (mg/dL)	Mortality and T v C (RR, 95% CI)	Hypoglycemia Definition (mg/dL), rate T v C, RR (95%CI)	Other reported outcomes* T v C	Quality
Stroke Mutlicenter Britain ⁶³	Conducted as a "pragmatic" trial as part of routine clinical care. No clear explicit training prior to study.	17	72-126 v <306	24 hour mean difference I v C (95% CI): 10.3 (4.9 - 15.5), p < .0001†	90-day mortality: 30.0% v 27.3%, OR (95% CI) = 1.14 (0.86- 1.51) 90 day severe disability: 35.1% v 36.0%, OR (95% CI) = 0.96 (0.70- 1.32)	< 72 for > 30 mins, 15.7, control group rate NR		Poor

Abbreviations: BG = Blood glucose; d = day; CCU = coronary care unit ; ICU = intensive care unit; MICU = medical intensive care unit; SICU = surgical intensive care unit; C = comparator; DM = diabetes mellitus; NR = not reported; NS = not statistically significant; RR = relative risk; T = treatment

Other reported outcomes include renal replacement, infection, cardiovascular events, and long-term disability.

Quality was assessed using criteria from the US Preventive Services Task Force.

SI unit conversion for glucose: 1 mg/dL x 0.0555 = 1 mmol/L.

* Infection includes wound infection, urinary tract infection, or pneumonia; or a combination of these.

† Morning blood glucose.

‡ Average of blood glucose measurements, not otherwise specified.

§ Time weighted mean blood glucose.

□ Adjusted for chronic liver disease, traumatic brain injury, APACHE II and international normalized ratio.

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Evidence Tables for Chapter 23. Interventions To Prevent Contrast-Induced Acute Kidney Injury

Table 1, Chapter 23. Included studies

Study, publication date	Literature search end date	Intervention evaluated	Number of trials	Sample size	AMSTAR criteria	Evidence of benefit for intervention
Brar, 2010 ¹	11/2008	Bicarbonate	14	2290	10	N
Brown, 2009 ^{2,3}	2/2009	N-acetylcysteine and bicarbonate	10	1594	9	N
From, 2010 ³	12/2009	Iso-osmolar contrast	36	7166	11	N
Gonzales, 2007 ⁴	9/2004	N-acetylcysteine	22	2746	11	N
Heinrich, 2009 ⁵	8/2007	Iso-osmolar contrast	25	3270	11	N
Ho, 2008 ⁶	4/2008	Bicarbonate	4	573	8	Y
Hogan, 2008 ⁷	10/2007	Bicarbonate	7	1307	9	N
Hoste, 2009 ⁸	2/2009	Bicarbonate	18	3055	11	N
Joannidis, 2008 ⁹	Not stated	Bicarbonate	9	2043	7	N
Kanbay, 2009 ¹⁰	11/2008	Bicarbonate	17	2448	9	Y
Kelly, 2008 ¹¹	11/2006	N-acetylcysteine	26	3352	9	Y
Kunadian, 2010 ¹²	9/2008	Bicarbonate	7	1734	6	Y
Meier, 2009 ¹³	12/2008	Bicarbonate	17	2633	11	Y
Navaneethan, 2009 ¹⁴	1/2008	Bicarbonate	12	1854	8	Y
Reed, 2009 ¹⁵	11/2008	Iso-osmolar contrast	16	2763	10	N
Song, 2010 ¹⁶	6/2010	Renal replacement therapy	9	751	9	N
Trivedi, 2009 ¹⁷	10/2008	Bicarbonate	10	1090	11	Y
Trivedi, 2010 ¹⁸	1/2008	N-acetylcysteine	16	1677	9	Y
Zhang, 2011 ¹⁹	7/2010	Statins	12	1194	8	N
Zoungas, 2009 ²⁰	12/2008	Bicarbonate	23	3563	11	N

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Evidence Tables for Chapter 24. Rapid Response Systems (NEW)

Table 1, Chapter 24. RRS evidence table: effectiveness

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Anwar ul, 2010 ¹	PICU physicians (Pediatric MET)	Pre-post 9340	NA	600 bed tertiary teaching hospital (75 pediatric beds) in Pakistan		Education sessions with quarterly reinforcement	Mortality : ICU mortality of patients admitted to ICU from floor (total sample 77) Results:50% to 15% Statistics: p=0.001 OR 0.18 (0.09-0.35) Cardiac arrest: Results: 5.2 to 2.7/ 1000 admits Statistics: p=0.004 OR=.52 (0.12-2.26)			

Author, year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Bader, 2009 ²	<p>Nurse led. Had Critical care outreach component as well (proactive rounding on ICU discharged patients and also responded to ED (most RRS don't go to the ED.)</p> <p>RRT model with CCOT function</p>	Pre-post not given	NA	304 bed acute care non-teaching hospital, part of large health system including 13 other hospitals in US.	Organizational characteristics: Director of quality Leadership: Leadership team	12 month review and development of RRT, activation criteria, integration into ED nursing, development of CCOT component followed by rapid cycle pilot test then full implementation.	<p>Mortality : non-ICU arrests Results:61% to 26% Statistics: p<0.05</p> <p>Cardiac arrest: no denominator Results: 36 to 17/ year Statistics no value given though stated to be statistically significant suggesting p<0.05</p> <p>Transfer to ICU per RRT call Results:21% to 14% Statistics: p<0.05</p>			Authors do not give denominator data for cardio-respiratory arrest nor mortality data though they do give denominator data for number of RRS calls.

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Benson, 2008 ³	1 of 4 advanced practice nurses (APN) responded to nurse initiated calls with intensivists and other disciplines involved as needed by the APN; if two calls received simultaneously ICU physician served as back up (RRT model with physician back-up)	Pre-post Not reported	NA	350-bed teaching hospital, US		Credentialing, information and education interventions (email, newsletter articles, rounding, informational sessions at meetings), clinical practice protocols developed	Mortality : average mortality per month Results:9% decrease (no actual rates or stats reported) Statistics: NR Cardiac arrest: 58.7% reduction in codes per 1000 admissions Results: 9.41 vs. 3.89 Statistics p = .0065 National Database of Nursing Quality Indicators (NDNQI®) Failure to Rescue rate Results:19.5% reduction (no actual rates or stats reported) Statistics: NR			

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Campello, 2009 ⁴	MET consists of ICU physician and ICU nurse RRS and implementation	Pre-post 88407 admissions	NA	470 bed non-teaching hospital in Portugal		Trained all staff in BLS then widened emergency call criteria (code) to include standard RRS criteria for deteriorating patients. Simulation training with mannequins, education, information posters.	Mortality : In-hospital total Results:5.35 (4.3-6.4) to 5.65 (4.9-6.4) 1000 admits Statistics: p=0.152 Cardiac arrest: Results: 4.21 (3.3-5.2) to 3.38 (2.8-4.0) 1000 admits Statistics p=0.037 cardiac arrest mortality Results:3.65 (2.8-4.5) to 3.18 (2.6-3.8) 1000 admits Statistics: p=0.014			Two data sets, one in the first 2 years after RRS and then 4 years post. Results in outcomes are for the 2-year follow-up; none of the significant differences were present at the 4-year follow-up.

Author, year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Chan, 2008 ⁵	Multi-component respiratory therapy and 2 ICU nurses (RRT model) RRS and education program	Pre-post 49171	NA	404 bed tertiary care academic urban medical center in US		education program but otherwise limited info	Mortality : hospital wide Results: 3.22 to 3.09/ 100 admits Statistics: AOR 0.95 (0.81-1.11) p=0.52 Cardiac arrest: non-ICU codes Results: 6.08 to 3.08/ 1000 admits Statistics: 0.59 (0.40-0.89) p=0.01 Hospital wide codes- Results: 11.2 to 7.5/ 1000 admits Statistics: AOR 0.76(0.57-1.01) p=0.06			Chose as a primary outcome total hospital code rate (including ICU codes) and found no benefit. ICU patients are not part of RRS exposure group. Their non-ICU (general ward) codes did drop significantly.

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Gerdik, 2010 ⁶	respiratory therapists and critical care nurses (RRT model) RRT and education	Pre-post not given	NA	696 bed academic medical center in US		Pilot program followed by campus wide implementation 8 months later. Worked with UHC collaborative in developing implementation. Secured stakeholders, then added patient and family activation	Mortality : total Results: 32.5 vs. 31.0/1000 admits Statistics: ns Cardiac arrest: Results: 25.2 vs. 17.4/month Statistics: none given ICU readmission Results: no data given Statistics: ns change			ICUs contributed FTE's to structure team. gave mortality data/1000 admissions but gave code data per month

Author, year	Description of PSP	Study Design	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Hanson, 2009 ⁷	<p>Peds MET consists of PICU fellow, PICU resident, PICU nurse and respiratory therapy</p> <p>RRS and education</p>	Pre-post approximately 11,800	NA	136 bed pediatric university affiliated hospital in US		Criteria development, Collaborative participation (IHI), planning, education, hospital wide implementation	<p>Mortality : ward (not total) but included those with DNR (i.e. expected and unexpected) Results: 1.5 vs. 0.45/ 1000 admits Statistics: RR= 0.30 (0-1.04) p= 0.07</p> <p>Cardiac arrest: ward Results: 1.27 vs. 0.45/ 1000 admits Statistics RR= 0.35 (0-1.24) p=0.126</p> <p>time between codes Results: 2512 to 9418 patient days Statistics: not given</p> <p>Total hospital mortality Results: 9.64 vs. 7.31/ 1000 admits Statistics: RR=0.076 (0-1.03) p= 0.078</p>			

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Hatler, 2009 ⁸	ICU nurse and respiratory therapy (RRT model) RRT and education	Pre-post 50209	NA	620 bed not-for profit urban non-teaching hospital in US		Team structure, alert criteria, documentation development, education	Cardiac arrest: Results: 0.93 vs. 0.63/1000 discharge Statistics not given, may be ns			
Konrad, 2010 ⁹	MET consists of ICU nurse and ICU physician afferent and efferent limbs, education	Pre-post 277717 admissions	NA	900 bed teaching hospital in Sweden		direct and online intranet education, pocket cards for alert criteria with an education period during the initial implementation	Mortality : adjusted total Results: RR 0.9 Statistics: p=0.003 Cardiac arrest: Results: 1.12 vs. 0.83/1000 admissions Statistics p=0.035 180 day mortality Results: 37% vs. 15.8% Statistics: NR LOS Results: no change		Adjusted mortality was significantly decreased in both medical and surgical patients	Only study to report long-term mortality

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Kotsakis, 2011 ¹⁰	Peds MET consists of Peds ICU attending and/or fellow, respiratory therapists and ICU nurse available to inpatients on general wards via paging. Had family activation. MET and Code team were same group of people (unified team)	Pre-post 111432 hospital admissions	NA	4 tertiary level pediatric hospitals Canada. Hospital sizes not given.	External : Funded by Ministry of Health	3 phases, development 1. education phase 2. pilot phase when team only avail M-F during day 3. Full 24/7 7d/week implementation. MET and Code Blue Team were the same group (unified team)	Mortality: total hospital mortality: 10 vs. 9.6/1000 admits Statistics: NS Cardiac arrests: Results: 1.9 vs. 1.8/ 1000 admits Statistics: NS ICU mortality Results: 0.3 vs. 0.1/ 1000 hospital admits Statistics: p=0.05 ICU readmission Results: NR Statistics: NR			Prospectively collected after implementation

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Laurens, 2011 ¹¹	MET consisted of anesthesiologist, medical house officer and ICU/ED nurse. responds to any patient outside ICU describes the alert criteria, education process and RRS process	Pre-post 96000 admissions	NA	150 bed regional teaching hospital in Australia		One month education program prior to introduction of the MET with ongoing education. Formal training for MET team members and index cards for staff with alert criteria	Mortality: unadjusted hospital Results: 9.9 vs. 7.5/ 1000 admissions Statistics: RRR=24.2% p=0.003 Cardiac arrests: Results: 77 vs. 42/1000 admits Statistics: RRR=45.5% p=0.0025 ICU admissions Results: 22.4 to 17.6/ 1000 admissions Statistics: RRR=21.4% p=0.003			Decline in cardiac arrests may have been affected by increase in number of patient deemed Do Not Resuscitate by the team; use of MET was low, denominator based on average annual admits, did not give the exact number. Did not give confidence intervals. Did not present cardiac arrest data/1000 admits in text, only in graph.

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Lighthall, 2010 ¹²	MET consisted of ICU fellow, anesthesiologist, ICU tending, ICU nurse, pharmacist, respiratory therapist available 24/7 to general ward patients	Pre-post unclear	NA	150 bed VA hospital affiliated with a university medical school		Implemented after a 4 month education period	<p>Mortality : all Results: 2.71 vs. 2.24/100 discharges Statistics: p=0.04</p> <p>Mortality: non-DNR Results: 0.68 vs.0.39/ 100 discharges Statistics: p=0.003</p> <p>Cardiac arrest: Results: 10.1 vs. 4.36/100 discharges Statistics p<0.01</p>			Results for mortality were no longer significant after adjusting for secular trends in mortality; reduction in arrests was not significant until 10 months after RRS implementation; potential underutilization of the team; gives annual admissions but not the actual number of discharges/admissions as a denominator

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Rothberg, 2011 ¹³	Hospitalist-led MET including critical care nurse, respiratory therapist, intravenous therapist, and patient's physician (ICU physician served as back up)	Time series 154,382 admissions	NA	670-bed tertiary teaching hospital in US	Implementation tools : In accordance with the IHI program	Initial implementation on 2 med floors then spread to entire hospital over 3 months; Education included meetings, e-mails, and posters; anyone could activate; 75% calls from med, 20% from surgical	Mortality : Overall hospital mortality Results: 22 deaths/1000 admissions across study period Statistics: NS Cardiac arrest: Cardiac arrests did not change significantly Results: 7.3 to 4.2/1000 admissions Statistics p<0.0001 Rate of fatal codes/1000 admissions Results: Delta = 0.06 (no specific pre post rate reported in text, graphed in figure 4 only) Statistics: p = .65		Stratified analyses by codes within critical care vs. codes outside critical care:	Codes called for medical crises declined for units outside critical care only; Rate of MET activation (18 calls/1000 admissions)

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Santamaria, 2010 ¹⁴	MET consists of ICU registrar, general medical registrar and the ICU nurse. separate code team Describes a MET program	Other controlled study (see comments) Between 14,838 and 26,575 admissions, depending on sample point	NA	400 bed tertiary teaching hospital	Implementation tools: Part of the MERIT study	Created MET as part of MERIT study, they were a MET hospital in that study	Mortality : unexpected Results: 0.58 vs. 0.30/1000 admits in last time period Statistics: p<0.05 Cardiac arrest: Results: 0.78 vs. 0.25/1000 admits in last time period Statistics p<0.001 Unanticipated ICU admission Results: 0.65 vs. 0.89/1000 admits in last time period Statistics: ns			Was one of the MERIT study MET hospitals but this data includes time periods beyond the MERIT study. They have several sample epochs for comparison of the longitudinal long term effects of MET -rates of calling the MET increased over each time period, as cardiac arrest and mortality rates fell
Sarani*, 2011 ¹⁵	2 separate METs one for surgery and one for medicine. Both teams have critical care nurse, pharmacy, reps therapy, resident from primary team, ICU attending or fellow during daytime and a telemedicine ICU attending at night. describes criteria for RRS and the structure	Pre-post 140,583 discharges	NA	Academic hospital in US. Size not given		Limited, states cardiac surgical service did not participate but nothing beyond that	Mortality: hospital mortality Results: Medical: 4.29 vs. 3.23%, p<0.001; Surgical: 1.21 vs. 1.11% Statistics: ns Cardiac arrest Results: 4.07 vs. 2.32/1000 discharges Statistics: p<0.001		Surgical vs. medical	Significantly higher reduction in cardiac arrest rate in medical (40%) vs. surgical (32%) (p<0.001); mortality decreased significantly only on medical service; medical service had 3 times higher cardiac arrest rate - otherwise, few differences. Describes case-mix but does not explicitly state there was adjustment.

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Scott, 2009 ¹⁶	ICU nurse and respiratory therapy (RRT model) RRT and education	Pre-post not given	NA	640 bed tertiary teaching hospital		1 month pilot followed by house-wide implementation	Cardiac arrest: Results: 7 vs. 2/1000 patient days Statistics: unknown			No sample size and no statistical analysis
Shah*, 2011 ¹⁷	ICU nurse and respiratory therapist (RRT model) describes criteria and what constitutes a code	Pre-post 231,305 patient days, 61,389 admissions	NA	3 affiliated academic hospitals in the US.		Pre-intervention period followed by a 9 month roll-out followed by full intervention period	Mortality: In-hospital: Results: 2.4% vs. 2.06%, 1.94%, 2.46% in subsequent post-implementation period, respectively Statistics: p=0.03, 0.01, and 0.83 respectively for each post-implementation period. Cardiac arrests Results: 0.83 vs. 0.98/1000 final period Statistics: p=0.3			Existing in-house code team could have affected effectiveness- physicians are already available; RRT call rate was 26.7 per 1000 hospital admissions

Author, year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Description of Organization	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes	Comments
Tibballs, 2009 ¹⁸	Directed by hospital's resuscitation officer, RN coordinating position, MET included ICU physician and RN, ED physician and RN	Pre-post 104780 admissions pre, 138424 post	NA	215-bed tertiary care pediatric hospital, Australia		Included intensive education, hiring additional ICU nurses	<p>Mortality: total in-hospital Results: 4.38 vs. 2.87/1000 admits Statistics: RR=0.65 (0.57-0.75) p<0.0001</p> <p>Mortality: unexpected general ward Results: 0.12 vs. 0.04/1000 Statistics: RR=0.35 (0.13-0.92) p=0.03</p> <p>Cardiac arrest: unexpected non-ICU Results: 0.19 vs. 0.17/1000 admits Statistics RR=0.91 (0.50-1.64) p=0.75</p> <p>Cardiac arrest: preventable non-ICU Results: 0.16 vs. 0.07/1000 admits Statistics: RR=0.45 (0.2-0.97) p=0.04</p>			Article also discussed issues with definitions of cardiac arrest, preventable arrest

* one reviewer had indicated that the article did not apply but a subsequent reviewer included and data was available

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Table 2, Chapter 24. Implementation table—RRS

Author, year	Description of RRS	Study Design	Main Study objectives	Description of Organization	Implementation Themes	Comments
Adelstein, 2011 ¹	offered in Appendix A but appendix not with pdf. uses two tiered mechanism for calling for assistance	prospective evaluation of breaches of PACE system before and after changes	to assess if new strategies could improve the time to delivery of MET components as compared to previous MET system	750 bed tertiary university affiliated hospital	centralized activation system, review of all events, automatic escalation to code team if MET did not respond within 30 min, institution of nurse educator for training and compliance	quantitative
Buist,* 2007 ²	Senior ICU nurse, senior ICU registrar and medical ward registrar.	before after design	too assess impact of change programs (education program for new interns, nurse liaisons, and development programs for hosuestaff) on incidence of cardiac arrest	400 bed suburban teaching hospital (first one in the world to have a true MET)	nurse liaison, career development and education/oreintation	
Calzavacca, 2010 ³	MET system with ICU registrar and ICU nurse, 24/7 coverage for inpatients on general wards.	cohort comparison (early MET time period and another time period several years later)	Does maturation of a RRS improve the failure to rescue rate (recognition of deterioration) and the associated outcomes	400 bd teaching hospital with several years of having a MET program (one of the earliest hospitals to have one)	change in delayed activations (late recognition), unanticipated ICU admission institution of NFR (DNR) orders	
Chen, 2010 ⁴	physician led MET consisting of senior ICU registrar, general med registrar and ICU nurse (MERIT study)	cluster-randomized	to assess reasons for calling emergency help between hospitals with a MET and those without	multiple (MERIT study hospitals)	effect of teaching hospital, metropolitan hospital, patient location and time of activation	
Cretikos, 2007 ⁵	ICU registrar, ICU nurse, general medicine registrar (MERIT trial MET hospitals)	prospective	To assess the process components of MET implementation that correlated with utilization	12 hospitals of varying sizes (the 12 MET hospitals in the MERIT trial)	knowledge of activation criteria, understanding of MET purpose, perceptions of readiness for change, overall attitude to MET program	Quantitative but only to utilization rates not outcomes

Author, year	Description of RRS	Study Design	Main Study objectives	Description of Organization	Implementation Themes	Comments
Donaldson, 2009 ⁶	not known as it involved multiple hospitals, probably varied	multi-modal (qualitative using interviews)	Identify factors associated with successful implementation, develop plans to help others replicate such success, standardize process measures, evaluate impact through nurse perceptions.	multiple (>500 hospitals, nested within 9 multihospital grantee organizations)	Extra resources, rapid transfer, communication enhancement, "one stop shopping"(single team assessment), robust early adopters vs. late or poor functioning RRS	Very qualitative, did not define successful RRSs by any objective criteria
Foraida, 2003 ⁷ , DeVita, 2004 ⁸	ICU registrar, Anesthesia, ICU nurse, resp therapy; 8 defined roles-Team leader airway manager, airway assistant, procedure physician, chest compressions, runs medication/ equipment chart, recorder, bedside nursing	prospective	to determine if specific educational and feedback interventions would increase MET utilization	567 bed tertiary urban teaching hospital	immediate review of all stat sequential paging events, feedback to those involved in delaying MET activation, creating better objective alert criteria, dissemination and education for those new criteria. Increase MET calls, and decrease multiple primary service stat sequential pages.	Quantitative data on utilization and incidence of cardiac arrest but not mortality
Genardi, 2008 ⁹	not given	prospective	to revitalize their existing RRT and improve on code reductions	community hospital (size not given)	education, support for nurses, critical thinking skills, increase access to RRT, change to centralized paging rewards program (recognition of effort), improved documentation, alter alert criteria, ensure competencies	Quantitative, gives change in codes and mortality before and after change (% decrease only, no statistics reported)

