

Report on the development of the GuNFT Guideline «Guideline for Not Funding existing health Technologies in health care systems»

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Executive summary

Title: Report on the development of the GuNFT Guideline: Guideline for Not Funding existing health Technologies in health systems

Authors: Ibarгойen-Roteta Nora, Gutiérrez-Ibarluzea Iñaki, Asua José

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Introduction

One of the processes that might help to improve the quality of care is based on saving resources through disinvestment in health technologies that «are deemed not to be suitable» and re-investing the resources in other health technologies that meet the criteria of safe, effective and cost-effective care. Unfortunately, experience has shown that this is a difficult process partly due to the lack of reliable administrative mechanisms to identify and prioritise health technologies and/or practices of doubtful clinical efficiency or cost-effectiveness. In the last year, a nationwide project was undertaken in Spain aimed at «the identification, prioritisation and evaluation of potentially obsolete health technologies». Disinvestment must also, however, deal with those health technologies that are ineffective, inefficient or potentially harmful, and this supports the elaboration of a guideline that would help to develop a process in order to disinvest in those kinds of technologies.

Aim

The aim of this guideline is to facilitate the establishment of such a process, in other words a transparent, systematic and explicit process to assess the potential for disinvestment in certain health technologies or in some of their indications which, for whatever reason, fail to achieve the objective(s) for which they were originally financed.

Methodology

The «Nominal Group» technique was used to determine the most relevant aspects to be taken into consideration regarding disinvestment decision making. For this purpose, 10 prominent experts working in different areas related to health care delivery, administration and technology assessment were selected. Eight questions related to technological disinvestment were presented to the group, and proposed ideas were discussed by teleconference. For each question, each member selected a maximum of 10 ideas that he or she considered to be the most important, ranking these on a scale of 1 (less important) to 10 (most important). The ideas with the highest consensus were those receiving at least five votes with six or more points.

The structure and domains of the «Guideline for the Acquisition of New health Technologies» (GANT) and the «Guideline for decision making on the introduction of new genetic tests» (GEN), published by the Health Technologies Assessment Agency of Andalusia (AETSA) were, together with the results obtained from the nominal group, taken into account in order to draft the new guideline. This draft was reviewed by two external experts in the area of health technology assessment in hospitals, then translated into English and reviewed once again by two English-native international experts in the area of disinvestment processes in health technologies.

Economic Analysis: YES **NO** **Experts Opinion:** **YES** **NO**

Results

Thirty five of the 139 ideas proposed by the nominal group were finally selected. Basically, a technology should not be funded if there is evidence of an overall deterioration in the health of the patient to whom it is applied, if the potential risk of that technology is not acceptable or if it produces a high degree of discomfort or has a negative impact on the patient's health. To facilitate the acceptance of disinvestment, detailed information regarding the reason for taking the decision should be made available to both the patient and the health professionals using the technology, and the latter should participate in the process. The guideline, presented in Annex II of this report, was divided into different sections: a) General preliminary recommendations, b) Completing the application, c) Checking and prioritising applications, d) Assessing applications, e) Taking the final decision and f) Action plan.

Conclusions y recommendations

This is the first guideline that has been elaborated to design a scenario to disinvest in established health technologies. Nevertheless, this is only the first version and it should therefore be tested and refined if/when necessary.

I. Introduction

Health systems and organisations have to take decisions on the services that are going to be introduced into the Health System, whilst at the same time recognising their funding limits (1). Resources are always scarce and can never meet the demands of the Health System. The use of a resource for specific conditions prevents the same resource from being used for a different condition, which can be measured by the opportunity-cost (the health benefit that could have been achieved had the money been spent on the next best alternative intervention or healthcare programme). Unfortunately, more often than would be desirable, some health resources are invested in technologies and practices¹ that are not the most suitable for a given purpose or in those that represent a «technical» improvement in existing technologies at a price that does not justify their acquisition, thus making it difficult to comply with health care objectives. Sometimes, the investment may not respond to priority needs or may involve technologies that are too complex and incompatible with existing infrastructures and services or require excessively expensive maintenance. This, together with the irrational or inappropriate use of technologies and the shortage of health professionals, may also lead to the waste of precious health services and resources that could be used to acquire other essential health care items (2).

The World Health Organisation announced recently that in order to improve the safety and quality of health care it is important to strengthen science-based methods for assessing medical technologies and equipment, in terms of efficiency, quality, safety, profitability, availability and access (3).

Although Health Technology Assessment has improved the situation, particularly for assessing new and emerging technologies (4;5), there is still a lack of efficient mechanisms to determine the suitability of health technologies and to facilitate the assessment and management of existing health technologies.

One of the processes that might help to improve the quality of care is based on securing resources through disinvestment in health technologies that «are deemed not to be suitable» and re-investing the resources in other health

¹ This guideline includes within its scope all health care related devices, pharmaceuticals, practices, procedures and programmes. These will collectively be referred to as «technologies throughout this document.»

technologies that meet the criteria of safe, effective and cost-effectiveness. Disinvestment is understood as the process that removes resources partially or totally from practices, procedures, technologies or medicines that are considered to have little or no benefit to health, representing, therefore, an inefficient allocation of resources. There is currently a lack of resources to support disinvestment, including the study and development of procedures and methods required to support the disinvestment process. Furthermore, there are no reliable administrative mechanisms to identify and prioritise health technologies and/or practices of doubtful clinical efficacy or cost-effectiveness. Indeed, there is often no conclusive evidence indicating that certain existing technologies have little or no benefit, partly due to the tendency for negative trials not to be published. Finally, political, clinical and social resistance to the elimination of established technologies is common (6).

A recent qualitative study (7) has highlighted some of the key points that should be emphasised in order to improve the process; these can be summarised as follows:

- a. Insufficient attention is given to existing health technologies. This is probably due to a lack of resources and to the complexity of the methodology. A model such as that used to identify and assess new health technologies may be useful in this case.
- b. In order to highlight the importance of disinvestment, it would be necessary to convince decision-makers that disinvestment is going to result in both a saving and an improvement in the quality of care, or at least a reduction in the risks for patients and users.
- c. It is necessary to invest in the methodology that facilitates the disinvestment process.

Moreover, it is interesting to note that disinvestment depends on the local environment and its priorities (7). Some authors consider that this process should not be mandatory but should instead take the form of recommendations or guidelines that offer advice on the best way to carry out this process (9).

In the Basque Country, a new procedure for the incorporation of new techniques into the health care system was published by the Health Minister in the Order of 12 November 2004. This order also specifies that the managers of the Basque Health Service's (Osakidetza) service providers should inform Central Management of those techniques and medical procedures that are no longer being used, explaining the reasons why and, when relevant, the authorized technique or procedure that has replaced them. At a state level, the Royal Decree 1030 of 15 September 2006, establishes the package of common services in the Spanish Health System and the procedures designed to ensure

that these are kept up to date. This Royal Decree also contemplates the possible exclusion of any technique, technology or procedure from the package of common health services under the following circumstances: a) existing evidence of a lack of efficacy, effectiveness or efficiency or an unfavourable risk benefit ratio; b) no further interest as a consequence of technological and scientific progress or not demonstrated utility and c) it no longer complies with the requirements established by current legislation.

In Galicia, Order SCO/3422 of 28 November 2007, regulates the procedure for incorporating techniques, technologies or procedures into the package of services offered by the public health system of Galicia. This Order supports the process whereby the package of common health services of the National Health System is updated, and also includes the exclusion of those technologies, as per the Royal Decree.

In response to the above legislation, a nationwide project was undertaken in Spain in 2008 concerning «The identification, prioritisation and evaluation of potentially obsolete health technologies». These technologies were defined by the working group as «those health technologies in use for one or several indications, whose clinical benefit, safety or cost effectiveness have been exceeded significantly by other available alternatives» (10). Nevertheless, disinvestment cannot be restricted only to these cases-it must also deal with those health technologies that are ineffective, inefficient or potentially harmful. Hence this document sets forth a guideline that could help to develop a process in order to disinvest in hospitals or other health settings and provide a standardised, transparent and explicit methodology to ensure that all disinvestment-related decisions have taken into consideration all relevant aspects, thereby facilitating their implementation.

II. Aim of the guideline

The aim of this guideline is to facilitate the establishment of a suitable process, in other words a transparent, systematic and explicit process for assessing the potential for disinvestment in certain health technologies or in some of their indications which, for whatever reason, fail to achieve the objective(s) for which they were originally financed.

Nb:

The term «health technology» includes all the methods used by health professionals to promote or improve the health of patients, prevent or treat diseases, rehabilitate or provide long-term care. This includes all the activities carried out by all health professional levels and the use of all kinds of equipment, pharmaceuticals and procedures to promote improvements in health (9).

III. Declaration of intentions

This guideline has been drawn up to assist health care providers to:

- Take into account both the economic aspects of the disinvestment process, and the different factors that influence this process.
- Improve the efficiency of the health services offered.
- Design a process that can be adapted to the local context.
- Ensure both the «withdrawal» (or replacement) of health technologies of less benefit to patients in terms of safety and effectiveness, and those that are of less benefit in terms of their quality of life, those that are more invasive or those that have increased costs for the patient.
- Ensure that the process takes into account the services offered by the Centre, the National Health Service or equivalent, in order that disinvestment does not leave an undesired gap in the service affected.
- Ensure that all health professionals take part in the process (in either the identification process and/or the assessment process).
- Take into consideration the importance of disseminating the decision in an adequate manner, thereby ensuring the transparency of the process. This includes providing the rationale for the decision and the strategy the hospital or Health Service implicated has designed to enforce the decision.
- Ensure that any action deriving from this process will ultimately be of benefit to patients or the wider population.