Author, year	Description of RRS	Study Design	Main Study objectives	Description of Organization	Implementation Themes	Comments
Jones, 2006 ¹⁰	Pre-intervention had a unified code/MET team with anesthesiology, ICU and cardiology registrars, ICU nurse and primary service physician, post intervention separate the functions dropping the cardiology and anesthesiology members from the separate MET	prospective before after trial	to assess whether systems changes in existing MET would increase utilization rate	350 bed tertiary university affiliated hospital	Team composition (separation of unified code/MET into separate teams with separate activations), Method of activation (changing the activation methods to separate the teams), Triggers (changing alert criteria for calling a MET) re-education on purpose of MET, criteria, and the changes	Quantitative data for utilization rates and incidence of true code calls
Jones, 2006 ¹¹	ICU registrar, ICU nurse and receiving unit medical registrar. Separate from the code team	prospective interventional but continuous as opposed to before after with defined intervention change	assess education program to increase utilization of existing MET	400 bed tertiary university affiliated hospital	education, improved communication, on-the-job aids (e.g., posters, observational charts), differences in MET usage for medical vs. surgical admissions	Quantitative data on utilization rate but it is continuous so may wish to exclude
Jones, 2010 ¹²	Rapid response nurse (2 dedicated positions), patient's on-call physician	prospective	to determine if mandatory activation of MET improves outcomes compared to elective activation	872 bed academic hospital	conversion from elective MET activation to mandatory based on alert criteria Almost all METs/RRTs are not mandatory activation by staff despite alert criteria being met	Quantitative data on utilization and incidence of cardiac arrest.
Shapiro, 2010 ¹³	various, different hospitals	mixed, mostly semi-structured focus groups	to determine nurses perceptions of RRS impact on practice and what constitutes a successful RRS	multiple	impact on practice, characteristics of successful teams	

Author, year	Description of RRS	Study Design	Main Study objectives	Description of Organization	Implementation Themes	Comments
Williams,* 2011 ¹⁴	RRT model with ICU nurse, ED nurse, reps therapist	focus group methodology	clarify nurses perceptions of RRS	156 bed community hospital	experience with activation, composition of teams, concerns about activating a RRT advantage of RRT to nurses and patients	

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Table 3, Chapter 24. Patient safety-RRT: risk of bias

Author, year	Was the allocation sequence adequately generated?	Was the allocation adequately concealed?	Were baseline outcome measurements similar?*	Were baseline characteristics similar?	Were incomplete outcome data adequately addressed?	Was knowledge of the allocated interventions adequately prevented during the study?	Was the study adequately protected against contamination?	Was the study free from selective outcome reporting?
Anwar ul, 2010 ¹	No	No	Unclear	No	Unclear	No	Yes	Yes
Bader, 2009 ²	No	No	Unclear	No	Unclear	No	Yes	Unclear
Benson, 2008 ³	No	No	Unclear	No	Unclear	No	Unclear	No
Campello, 2009 ⁴	No	No	Yes	Unclear	Unclear	No	Yes	Yes
Chan, 2008 ⁵	No	No	Yes	No	Unclear	No	Yes	No
Gerdik, 2010 ⁶	No	No	Unclear	No	Unclear	No	Yes	Yes
Hanson, 2009 ⁷	No	No	Unclear	No	Unclear	No	Yes	Yes
Hatler, 2009 ⁸	No	No	Unclear	No	Unclear	No	Yes	Yes
Konrad, 2010 ⁹	No	No	Yes	No	Unclear	No	Yes	Yes
Kotsakis, 2011 ¹⁰	No	No	Yes	Yes	No	Yes	Yes	Yes
Laurens, 2011 ¹¹	No	No	Yes	No	Unclear	No	Yes	Yes
Lighthall, 2010 ¹²	No	No	Yes	Unclear	Unclear	No	Yes	Yes
Rothberg, 2011 ¹³	No	Unclear	Unclear	No	Yes	No	Unclear	Yes
Santamaria, 2010 ¹⁴	No	No	Yes	Unclear	Unclear	No	Yes	Yes
Sarani*, 2011 ¹⁵	No	No	No	Unclear	Unclear	No	Yes	Yes
Scott, 2009 ¹⁶	No	No	Unclear	No	Unclear	No	Yes	Unclear
Shah*, 2011 ¹⁷	No	No	Yes	Yes	Unclear	No	Unclear	Yes
Tibballs†, 2009 ¹⁸	No	No	Unclear	No	Yes	No	Yes	Yes

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Evidence Tables for Chapter 25. Medication Reconciliation Supported by Clinical Pharmacists (NEW)

This review had no additional evidence tables.

Evidence Tables for Chapter 26. Identifying Patients at Risk for Suicide: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 27. Strategies To Prevent Stress-Related Gastrointestinal Bleeding (Stress Ulcer Prophylaxis): Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 28. Prevention of Venous Thromboembolism: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 29. Preventing Patient Death or Serious Injury Associated With Radiation Exposure from Fluoroscopy and Computed Tomography: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 30. Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 31. Human Factors and Ergonomics

This brief review had no additional evidence tables.

Evidence Tables for Chapter 32. Promoting Engagement by Patients and Families To Reduce Adverse Events (NEW)

Table 1, Chapter 32. Evidence table: patients engagement

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes	Comments
Weingart, 2004 ¹	Proving patients with personalized medication list to help prevent medication errors	RCT 209	No	Boston teaching hospital	Organizational characteristics: a 40-bed unit; The unit used paper medication order forms that were faxed to the pharmacy and entered into the hospital's electronic pharmacy information system; CPOE not available at time of study		Patient surveys; identification of med incidents through interviews of pharmacists, housestaff, electronic review	adverse drug rate between intervention and control 8.4% versus 2.9%, p=0.12 close-call rate between intervention patients and controls (7.5% versus 9.8%) p=0.57 patients aware of drug-related mistakes during the hospitalization-11%			
McGuckin, 2004 ²	Asking all health care workers who had direct contact with them, "Did you wash/sanitize your hands?"	Pre-post 35	No	A 24-bed inpatient rehabilitation unit located in an acute care university hospital	Teamwork, leadership, culture: Nurse manager was member of research team	Visit with patient by premed to discuss hand hygiene (HH); education brochure; prompt to ask providers re HH; video; visual aid prompt	soap/sanitizer usage per resident-day before, during, and after the intervention	Hand Hygiene per resident day 5 to 9.7 during intervention, 6.7 at 6 weeks, 7.0 at 3 months. p<0.001 for all timepoints		Patients asked physicians 40% of time, nurses 95% of time	% of patients comfortable asking - 75% % of HCWs washing hands when asked by patient-60%

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes	Comments
Stone 2007 ³	<p>'Patient empowerment' (materials telling patients to ask HCWs to clean their hands).</p> <p>Included other interventions as well as patient engagement: bedside alcohol hand rub, ward posters changed monthly, pts encouraged to ask HCWs to clean their hands). An optional component was six-monthly audit and feedback of hand hygiene</p>	Pre-post 187 acute hospitals	No	187 acute hospitals	Implementation Tools: National Patient Safety Agency's 'Clean Your Hands Campaign' (CYHC) seeks to improve 293 healthcare workers' (HCWs) hand-hygiene behaviour in England and Wales			<p>Monthly median alcohol hand rub (AHR) use: 44 pre to 56 post; p<0.001</p> <p>Combined median use of AHR and soap: 13.2 to 31 ml/patient bed-day;</p> <p>Health care-associated infection rates: No changes apart from seasonal changes in norovirus and CDAD</p>		increase may have been confounded by a change in soap/AHR provider	limitations of self-reported data; high response rate; targeting use of AHR, changed many aspects of hand-hygiene behaviour, increasing AHR use in particular, across the acute sector of the NHS without reducing soap usage. Audit and feedback, a component emphasized much less than AHR and posters, was less widely implemented.

Table 2, Chapter 32. Evidence table: patient's engagement, risk of bias

	Was the allocation sequence adequately generated?	Was the allocation adequately concealed ?	Were baseline outcome measurements similar?*	Were baseline characteristics similar?	Were incomplete outcome data adequately addressed?*	Was knowledge of the allocated interventions adequately prevented during the study? *	Was the study adequately protected against contamination?	Was the study free from selective outcome reporting?
Weingart, 2004 ¹	Yes	Unclear	Yes	No	Unclear	Yes	No	Yes
McGuckin, 2004 ²	No	No	Yes	Yes	No	No	No	No
Stone 2007 ³	No	No	Unclear	not applicable	Unclear	No	Yes	Yes

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Evidence Tables for Chapter 33. Promoting a Culture of Safety

Table 1, Chapter 33. Patient safety culture: evidence table

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Abstoss, 2011 ¹	<p>7 interventions: -Culture: Feedback on errors (posters and emails), QI education and training (TV channel and curriculum) -System: CPOE, medication management (pharmacist), pt safety report form revisions</p> <p>4 cultural & 3 system-level interventions</p>	<p>Pre-post</p> <p>Post 2009 (n = 85, resp. rat = 90%)</p>		University of Michigan's C.S. Mott Children's Hospital PICU	Organizational: characteristics 2007-2009	Cannot tell how much training staff got and who received it//Poster tracking 'Days since last medication error with harm' and detailed emails	Safety Attitudes Questionnaire (SAQ) *only 13 items related to medication error/reporting are reported in this study	<p>Culture survey: Teamwork climate: 52.8% to 71.8% agreement; Safety climate: 54.6% to 63.4% agreement (not sig) (p < .01) and (p = .13)</p> <p>Reported errors resulting in harm 0.56 to 0.15 events/10,000 doses p<0.01</p> <p>Overall error reporting rate 3.16 to 3.95/10,000 doses ns</p>			**Still abstracting

Table 1, Chapter 33. Patient safety culture: evidence table (continued)

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Adams-Pizarro, 2008 ²	Regional improvement collaboratives; ICU initiatives included rounding and daily goals, ventilator bundle	Pre-post 429 in 14 hospitals (individual response rate = 65%)	IHI breakthrough series model, Culture Improvement Guide	20 ICUs	External: Collaborative, state safety organization Organizational characteristics: Average 272 inpatient beds, 86% urban, 36% teaching	IHI model, facilitated workshops and coordination through outside safety organizations//Culture improvement guide toolkit - resources for understanding culture, planning culture interventions based on the initial culture assessment in each unit; OR improved more dimensions than ICU, ED	AHRQ Hospital Survey on Patient Safety (HSOPS)	Culture survey: only 3 of 12 domains showed improvement; decrease by 13.6 in one overall measure (Safety Grade) and Overall Perception of Safety decreased 1%			Also included EDs and ORs - only including ICU data here. Only 56% of ICUs completed both surveys and are included

Table 1, Chapter 33. Patient safety culture: evidence table (continued)

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Blegen, 2010 ³	Triad for Optimal Patient Safety (TOPS): (1) team training, (2) unit based safety team, (3) patient engagement in daily goals	Pre-post -3 inpatient medical units nested in 3 different hospitals; post n = 368 (response rate = 81%)		1 academic, 1 community, 1 integrated healthcare system; 26-34 beds; 1 nurse:4-5 patients	Organizational: characteristics: All hospitals located in San Francisco Bay area, CA; Differed in physician care model, pharmacy presence on the unit, and use of information technology, 2006-2007 Leadership: leadership provided protected time for a unit-level project champion on each unit	(1) 4hr. team training (2) Unit safety team; identified safety concerns, model effective team behavior, small group learning sessions (3) Nurses worked with patient/family daily on daily goals card	AHRQ Hospital Survey on Patient Safety (HSOPS)	Culture survey: Increases in mean dimension score significant for 5 of 10 dimensions p < .05 for all 5		Site x time interaction on 6 dimensions; Post diffs among professional groups, 3 culture dimensions	-Significant site x time interactions- culture scores for one hospital did not change or changed in negative direction - without that unit, the analysis in the other 2 hospitals showed changes in all 10 dimensions (no indication of which unit was dropped) -Differences also found between professional groups on 3 dimensions, overall perceptions of safety, and frequency of event reporting; nurses tended to score culture most positively post intervention compared to physicians and pharmacists

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Cooper, 2008 ⁴	Simulation-based anesthesia crisis resource management training.	pre-post with control hospitals 293, response rate 38%		4 academic medical centers associated with Harvard. 2 control academic medical centers. in Massachusetts.	Not reported	One-day, 6 to 7 hour simulation-based anesthesia crisis resource management training session in 4 hospitals. 2 control hospitals, staff did not receive training.	Patient Safety Climate in Healthcare Organizations (PSCHO)	Culture survey: No significant differences			

Table 1, Chapter 33. Patient safety culture: evidence table (continued)

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Donahue, 2011 ⁵	prepare paraprofessionals to communicate changes in patient status using structured communication, including reducing cultural barriers to interdisciplinary communication	Pre-post 111 (41%) post survey (paraprofessionals only)	IHI Spread for Change Framework, Crew Resource Management techniques	Danbury Hospital, Danbury, CT; Not described	Leadership: Chief Nursing Executive, Chief Medical Officer - involvement and messaging	IHI "Spread for Change" Framework/Meetings with stakeholder groups; unit-based champions, education and training (SBAR, communication focused); executive walk rounds	AHRQ Hospital Survey on Patient Safety (HSOPS)	Culture survey: Reported change (improvement of >10%) on 4/42 survey items Use of structured communication (SBAR) 74% to 90% increase Not reported Rapid response events reported Increase from 351 to 487; Decrease in number of RRS events that led to code events (29% pre, 22% post) Not reported			Also includes some qualitative data from focus groups describing change in communication after implementation

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Frankel, 2008 ⁷	rigorous WalkRounds	Pre-post 702 of all professions, 21 patient care areas, resp rate 60% (n =1, 256; 45% RN)		1 academic, 1 community teaching, US	Organizational characteristics: US, 2002-2005, Leadership: Senior leaders were core participants in intervention planning and execution	Quality and safety personnel responsible, training, feedback//Hospital senior executive rounds on unit; database of safety concerns, recommendations, and actions taken to address the issues	Safety Attitudes Questionnaire (SAQ)	Culture survey: 62% to 77% in 1 hospital, 46% to 56% in 2nd hospital p=0.03 and 0.06 in the 2 hospitals			Only 2 of 7 hospitals complied fully with approach & only those results are reported; also only SAQ results from units with >50% response rate are reported (about half of the units). 2 hospitals did not implement Walk Rounds rigorously -no significant change in those units

***Table 1, Chapter 33. Patient safety culture: evidence table (continued)**

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
O'Leary, 2010 ⁹	Structured interdisciplinary rounds, regular interdisciplinary meetings Structured interdisciplinary rounding format, regular interdisciplinary meetings	Concurrent control n = 147 (response rate = 92%)		2 teaching service units (30 beds each) in a 897-bed tertiary care teaching hospital	Not reported	Structured interdisciplinary rounds each weekday using structured communication tool; Interdisciplinary working group met for 12 weeks before implementation, developed format, frequency, timing	Safety Attitudes Questionnaire (SAQ)	Culture survey: Teamwork climate: Mean, control = 77.3, intervention = 82.4; Safety climate, mean: Control = 75.4, Intervention = 76.5 Teamwork (p = .01); Safety (n.s., p = .90) Length of Stay adjusted LOS was 0.19 days longer for the intervention unit vs. control n.s. (p = 0.17) Cost adjusted cost was \$24.05 less for the intervention unit vs. control n.s. (p = 0.94)			Teamwork climate was significantly higher for intervention unit nurses (83.5 vs. 74.2, p = .005), but there was no significant difference on safety climate. Teamwork and safety climate were rated higher by intervention Physicians but not statistically significant

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
O'Leary, 2011 ⁸	Structured Inter-Disciplinary Rounds	concurrent control 49 nurses in both units (84% response rate)		large tertiary care teach hospital, hospitalist unit, 30 beds	Not reported	every weekday, 30 minutes, led by nurse manager and unit medical director, used structured communication tool	Safety Attitudes Questionnaire (SAQ) (teamwork and safety domains)	Culture survey: median 75 intervention, 61.1 control p=0.03 Rating of quality of communication and collaboration with hospitalizes 80% intervention vs. 54% control p<0.01 Teamwork climate median 85.7 intervention, 61.6 control p=0.008			

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Paine, 2010 ¹⁰	Comprehensive Unit-Based Safety Program, hospital-wide training, culture score goal setting Hospital-wide, multiple interventions	Pre-post 5461 surveys post (144 units), 79% response rate		Large urban academic center	Organizational: characteristics: Substantial safety infrastructure, event reporting Leadership: Leadership representative for each CUSP, Board of Trustees engagement	CUSP includes patient safety office coach; units with low safety climate encouraged to implement CUSP	Safety Attitudes Questionnaire (SAQ)	Culture survey: Improvements in all SAQ domains except stress recognition p<0.001			Culture scores decreased in 17 of 144 units, details not reported, informal interviews suggested that manager turnover, unit construction, and implementation of new IT may have contributed to lower scores
Pettker, 2009 ¹¹	protocol standardization, creation of patient safety RN position and patient safety committee, team skills training risk-reduction clinical practices and creation of a comprehensive culture of safety.	Pre-post not reported		Tertiary-level academic medical center. OB service averages 5500 admissions per year.	Organizational: characteristics: academic medical center, OB service, urban/suburban	Incremental 2004-2006: expert review, protocol standardization, patient safety RN and committee, team skills training, fetal heart monitoring certification, crew resource management team training	Safety Attitudes Questionnaire (SAQ)	Culture survey: %reporting good teamwork climate & good safety climate improved from 38.5% to 55.4% and 33.3% to 55.4%, respectively. Adverse outcomes index indicators 3.3% pre to 1.6% post P= .011			

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Pettker, 2011 ¹²	NOT ABSTRACTED- this article already abstracted - just culture results are here	Not recorded post 183 - response rate 72%						Culture survey: Statistically significant improvements on 4 domains, worsening 1 (Perceptions of favorable working conditions, no change 1 <p 0.05 for 5 (4 improved, 1 worse)			NOT ABSTRACTED- this study already abstracted for the other article reporting on this - just culture results are here. NO ROB done either.
Riley, 2011 ¹⁴	TeamSTEPPS® didactic training program, TeamSTEPPS with in-situ simulation training exercises Didactic training with in-situ simulation v. didactic only	Cluster RCT not reported how many completed survey	Reason's model	3 rural/suburban US community labor and delivery units, 50-66 beds	Organizational: characteristics: midwest, 2005-2008	Local tailoring of TeamSTEPPS; simulation included detailed debriefing// 1 hospital - TeamSTEPPS didactic training (condensed); 1 - TeamSTEPPS with series of in-situ training exercises, repeated until staff targets were met	Safety Attitudes Questionnaire (SAQ)	Culture survey: perinatal outcomes - Weighted Adverse Outcomes Score %change -37% full, -1% didactic, +43% control p<0.05 for full intervention			cluster RCT

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Sexton, 2011 ¹⁵	CUSP (Comprehensive Unit-Based Safety Program), as part of Keystone ICU project	Pre-post Pre n = 4,260 (overall res. rate = 71%; 99 ICUs); Post n = 3,533 (overall res. rate = 73%; 71 ICUs)		71 Michigan hospitals 71 ICUS -68% Teaching -31% Faith-based -27% bed sz. >=500 -25% bed sz. 200-299	Organizational: characteristics: see description	CUSP Intervention_4Steps: (1) Educate staff on science of safety; (2) Identify errors/defects, (3) partner with senior leadership, (4) Use tool to learn from one defect per month//ICU project teams created. In addition to CUSP, also implemented intervention to reduce CLABSI and/or VAP, and Daily Goals checklist. Implementation period for each intervention approx. 3 months.	Safety Attitudes Questionnaire (SAQ)	Culture survey: The overall mean percent positive scores increased significantly from baseline to follow-up. Nine ICUs met 60% positive criteria for success in 2004 Mean safety culture %positive (pre = 42.5%, post = 52.2%, p < .001); (Results for specific questions reported in Table 2)		Hosp. size, faith-based: Gain higher for faith-based and small h., though diffs. not tested directly	Only reported data from ICUs that reported culture surveys at both time points (71 of 127 total ICUs)

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Thomas, 2005 ¹⁶	Executive walkrounds	Cluster RCT		711 bed academic tertiary care hospital inpatient units.	Not reported	In units randomized to receive executive walk rounds intervention, executives rounded once every 4 weeks for 3 visits per unit.	Safety Attitudes Questionnaire (SAQ)	Culture survey: 78 in both types of units NS			
Tiessen, B., 2008 ¹⁷	evaluate and reevaluate patient safety culture, encourage patient safety learning, share stories, weekly executive walkrounds, prioritize improvement efforts, identify staff safety concerns, implement improvements 8 point patient safety plan	Pre-post not stated; 35% response rate		88-bed, acute care, rural community hospital in Ontario, Canada.	External: Canadian Council on Health Services Accreditation new Patient Safety Required Practices, upcoming accreditation survey Organizational: characteristics: hospital financial situation issues, staffing changes and reductions Leadership: created Patient Safety Action Plan	The patient safety practices were rolled out, hospital-wide over a 2 year period (2005-2007).	Patient Safety Climate in Healthcare Organizations (PSCHO)	Culture survey: significant improvement on only 2 of 30 statements, significant decrease on one statement	one statement did show decrease 46 to 29% p=0.01	Hospital financial issues may have impacted effectiveness	Significant improvement on 2 statements: asking for help not a sign of incompetence, and If I make a mistake that has serious consequences, I tell someone about it.

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Timmel, 2010 ¹⁸	CUSP; video, identify safety hazards, learn from defects, teamwork and communication tools	Pre-post n = 28 (100% response rate)		1 surgical unit in a large, urban academic medical center	Leadership: Senior hospital executive participated as part of CUSP team	CUSP team met monthly, science of safety training, staff safety assessment, learning from 1 defect per month; baseline 2006, follow up in 2007 and 2008	Safety Attitudes Questionnaire (SAQ)	Culture survey: Safety climate: 80% to 90%; Teamwork climate: 56% to 80%; hospital management: 39% to 47%; Unit Management: 62% to 68%; Working conditions: 48% to 55%; Stress recognition: 45% to 46% all composite scores except stress recognition significantly improved from 06 to 08 (p < .001) Nurse turnover 3/12 FTEs left in 2006; 0/16 left in 2008 and 2009			

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Edwards, 2008 ⁶	Ad-hoc safety rounds, enhancements to error reporting system and related education, standardized communication protocols (SBAR), transfer of care checklist, implementation of EMR system 5 components, staggered implementation over time	Pre-post n = 428 (Response rate = 32%)		2 metropolitan pediatric tertiary care hospitals in same health system; 1 academic, 1 community	Organizational: see description Leadership: supported survey	2 initiatives to address error & perceptions of safety: Safety rounds, reporting system updates; 3 initiatives designed to improve hand offs and transitions across units: SBAR, transfer checklist, EMR	AHRQ Hospital Survey on Patient Safety (HSOPS)	Culture survey results: 6/11 domains significantly increased, 1 significantly decreased, 2 no significant change. P< 0.01		community hospital scored higher on 3 domains compared to academic hospital	Physicians were not surveyed, significant pre-intervention differences reported between hospitals on two domains of culture, but not accounted for in analyses; 3 interventions designed to improve hand-offs and care transitions-however, this domain score significantly decreased post-implementation; 2 interventions to improve overall perceptions, but no change post-implementation. Significant differences in post scores between hospitals; hospital x time interaction likely but not tested

Author, year	Description of PSP Multiple interventions or multifaceted interventions	Study design Sample size	Theory or logic model	Description of organization	Contexts	Implementation details	Measurement tool	Outcomes: Benefits	Outcomes: Harms	Influence of contexts on outcomes comment	Comments
Pronovost, 2005 ¹³	Comprehensive unit based safety program: (1) assess culture, (2) science of safety education, (3) staff identification of safety concerns, (4) senior executive involvement, (5) improvements implemented from #3, (6) efforts documented, (7) results shared, (8) reassessment of culture CUSP (8 step version)	Quasi-stepped wedge design WICU n = 64 (response rate = 86%); SICU n = 23 (Response rate = 84%)		2 ICU units in a large metropolitan tertiary care hospital	Leadership: Each unit was adopted by a senior level executive; dedicated improvement team to support intervention implementation	Forms for collecting/sharing improvement success stories, daily goals sheets, tool for medication errors. Science of safety education, staff identify how next patient will be harmed and how to prevent	Safety climate scale (SCS)	Culture survey results (nurse turnover and length of stay) WICU : 35% positive climate to 52% positive climate post; SICU 35% positive climate to 68% positive climate post Stats reported for individual questions, but not for overall domain changes; 8/10 p <0.05 in WICU, 3/10 in SICU had p < .05 WICU: decreased from 9% to 2%; SICU: Decreased from 8% to 2% P = NS WICU: decreased from 2 days to 1 day; SICU: Decreased from 3 days to 2.3 days P< 0.05			pre-post study in both units

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Evidence Tables for Chapter 34. Effect of Nurse-to-Patient Staffing Ratios on Patient Morbidity and Mortality

Table 1, Chapter 34. Evidence table

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Unruh and Zhang, 2012 ¹	Not a study of an intervention	Retrospective cohort 124 Florida hospitals between 1996 – 2004	A conceptual model is presented that relates case mix, location, ownership, size, and payer mix with changes in nurse staffing over time	124 Florida hospitals USA Academic status not reported No assessment of existing quality / safety infrastructure No assessment of organizational complexity SCTL: Not assessed	Not relevant, not a study of an intervention	Higher RN FTE were associated with better outcome for most, but not all AHRQ patient safety indicators, including failure-to-rescue	None mentioned	Case mix, urban status, Medicaid, and HMO days of care were all positively related to changes to failure-to-rescue	High
Needleman, et al., 2011 ²	Not a study of an intervention	Longitudinal assessment of changes in nurse staffing, and mortality in one hospital 197,961 patient admissions 176,696 nursing shifts	None	A single tertiary academic hospital recognized for exemplary care USA Nurse: careful assessment of actual nurse workload for specific patients Academic status assessed Existing quality and safety infrastructure and organizational complexity inferred from recognition by authorities as a “high quality” hospital	Not relevant, not a study of an intervention	Exposure to each shift with a RN staffing level below target increased risk of death by 2% In non-ICU patients, risk increased 4%	None mentioned	High patient turnover also associated with worse outcomes	Low

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Twigg et al., 2011 ³	Not a study of an intervention per se, Western Australia ordered the introduction of a new staffing method for nurses	Described as an interrupted time series, but presented as a pre / post assessment 236,454 patients 150,925 nurse staffing records	None	3 adult tertiary teaching hospitals Australia Nurse hours of care and skill mix Academic states assessed No assessment of existing quality / safety infrastructure Organizational infrastructure described in terms of comprehensive clinical services being provided SCTL: Not assessed	Not relevant, not a study of an intervention per se	For all patients and for medical and surgical patients the death rate decreased significantly	None mentioned	None mentioned	High
Aiken et al., 2010 ⁴	Not a study of an intervention per se, rather California legislation mandated certain nurse-to-patient ratios	Cross-sectional 22,336 hospital nurses in California	None	California staff nurses USA RN staffing, patient-nurse workload Academic status assessed No assessment of existing quality / safety infrastructure SCTL: Not assessed	Not relevant, not a study of an intervention per se	Lower patient-to-nurse staffing ratios were associated with lower 30-day mortality and failure to rescue	25% of RNs reported they perceived decreased support from LVNs, 34% of RNs reported decreased support from unlicensed personnel	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Harless and Mark, 2010 ⁵	Not a study of an intervention Longitudinal analysis of changes in nurse staffing in California between 1996 - 2001	283 California hospitals 11,945,226 adult inpatients	None	283 acute care hospitals USA Numerous financial and economic payer variables No assessment of quality / safety infrastructure No assessment of organizational infrastructure SCTL: Not assessed	Not relevant	Each increase in one RN FTE per 1,000 patient days was associated with a 4.3% decrease in mortality	None mentioned	None mentioned	High
Schilling et al., 2010 ⁶	Not a study of an intervention	Retrospective cohort 166,920 adults admitted to Michigan hospitals in 2003 - 2006 with an emergency department admission for any of 4 diagnosis	None	39 Michigan hospitals USA Nurse staffing estimated by taking the ratio of each hospital's FTE for RN and dividing by patient-days No assessment of existing quality / safety infrastructure No assessment of organizational infrastructure SCTL: Not assessed	Not relevant, not a study of an intervention	Each additional RN FTA per patient-day was associated with a 0.25% decrease in mortality	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Aiken et al., 2008 ⁷	Not a study of an intervention	Retrospective cross-sectional 10,184 nurses (50% random sample, response rate 52%) and 232,342 surgical patients	None	168 acute care hospitals in Pennsylvania 1998-1999 USA RN staffing – mean patients per nurse, Nurse education , A composite score of the care environment, encompassing subscales from the Nursing Work Index Academic status assessed No assessment of existing quality safety infrastructure High vs. low technology assessed SCTL: Practice Environment Scale (PES) of the Nursing Work Index (NWI) gets at a related concept.	Not relevant, not a study of an intervention	30-day mortality rate for general surgical patients reported as 19.5 per 1,000 admissions (1.95%). 30-day-failure-to-rescue rate reported as 84.4 patients per 1,000 admissions (8.4%). More nurse staffing and higher nurse education levels were found to be associated with lower 30 day mortality and lower 30-day failure-to-rescue.	None mentioned	Better care environments were found to be associated with lower 30 day mortality and lower 30-day failure-to-rescue.	High
Cho et al., 2008 ⁸	Not a study of an intervention	Retrospective cross-sectional 27,372 ICU patients	None	236 hospitals Korea Mean years of ICU nurse experience, RN staffing SCTL: Non-US/UK/Canada/Australia/New Zealand study	Not relevant, not a study of an intervention	Each additional assigned patient per RN in secondary hospitals was associated with a 9% increase in odds of dying; there was no statistically significant association of nursing experience with mortality.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Kiekkas et al., 2008 ⁹	Not a study of an intervention	Observational prospective cross-sectional Convenience sampling of 396 patients	None	A general tertiary 14-bed academic hospital between October 2005 and September 2006 Greece Daily nursing workload/ workload exposure SCTL: Non-US/UK/Canada/Australia/New Zealand study	Not relevant, not a study of an intervention	No statistically significant associations were found in risk-adjusted ICU mortality.	None mentioned	None mentioned	High
Hamilton et al., 2007 ¹⁰	Not a study of an intervention	Prospective cohort 2,636 low birth weight or preterm infants	None	54 neonatal ICUs. UK Total number of RNs per shift, Nursing provision ratio per shift, Specialist nursing provision ratio per shift Academic status not reported No assessment of existing quality / safety infrastructure No assessment of organizational complexity SCTL: Not assessed	Not relevant, not a study of an intervention	Higher specialist nursing provision was statistically significantly associated with a lower risk-adjusted observed mortality rate.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Mark et al., 2007 ¹¹	Not a study of an intervention	Retrospective cross-sectional 3.65 million pediatric patient discharges	None	286 general acute care and children's hospitals in California between 1996 and 2001. USA RN staffing, Licensed vocational nurse (LVN) staffing, Unlicensed hours of care provided per patient day Academic status assessed No assessment of existing quality/safety infrastructure Presence of pediatric ICU or NICU SCTL: Not assessed	Not relevant, not a study of an intervention	No relationship was found between in-hospital pediatric death and nurse staffing for hospitalized California pediatric patients.	None mentioned	None mentioned	High
Rafferty et al., 2007 ¹²	Not a study of an intervention	Retrospective cross-sectional 118,752 surgical patients and 3,984 nurses (mostly RNs) (response rate = 49.4%)	None	30 acute trusts in 1998. UK Mean hospital patient-nurse ratio derived from survey of nurses Academic status assessed No assessment of existing quality/safety infrastructure No assessment of organizational infrastructure SCTL: Not assessed	Not relevant, not a study of an intervention	The highest quartile of patient-to-nurse ratios was associated with a 26% higher mortality rate and 29% higher failure-to-rescue rate than the lowest quartile of patient-to-nurse ratios.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Stone et al., 2007 ¹³	Not a study of an intervention	Retrospective cross-sectional Convenience sample of 15,846 ICU patients and 1,095 RN were surveyed (average response rate = 60%)	A conceptual framework was presented that related the potential contributions of patient characteristic, structures of care, and administrative processes including organizational climate, staffing, overtime and wages on patient outcomes.	51 ICUs in 31 acute care hospitals. USA Nursing staffing measured by RN hours per patient day in the ICU, Overtime use measured as proportion of overtime to regular hours, Organizational climate in ICU measured as composite score of Perception of Nurse Work Environment (Choi et al., 2004). Academic status assessed Financial status assessed No assessment of existing quality/safety infrastructure No assessment of organizational infrastructure SCTL: Organizational climate assessed with the perceptions of Nurse Work Environment	Not relevant, not a study of an intervention	Patients admitted to ICUs with more RN hours per patient day had significantly lower 30-day mortality. No significant relationship was observed between overtime use and 30-day mortality.	An increase in catheter-associated bloodstream infections in organization with a more positive organizational climate	No significant relationship was observed between organizational climate and 30-day mortality.	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Tourangeau, Doran, et al., 2006 ¹⁴	Not a study of an intervention	Retrospective cross-sectional 49,993 patients with four diagnoses: acute myocardial infarction, stroke, pneumonia, or septicemia and 3,886 nurses (response rate = 65%)	A conceptual framework was presented that included numerous variables in six categories: condition of the hospital practice environment, nurse staffing, physician expertise, nurse and nurse employment characteristic, care management processes (use of care maps/protocols), and hospital type/location on 30-day mortality.	75 Ontario teaching and community acute care hospitals in 2002-2003. Canada Nursing staff mix, Nursing staff dose, Percentage of full time nursing staff, Years experience on unit, Percentage of nurses with baccalaureate or higher, Overall health nurse level, Hours of missed work in preceding 3 months, Quality of nurse-physician relationships, Nurse-rated manager ability and support, Nurse-rated adequacy of staffing and resources, Amount of teamwork, Overall nurse job satisfaction, Nurse-reported quality of care, Nurse burnout. Amount of professional role support available for nursing staff. Frequency of use of care maps/protocols to guide patient care (one nurse survey item with 5-point frequency response options). SCTL: Teamwork, nurse burnout, nurse-physician relationship all explicitly measured via nurse survey	Not relevant, not a study of an intervention	Lower 30-day mortality rates found to be associated with: higher proportion of registered nursing staff, higher proportion of baccalaureate-educated nurses, lower total dose of all categories of nursing staff, higher nurse-reported adequacy of staffing and resources, higher use of care maps/protocols, higher nurse-reported quality of care, lower nurse-reported manager ability and support, and higher nurse burnout	None mentioned	Teamwork and physician relationship were not associated with differences in mortality, but higher nurse burnout was associated with lower 30-day mortality.	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Estabrooks et al., 2005 ¹⁵	Not a study of an intervention	Retrospective cross-sectional 18,142 patients with an acute medical diagnosis of acute myocardial infarction, congestive heart failure, chronic obstructive pulmonary disease, pneumonia, or stroke 4,799 nurses working (response rate = 52.8%)	None	49 Alberta acute care hospitals during fiscal year 1998-1999. Canada Nurse: education level, Skill mix, employment status, Nurse-reported autonomy, job satisfaction, perception of staffing adequacy, perception of unmet patient needs, Amount of non-nursing activities performed, support for float policy, Nurse-physician relationship, Frequency of emotional abuse experience. Academic status assessed No assessment of existing quality / safety infrastructure "use of high technology" SCTL: Nursing Work Index and Maslach Burnout Inventory assessed	Not relevant, not a study of an intervention	Four factors were found in a multivariable regression to be associated with lower 30-day mortality rates: a higher proportion of baccalaureate prepared nurses; a higher proportion of RNs in nursing staff mix; a higher proportion of permanent RNs; and a higher reported nurse-physician collaboration.	None mentioned	Nurse-physician collaboration was associated with lower 30 day mortality rates.	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Halm et al., 2005 ¹⁶	Not a study of an intervention	Retrospective cross-sectional 2,709 general-surgical patients and 140 staff RNs	None	One large Midwestern acute care hospital. USA RN staffing Academic status not reported No assessment of existing quality / safety infrastructure No assessment of organizational complexity SCTL: Maslach Burnout Inventory assessed	Not relevant, not a study of an intervention	Nurse staffing was not statistically significantly associated with 30-day mortality or inpatient failure-to-rescue.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Person et al., 2004 ¹⁷	Not a study of an intervention	Retrospective cross-sectional 118,940 acute myocardial infarction (AMI) patients	None	4,401 acute care hospitals in 1994 – 1995. USA Ratio of full-time equivalent RNs to average daily census, Ratio of full-time equivalent licensed practical and vocational nurses per average daily census, Part-time nursing staff estimated as 0.5 full-time equivalent. Academic status assessed No assessment of existing quality / safety infrastructure Types of cardiac services offered SCTL: Not assessed	Not relevant, not a study of an intervention	Lower in-hospital mortality rates were associated with higher RN staffing in hospitals. Higher in-hospital mortality rates were associated with higher licensed vocational/practical staffing in hospitals.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Aiken et al., 2003 ¹⁸	Not a study of an intervention	Retrospective cross-sectional 10,184 nurses (50% random sample, response rate 52%) and 232,342 surgical patients	None	168 acute care hospitals in Pennsylvania 1998-1999 USA Registered nurse education level, Nursing workload, Mean years of nurse experience Academic status assessed No assessment of existing quality or safety High vs. low technology assessed SCTL: Not assessed	Not relevant, not a study of an intervention	A higher proportion of baccalaureate educated nurses and lower nursing workload were associated with a lower risk-adjusted mortality and failure to rescue rates.	None mentioned	None mentioned	High
Sasichay-Akkadechanunt et al., 2003 ¹⁹	Not a study of an intervention	Retrospective cross-sectional 2,531 medical-surgical patients with principal diagnoses in following groups: disease of the heart, malignant neoplasms, hypertension, cerebrovascular diseases, and pneumonia/other lung diseases.	None	17 inpatient units in one university hospital Thailand Ratio of total nursing staff to patients, Proportion of RN to total nursing staff, Mean years RN experience, Percentage of baccalaureate-educated nurses. SCTL: Non- US/UK/Canada/ Australia/New Zealand study	Not relevant, not a study of an intervention	A higher nurse-patient ratio was significantly associated with lower inpatient unit mortality rates.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Aiken et al., 2002 ²⁰	Not a study of an intervention	Retrospective cross-sectional 10,184 nurses (50% random sample, response rate 52%) and 232,342 surgical patients	None	168 acute care hospitals in Pennsylvania 1998-1999 USA RN staffing Academic status assessed No assessment of existing quality or safety High vs. low technology assessed SCTL: Not assessed	Not relevant, not a study of an intervention	Higher patient-to-nurse ratio found to be associated with higher 30-day mortality ($p < .001$). Odds of patient death increased by 7% for every additional patient in nurse workload.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Needleman et al., 2002 ²¹	Not a study of an intervention	Retrospective cross-sectional 5,075,969 medical patient discharges and 1,104,659 surgical patient discharges	None	799 hospitals in 11 states from 1997 and 1998 fiscal years USA Eight nurse staffing indicators were assessed: Number of RN hours of nursing care per patient day, Number of licensed practical nurse hours per patient day, Number of aid hours of care per patient day, Total hours of nursing care per patient day, Proportion of RN hours of all hours of nursing care, Proportion of licensed practical nurse hours of all hours of nursing care, Number of hours of care provided by licensed nurses (RN + practical nurse) per patient day, RN hours as a proportion of licensed nurse hours. Acute care hospitals Academic status assessed No assessment of existing quality / safety infrastructure No assessment of organizational complexity SCTL: Not assessed	Not relevant, not a study of an intervention	No statistically significant relationships were found between in-hospital mortality rates and nurse staffing indicators. Two statistically significant relationships were found between lower hospital failure-to-rescue rates and nurse staffing: For medical patients, a higher proportion of hours of care provided by RNs. For surgical patients, a greater number of hours of care provided by RNs.	None mentioned	None mentioned	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Tourangeau et al., 2002 ²²	Not a study of an intervention	Retrospective cross-sectional 49,993 patients with four diagnoses: acute myocardial infarction, stroke, pneumonia, or septicemia and 3,988 RNs (response rate = 57%)	A conceptual framework was presented that included eight domains: nurse staffing, nurse skill mix, professional role support, nurse characteristic, nurse practice environment condition, continuity of registered nurse care provider, and other determinants on 30-day mortality.	75 Ontario teaching and community acute care hospitals in 1998-1999. Canada Academic status assessed No assessment of existing quality / safety infrastructure No assessment of organizational complexities SCTL: Canadian Practice Environment Index assessed (drawn from the Nursing Work Index NWI-R)	Not relevant, not a study of an intervention	Lower 30-day mortality was found to be significantly associated with: higher proportions of RN staffing, more years if nurse experience on the clinical unit, and higher number of shifts missed by nurses in the preceding 3 months	None mentioned	Condition of nursing practice environment was not associated with lower 30-day mortality.	High

Author, Year	Description of PSP Multi-component	Study Design Sample Size	Theory or Logic Model	Contexts	Implementation Details	Outcomes: Benefits	Outcomes: Harms	Influence of Contexts on Outcomes*	Overall Risk of Bias
Tarnow-Mordi et al., 2000 ²³	Not a study of an intervention	Retrospective cross-sectional 1,050 patient episodes	None	<p>One medical-surgical ICU in Scottish acute care hospital between 1992 and 1995.</p> <p>UK</p> <p>Average and peak values of nursing requirements per ICU shift were calculated for each patient's day of stay in the ICU.</p> <p>Academic status not reported</p> <p>No assessment of existing quality / safety infrastructure</p> <p>No assessment of organizational complexities</p> <p>SCTL: Not assessed</p>	Not relevant, not a study of an intervention	Higher hospital mortality was significantly associated with patients' exposure to high versus moderate overall ICU workload.	None mentioned	None mentioned	High

Abbreviations: CI = confidence interval; FTR = failure-to-rescue; ICU = intensive care unit; OR = odds ratio; SCTL = Safety/Culture/Teamwork/Leadership

*Since there are no interventional studies in this section, we used this column to report results of context variables other than nurse staffing or workload as a modifier of the effect of nurse staffing on patient outcome.

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Evidence Tables for Chapter 35. Patient Safety Practices Targeted at Diagnostic Errors (NEW)

Table 1, Chapter 35. Evidence table

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Single Intervention Type					
Additional Review Methods					
Galasko, 1971 ⁽⁵¹⁾	Diagnostic interpretation of radiographs	Review of x-ray films of outpatients attending accident services by radiologist and other staff within a short turn around (24hrs)	Identification of a missed injury	Other: Retrospective review of radiographs 24 hrs after initial interpretation. In 0.6% of cases, review identified a missed injury. In 0.4% of cases, the radiologist failed to identify the injury while the senior houseman on duty did. In 0.6% of cases, review identified a missed injury, and in only 2 of 4,665 (0.04%) of cases, both review sessions missed the injury.	Missed diagnosis; misdiagnosis
Carew-McColl, 1983 ⁽⁴⁹⁾	Diagnostic interpretation of radiographs	Review of x-rays in an accident and emergency department	Number of patients allowed home with serious injuries which were radiologically apparent but which have been overlooked	Other: The majority (85%) of abnormalities were identified. Most overlooked abnormalities were not clinically significant.	Missed diagnosis; misdiagnosis; proof of concept
Robson, 1985 ⁽⁵⁸⁾	Diagnostic interpretation of radiographs	Review of x-ray films by radiologist and other staff	Diagnostic accuracy of the interpretation of fractures impacting patient treatment and prognosis	Other: Diagnostic accuracy is correlated with seniority and experience (the casualty officer was more accurate than the students, second only to the radiologist).	Missed diagnosis; misdiagnosis
Ciatto, 1995 ⁽⁴⁰⁾	Diagnostic errors during readings of mammograms	Independent double read of mammograms by experienced radiologists	Breast cancer detection rates and referral rates	Other: The mean increase in referral rate for double reading compared with single reading was 15.1%, and increased cancer detection by 4.6%.	Missed diagnosis
Lind, 1995 ⁽⁵³⁾	Diagnostic errors in surgical pathology reports	Review of surgical diagnostic pathology biopsies by a second pathologist prior to release of final reports	Major diagnostic errors in surgical pathology reports that could directly affect patient care	Other: 380 errors in 2,694 cases. 32 major errors with a potential for inappropriate patient care, 104 diagnostic discrepancies, 192 minor errors and 52 clerical errors.	Misdiagnosis; delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Bruner, 1997 ⁽⁴⁷⁾	Diagnostic discrepancies in brain and spinal biopsy reports	Review of brain or spinal cord biopsy results by a neuropathology consultation service	Substantial and serious neuropathology diagnostic errors	Other: Disagreement between original and review diagnoses in 42.8% cases, with 8% serious errors in diagnosis. 96 cases (44%) less serious, but still clinically substantial. 31.9% disagreements occurred in patients referred directly compared to 51.0% of disagreements in review done solely based on pathology consultation.	Misdiagnosis
Dudley, 1997 ⁽²⁹⁾	Serious errors of electrocardiograph (ECG) interpretation in an accident and emergency department	Provision of an (ECG) report by a cardiac technician at the time of recording, before senior house officers' ECG interpretation	Serious errors of ECG interpretation	Other: Serious errors reduced by 59% when there was a prior technical report provided by an ECG technician. Many of these errors led to worse clinical outcomes. Independent review of ECG revealed moderate agreement between technicians and senior officers (kappa = 0.45) and between senior officers from different departments (kappa = 0.42).	Missed diagnosis
Thiesse, 1997 ⁽⁵⁹⁾	Incorrect radiologic evaluation of overall response (to therapy) status in oncologic patients participating in multi-center trials	Independent ascertainment of therapy response status of cancer patients by review of radiologic findings by an evaluation committee (EC)	Response status of cancer patients - major and minor disagreements between trial investigators and evaluation committee (that could impact patient management)	Other: Major disagreements occurred in 43% and minor in 8% of reviewed files. Number of tumor responses to therapy designated as significant was reduced by 23.2% after review by EC.	Diagnostic discrepancy: proof of concept
Lufkin, 1998 ⁽⁵⁴⁾	Incorrect radiologic diagnoses by emergency department physicians	Radiologists' review of radiographs interpreted by emergency room physicians	Clinically significant discordant radiographic interpretations that alter patient's treatment	Other: Emergency department physicians were confident in their interpretations in 9,599/16,410 cases (58%). Review of the 118 discordant interpretations in the confident group demonstrated 11 were significant. Discordant interpretations were higher in cases when emergency department physicians were not confident.	Misdiagnosis
Espinosa, 2000 ⁽⁵⁰⁾	Radiograph interpretation errors in emergency department	Review of radiograph discrepancies at monthly meetings by radiologists; team redesigned the review process after intervention	Reduction of errors, including missed fractures or foreign bodies.	Pre/Post: Longitudinal study; after implementation, false negative error rate decreased from 3% to 1.2%. Review process revised; patient satisfaction improved, as did turnaround time for interpretations.	Missed diagnosis; misdiagnosis; delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Nam, 2001 ⁽³⁰⁾	Misdiagnosis due to inaccurate interpretation of colonic transit study in patients with chronic constipation	Repeat colonic transit study in patients with chronic constipation and suspected colonic inertia to confirm the diagnosis prior to colectomy	Success rate post colectomy for chronic constipation	Experimental Design: The success rate of colectomy for colonic inertia was significantly higher in patients who underwent a repeat transit study confirming inertia than in patients who underwent colectomy based on a single study.	Misdiagnosis
Westra, 2002 ⁽⁶⁰⁾	Missed diagnosis of head and neck cancers	A secondary review of histopathologic diagnoses	Treatment modification based on changes in diagnoses	Other: Retrospective review; in 87% of diagnoses changes treatment was modified.	Missed diagnosis; misdiagnosis
Canon, 2003 ⁽⁴⁸⁾	Detection of polyps and/or colorectal carcinomas	Secondary reading of barium enemas	Diagnostic accuracy of polyps and carcinomas	Other: Prospective study; double reading of barium enemas did not improve sensitivity and increased false positive rate.	Missed diagnosis; misdiagnosis
Kwek, 2003 ⁽⁵²⁾	Breast cancer detection	Double reading of mammograms in Singapore Breast Screening Project	Diagnostic accuracy of mammography screening results	Other: Retrospective review; double-reading mammography intervention led to cancer detection improvement. Double reading increased the number of patient recalls. Positive predictive value (PPV) decreased from 8.2% to 6.1%.	Missed diagnosis; misdiagnosis
Nordrum, 2004 ⁽⁴⁴⁾	Incorrect histologic diagnoses	Use of still images sent via electronic network (from glass slides of paraffin-embedded histologic material) to obtain second pathologist's opinion diagnosis	Discordant diagnoses expected to have clinical implications	Other: Agreement 67.8% of the time with still images, and 68.9% of the time with reviewing glass slides, when compared to an original second opinion diagnosis. The cause of error was interpretation for 15 (of 90 cases), both image selection and interpretation for 9 cases, image selection alone in 3 cases, and image quality, selection and interpretation in 2 cases. 37.9% of still image discrepancies are likely to have had significant clinical implications.	Misdiagnosis; delayed diagnosis
*Howard, 2006 ⁽⁴²⁾	Missed injuries in trauma patients in a Level II trauma center	Implementation of a trauma tertiary survey (reevaluation of laboratory studies) within 24 hours of admission	Missed injuries in trauma patients in a Level II trauma center	Other: 14% of patients had one or more injuries missed in primary and secondary examinations that were captured during tertiary examination.	Missed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Raab, 2006 ⁽⁴⁵⁾	Diagnostic errors in interpretation of pulmonary cytology slides (based on correlation of cytology and surgical specimens histology results)	Pre sign-out double viewing of all pulmonary cytology slides	Incorrect diagnoses (that could impact patient management and outcome)	Pre/post: Double viewing did not lower the frequency of cytologic-histologic correlation false-negative errors. Double viewing detects errors in up to 1 of every 37 cases. While the double cytology slide viewing was helpful at some project sites in detecting pre-sign out error, the intervention did not significantly reduce error frequencies at any of three study sites. Agreement with subsequent surgical diagnosis was moderate when definitive diagnoses were made.	Missed diagnosis; misdiagnosis
Singh, 2006 ⁽⁴⁶⁾	Diagnostic error for head and neck cancer	Urgent referral; timing-based referral to reduce delay in diagnosis and influence on diagnostic pathway	Presence of cancer diagnosis, and the time delay to reach diagnosis	Other: Retrospective review and audit; 86% of 'urgent' patients were seen within 2 weeks. 24% had oral squamous cell carcinoma.	Delayed diagnosis
Duijm, 2007 ⁽⁴¹⁾	Missed breast cancer diagnosis	Independent double reading of mammograms by two mammography technologists beyond the standard double reading by two radiologists	Cancer detection rates and referral rates of women with positive screening results from any reader	Other: Additional reading by technologists increased the cancer detection rate by 0.36 cancers per 1,000 women and the referral rate by 0.13%.	Missed diagnosis
Manion, 2008 ⁽⁴³⁾	Clinically significant diagnostic errors (varied clinical conditions)	Second opinion in pathology to expose clinically significant errors	Diagnostic accuracy – no major disagreement in pathology that would impact treatment or prognosis	Other: Retrospective chart review of major diagnostic disagreements (2.3% of reviewed cases). Second opinion for clinically significant error validated in 34 of 132 cases reviewed.	Missed diagnosis; misdiagnosis
Parameswaran, 2008 ⁽⁵⁶⁾	Missed abnormal findings in histology specimens	Sampling the remaining tissue of colorectal biopsies originally diagnosed as normal- with additional step sections- to reveal pathologic abnormalities	Identification of pathologic abnormalities in remaining biopsy tissues (originally reported as normal)	Other: Review sampling showed pathologic abnormality in 3.9% cases. New diagnostic information identified in 1.7% of cases, but lost in 1.3% of cases (present in initial sections but not in remaining tissue).	Missed diagnosis; delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Raab, 2008 ⁽⁵⁷⁾	Incorrect surgical pathology diagnoses	Two diagnostic error detection processes: targeted review of a random 5% of surgical pathology specimens, and focused review by 3 subspecialty pathologists of cases with a perceived higher level of diagnostic uncertainty or lack of standardization in terminology	Although this was a retrospective review of surgical pathology specimens, the study evaluated: a) impact identified diagnostic errors could have had on patient outcomes, including management, and b) whether the patient experienced subsequent harm	Other: Targeted review process identified 195 errors, (2.6% of reviewed cases) and focused review process identified 50 errors (13.2%). The number of major errors detected was 27 (0.36%) and 12 (3.2%), respectively. In secondary review of major errors (follow-up range from 8 months to 5.5 years), subsequent harm to the patient was observed in 11 cases (41%) from the targeted review and 7 cases (58%) from the focused review.	Missed diagnosis
Murphy, 2010 ⁽⁵⁵⁾	Missed colonic and extra-colonic lesions in minimal preparation Computer Tomography (CT) of colon	Double reporting by two radiologists of minimal preparation CT of colon (MPCTC) in elderly patients	Identification of clinically relevant colonic and extra-colonic lesions that could impact future patient management	Other: Double reporting of colonic identified one extra-colonic cancer, at the expense of 5 unnecessary endoscopies. The positive predictive value for colon cancer was 69% for single reporting and 54.5% for double reporting.	Missed diagnosis
Hamady, 2005 ⁽⁷¹⁾	Incorrect interpretation of pathology reports for thyroid cancer	Pathology reports that received discrepant interpretations from a referring and receiving clinician were reviewed by a third clinician blinded to the thyroid cancer diagnosis	Malignancy status of tumor, indicated course of treatment and expected prognosis	Other prospective design: Of 66 patients with thyroid cancer referred from general hospitals to specialty clinics for a second opinion on diagnosis, 12 cases (18%) received disagreement between initial and second review of the pathology report, resulting in re-review by a third, blinded reviewer. Five cases involved strong disagreement leading to change in both prognosis and treatment strategy. All 12 cases involved a change in prognosis: worsened in 8 (67%) and improved in 4 (33%). There were two cases each where re-review resulted in a switch from benign to malignant and vice versa.	Misdiagnosis
Educational Interventions					
McCarthy, 1990 ⁽⁸⁶⁾	Incorrect diagnosis by parents of symptoms of serious illness	Teach parents Acute Illness Observation Scale (AIOS) to detect child's illness vs. 3-point global scoring system for evaluating chance of serious illness	Number of infants with serious illnesses	RCT: Judgments of the intervention group were more reliable than those of the control group (weight kappa = 0.50 vs. 0.26). Sensitivity, positive and negative predictive values not statistically different.	Misdiagnosis; proof of concept

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Fridriksson, 2001 ⁽⁸⁷⁾	Misdiagnoses of sudden onset headache (an early sign of ruptured aneurysm)	A community teaching program on educating local physicians about sudden onset of headache in subarachnoid hemorrhage (SAH); continuous interaction between neurosurgeons and local physicians including seminars on SAH, individual follow-up of all referred patients	Early misdiagnoses of ruptured aneurysms; aneurysm surgery rates, surgery outcomes and morbidity and mortality outcomes at 6 months post SAH	Other: An initial misdiagnosis was identified in 12% of patients, and diagnostic error decreased by 77% with intervention.	Missed diagnosis
Thaler, 2010 ⁽⁸⁸⁾	Errors in ECG readings due to switched electrode cables	A 45 min teaching session for ICU nurses and physicians about correct ECG recording and errors resulting from improper electrode placements	Reduction of cable reversal rates (which could lead to incorrect ECG diagnoses and unnecessary subsequent tests and hospitalizations)	Pre/post: Frequency of electrode cable misplacements was 4.8% pre-intervention and 1.2% post-intervention. This translates to a 75% reduction in ECG errors due to electrode cable reversals.	Missed diagnosis; misdiagnosis
Personnel Changes					
De Lacey, 1980 ⁽⁸⁴⁾	Incorrect diagnoses of radiographs in accident and emergency departments	Comparison of diagnostic accuracy between casualty officers and radiologists	Diagnostic accuracy of radiograph interpretation	Other: Prospective study to compare radiograph interpretation between casualty officers and radiologists. Uncertain or incorrect interpretation led to 6.8% of all patients receiving unnecessary procedures (e.g., casting an unbroken limb), 1.7% unnecessary return to X-ray, and 0.6% unnecessary outpatient referral.	Missed diagnosis; misdiagnosis
Sakr, 1999 ⁽³⁷⁾	Clinically important errors, including errors in the diagnosis pathway (i.e., history, physical examination, and radiographic interpretation errors)	Use of junior doctor or nurse practitioner (NP) in providing care in the Emergency Department	Clinically important errors in history, examination, radiograph interpretation, treatment and/or advice and/or follow-up	RCT: There was no difference between the clinically important radiographic diagnostic errors made by NPs and by junior doctors (e.g., 89.8% of patients seen by junior doctors reported improvement in condition, while 91.1% of patients seen by NPs reported improvement). 15% of patients seen by junior doctors required follow-up visits within 28 days while 9.7% of patients seen by NPs required follow-up visits within 28 days.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Structured Process Changes					
Enderson, 1990 ⁽⁹¹⁾	Missed injuries associated with trauma	Tertiary Survey to capture missed trauma injuries	Diagnostic accuracy; improvement of patient outcomes (mortality and morbidity) by identifying missed injuries	Pre/Post: 41 missed injuries were identified in 37 patients (N = 399) with Tertiary survey.	Missed diagnosis
Klassen, 1993 ⁽⁹²⁾	Missed positive radiographic findings (fracture, dislocation or effusion) after trauma	Brand protocol (protocol for ordering radiographs of injured extremities in patients >15 years old) applied by triage nurses to determine the need for a radiograph in the pediatric emergency department	Number of positive radiographic findings; number of missed positive radiographic findings and long-term clinical importance thereof, in pediatric trauma patients	RCT: Brand group ordered 81.9% radiographs; control 87.1%. Positive radiograph percentage was 40.8% vs. 42.6%, respectively. 3.2% were missed in Brand compared to 0% in control.	Missed diagnosis
Schriger, 2001 ⁽³⁹⁾	Occult mental illness	Implementation of computerized psychiatric interview (PRIME-MD)	Detection of occult mental illness (upon admission to emergency department)	RCT: PRIME-MD survey, completed by emergency department patients, provided to emergency physician did not improve the frequency of diagnosing psychiatric conditions. 42% of patients within the study were identified as high risk for occult psychiatric illness according to PRIME-MD. Physicians reached psychiatric diagnosis 5% and offered psychiatric consultations to 3%.	Missed diagnosis
Biffi, 2003 ⁽⁹³⁾	Missed injuries in Level I trauma center	Routine trauma survey (TS) in trauma intensive care unit patients	Missed injuries in level I trauma center	Pre/post: Missed injuries decreased from 2.4% to 1.5% overall, and from 5.7% to 3.4% in Trauma ICU patients after TS implementation. Missed injuries occurred more often in older patients, those that were admitted and those with high injury severity scores.	Missed diagnosis; delayed diagnosis
Soundappan, 2004 ⁽⁹⁴⁾	Missed injuries associated with trauma (pediatric)	Extended tertiary survey in pediatric trauma patients	Incidence of missed diagnosis	Other: Prospective study; 13 missed injuries identified in 12 of 76 pediatric trauma patients. Fractures were the most common missed injury. Children involved in motor vehicle incidents were most likely to have missed injuries.	Missed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
*Perno, 2005 ⁽²⁵⁾	Delayed diagnosis of injury in a Pediatric Trauma Center	Implementation of a Pediatric Trauma Response team and trauma service for severely injured children in Pediatric Trauma Centers	Delayed diagnoses of injury (DDI) in admitted pediatric trauma patients	Other: DDI occurred in 15 (0.46%) of trauma patients. Previous study by same group revealed 4.3% DDI, an almost 10-fold decrease between the two studies. Among the 15 DDI cases in the latter study, 13 diagnoses were identified by tertiary examination, and 2 patients were discharged without diagnosis and returned to the hospital after worsening symptoms.	Missed diagnosis; delayed diagnosis
Ursprung, 2005 ⁽⁹⁵⁾	Diagnostic errors related to laboratory tests or radiologic studies; delays in patient care or information transfer/communication (additional errors probed)	Real time patient safety auditing during routine clinical work in the ICU (36-item patient safety checklist focused on several errors including diagnostic errors)	Impact of errors (i.e., delays in patient services or errors in information transfer) on patient clinical management and on adverse outcomes	Other: 338 errors detected; 27 of 36 items on checklist detected >1 error. Significant safety errors were detected promptly and rapid changes in policy and practice ensued.	Missed diagnosis; misdiagnosis; delayed diagnosis
Raab, 2006 ⁽⁹⁸⁾	Incorrect interpretation of frozen sections of pathology specimens	Continuous monitoring over time of data correlation between frozen sections and permanent sections via the Q-Tracks Quality Improvement Program	Number of frozen-permanent section discordant results and deferred diagnoses (that could impact patient management and outcome)	Other: Mean frozen-permanent section discordant frequencies 1.36%. Longer participation in Q-Tracks significantly associated with lower discordant frequencies; 4- or 5-year participation showed decrease in discordant frequency of 0.99%; 1-year was 0.84%. Median discordant rates increased with increased bed size of institution. Government-owned institutions exhibited lower deferred diagnoses than non-government institutions.	Missed diagnosis; misdiagnosis
Raab, 2006 ⁽⁹⁶⁾	Improved diagnostic accuracy from Pap test	Toyota production system redesign to improve workflow by 1-by-1 continuous flow process	Decrease in additional Pap test or surgical procedure, increase in diagnostic accuracy	Experimental Design; Pre/Post: 8-month non-concurrent cohort study; the number of correlating Pap tests and surgical pathology specimens increased from 42 in pre-intervention to 51 in the intervention group. Slight, but not significant, decrease in diagnostic discrepancies between pre-intervention/post-intervention.	Missed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Raab, 2006 ⁽⁹⁷⁾	Thyroid gland fine needle aspiration (FNA) diagnostic error	Standardized terminology scheme (Toyota Production System Process Redesign) for reporting of cytologic results from thyroid fine needle aspirations (FNA)	Diagnostic accuracy of the FNA interpretation; surgery rates and repeated FNA rates	Pre-post: Separate cohorts/interventions analyzed; post intervention significantly fewer patients had surgery, received non-interpretable results, or repeated FNA. False-negative diagnosis rate decrease from 41.8% to 19.1% ($p = .006$), FNA sensitivity increased from 70.2% to 90.6% ($p < .001$), and atypical diagnoses rate decreased from 8.2% to 3.7% ($p < .001$). The false positive rate increased slightly and FNA specificity decreased but neither difference was significant.	Missed diagnosis
Raab, 2008 ⁽⁹⁹⁾	Incorrect Pap test cytologic diagnoses	Continuous monitoring of the correlation of Pap test cytologic-histologic data - via the Q-Tracks Quality Improvement Program	Pap test diagnostic accuracy and detection of pre-neoplastic lesions (that could impact patient management and outcome)	Other: Longer participation in program by an institution associated with higher Pap test sensitivity and higher proportion of positive histologic diagnoses for a Pap test of atypical squamous cells (ASC). Longer participation also associated with higher proportion of women with follow-up positive histologic diagnoses for ASC. Compared to government-owned institutions, non-government institutions exhibited slightly higher predictive value of positive tests. Larger institutions had significantly lower sensitivity, but time of participation in the quality improvement program remained a significant factor in all analyses.	Missed diagnosis; misdiagnosis
Mueller, 2010 ⁽¹⁰⁰⁾	Geriatric health problems previously unknown to a general practitioner (GP) and overlooked treatment needs	Standardized Assessment for Elderly Patients in a Primary Care Setting (a 44-item STEP instrument based on self-reporting and standardized patient interview), to explore conditions new to GPs	Further management interventions planned by GPs for previously overlooked geriatric health problems and treatment needs (that could affect patient outcome)	Other: STEP intervention helped GPs identify missing or unknown immunizations, anxiety in patients, chest pain, depression, urinary incontinence, breathlessness, smoking habits as well as claudication, abnormal clock drawing test, and thyroid dysfunction. Patients had a median of 11 health problems identified by STEP, of which 2 were new to the GP.	Missed diagnosis; delayed diagnosis
De Vries, 2011 ⁽¹⁰¹⁾	Surgical diagnosis accuracy	Surgical checklist, SURgical PATient Safety System (SURPASS); review of claims records to see if checklist could have prevented claims	Morbidity, mortality, level of patient disability and need for additional operations; malpractice claims	Other: Retrospective review; cognitive, system, technical or unknown categorization of errors determined postoperatively.	Missed diagnosis; misdiagnosis; delayed diagnosis; proof of concept

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Technique					
Attard, 1992 ⁽⁷²⁾	Incorrect diagnosis in patients presenting with abdominal pain	Pain relief with paraveretum for acute abdominal pain	Incorrect management decision (to operate or not) and incorrect discharge diagnoses	RCT: Reduction in pain after paraveretum, without reducing diagnostic accuracy. Subsequent decision to operate or observe was considered incorrect in fewer cases treated with paraveretum vs. the saline group (2/50 vs. 9/50; p=0-051, Fisher's exact test).	Misdiagnosis
Resnick, 1996 ⁽⁷³⁾	Incorrect diagnosis of urinary incontinence in nursing home women	Stress test combined with cystometry to diagnose urinary incontinence	Misdiagnoses of urinary stress incontinence	Other: Combining cystometry with stress test improved diagnostic accuracy drastically. Of the 77% of women in whom the results of both tests were congruent, all were correctly classified (vs. video-urodynamic evaluation). No woman with stress incontinence was missed by the two-test strategy, nor was anyone with DH misclassified. Neither test was more accurate in cases where the test results diverged.	Missed diagnosis; misdiagnosis
Borgstein, 1997 ⁽⁷⁴⁾	Incorrect appendicitis diagnosis	Diagnostic laparoscopy for female patients of child-bearing age with clinical signs of acute appendicitis, prior to appendectomy	Correct diagnoses post laparoscopy (and post-appendectomy when surgery was performed)	Other: The negative appendectomy rate after laparoscopy was 5%. In the group of fertile females without laparoscopy the negative appendectomy rate was 38%.	Misdiagnosis; delayed diagnosis
Vermeulen, 1999 ⁽⁷⁵⁾	Incorrect appendicitis diagnosis	The influence of pain medication administration on diagnosis of appendicitis	Diagnostic accuracy; whether surgery was deemed necessary or not	Experimental Design: Emergency department patients presenting with pain in lower right abdominal quadrant were randomized to receive morphine or placebo. The morphine cohort had a higher positive predictive value, and lower negative predictive value; differences between morphine and placebo group were not statistically significant.	Misdiagnosis
Prieto, 2003 ⁽⁷⁶⁾	Incorrect indication of surgical margins of melanocytic lesions in en face frozen compared to permanent paraffin-embedded sections	Use of en face frozen sections (i.e., sections cut parallel to the surgical margin) for evaluation of surgical margins of melanocytic lesions	Although no direct patient outcomes studied, evaluation of the diagnostic accuracy of a rapid method to identify the surgical margins of melanocytic lesions could have had impact on patient management and outcome	Other: Poor overall agreement by frozen v. permanent analysis (kappa = .03). Better agreement between frozen and permanent section diagnoses for the non-melanocytic lesions (NML) than for the malignant melanomas (MM) cases. Within-physician agreement ranged from poor to moderate (kappa range from -.1 to .4).	Misdiagnosis; proof of concept

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Thomas, 2003 ⁽²⁶⁾	Diagnostic errors based on altered physical examination findings	Morphine sulfate (MS) administered for pain during diagnostic process	Patient disposition and ultimate diagnosis (including presence and severity of physical findings)	RCT: No differences between control and MS group with respect to disposition from the emergency department, ultimate need for operation, ultimate diagnosis (according to medical records and patient's follow up) and need for repeat physician visit within a week for abdominal pain.	Missed diagnosis; misdiagnosis
Kokki, 2005 ⁽⁷⁷⁾	Delay in diagnosis or decrease in diagnostic accuracy of physical examination findings for appendicitis	Oxycodone for pain relief in children presenting to the emergency department with moderate to severe abdominal pain	Pain relief and diagnostic accuracy of physical examination findings and clinical outcomes	RCT: Prospective, double-blind, and placebo-controlled clinical trial; there was significantly greater reduction in pain reported on a visual analog scale among patients that received oxycodone than those administered saline placebo. From before drug or placebo administration to after administration, diagnostic accuracy increased from 72% to 88% in those treated with oxycodone and remained at 84% in the placebo group. The rate of negative exploratory laparotomy was similar in both groups.	Missed diagnosis; misdiagnosis; delayed diagnosis
Hewett, 2010 ⁽⁷⁸⁾	Missed colorectal adenoma diagnosis in colonoscopy	Cap-fitted colonoscopy, which allows for flattening of haustral folds and/or improves mucosal exposure	Missed colorectal adenoma diagnosis in colonoscopy	Experimental Design: Patients undergoing cap-fitted colonoscopy had significantly lower miss rate for all adenomas compared with regular colonoscopy (21% vs. 33%), but there was no difference when analyzed at the patient level rather than number of adenomas.	Missed diagnosis
Technology-based Systems Interventions					
Wexler, 1975 ⁽¹⁰³⁾	Time to correct diagnosis	Computer-assisted system of diagnosis (MEDITEL)	Diagnostic accuracy; time to reach diagnosis	Experimental Design: In control group, MEDITEL identified correct diagnosis in 85% of cases; physicians reached the correct diagnosis in 65% of cases. In the experimental group, MEDITEL reached correct diagnosis in 58% of cases, and physicians in 83%. Time to diagnosis reduced in the experimental group, but did not reach statistical significance.	Missed diagnosis; misdiagnosis; delayed diagnosis
Wellwood, 1992 ⁽¹⁰⁴⁾	Appendicitis diagnosis accuracy	Computer-aided diagnostic (CAD) tool; abdominal pain interpretation	Discharge diagnosis accuracy	RCT: Randomized trials with prospective data collection; predictive accuracy of CAD was 48% initially, but rose to 69% with decision aids, computers and performance feedback.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Selker, 1998 ⁽¹⁰⁵⁾	Missed diagnosis of acute cardiac ischemia	Implementation of a computerized acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI)	Diagnostic accuracy (proxy – CCU or telemetry unit admission)	Experimental Design: controlled clinical trial. Appropriate admission to CCU or telemetry unit did not change for patients with acute MI or unstable angina when ACI-TIPI implemented. Use of ACI-TIPI reduced CCU admissions from 14% to 10%, telemetry unit admissions from 39% to 31% and increased discharges to home from 45% to 65% for non-AMI patients. Among patients with stable angina, use of ACI-TIPI reduced CCU admissions from 26% to 13% and increased discharges from 20 to 22%. Telemetry unit admissions decreased from 68% to 59%.	Missed diagnosis or delayed diagnosis (presumed from “appropriate admissions”)
Pozen, 1984 ⁽¹¹⁷⁾	Missed diagnosis of acute cardiac ischemia	Implementation of an acute cardiac ischemia predictive instrument, similar to acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI), calculated and delivered in hardcopy to clinicians	Diagnostic accuracy and proxy of CCU admission	Experimental Design: interrupted time series. Of the 2,320 patients seen across six emergency departments, diagnostic accuracy (83.4% vs. 79.6%, $p = .002$) and specificity (78.1% vs. 73.2%, $p = .002$), but not sensitivity (94.5% vs. 95.3%), were significantly improved by providing physicians with predictive instrument results. False-positive rate among patients with a low probability of ischemia dropped significantly (47% vs. 60%, $p = .002$), and admissions to CCU significantly decreased from 44% to 33% ($p = .001$) among patients without ischemia when physicians had access to predictive instrument results.	Missed diagnosis, misdiagnosis
Kuperman, 1999 ⁽²⁸⁾	Time interval between laboratory results and clinical action	Computer system to detect critical conditions and notify the physician	Interval from when a critical result was available for review until appropriate treatment administered	RCT: Prospective, randomized controlled trial; intervention group had a 38% shorter median time interval between receipt of critical laboratory result and action with patient. However, the time until alerting condition was resolved did not reach clinical significance.	Delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Bogusevicius, 2002 ⁽²⁷⁾	Acute mechanical small bowel obstruction	Computer-aided diagnosis (CAD) and contrast radiography for diagnosis of acute mechanical small bowel obstruction	Time to diagnosis; morbidity, mortality, sensitivity, specificity and positive/negative predictive values	RCT: Prospective, randomized clinical trial; CAD had no significant advantage over contrast radiography in terms of diagnostic accuracy, but reduced time to diagnosis. Mean time to diagnosis was 1 hour for CAD and 16 hours for contrast radiography.	Missed diagnosis; misdiagnosis; delayed diagnosis
Major, 2002 ⁽³²⁾	Diagnostic errors from omission of laboratory alerts and physiologic condition alerts	Computer system coupled to an alert engine to reduce errors of omission for critical care units. Patients randomly assigned to (1) alerts group, or (2) no alerts group.	Mortality	Experimental Design /Other: Prospective data collection; patients in alerts group had a higher mortality rate in both SICU and ward compared to no alerts. Critical alerts for ICU patients increased morbidity and mortality.	
*Poon, 2002 ⁽¹⁰⁶⁾	Inadequate communication to physicians of patients' laboratory test results	"Result Notification via Alphanumeric pagers" (ReNAP) feature in clinical information system for real-time laboratory notification of physicians via pagers	Although no patient outcomes studied (only usage patterns and users' satisfaction studied) related to unnecessary delays in patient care	Pre/post: Improved ReNAP usage patterns and satisfaction.	Delayed diagnosis
Gur, 2004 ⁽¹⁰⁷⁾	Recall and breast cancer detection rates	Introduction of computer-aided detection (CAD) and mammography diagnosis system	Diagnostic accuracy of breast cancer	Other: Retrospective review; recall rates were 11.39% and 11.40% for without CAD and with CAD, respectively. Cancer detection rates were 3.49% and 3.55% without CAD and with CAD, respectively.	Missed diagnosis; misdiagnosis
Kakeda, 2004 ⁽¹⁰⁸⁾	Lung cancer detection	Computer-aided diagnosis (CAD) system to detect nodules from lung cancers	Diagnostic accuracy of lung cancer	Other: Retrospective review; CAD system improved the detection of lung nodules by improving area under ROC curve from 0.924 to 0.986.	Missed diagnosis; misdiagnosis
Cupples, 2005 ⁽¹⁰⁹⁾	Breast cancer detection rates (from mammography screening program)	Implementation of computer-aided detection (CAD) program	Screening results (diagnostic accuracy) of breast cancer detection rates	Other: Prospective study; cancer detection increased 16.3%, with invasive cancer detection increasing 164% while in situ cancer detection declined 6.7%.	Missed diagnosis
Ramnarayan, 2006 ⁽¹¹⁰⁾	Unsafe workups	Implementation of computer-aided detection (CAD) program	Diagnostic accuracy	Pre/Post: Prospective study; CAD reduced the number of 'unsafe' workups from 45.2% to 32.7%.	Missed diagnosis; misdiagnosis
Fenton, 2007 ⁽¹¹¹⁾	Breast cancer detection rates	Implementation of computer-aided detection (CAD) technology to assist in the interpretation of mammography	Diagnostic accuracy	Other: Comparative study; cancer detection rate did not improve with use of CAD in mammography screening. Specificity decreased from 90.2% to 87.2%.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Park, 2008 ⁽¹¹²⁾	Interval between results and clinical action	Starting in 2005, SMS text message notifications with patient critical values sent to clinician. From 2001-, a callback system had been in place to send patient critical values to clinicians	Time delay between receipt of clinically significant information and appropriate course of patient treatment	Pre/post / Other: Comparative study; time to action for critical hyperkalemia in ICUs and general wards in 2001 was 213 minutes and 476 minutes, respectively. In 2005, with SMS, times dropped to 74.5 minutes and 241 minutes, respectively. Clinical response to callback alerts was 73.3%, and was 79.3% for SMS texts.	Delayed diagnosis
*Piva, 2009 ⁽¹¹³⁾	Failure to adequately communicate a critical laboratory value	Computerized notification system for reporting critical values	Although no patient outcomes studied, timely physician notification could have had impact on patient events	Other: The computerized system improved communications within 1 hour timeframes as compared to the traditional phone process for all hospital services except medical specialties.	Delayed diagnosis
*Singh, 2009 ⁽¹¹⁴⁾	Inadequate communication of abnormal cancer-screening test results in electronic health records	Electronic medical record alert for positive fecal occult blood (FOBT) cancer screening test results	Timely follow-up of abnormal cancer screening test results (FOBT) to reduce missed or delayed diagnoses of colorectal cancer	Pre/post: Lack of timely follow-up decreased immediately from 29.9% to 5.4% and was sustained at month 4 after implementing the intervention.	Missed diagnosis; delayed diagnosis
David, 2011 ⁽¹¹⁵⁾	Misdiagnosis of non-infectious conditions as cellulitis	Visually-based computerized diagnostic decision support system (VCDDSS, also named VisualDx) to generate an improved differential diagnosis	Number of patients admitted to the hospital with an incorrect cellulitis diagnosis	Other: In 18/28 of misdiagnoses, VCDDSS included the correct diagnosis, while in only 4/28 cases did the physician identify the correct diagnosis.	Misdiagnosis
Etchells, 2011 ⁽³³⁾	Diagnostic errors due to lack of timely information of physicians for critical laboratory abnormalities	Real-time clinical alerting systems for critically abnormal laboratory values via text messages sent to physicians using alphanumeric pagers or smart phones (decision support also provided via smart phones or hospital intranet)	Clinical actions completed in response to the alerts (that could affect patient outcome) and patients' adverse events	Experimental Design: Based on laboratory values, 50% of potential clinical actions occurred when the alert system was on as well as 50% while off. Adverse events within 48h were actually higher in cases while alert system was on (42%) than while off (33%) but this difference only approached significance ($p = .06$).	Delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Fitzgerald, 2011 ⁽³⁴⁾	Errors during reception and resuscitation of severely injured adult trauma patients (including errors in the diagnosis pathway)	Real time computer-prompted evidence-based decision support system (with decision and action algorithms) during reception and resuscitation of severely injured adults in Level I adult trauma center	Patient morbidity and mortality; including length of hospital stay	RCT: Error free resuscitation in 16% of baseline controls and 21.8% intervention. Predicted mortality rate 11%, but actual of 5.2%, meant insufficient power for analyzing a true mortality difference statistically. No significant reduction in sepsis or adult respiratory distress syndrome, but aspiration pneumonia was reduced from 5.3% (control group) to 2.5% (intervention).	Misdiagnosis; delayed diagnosis
Olsson, 2006 ⁽¹¹⁶⁾	Missed or delayed diagnosis of acute cardiac ischemia	Neural network-based decision making tool added to ECG results to recommend statistical likelihood that results indicated thrombolytic agents and revascularization	Diagnostic accuracy (proxy for indicated treatment for ST-segment elevation myocardial infarction)	Other prospective design: Compared to cardiology attending, interns regularly treating chest pain patients in the emergency department classified 68% ECGs indicating ischemia and 92% of normal ECGs correctly without the decision aid. After switching to the decision aid two weeks following baseline, the interns' rates changed to 93% and 87%, respectively, with significant increases in sensitivity and decreases in specificity.	Missed diagnosis, misdiagnosis
Multiple Intervention Types					
Additional Review Methods and Educational Interventions					
Seltzer, 1981 ⁽⁶¹⁾	Interpretation of radiographs	Film review process and education sessions with medical students	Diagnostic accuracy	Other: Retrospective review; seniority positively correlated to diagnostic accuracy. 80% of abnormalities were thought to be of clinical importance. First year residents had an omission rate of 6.1% while second and third year residents had 4.8%.	Missed diagnosis; misdiagnosis; proof of concept
Thomas, 1992 ⁽⁶⁴⁾	Interpretation of radiographs	Red star report reminds or indicates something possibly missed or incorrectly interpreted. Educational conference held to discuss results of reports	Diagnostic accuracy	Other: Internal audit system; Red star reports issued in 2.8% of cases. 0.7% of patients needed to return for follow-up due to incorrect interpretations. Less than 50% required an alteration to treatment.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Additional Review Methods, Educational Interventions, and Structured Process Changes					
Kundel, 1990 ^(62,63)	Diagnostic accuracy of pulmonary nodule interpretation	Visual (gaze-duration threshold algorithm) feedback to radiologists based upon eye-position recordings. Re-review of radiographs	Proper interpretation of chest radiographs	Other: The more time spent looking at a certain section of a radiograph, the higher the chance for error. Feedback cohort outperformed the control group. Feedback led to more confident true-positive diagnoses. 42% of nodules missed initially were identified after feedback.	Missed diagnosis; misdiagnosis; proof of concept
Additional Review Methods, Educational and Technology-based Systems Interventions					
McPhee, 1989 ⁽⁶²⁾	Missed cancer diagnosis	Cancer screening reminders, audit with feedback or control (no intervention). Half the cohort was also provided with educational course; 6 intervention cohorts with medical residents randomly assigned.	Cancer screening test performance	RCT: 20% of patients had active colorectal symptoms, 37% had one or more colorectal cancer risk factors, and 48% had one or more cervical cancer risk factors. Cancer screening reminders increased performance the most, followed by audit with feedback.	Missed diagnosis; misdiagnosis; delayed diagnosis
Additional Review Methods and Personnel Changes					
Trotter, 2003 ⁽⁶⁷⁾	Diagnostic errors from interpretation of skin biopsies by general pathologists (vs. dermatopathologists)	Interpretation of skin biopsies by general pathologists (vs. dermatopathologists)	Clinical importance of discrepant skin biopsy results between general pathologists and dermatopathologists	Other: Agreement in 93.5% of cases; blinded review of skin biopsies by dermatopathologists had a sensitivity of 100% in review of general pathologist identification of lesions. 1.4% of biopsies had discrepancies that were of potential clinical significance.	Missed diagnosis; misdiagnosis
Additional Review Methods, Personnel Changes, and Structured Process Changes					
Tsai, 2005 ⁽⁶⁹⁾	Incorrect diagnosis of acute renal failure (ARF) based on urine analysis interpretation	Interpretation of urine analysis by a nephrologist for patients with kidney disease; Urinalysis conducted and report written by a nephrologist rather than clinical laboratory	Correct diagnosis of acute renal failure based on urine analysis interpretation (that can impact patient management and outcome)	Other: The first nephrologist ("A") provided correct cause of ARF in 24 of 26 cases (92.3%) when performing urinalysis directly. However, diagnosis was correct by nephrologist A in only 23.1% and by a second nephrologist ("B") in 19.2% when analyzing clinical laboratory-generated urinalysis reports. Diagnosing from nephrologist A's direct urinalysis report, nephrologist B increased diagnostic accuracy to 69.3%. Nephrologists were more likely to recognize presence of RTE cells, granular casts, and dysmorphic RBCs in urine.	Missed diagnosis
Additional Review Methods and Structured Process Changes					

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Ross, 1996 ⁽⁶⁵⁾	Incorrect vertebral fracture diagnoses	Blinding of X-ray readings to film sequence and patient identity for the detection of vertebral fractures	Incorrect vertebral fracture diagnoses (that can impact patient management and outcome)	Other: Blinding x-rays to sequence offers no advantages, increases frequency of errors and may inflate incidence rates. "Incidents" in this study are when there was no fracture at index x-ray but fracture was present at follow-up x-ray (average = 3.6 yrs follow-up).	Missed diagnosis; misdiagnosis
Goodyear, 2008 ⁽⁷⁰⁾	Laboratory error	Daily supervisory review of culture reports in microbiology laboratory	Proper treatment; if microorganism susceptibility is mistaken, incorrect antibiotic prescribed	Other: Prospective assessment; review of culture results and antibiotic susceptibility were found to correct errors in 0.8% of cases, and in 0.3% of cases the corrections were clinically significant. Most clinical significance was related to the susceptibility issues concerning culture results. 302 positive cultures / 101,703 were considered potentially clinically significant.	Missed diagnosis; misdiagnosis
Additional Review Methods and Technique					
Beigi, 2007 ⁽³¹⁾	Incorrect diagnosis of lacrimal duct obstruction/stenosis/functional block	Re-examination of patients scheduled for dacryocystorhinostomy based on lacrimal duct syringing with four tests	Epiphora status at 12 months follow-up; and surgery rates	Other: Re-examination resulted in 18% not requiring previously scheduled major surgical intervention.	Misdiagnosis
Additional Review Methods and Technology-based Systems Interventions					
Jiang, 2001 ⁽⁶⁶⁾	Breast cancer detection	Computer-aided diagnosis (CAD) program	Diagnostic accuracy, as measured by interobserver variability, of breast cancer via mammogram interpretation	Other, Pre/Post: Prospective review; access to the tool improved radiologist agreement and reduced the occurrence of substantial disagreements. Among attending radiologists, and residents, the reductions were statistically significant at 63% and 28%, respectively.	Missed diagnosis; misdiagnosis; proof of concept
Peldschus, 2005 ⁽⁶⁸⁾	Lung lesions/cancer detection	Reevaluation of chest CT studies for focal lung lesions with the computer-aided detection (CAD) system as a second reader	Diagnostic accuracy of lung lesions	Other: Retrospective review; CAD detected significant lung lesions in an additional 33% of patients.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Moore, 2009 ⁽⁹⁾	Delayed sepsis detection in surgical intensive care	For early identification of sepsis, utilized routine bedside nursing measurements taken every 12 hours to determine whether a patient met threshold for escalating further assessment by nurse practitioner or resident physician. If one of these providers identified a source of infection, an intensivist was then included to determine whether treatment for sepsis was initiated.	Mortality as a proxy of delayed diagnosis of sepsis	Other Prospective Design, Pre/Post: Of 4,991 sepsis screens with 920 patients across 927 admissions to the surgical ICU, the sepsis early identification tool and protocol yielded a sensitivity of 96.5%, specificity of 96.7%, positive predictive value of 80.2%, and negative predictive value of 99.5%. Compared to the year before implementing the sepsis tool, mortality from severe sepsis and septic shock decreased from 35.1% to 24.2%. The authors reported that mortality in the medical and cardiovascular ICUs did not decrease notably at the same location during the study period.	Delayed diagnosis
Educational Interventions and Structured Process Changes					
Gleadhill, 1987 ⁽⁸⁹⁾	Diagnostic error in radiograph interpretation	Casualty officer's interpretation reviewed by radiologist, who was considered to have the correct report. Clinical guidelines introduced to standardize patients selected for referral	Reduction in clinically significant errors; late error detection	Experimental Design, Pre/Post: Number of referrals to Radiology dropped significantly from 59% to 48%, while rate of late error detection was unchanged.	Missed diagnosis; delayed diagnosis
Chern, 2005 ⁽³⁵⁾	Diagnostic errors in high-risk patients discharged from the emergency room	Feedback to physicians of outcomes for high-risk patients discharged from the emergency department according to telephone follow-up and review of 3-day return emergency department visits; residents educated about uncertain presentations of serious diseases	Return visits to the emergency department and clinically significant adverse events (including return visits with serious misdiagnoses)	Pre/post: Intervention reduced adverse events (diagnostic and other) from 4.1% to 1.5%, and return emergency department visits from 10.1% to 4.9%. Of the 54 patients across both study periods that experienced adverse events, 40 had misdiagnoses.	Misdiagnosis; delayed diagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Educational and Technology-based Systems Interventions					
Linver, 1992 ⁽⁹⁰⁾	Breast cancer detection	Dedicated mammography computer system. Educational mammography courses dedicated to radiologists.	Diagnostic accuracy	Pre/Post: Breast cancer diagnoses increased 50% pre-training and post-training, sensitivity increased from 80 to 86%. Positive predictive value remained 32%. Surgical consultations increased significantly.	Missed diagnosis; misdiagnosis
Personnel Changes and Technology-based Systems Interventions					
Jacobs, 2002 ⁽⁸⁵⁾	Facial fractures	Telemedicine system compared to plain radiography and diagnosis by oral and maxillofacial surgeons (OMFS) and accident and emergency department doctors	Diagnostic accuracy of facial fractures	Other: Comparative study; sensitivity and specificity of diagnosis by OMFS and A&E higher while viewing plain radiography than telemedicine system.	Missed diagnosis; misdiagnosis; Proof of concept;
Personnel Changes and Structured Process Changes					
Vernon, 1999 ⁽³⁶⁾	Interval between emergency department arrival and critical tests	Development of a formal trauma response team	Mortality, time to receiving necessary medical attention (CT scan, etc.)	Experimental: prospective, case-control study; patients treated by trauma response team had shorter wait times for computerized tomography scanning, operation room and overall time within the emergency department. Mortality rate was similar for both groups, but better for severely injured children treated by response team in comparison to reference population.	Missed diagnosis; misdiagnosis; delayed diagnosis
Structured Process Changes and Technology-based Systems Interventions					
Lewis, 1996 ⁽¹⁰²⁾	Mental illness; referral to mental health specialist	Three cohort intervention: (1) no additional information, (2) results of 12-item General Health Questionnaire (GHQ), and (3) results of self-administered computerized assessment (PROQSY) of common mental disorders	Clinical outcome; referral to mental health specialist	Other: GPs given varying levels of information to accurately diagnose mental disorders. Those given computerized assessment results saw modest clinical improvements in patients. No increase in referral rates to mental health professionals in computerized results group.	Missed diagnosis; misdiagnosis

Author, Year	Diagnostic Error	Experimental Intervention	Patient or Related Outcome	Study Design: Result	Notes
Rollman, 2002 ⁽³⁸⁾	Depression screening and diagnosis	PRIME-MD survey with 3 levels of electronic medical record feedback: (1) active care, (2) passive care, and (3) usual care	Diagnosis; treatment plan	RCT: Patient depression score on Hamilton Rating Scale for Depression decreased similarly regardless of physicians' level of feedback. Screening for major depression, assisted diagnostic tools, and exposure to evidence-based treatment guidelines did not influence treatment plan.	Missed diagnosis; misdiagnosis
Structured Process Changes and Technique					
Brossner, 2000 ⁽⁷⁹⁾	Prostate biopsies and cancer detection	Ultrasound-guided prostate biopsy technique; comparative study of two techniques to ascertain which is more accurate at identifying prostate cancer	Cancer detection rate; morbidity differences between techniques	Other: Comparative study; diagnostic accuracy did not differ between approaches; morbidity and duration of pain increased with 12-core biopsy procedure.	Missed diagnosis
Naughton, 2000 ⁽⁸⁰⁾	Prostate biopsies and cancer detection	12 vs. 6 biopsy cores taken via transrectal ultrasound	Diagnostic accuracy of prostate cancer	Other: Comparative study; no difference in overall prostate cancer detection rate or in pain assessment.	Missed diagnosis; misdiagnosis
Presti, 2000 ⁽⁸¹⁾	Prostate biopsies and cancer detection	Adding additional biopsies to the diagnostic process	Diagnostic accuracy of prostate cancer	Other: Trends did not achieve statistical significance between 8- and 10-biopsy regimens. Routine sextant biopsies detected 82% of cancers, and 77% of missed cancers were detected by lateral peripheral zone biopsies. Performing 10 biopsies of peripheral zone increased cancer detection rates by 14%.	Missed diagnosis
Ravery, 2000 ⁽⁸²⁾	Prostate cancer detection	Extensive biopsy protocol implemented	Diagnostic accuracy of prostate cancer	Other: Prospective study; protocol had a 6.6% improvement in prostate cancer detection rate. DRE significantly influenced detection rate of each protocol.	Missed diagnosis
Technique and Technology-based Systems Interventions					
*Weatherburn, 2000 ⁽⁸³⁾	Overall rate of misdiagnoses and rate of serious misdiagnoses leading to patient recall and treatment change	Picture Archiving and Communications System (PACS) in the accident and emergency department	Overall rate of misdiagnoses and rate of serious misdiagnoses leading to patient recall and treatment change	Experimental Design / Pre/post: Significant reduction in misdiagnosis when PACS was used (1.5% for film vs. 0.7% for PACS), but the rate of serious misdiagnoses involving patient recall did not change significantly. PACS reduced false negative interpretations but not rate of serious misdiagnosis.	Missed diagnosis

* The evaluations of interventions (n=6) with evaluations that were identified in the Singh 2012 systematic review⁽²³⁾.

Table 2, Chapter 35. Summary of randomized trials

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Diagnostic Accuracy Outcome						
Attard, 1992 ⁽⁷²⁾	Incorrect diagnosis in patients presenting with abdominal pain	T	Pain relief with papaveretum for acute abdominal pain	Placebo	Wrong Diagnosis	0.22 (0.05-0.98)
Thomas, 2003 ⁽²⁶⁾	Diagnostic errors based on altered physical examination findings	T	Morphine sulfate administered for pain during diagnostic process	Placebo	Diagnostic accuracy (based on information from follow-up visits/hospital discharges)	0.96 (0.73-1.27)
Hewett, 2010 ⁽⁷⁸⁾	Missed colorectal adenoma diagnosis in colonoscopy	T	Cap-fitted colonoscopy (allows for flattening of haustral folds and/or improves mucosal exposure)	Regular high resolution colonoscopy	Missed adenoma diagnoses (per adenomas)	0.63 (0.41-0.99)
McCarthy, 1990 ⁽⁸⁶⁾	Incorrect diagnosis by parents of symptoms of serious illness	EI	Teaching parents an Acute Illness Observation Scale (AIOS) to detect child's serious illness	3-point global scoring system for evaluating the chance of serious illness	False positives	0.24 ($P < 0.0001$)
					False negatives	1.78 (not statistically significant)
Klassen, 1993 ⁽⁹²⁾	Missed positive radiographic findings (fracture, dislocation or effusion) after trauma	SPC	Triage nurses using the Brand protocol (for ordering X-rays of injured extremities) in the pediatric emergency department	Physicians carrying out standard procedures	Patients with false negative radiograph interpretations	33.33 (2.01-554.09)
Wellwood, 1992 ⁽¹⁰⁴⁾	Misdiagnosis of appendicitis	TBS	Diagnostic aid with a standardized data collection form for abdominal pain interpretation	No diagnostic aid	Diagnostic accuracy for appendicitis	$P = 0.66$
			Diagnostic aid with a standardized data collection form and computer-aided diagnostic tool for abdominal pain interpretation	Standardized data collection forms only	Diagnostic accuracy for appendicitis	$P = 0.66$

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Bogusevicius, 2002 ⁽²⁷⁾	Missed acute mechanical small bowel obstruction	TBS	Computer-aided diagnosis for diagnosis of acute mechanical small bowel obstruction (SBO)	Contrast radiography	False positives for complete SBO	Relative risk could not be calculated (0 events)
					False negatives for complete SBO	
					False positives for partial SBO	0.54 (0.11-2.77)
					False negatives for SBO	Relative risk could not be calculated (0 events)
Further Diagnostic Test Use Outcome						
Sakr, 1999 ⁽³⁷⁾	Clinically important errors, including errors in the diagnosis pathway (i.e., history, physical examination, and radiographic interpretation errors)	PC	Use of nurse practitioner in providing care in the emergency department	Use of junior doctors in the emergency department	Inappropriate radiologic follow-up (unnecessary request or failure to request)	0.94 (0.75-1.18)
Klassen, 1993 ⁽⁹²⁾	Missed positive radiographic findings (fracture, dislocation or effusion) after trauma	SPC	Triage nurses using the Brand protocol (for ordering X-rays of injured extremities) in the pediatric emergency department	Physicians carrying out standard procedures	Patients with radiographs ordered	0.94 (0.75-1.18)

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
McPhee, 1989 ⁽⁶²⁾	Missed cancer diagnosis	ARM, EI, and TBS	Computer generated list of overdue tests at patients' visits (cancer screening reminders)	No intervention	Further cancer screening (Results given as post-intervention compliance scores relative to standards according to the American Cancer Society recommendations)	Statistically significant [†]
			Audit with feedback	No intervention	Further cancer screening (results given as post-intervention compliance scores relative to standards according to the American Cancer Society recommendations)	Statistically significant [†]
			Patient education	No intervention	Further cancer screening (results given as postintervention compliance scores relative to standards according to the American Cancer Society recommendations)	Statistically significant**
Therapeutic Use Outcome						
Attard, 1992 ⁽⁷²⁾	Incorrect diagnosis in patients presenting with abdominal pain	T	Pain relief with papaveretum for acute abdominal pain	Placebo	Inappropriate management (surgery or patient observation)	0.22 (0.05-0.98)
Thomas, 2003 ⁽²⁶⁾	Diagnostic errors based on altered physical examination findings	T	Morphine sulfate administered for pain during diagnostic process	Placebo	Admissions for observation or discharge home	<i>P</i> = 0.50
					Surgeries	<i>P</i> = 0.51
					Repeat physician visit for abdominal pain within 7 days	2.84 (0.31-26.08)
	Possible incorrect surgical management	2.84 (0.31-26.08)				

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Kuperman, 1999 ⁽²⁸⁾	Delays between laboratory results and clinical action	TBS	Computer system to detect critical laboratory conditions and notify the physician via Hospital's paging system	No automatic notification for alerts	Time to appropriate treatment	$P = 0.003$
Sakr, 1999 ⁽³⁷⁾	Clinically important errors, including errors in the diagnosis pathway (i.e., history, physical examination, and radiographic interpretation errors)	PC	Use of nurse practitioner in providing care in the emergency department	Use of Junior Doctors in the emergency department	Unplanned follow-up visits	0.65 (0.45-0.96)
Wellwood, 1992 ⁽¹⁰⁴⁾	Misdiagnosis of appendicitis	TBS	Diagnostic aid with a Standardized data collection form for abdominal pain interpretation	No diagnostic aid	Admissions	0.91 (0.84-0.99)
					Surgeries	0.98 (0.82-1.16)
			Diagnostic aid with a Standardized data collection form + computer-aided diagnostic tool for abdominal pain interpretation	Standardized data collection forms only	Admissions	1.01 (0.91-1.12)
					Surgeries	1.09 (0.90-1.32)
Rollman, 2002 ⁽³⁸⁾	Missed depression diagnosis	SPC and TBS	Active care: Primary care providers (PCPs) were exposed to advisory messages on the paper encounter-based upon AHCPR's guidelines AND advise to click on the computer desk top icon to obtain further treatment advise from the EMR intranet site	Passive care: PCPs provided with a reminder of their patients' depression dx on the paper encounter form to treat depressive episodes, but offered no details on how to do so	PCP counsels patient for depression	1.25 (0.67-2.33)
					Mental health referral suggested	0.74 (0.45-1.23)
					Antidepressant medications prescribed	1.25 (0.67-2.33)
			Passive care: PCPs provided with a reminder of their patients' depression diagnosis on the paper encounter form to treat depressive episodes, but offered no details on how to do so	Usual care	PCP counsels patient for depression	0.95 (0.49-1.87)
					Mental health referral suggested	1.01 (0.64-1.59)
					Antidepressant medications prescribed	0.95 (0.49-1.87)
Active care: PCPs were exposed to advisory messages on the paper encounter-based upon AHCPRs guidelines AND advise to click on the computer desk top icon to obtain further treatment advise from the EMR intranet site	Usual care	PCP counsels patient for depression	1.19 (0.63-2.25)			
		Mental health referral suggested	0.75 (0.44-1.25)			
		Antidepressant medications prescribed	1.19 (0.63-2.25)			

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Patient Outcomes						
Sakr, 1999 ⁽³⁷⁾	Clinically important errors, including errors in the diagnosis pathway (i.e., history, physical examination, and radiographic interpretation errors)	PC	Use of nurse practitioner in providing care in the emergency department	Use of junior doctors in the emergency department	Non improvement in condition	0.94 (0.68-1.30)
Bogusevicius, 2002 ⁽²⁷⁾	Missed acute mechanical small bowel obstruction	TBS	Computer-aided diagnosis for diagnosis of acute mechanical small bowel obstruction	Contrast radiography	Mortality	5 (0.25-100.97)
					Morbidity outcome	1.33 (0.32-5.58)
Fitzgerald, 2011 ⁽³⁴⁾	Errors during reception and resuscitation of severely injured adult trauma patients (including errors in the diagnosis pathway)	TBS	Real time computer-prompted evidence-based decision support system (with decision and action algorithms) during reception and resuscitation of severely injured adults in Level I adult trauma center	Control (without computer-aided decision support system)	Error rate	0.89 (0.79-1.00)
					Morbidity from shock management	$P = 0.03$
					Aspiration pneumonia	$P = 0.046$
					Sepsis	Not statistically significant
					ARDS (acute respiratory distress syndrome)	Not statistically significant
					Functional independence measure score	Not statistically significant
					Hospital length of stay	Not statistically significant
					Transfusion of blood productions	$P < 0.001$
Mortality	1.15 (0.65-2.03)					
Kuperman, 1999 ⁽²⁸⁾	Delays between laboratory results and clinical action	TBS	Computer system to detect critical laboratory conditions and notify the physician via hospital's paging system	No automatic notification for alerts	Time to resolution of alerting conditions	$P = 0.11$
					Adverse events	$P = 0.41$

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Rollman, 2002 ⁽³⁸⁾	Missed depression diagnosis	SPC	Active care: PCPs were exposed to advisory messages on the paper encounter-based upon AHCPRs guidelines AND advise to click on the computer desk top icon to obtain further treatment advise from the EMR intranet site	Passive care: PCPs provided with a reminder of their patients' depression diagnosis on the paper encounter form to treat depressive episodes, but offered no details on how to do so	Nonimprovement of depressive symptoms	1.06 (0.78-1.44)
			Passive care: PCPs provided with a reminder of their patients' depression dx on the paper encounter form to treat depressive episodes, but offered no details on how to do so	Usual care	Nonimprovement of depressive symptoms	0.88 (0.65-1.19)
			Active care: PCPs were exposed to advisory messages on the paper encounter-based upon AHCPRs guidelines AND advise to click on the computer desk top icon to obtain further treatment advise from the EMR intranet site	Usual care	Nonimprovement of depressive symptoms	0.93 (0.70-1.25)
Composite Clinical Outcomes						
Sakr, 1999 ⁽³⁷⁾	Clinically important errors, including errors in the diagnosis pathway (i.e., history, physical examination, and radiographic interpretation errors)	PC	Use of nurse practitioner in providing care in the emergency department	Use of junior doctors in the emergency department	DAO+ TUO: Clinically important errors (composite outcome for diagnostic errors, treatment/follow-up errors)	0.86 (0.63-1.18)
Schriger, 2001 ⁽³⁹⁾	Misdiagnosis of occult mental illness	SPC	Report of a computerized psychiatric interview (PRIME-MD) given to the physician	PRIME-MD report not given to the Physician	Consultation or referral for mental illness plus other (psychiatric diagnosis)	1.60 (0.47-5.48)

Author	Diagnostic Error	Type of Intervention	Experimental Intervention	Compared intervention	Description of Outcome	Effect Size (95% CI)*
Kuperman, 1999 ⁽²⁸⁾	Delays between laboratory results and clinical action	TBS	Computer system to detect critical laboratory conditions and notify the physician via hospital's paging system	No automatic notification for alerts	TUO+PO: Adverse events (cardiopulmonary arrest, ICU admissions, strokes, acute renal failure, death, need for surgery)	1.20 (0.78-1.84)

Abbreviations: AHCPR = Agency for Health Care Policy and Research; ARM = additional review methods; DAO = diagnostic accuracy outcome; EI = educational intervention; EMR = electronic medical record; ICU: intensive care unit; nss = not statistically significant; PC = personnel change; PCP = primary care physician; PO = patient outcomes; PRIME-MD: Primary Care Evaluation of Mental Disorders; SBO = small bowel obstruction; SPC = structured process change; ss = statistically significant; T= technique; TBS = technology-based systems intervention; TUO = therapeutic use outcome.

*Effect size is relative risk except for Fitzgerald et al. where error rate was used; McPhee et al, where difference in scores post intervention was used and Kuperman et al. where time to appropriate treatment was used.

†Results were significant for: stool occult blood testing, rectal examination, sigmoidoscopy, pelvic exam, breast exam, mammography AND non-significant for Pap smear.

‡Results were significant for: breast exam, mammography AND non-significant for: occult blood test, rectal exam, sigmoidoscopy, Pap smear, pelvic exam

**Results were significant for breast exam AND non-significant for mammography.

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Evidence Tables for Chapter 36. Monitoring Patient Safety Problems (NEW)

The layout of this evidence table is customized based on the data reported by the included studies. Some columns in the evidence tables for other PSP topics are not included in this table or merged with other columns. For example, the “Description of Organization” column is merged into the “Context” column. There is no “Theory or Logic Model” column in this table because none of the included studies reported such data. The customized layout allows the data collected to fit into the table appropriately.

Table 1, Chapter 36. Evidence from studies comparing methods for detecting patient safety problems

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
Olsen 2007 ¹	<p>Three methods for detecting adverse events (AEs) were studied:</p> <p>1) <u>Incident reports</u> At the time of data collection risk managers encouraged reporting of AEs and near misses but provided no further criteria or guidelines for reporting except that it was mandatory to supply details of incidents in which security staff are involved. Reporting is confidential but not anonymous. The forms contain both mandatory data fields and space for free text. During the periods of data collection there were neither additional incentives nor specific encouragements to enhance reporting.</p> <p>2) <u>Active surveillance of prescription charts by pharmacists</u> Hospital pharmacists attend the wards on weekdays during normal working hours to ensure continuity of pre-admission medications and to detect prescribing errors. After discussion with ward doctors errors and omissions are corrected on the prescription charts. For each intervention a brief record is made on a standardized form. The forms related to the care of the 288 patients entered into the study were collected and analyzed centrally in the pharmacy.</p> <p>3) <u>Record review at time of discharge</u> Specialist registrars (senior residents) monitored by external reviewers assessed all case records within 10 days of discharge of consecutively discharged or deceased patients from the participating firms. The occurrence of an adverse event or potential</p>	<p>This is a prospective observational study. Data on AEs were collected on 288 patients discharged from adult medical and surgical units in an acute care hospital</p>	<p><u>External:</u> In the UK, several initiatives had been established by the Department of Health to promote patient safety. The National Reporting and Learning System (NRLS) established by the National Patient Safety Agency (NPSA) is one of the initiatives. Incidents reported to nine types of the National Health System (NHS) Trust (ranging from acute general hospitals to community optometry), are relayed centrally for classification and analysis.</p> <p><u>Organizational Characteristics:</u> A district general acute care hospital in the NHS in the UK. The hospital had an 850-bed and received around 40 000 admissions per year. The hospital trust covers a full range of medical and general surgical specialties backed up by full intensive care facilities.</p> <p><u>Teamwork:</u> Safety data were collected from three general medical and three general surgical teams. The teams were selected by the head of risk management.</p> <p><u>Leadership:</u> None mentioned</p>	<p>Record review detected 26 (9%) AEs and 40 (14%) potential adverse events (PAEs) occurring during the index admission. Three adverse events and 11 potential adverse events were associated with medications. Other commonly occurring events included inadequate clinical monitoring and management (17/66), technical problems with a procedure (9/66), infection-related problems (8/66) and failure to arrange adequate follow-up or care at discharge (7/66). Incident reporting detected 11 PAEs and no AEs. These PAEs included delay in cross-matching blood for a patient requiring surgery; poor clinical hand over of a patient from accident and emergency to ward staff; a fall causing a bruised head that required medical assessment, an intravenous cannula misplaced in the brachial artery, five concerned falls without significant injury and two episodes in which security staff were called in relation to absconded or aggressive patients. Pharmacy surveillance found</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>adverse event was determined for each case. Each event was classified according to the stage of care and a mutually exclusive problem category (diagnosis, overall assessment of patient's condition including comorbidities, technical problems occurring during a procedure, infection-related, general problems with ongoing monitoring and management of patients and medication-related problems). Record review was also carried out by members of the clinical team caring for the patients. But in this report only the data collected by the external assessors were used.</p>		<p><u>Culture</u>: "In this hospital, as throughout the NHS, risk managers encourage clinical staff to report, on printed forms, incidents that may affect patients adversely." <u>Implementation tools</u>: Various forms were used for data collection.</p>	<p>30 medication errors all of which were PAEs. The most common problems related to failure to prescribe regular or indicated medication (15/30) and failure to prescribe the correct dose of a drug (9/30). There was little overlap in the nature of events detected by the three methods.</p>
Wetzels 2008 ²	<p>Five methods for identifying adverse events in general practice:</p> <p>1) <u>Physician reported adverse events</u> The physicians recorded all events using a simplified computerized registration form based on an existing international taxonomy for errors in general practice. The physicians registered event date, birth date of patient, gender, event category (practice administration (archive; medical record; appointment; other), diagnostic (wrong diagnosis; delayed diagnosis; missed diagnosis; other), therapeutic (wrong, incomplete; delayed; none, though it should be; other), communication (with patients; with caregivers; other), and additional remarks and/or context.</p> <p>2) <u>Pharmacist reported adverse events</u> The pharmacist recorded events from her point of view using an adjusted form developed for this purpose. Event date, birth date of patient, gender, practice, event category (prescribing error (wrong prescription, wrong administration; wrong dose; other), adverse reaction (adverse reaction; allergic reaction; overdose; interaction; contra-indication; other), dispensing error (too late; wrong medicine; wrong dose; other), and additional remarks or context were recorded.</p> <p>3) <u>Patients' experiences of adverse events</u> In the waiting room of the two practices samples of 50 patients, consecutively visiting the practice, were invited to complete a questionnaire on</p>	<p>A prospective observational study, comparing the five methods in two general practices in a period of five months (May to October 2006) A total of approximately 8,250 patients were registered with the two practices</p>	<p><u>External</u>: None mentioned <u>Organizational Characteristics</u>: Two general practices in the Netherlands; no other detail provided <u>Teamwork</u>: Multiple physicians, pharmacists, or researchers were involved in the study collecting or reviewing data. <u>Leadership</u>: None mentioned <u>Culture</u>: None mentioned <u>Implementation tools</u>: The physicians recorded all events using a simplified computerized registration form based on an existing international taxonomy for errors in general practice. The pharmacist recorded events from her point of view using an adjusted form developed for this purpose. A questionnaire was used to collect data patients' experience. Refer to "Description of PSP" for more description.</p>	<p>A total of 68 events were identified using these methods. The events detected in four categories: 1) Events in office administration, 2) Events in diagnosis, 3) Treatment events, and 4) Events in Communication. All five methods proved to identify a number of adverse events. Each of the methods provided events that were not found with other methods. There was no overlap between the methods regarding the identified events. The patient survey accounted for the highest number of events and the pharmacist reports for the lowest number. All methods resulted in a variety of events, except for the pharmacist reports, which only referred to pharmaceutical treatment. The identified events referred to adult male and female patients of all ages, but events on children were very seldom reported.</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>experienced problems with safety of their health care in the previous six months. A drop box was used to collect the completed questionnaires. Questions were derived from items of the Medical Harvard Study, and from questions of two survey studies. The questionnaire guaranteed anonymity of participating patients.</p> <p>4) <u>Assessment of a random sample of medical records</u> Thirty medical records per physician were randomly selected from patients who had visited their general practice in the observation period. Anonymous medical records, containing the information from this period were printed out. Two clinical researchers examined the information independently. They scrutinized the records for indications of events and, when found, categorized the event (errors in office administration, diagnosis, treatment or communication with their subcategories); and added demographic data of the patient. Subsequently the physicians discussed their findings and reached consensus.</p> <p>5) <u>Assessment of all deceased patients</u> One physician examined the medical records of the patients who had died in the period of the study for events. The same registration form and analysis procedure as for the audits of medical records was used.</p>			
Ferranti 2008 ³	<p>Two ADE detection systems were studied:</p> <p>1) <u>Voluntary reporting</u> The safety reporting system was developed as a home-grown web application to provide a single point of entry for voluntary reporting and allow standardized evaluation of safety events across Duke University Health System (DUHS). All DUHS employees may access the reporting system and are encouraged to report any safety events witnessed, including near misses. Although anonymous reporting is possible, DUHS policy supports a non-punitive culture of safety. Safety reporting system captures a myriad of event types including medication/intravenous-related, blood</p>	<p>The study retrospectively analyzed all ADEs detected using the two independent system in adults treated in the hospital (all inpatients receiving service on 23 adult care nursing units between December 1st, 2006 and June 30th, 2007). Adult, inpatient ADEs were evaluated and scored using a standardized methodology. ADEs per 1,000 patient days were calculated.</p>	<p><u>External:</u> None mentioned <u>Organizational Characteristics:</u> It is a large, tertiary care academic medical center in the DUHS <u>Teamwork:</u> For both voluntary reporting and computerized surveillance, multidisciplinary teams were used for investigating reviewing and confirming the findings. Refer to "Description of PSP" for more detail. <u>Leadership:</u> For voluntary reporting, a multidisciplinary leadership team reviewed and</p>	<p>Computerized surveillance detected 710 ADEs (6.93/1,000 patient days), whereas voluntary reporting identified 205 ADEs (1.96/1,000 patient days). For each major drug category (anticoagulants, hypoglycemia, narcotics and benzodiazepines, and miscellaneous), surveillance and voluntary reporting detected significantly different event rates. Most surveillance events were hypoglycemia-related, whereas most voluntarily-reported events</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>transfusions, surgical, falls, treatment/testing, dissatisfied patient, and others. Each medication/intravenous-related report was investigated by a team of 4 medication safety pharmacists and scored for severity before submission to a multidisciplinary leadership team for review and confirmation. All events with a severity score were deemed adverse drug events (ADEs).</p> <p>2) <u>Computerized surveillance</u> The DUH's computerized ADE-S system was deployed by an internal team of technical and safety experts. Each evening, ADE-S evaluates medication, laboratory, and patient demographic information against a set of clinical rules or triggers to detect potential ADEs or evolving unsafe conditions. Nearly 130 rules have been deployed since the system's inception, but only 14 high-risk rules with high true-positive rates were considered in surveillance. These 14 rules span 3 main categories: abnormal laboratory results, use of antidotes, and drug-lab combinations. Adverse drug event surveillance delivers an electronic daily report to a web-based surveillance application that details all triggers fired by the system. This list was evaluated by 3 clinical pharmacists who perform a chart review to determine whether an ADE occurred. Pharmacists identified all possible medications involved in the event and assigned a causality score using the Naranjo algorithm and a severity score using the DUH 7-point scale. All events scored with causality Q5 and a severity Q3 were considered ADEs. Pair wise inter-rater reliability scores (J statistic) exceeded 0.88 for each rater pair.</p>		<p>confirmed the findings. <u>Culture</u>: There is "a highly vigilant, non-punitive culture of safety at DUH" <u>Implementation tools</u>: Business intelligence software was used to provide real time access to event reports from both the For both voluntary reporting and computerized surveillance systems to empower caregivers with safety data originating from their clinical care areas.</p>	<p>were in the miscellaneous category. The 2 systems detected statistically different ADE rates when stratified by nursing station. Of all unique ADEs (875), only 40 (5.6%) were common between the systems.</p>
Levinson 2010 ⁴	<p>The following safety problem monitoring methods were assessed: 1) <u>Nurse Reviews</u> Contracted registered nurses reviewed medical records for each sampled 278 Medicare beneficiary's hospitalization. Nurses used a standardized review process developed by the</p>	<p>The study retrospectively evaluated the usefulness of five methods for identifying patient safety events in 278 Medicare beneficiary hospitalizations selected from all Medicare discharges from acute care</p>	<p><u>External</u>: None mentioned <u>Organizational Characteristics</u>: None mentioned <u>Teamwork</u>: None mentioned <u>Leadership</u>: None mentioned <u>Culture</u>: None mentioned <u>Implementation tools</u>: IHI's GTT</p>	<p>Nurse reviews and POA analysis identified the greatest number of safety events. Nurse reviews identified 93 of the 120 safety events in the case study and POA analysis identified 61 events. Beneficiary interviews identified</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>Institute for Healthcare Improvement (IHI) as part of its Global Trigger Tool (GTT) protocol. The nurse review used IHI's GTT worksheet that listed 54 "triggers" that could be found within a medical record to indicate the possibility of an event. When a trigger was found, the nurse reviewer explored the medical record further to identify possible events and associated level of harm.</p> <p>2) <u>Analysis of present-on-admission (POA) Indicators</u> Administrative billing data directly from hospitals for each of the 278 sample Medicare beneficiary hospitalizations was analyzed. POA indicators in the billing data was used to identify hospitalizations that may have had events. When the POA indicator showed that a diagnosis was not present upon admission, the investigator concluded that the condition developed during the hospital stay and might have been the result of an event.</p> <p>3) <u>Beneficiary Interviews</u> The investigators conducted telephone interviews with 220 of the 278 Medicare beneficiaries or their family members to learn about the medical care experienced during sampled hospitalizations. The interview protocol was designed to determine whether beneficiaries experienced any episodes while in the hospital that might have involved events. It also included questions about such topics as medications, procedures, infections, and falls.</p> <p>4) <u>Hospital Incident Reports</u> The investigators requested that hospitals provide any internal incident reports, such as submissions to any hospital incident-reporting systems, adverse drug reaction reports, complaints, peer reviews, and mortality and morbidity reviews associated with the 278 sample Medicare beneficiary hospitalizations. Reports provided by hospitals included issues related to risk management, hospital infections, surgical management, and others.</p> <p>5) <u>Analysis of Patient Safety Indicators</u> The investigators applied the Agency for</p>	<p>hospitals in two selected counties during a 1-week period in August 2008. The investigators compared events flagged by each method to the 120 events identified and/or confirmed through physician reviews.</p>	<p>worksheet, POA indicators, and AHRQ's PSI software program were used in the study. Detailed description of these tools was provided in the appendix of the Levinson study.⁴</p>	<p>22 events, and the remaining 2 screening methods identified 8 events each. Of the 120 events, 55 (46 percent) were identified by only 1 screening method. Nurse reviews identified 35 events (29 percent of the 120 events) not flagged by any other screening method. POA analysis alone flagged 14 events (12 percent of the 120 events). Although the five screening methods were useful in identifying events, 406 of the 662 flags generated by the methods were not associated with any of the 120 events identified in the case study. The POA analysis generated the most flags that were not associated with events (183 flags) and PSI analysis generated the fewest (4 flags).</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>Healthcare Research and Quality's (AHRQ's) Patient Safety Indicator (PSI) software program to hospital administrative billing data for the 278 sample Medicare beneficiary hospitalizations. AHRQ developed the PSI software to monitor health care quality using administrative data, such as patient demographics (e.g., age, gender), and diagnoses and procedure codes. The PSI software is based upon a series of algorithms that detect 20 provider-level complications that indicate possible events (e.g., death of a low-risk patient).</p>			
Levtzion-Korach 2010 ⁵	<p>The following safety problem monitoring methods were assessed:</p> <p>1) <u>An incident reporting system</u> The hospital used a commercially available Web-based incident reporting system. Hospital personnel could report confidentially through any hospital computer using a secure login and could report anything that they perceive might be an issue. Each adverse event report contains the reporter's initial comments and a section for the departmental manager to clarify issues further and add comments and actions. The manager is responsible for reviewing each report and assigning one or more contributing factors from a drop-down list of 50 potential contributing factors. For the most important reports, management will have direct conversation with the reporters after the evaluation is complete</p> <p>2) <u>Reports to hospital risk management</u> A nurse-lawyer leads the risk management team. Physicians and nurses, in about equal numbers, call the team to report adverse events and poor patient outcomes. Risk management staff members investigate each case and determine on the basis of the estimated risk whether to report the case to the malpractice carrier. This information is collected manually with no systematic categorization and is entered in an electronic index. Risk management also provides information back to managers or frontline individuals so that risks can be mitigated.</p> <p>3) <u>A patient complaints database</u></p>	<p>This is a prospective observational study, comparing the five safety problem detection methods. Data were collected for a 22-month period from May 10, 2004, to February 28, 2006. 8,616 incident reports (involving 13,255 contributing factors), 1,003 risk management reports, 4,722 patient complaints (involving 6,617 specific problems), 61 walk rounds (involving 572 comments), and 322 malpractice claims (involving 949 issues) were evaluated.</p>	<p><u>External:</u> None mentioned</p> <p><u>Organizational Characteristics:</u> This study was performed at Brigham and Women's Hospital, a 747-bed tertiary care academic medical center affiliated with Harvard Medical School. There are approximately 52,000 inpatient admissions and 950,000 outpatient visits annually. The hospital employs more than 12,000 people, of whom approximately 3,000 are physicians. The hospital "had more independent data sources than is the norm."</p> <p><u>Teamwork:</u> The study mentioned multidisciplinary team efforts for some methods used (e.g., hospital risk management, handling patient complaints databases, and executive walk rounds). Refer to "Description of PSP" for more description.</p> <p><u>Leadership:</u> For executive walk round, the deep involvement by the top-level executives was mentioned in the study. Refer to "Description of PSP" for more description.</p>	<p>Across the five methods, the leading categories of safety problems were communication, 11.6%; technical skills, 10.9%; and clinical judgment, 9%. Each of the methods had a different category that was most frequent. Clinical judgment was the leading category in the malpractice claims data (24.3%) but was barely represented in the incident reporting system (1.1%) and not represented at all in executive walk rounds. Communication played an important role both in the malpractice claims (17.1%) and the patient complaints data (21.8%) but not in the hospital's risk management data (3%). Provider behavior accounted for 19% of complaints in the patient complaints system, second only to communication (clearly the two are closely related). However, provider behavior represented only 1.1% of the malpractice claims and 2.1% of reports to risk management and was not represented in the executive walk rounds or incident reporting</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>The hospital's Family and Patient Relations Department responds to patient and family complaints (concerns), suggestions, and compliments. The department's coordinators receive the complaints, assign them to one of 20 categories and one or more of 118 subcategories, and process them into a database. The department works directly with the hospital risk management team and safety team, which includes a physician, nurses, and safety analysts; although the analysts mostly do not have a medical background, they are trained in patient safety.</p> <p>4) <u>Executive walk rounds</u> Executive leadership walk rounds began at the hospital in January 2001. Semiweekly, a member of the hospital leadership (hospital chief executive officer, chief medical officer, chief nursing officer, chief operating officer) accompanied by the hospital's safety officer, a safety analyst, and a pharmacy representative visits a different service in the hospital and engages with the staff (mainly nurses but occasionally also physicians) about safety concerns. In stimulated discussions, staff is encouraged to speak freely and make suggestions for improvement. The staff comments (negative and positive) are assigned one or more (out of 51) contributing factors and a priority score, which are then recorded in an electronic database. Analyses of the comments are then compiled into action items that are discussed with the accountable vice president.</p> <p>5) <u>Malpractice claims</u> The hospital used a data collection system called CMAPS (Claims Management, Analysis, and Processing System) from the malpractice insurer, CRICO/Risk Management Foundation (RMF; Cambridge, MA). Initial information is obtained from potential claim reports, hospital risk managers, or from formal malpractice claims and suits. Further information is added as it becomes available (for example, depositions, expert reviews, medical</p>		<p><u>Culture</u>: The institution has "a history of patient safety awareness," and was "willing to allow all its defect data to be closely examined."</p> <p><u>Implementation tools</u>: The hospital used a commercially available Web-based incident reporting system. The hospital used CMAPS to collect data on malpractice claims. Refer to "Description of PSP" for more description about the incident reporting system and the CMAPS system.</p>	<p>system. Equipment (15.7%), electronic records (12.2%), and environment/infrastructure (12.1%) were the leading categories in executive walk rounds but were ranked low in the other systems. In the incident reports, identification issues (24.4%) and falls (16.8%) were the leading categories but were barely represented in the other systems. Overall, there is a low level of consistency across the five methods. The highest correlations between the different categories across the methods were between malpractice claims, reports to risk management, and patient complaints. The adverse event reporting system and executive walk rounds had low and negative correlation with the other four systems.</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>records, adjustor notes). Nurse coders assign one or more (from 170) risk management issues, factors that may have contributed to the allegation, injury, or initiation of the claim/suit. There are clear definitions, standardized coding algorithms, and collaboration between coders leading to high inter-rater reliability. The data are stored in an electronic database that is available for querying, analysis, and generation of reports. There are about 30 claims per year.</p>			
Tinoco 2011 ⁶	<p>Two methods for detecting inpatient adverse drug events (ADEs) and hospital-associated infections (HAIs) were studied: A computerized surveillance system (CSS) or manual chart review (MCR) For CCS, the HELP (Health Evaluation through Logical Processing) system was used. This electronic system manages billing and administrative codes for each hospital admission, as well as information from several clinical domains: admission, discharge, and transfer (ADT)/registration, pharmacy, laboratory, microbiology, nurse charting, and physician narratives, etc. The physician narratives stored in the HELP system as freetext documents include emergency department report, admission history and physical report, consultant note, radiology report, surgical procedure note, and discharge summary.</p> <p>The HAI detection criteria used by CSS were originally based on the guidelines from the Study of the Efficacy of Nosocomial Infection Control and the Centers for Disease Control and Prevention (CDC). In addition to routine HAI surveillance, daily urine samples from all catheterized patients were obtained as part of an existing, hospital-wide urinary catheter surveillance program. The ADE detection criteria used by CSS include various clinical triggers such as medication discontinuation orders, dose decrease orders, antidote orders, laboratory test orders, abnormal laboratory test results and vital signs. Suspected cases are flagged by CSS and reported to surveillance</p>	<p>The study retrospectively analyzed inpatient ADEs and HAIs detected either by CSS or MCR. Data were collected from 2,137 unique, prescreened admissions to the medical and surgical services of the LDS Hospital between October 1, 2000 and December 31, 2001. Descriptive analysis was performed for events detected using the two methods by type of AE, type of information about the AE, and sources of the information.</p>	<p><u>External:</u> None mentioned <u>Organizational Characteristics:</u> The study was performed at LDS Hospital, a major teaching hospital in Salt Lake City, Utah. <u>Teamwork:</u> None mentioned <u>Leadership:</u> None mentioned <u>Culture:</u> None mentioned <u>Implementation tools:</u> For CSS, the HELP system was used, which has an integrated CSS that prospectively screens electronic patient data for indicators of AEs, including HAIs and ADEs. Refer to "Description of PSP" for more description about the HELP system.</p>	<p>CSS detected more HAIs than MCR (92% vs. 34%); however, a similar number of ADEs was detected by both systems (52% vs. 51%). The agreement between systems was greater for HAIs than ADEs (26% vs. 3%). The CSS missed events that did not have information in coded format or that were described only in physician narratives. The MCR detected events missed by CSS using information in physician narratives. Some ADEs found by MCR were detected by CSS but not verified by a clinician.</p>

Author/ Year	Description of PSP	Study Design	Contexts	Outcomes: Benefits or Harms
	<p>personnel for validation. An infection preventionist or a clinical pharmacist verifies each HAI or ADE, respectively, using information from the patient record, direct bedside observations, and interviews with patients and their providers.</p> <p>The MCR data were from a previous multi-institutional research investigation of AEs ('workload study'). No other detail was provided about how MCR was performed.</p>			

References

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Evidence Tables for Chapter 37. Interventions To Improve Care Transitions at Hospital Discharge (NEW)

Table 1, Chapter 37. Included studies and interventions

Study, Year	Study Design	Patient Population	Sample Size		Readmission	Adverse Event	Costs	Acute care/ED utilization
			Control	Intervention				
Adler et al, 2009 ¹	CCT	General medical	144	156	<input type="checkbox"/>			<input type="checkbox"/>
Al-Rashed et al, 2002 ²	CCT	Geriatric/General medical	44	45	<input type="checkbox"/>			<input type="checkbox"/>
Balaban et al, 2008 ³	RCT	General medical	49	47	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Bolas et al, 2004 ⁴	RCT	General medical	124	119	<input type="checkbox"/>			<input type="checkbox"/>
Brand et al, 2004 ⁵	CCT	Geriatric/General medical	83	83	<input type="checkbox"/>			<input type="checkbox"/>
Coleman et al, 2004 ⁶	CCT	Geriatric/Mixed Diagnoses	1235	158	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Coleman et al, 2006 ⁷	RCT	Geriatric/Mixed Diagnoses	371	379	<input type="checkbox"/>		<input type="checkbox"/>	
Courtney et al, 2009 ⁸	RCT	Geriatric/General medical	64	64	<input type="checkbox"/>			<input type="checkbox"/>
Cowan et al, 2006 ⁹	CCT	General medical	626	581	<input type="checkbox"/>		<input type="checkbox"/>	
Dellasega et al, 2000 ¹⁰	RCT	Geriatric/General medical	43	30	<input type="checkbox"/>			<input type="checkbox"/>
Einstadler et al, 1996 ¹¹	CCT	General medical	229	243	<input type="checkbox"/>			<input type="checkbox"/>
Forster et al, 2005 ¹²	RCT	General medical	186	175	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Gallagher et al, 2011 ¹³	RCT	Geriatric	200	200	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gillespie et al, 2009 ¹⁴	RCT	Geriatric/General medical	201	199	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Gow et al, 1999 ¹⁵	CCT	General medical	59	18	<input type="checkbox"/>			
Graumlich et al, 2009 ¹⁶	RCT	Mixed patient population	315	316	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Hellstrom et al, 2011 ¹⁷	CCT	Geriatric	117	115	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Hogan and Fox, 1990 ¹⁸	CCT	Geriatric/General medical	66	66	<input type="checkbox"/>			
Jack et al, 2009 ¹⁹	RCT	General medical and surgical	376	373	<input type="checkbox"/>			<input type="checkbox"/>

Study, Year	Study Design	Patient Population	Sample Size		Readmission	Adverse Event	Costs	Acute care/ED utilization
			Control	Intervention				
Koehler et al, 2009 ²⁰	RCT	Geriatric/General medical	21	20	<input type="checkbox"/>			<input type="checkbox"/>
Lim et al, 2003 ²¹	RCT	Geriatric/General medical	314	340	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Lipton and Bird, 1994 ²²	RCT	Geriatric	356	350	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Makowsky et al, 2009 ²³	CCT	Mixed patient population	231	221	<input type="checkbox"/>			<input type="checkbox"/>
Martin et al, 1994 ²⁴	RCT	Geriatric/General medical	25	29	<input type="checkbox"/>		<input type="checkbox"/>	
Mudge et al, 2006 ²⁵	CCT	General medical	746	792	<input type="checkbox"/>			
Naylor et al, 1999 ²⁶	RCT	Geriatric/Mixed Diagnoses	186	177	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Naylor, 1990 ²⁷	RCT	Geriatric/General medical	20	20	<input type="checkbox"/>	<input type="checkbox"/>		
Nazareth et al, 2001 ²⁸	RCT	Geriatric/General medical	181	181	<input type="checkbox"/>	<input type="checkbox"/>		
Nikolaus et al, 1999 ²⁹	RCT	Geriatric/General medical	185	181	<input type="checkbox"/>		<input type="checkbox"/>	
Palmer et al, 2002 ³⁰	CCT	General medical	1014	1248	<input type="checkbox"/>		<input type="checkbox"/>	
Parry et al, 2009 ³¹	RCT	Geriatric/Mix Diagnoses	49	49	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schillig et al, 2011 ³²	RCT	General medical	250	250		<input type="checkbox"/>		
Schnipper et al, 2006 ³³	RCT	General medical	84	92	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
Scullin et al, 2007 ³⁴	RCT	General medical	391	371	<input type="checkbox"/>			
Scullin et al, 2011 ³⁵	CCT	General medical	84	749	<input type="checkbox"/>		<input type="checkbox"/>	
Siu et al, 1996 ³⁶	RCT	Geriatric/General medical	176	178	<input type="checkbox"/>			
Steeman et al, 2006 ³⁷	CCT	Geriatric/General medical	469	355	<input type="checkbox"/>			
Stewart et al, 1998 ³⁸	RCT	Mixed Diagnoses	453	453	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Styrborn et al, 1995 ³⁹	CCT	Geriatric/General medical	166+ 190 (2 groups)	43 (0-4 day stay)+ 137 (5+ day stay)	<input type="checkbox"/>		<input type="checkbox"/>	
Thomas et al, 1993 ⁴⁰	RCT	Geriatric/General medical	64	68	<input type="checkbox"/>			<input type="checkbox"/>

Study, Year	Study Design	Patient Population	Sample Size		Readmission	Adverse Event	Costs	Acute care/ED utilization
			Control	Intervention				
Voss et al, 2011 ⁴¹	CCT	General medical	736	257	<input type="checkbox"/>			
Walker et al, 2009 ⁴²	CCT	General medical	366	396	<input type="checkbox"/>			<input type="checkbox"/>
Weinberger et al, 1996 ⁴³	RCT	Mixed Diagnoses	701	695	<input type="checkbox"/>			<input type="checkbox"/>

Abbreviations: CCT=controlled clinical trial; RCT=randomized controlled trial

Table 2, Chapter 37. Study quality criteria

Study, Year	Study Design	Allocation Sequence Random?	Allocation Concealed?	Baseline Outcomes Similar?	Baseline Characteristics Similar?	Incomplete Data Addressed?	Outcomes Assessed Blind to Intervention?	No Contamination?	Free of Selective Outcome Reporting Risk?	Free from other Bias?
Adler et al, 2009 ¹	CCT	No	No	Unclear	No	Unclear	Unclear	Unclear	Unclear	No
Al-Rashed et al, 2002 ²	CCT	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes
Balaban et al, 2008 ³	RCT	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear	Yes
Bolas et al, 2004 ⁴	RCT	Yes	Unclear	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Yes
Brand et al, 2004 ⁵	CCT	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Coleman et al, 2004 ⁶	CCT	No	No	Unclear	No	Unclear	Unclear	Unclear	Yes	Unclear
Coleman et al, 2006 ⁷	RCT	Yes	Unclear	Unclear	No	Unclear	Yes	Yes	Yes	Yes
Courtney et al, 2009 ⁸	RCT	Yes	Yes	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Yes
Cowan et al, 2006 ⁹	CCT	No	Yes	Unclear	No	Unclear	Yes	Yes	Yes	Yes
Dellasega et al, 2000 ¹⁰	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Einstadler et al, 1996 ¹¹	CCT	No	No	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Yes
Forster et al, 2005 ¹²	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gallagher et al, 2011 ¹³	RCT	Yes	Yes	Unclear	Yes	No	Yes	Unclear	Unclear	Yes
Gillespie et al, 2009 ¹⁴	RCT	Yes	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Yes	Yes
Gow et al, 1999 ¹⁵	CCT	No	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	No	No
Graumlich et al, 2009 ¹⁶	RCT	Unclear	No	Unclear	Unclear	Unclear	Yes	Yes	Yes	Unclear
Hellstrom et al, 2011 ¹⁷	CCT	No	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Yes	Unclear
Hogan and Fox, 1990 ¹⁸	CCT	No	No	Unclear	Unclear	Yes	Unclear	Unclear	Yes	No
Jack et al, 2009 ¹⁹	RCT	Yes	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Unclear
Koehler et al, 2009 ²⁰	RCT	Yes	Yes	Unclear	Yes	Unclear	Unclear	Yes	Unclear	Unclear
Lim et al, 2003 ²¹	RCT	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Yes
Lipton and Bird, 1994 ²²	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Makowsky et al, 2009 ²³	CCT	No	No	Unclear	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Martin et al, 1994 ²⁴	RCT	Yes	Unclear	Unclear	No	Yes	Unclear	Yes	Yes	Yes
Mudge et al, 2006 ²⁵	CCT	No	No	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Yes
Naylor et al, 1999 ²⁶	RCT	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Yes
Naylor, 1990 ²⁷	RCT	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Yes
Nazareth et al, 2001 ²⁸	RCT	Yes	Unclear	Yes	Unclear	Unclear	Yes	Unclear	Yes	Yes
Nikolaus et al, 1999 ²⁹	RCT	Yes	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Yes	Yes
Palmer et al, 2002 ³⁰	CCT	No	No	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes
Parry et al, 2009 ³¹	RCT	Yes	No	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes
Schillig et al, 2011 ³²	RCT	No	No	Unclear	No	Unclear	No	Unclear	Yes	No
Schnipper et al, 2006 ³³	RCT	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes	No
Scullin et al, 2007 ³⁴	RCT	Yes	Yes	Unclear	Yes	Unclear	Yes	Unclear	Yes	Yes

Study, Year	Study Design	Allocation Sequence Random?	Allocation Concealed?	Baseline Outcomes Similar?	Baseline Characteristics Similar?	Incomplete Data Addressed?	Outcomes Assessed Blind to Intervention?	No Contamination?	Free of Selective Outcome Reporting Risk?	Free from other Bias?
Scullin et al, 2011 ³⁵	CCT	No	Unclear	Unclear	Unclear	Unclear	Yes	Unclear	Yes	Unclear
Siu et al, 1996 ³⁶	RCT	Yes	Unclear	Unclear	Unclear	Unclear	Yes	No	Yes	No
Steeman et al, 2006 ³⁷	CCT	Unclear	Unclear	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Unclear
Stewart et al, 1998 ³⁸	RCT	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Yes
Styrborn et al, 1995 ³⁹	CCT	No	No	No	No	No	Unclear	Yes	Unclear	No
Thomas et al, 1993 ⁴⁰	RCT	Yes	Unclear	Unclear	Yes	Yes	Yes	Unclear	Yes	No
Voss et al, 2011 ⁴¹	CCT	No	No	Yes	No	Unclear	Yes	Yes	Unclear	Yes
Walker et al, 2009 ⁴²	CCT	No	No	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Yes
Weinberger et al, 1996 ⁴³	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes

Table 3, Chapter 37. Included studies and outcomes

Source	Pre-discharge Interventions						Post-discharge Interventions			
	Risk Stratification	Individualized Patient Record	Patient Engagement	Facilitation of Communication	Multi-disciplinary Team	Dedicated Discharge Advocate	Medication Reconciliation	Facilitated Clinical Follow-up	Outreach to Patients	Medication Reconciliation
Adler et al, 2009 ¹			<input type="checkbox"/>			<input type="checkbox"/>				
Al-Rashed et al, 2002 ²			<input type="checkbox"/>						<input type="checkbox"/>	
Balaban et al, 2008 ³		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	
Bolas et al, 2004 ⁴		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Brand et al, 2004 ⁵		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Coleman et al, 2004 ⁶		<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Coleman et al, 2006 ⁷		<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Courtney et al, 2009 ⁸		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Cowan et al, 2006 ⁹				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Dellasega et al, 2000 ¹⁰			<input type="checkbox"/>						<input type="checkbox"/>	
Einstadler et al, 1996 ¹¹			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		
Forster et al, 2005 ¹²			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Gallagher et al, 2011 ¹³										
Gillespie et al, 2009 ¹⁴		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Gow et al, 1999 ¹⁵					<input type="checkbox"/>					
Graumlich et al, 2009 ¹⁶	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			
Hellstrom et al, 2011 ¹⁷			<input type="checkbox"/>							
Hogan and Fox, 1990 ¹⁸					<input type="checkbox"/>				<input type="checkbox"/>	

Source	Pre-discharge Interventions						Post-discharge Interventions			
	Risk Stratification	Individualized Patient Record	Patient Engagement	Facilitation of Communication	Multi-disciplinary Team	Dedicated Discharge Advocate	Medication Reconciliation	Facilitated Clinical Follow-up	Outreach to Patients	Medication Reconciliation
Jack et al, 2009 ¹⁹		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Koehler et al, 2009 ²⁰		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
Lim et al, 2003 ²¹						<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Lipton and Bird, 1994 ²²			<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Makowsky et al, 2009 ²³			<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			
Martin et al, 1994 ²⁴					<input type="checkbox"/>				<input type="checkbox"/>	
Mudge et al, 2006 ²⁵					<input type="checkbox"/>					
Naylor et al, 1999 ²⁶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Naylor, 1990 ²⁷			<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>	
Nazareth et al, 2001 ²⁸		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Nikolaus et al, 1999 ²⁹			<input type="checkbox"/>		<input type="checkbox"/>				<input type="checkbox"/>	
Palmer et al, 2002 ³⁰					<input type="checkbox"/>	<input type="checkbox"/>				
Parry et al, 2009 ³¹		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Schillig et al, 2011 ³²			<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>		
Schnipper et al, 2006 ³³			<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Scullin et al, 2007 ³⁴			<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			
Scullin et al, 2011 ³⁵			<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			
Siu et al, 1996 ³⁶			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Steeman et al, 2006 ³⁷	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>					
Stewart et al, 1998 ³⁸	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	

Source	Pre-discharge Interventions						Post-discharge Interventions			
	Risk Stratification	Individualized Patient Record	Patient Engagement	Facilitation of Communication	Multi-disciplinary Team	Dedicated Discharge Advocate	Medication Reconciliation	Facilitated Clinical Follow-up	Outreach to Patients	Medication Reconciliation
Styrborn et al, 1995 ³⁹			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
Thomas et al, 1993 ⁴⁰					<input type="checkbox"/>					
Voss et al, 2011 ⁴¹		<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Walker et al, 2009 ⁴²	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Weinberger et al, 1996 ⁴³			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	

Table 4, Chapter 37. Studies reporting 30-day readmissions

Author, Year	Study Design	Bridging Intervention (Y/N)	Total number of interventions	30-day readmission rate - control group	30-day readmission rate - intervention group	ARR - 30-day readmissions	30-day ED visits - control group	30-day ED visits - intervention group	ARR - 30-day ED visits	Statistically significant ARR (for either readmits or ED visits)	Comment
Al-Rashed et al, 2002 ²	CCT	Y	2	29.5%*	11.1%*	18.4%				Y	*Outcomes measured at 15-22 days post-discharge
Balaban et al, 2008 ³	RCT	Y	5	8.2%	8.5%	-0.3%	2.0%	2.1%	-0.1%	N	
Coleman et al, 2004 ⁶	CCT	Y	5	13.8%	8.9%	4.9%	14.2%	11.0%	3.2%	Y	Significant difference for readmissions, but not ED visits
Coleman et al, 2006 ⁷	RCT	Y	6	11.9%	8.3%	3.6%				Y	<hr/> □ appears only in graphical format; p<0.05 for comparison with control for
Courtney et al, 2009 ⁸	RCT	Y	6	~15%, only in graphics	~5%, only in graphics					Y	Data presented only in graphical format; significant improvement for ED visits
Dellasega and Zerbe, 2000 ¹⁰	RCT	Y	2	NR	NR					N	Exact rates not supplied
Einstadler et al, 1996 ¹¹	CCT	Y	3	14.4%	19.8%	-5.4%	19.2%	21.8%	-2.6%	N	
Forster et al, 2005 ¹²	RCT	Y	4	13.0%	19.4%	-6.4%	7.8%	9.6%	-1.8%	N	
Gow et al, 1999 ¹⁵	CCT	N	1	15.2%	16.7%	-1.5%				N	
Jack et al, 2009 ¹⁹	RCT	Y	8	20.7%	14.9%	5.8%	24.5%	16.5%	8.0%	Y	Significant difference for ED visits only

Author, Year	Study Design	Bridging Intervention (Y/N)	Total number of interventions	30-day readmission rate - control group	30-day readmission rate - intervention group	ARR - 30-day readmissions	30-day ED visits - control group	30-day ED visits - intervention group	ARR - 30-day ED visits	Statistically significant ARR (for either readmits or ED visits)	Comment
Koehler et al, 2009 ²⁰	RCT	Y	7	38.1%†	10.0%†	-28.1%				Y	†Composite outcome of ED visits and readmissions i.e. 284 CCT.284 Control 284 Intervention 284 General Medical 284 Mixed 284
Lipton and Bird, 1994 ²¹	RCT	Y	5	11.2%	15.4%	-4.2%				N	
Palmer et al, 2002 ³⁰	CCT	N	2	5.8%	5.5%	0.3%				N	
Parry et al, 2009 ³¹	RCT	Y	8	16.7%	6.8%	9.9%				N	
Schnipper et al, 2006 ³³	RCT	Y	6	30%‡	30%‡	0%				N	‡Composite outcome of total ED visits and readmissions
Steeman et al, 2006 ³⁷	CCT	N	3	5.1%§	2.8%§	2.3%				N	§Outcomes measured at 14 days post discharge
Voss, 2011 ⁴¹	CCT	Y	6	18.6%	12.8%	5.8%				Y	
Walker et al, 2009 ⁴²	CCT	Y	7	18.0%	22.1%	-4.1%	12.3%	9.5%	2.8%	N	

Table 5, Chapter 37. Studies reporting adverse events (including adverse drug events)

Study and Country	Study Design	Population	Sample Size	Intervention	Control	Adverse Drug Events (Control vs. Intervention rates, p-value)	ARR (95% CI)	Other Adverse Events (Control vs. intervention rates, p-value)	ARR (95% CI)	Timing
Balaban et al., 2008 ³ US	RCT	General medical (Safety net)	96	Discharge-transfer intervention	Usual care	-	-	Failure to complete recommended outpatient work-up (31.3 vs. 11.5%, 0.11)	-	NR
Forster et al., 2005 ¹² Canada	RCT	General medical	361	Discharge coordination led by nurse specialist	Usual care	-	-	Post-discharge adverse events (22.8 vs. 23.6%, 0.87)	-	30 days
Gallagher et al., 2011 ¹³ Ireland	RCT	Geriatric	400	Inpatient medication screening using validated criteria (STOPP/START)	Usual care	-	-	Falls (8.4 vs. 5.8%, 0.332)	-	6 months
Gillespie et al., 2009 ¹⁴ Sweden	RCT	Geriatric/ General Medical	400	Pharmacist discharge counseling and post-discharge follow-up	Usual care	Medication-related readmissions (24.2 vs. 4.8%, NR)	-	-	-	12 months
Graumlich et al., 2009 ¹⁶ US	RCT	Mixed Patient Population	631	Software-assisted discharge	Usual care	Probable adverse drug event (5.4 vs. 5.4%, N/A)	-	All post-discharge adverse events (7.3 vs. 7.3%, N/A)	-	1 month
Hellstrom et al., 2011 ¹⁷ * Sweden	CCT	Geriatric	210	Pharmacist-led systematic medication reconciliation and review	Usual care	Composite of medication-related admissions & ED visits (12.0 vs. 5.6%, 0.138)	6.4% (-1.2-14.8)	-	-	3 months
Naylor, 1990 ²⁷ US	RCT	Geriatric/ General medical	40	Comprehensive discharge planning led by nurse specialist	Usual care	-	-	Post-discharge infection rates (50 vs. 33.3%, NR)	-	12 weeks
Schillig et al., 2011 ³² US	RCT	General Medical/ Mixed (on warfarin therapy)	500	Pharmacist-directed anticoagulation service	Usual care	Composite endpoint (14.8 vs. 10.0%, 0.104) INR >5 (14.8 vs. 9.6%, 0.076) Major bleeding (0.8 vs. 0.4%, 0.563) Thrombosis (0 vs. 0%, N/A)	-	-	-	Inpatient & 30 days (combined)

Study and Country	Study Design	Population	Sample Size	Intervention	Control	Adverse Drug Events (Control vs. Intervention rates, p-value)	ARR (95% CI)	Other Adverse Events (Control vs. intervention rates, p-value)	ARR (95% CI)	Timing
Schnipper et al., 2006 ³³ US	RCT	General medical	176	Pharmacist discharge counseling and post-discharge follow-up	Usual care	Preventable medication-related ED visit or admission (8 vs. 1%, 0.03) Preventable ADEs (11 vs. 1%, 0.01) All ADEs (16 vs. 18%, >0.99)	-	-	-	30 days

*This was a nonrandomized controlled trial. All other studies are randomized controlled trials.

References for Tables 1-5

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Evidence Tables for Chapter 38. Use of Simulation Exercises in Patient Safety Efforts

This review had no additional evidence tables.

Evidence Tables for Chapter 39. Obtaining Informed Consent From Patients: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 40. Team-Training in Health Care: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 41. Computerized Provider Order Entry With Clinical Decision Support Systems: Brief Update Review

This brief review had no additional evidence tables.

Evidence Tables for Chapter 42. Tubing Misconnections: Brief Review (NEW)

This brief review had no additional evidence tables.

Evidence Tables for Chapter 43. Limiting Individual Provider's Hours of Service: Brief Update Review

This brief review had no additional evidence tables.