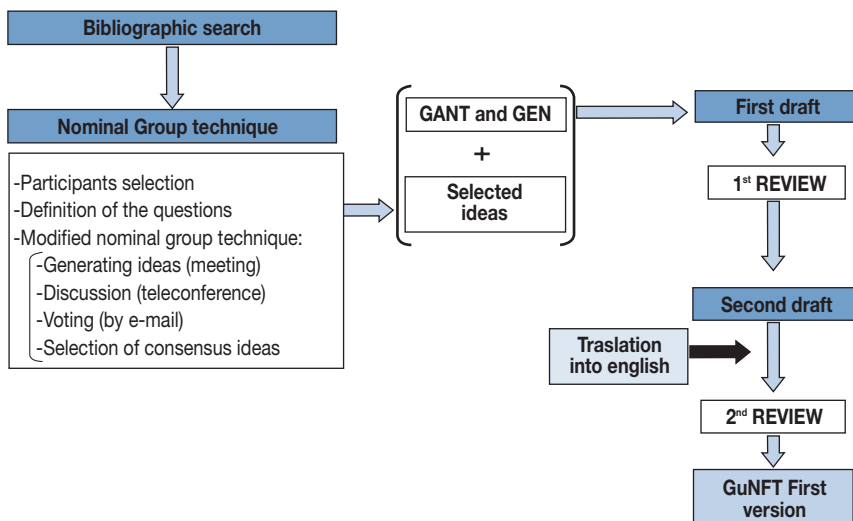
We are aware of the fact that this is the first guideline for disinvestment in established health technologies, therefore we recommend that it has to be tested and refined if/where necessary. As a next step, we intend to study the impact of implementation of this guideline under real-life conditions and identifying the problems that arise from its use. For instance, we expect to identify the problems and challenges that arise when implementing the described strategy in the Basque Country and to propose the changes that should be undertaken in order to make this process work.

IV. Methodology used

As it has been mentioned in the introduction, experience has shown that disinvestment in health systems is a complex process, due, among other reasons, to the existence of clinical, social and political resistance to the removal of already established technologies.

The process shown in Figure 1 was followed to draw up the GuNFT Guideline:

Figure 1. Procedure followed during the GuNFT Guideline development



GANT: New health technologies adquisition guideline
 GEN: New genetic tests adquisition guideline

The structure of the process is described below.

IV.1. Criteria to be used when deciding whether or not to fund existing health technologies

A modified «Nominal Group» technique was applied to determine the most relevant aspects to be taken into consideration regarding disinvestment decision making. The objective was to «extract all the aspects that must be taken into account when disinvesting in existing health technologies in hospitals».

A number of prominent experts from different areas related to health care delivery, administration and assessment were selected for this purpose (Table 1).

Table 1. Members of the nominal group

Participant	Area	Place of work*
Alberto Colina	Hospital Management	Zumárraga H. (Gipuzkoa)
José Luis Pinto	Finance	Pablo Olabide University (Seville)
Pilar Alcorta	Nuclear Medicine	Santiago H. (Vitoria-Gasteiz)
Teresa Cerdá	Health Technology Assessment	Avalia-t (Santiago de Compostela)
Alberto Ruano	Health Technology Assessment	Avalia-t (Santiago de Compostela)
Pablo Uriarte	Specialised Care	Osakidetza Central Services (Vitoria-Gasteiz)
Pilar Nicolás	Law	Professor of Law and Human Genome. University of Deusto and the Basque Country (Bilbao)
Teresa Hermosilla	Citizen Participation	AETSA (Seville)
Eduardo Briones	Hospital Quality	University H. Nuestra Sra de Valme (Seville)
Eduarne Eguino	Hospital Management	Navarra H. (Pamplona)

*H=Hospital; Avalia-t= Health Technology Assessment Agency of Galicia; AETSA= Health Technology Assessment Agency of Andalusia

The nominal group technique was developed at the University of Wisconsin by André Delbecq and Andrew Van de Ven in 1968. This technique began to be applied in health planning at the end of the 1970s, and coincides

in many aspects with the technique developed by the RAND Corporation (criteria for the appropriate use of diagnostic tests and treatments) (12).

In relation to this GuNFT project, the technique was carried out as follows:

1) Generating ideas

A meeting was held to carry out this stage of the process. The chairs presented eight questions to the group (Table 2). Each expert had to respond individually and was requested to prioritise a maximum of three ideas per question. This stage lasted 45 minutes.

Table 2. Questions posed to the Nominal Group

Questions posed for the Nominal Group	
1.	What are the characteristics that a technology must comply with in order for a hospital to consider that it should not be financed? (Example: scientific evidence of a lack of safety, ineffectiveness or obsolescence in one or several indications, etc.)
2.	What aspects related to the package of services offered by the hospital should be taken into consideration when assessing the potential disinvestment in these technologies?
3.	What organisational implications must be considered when assessing the potential for disinvestment in a technology?
4.	What patient characteristics must be considered when assessing a decision to disinvest?
5.	What are the alternatives and/or information that should be offered to the patients affected?
6.	What barriers can be found between health professionals when implementing a decision to disinvest in a technology?
7.	What measures would have to be adopted to secure the acceptance of health professionals for the decision to disinvest in a specific technology?
8.	What ethical, legal, social and political implications must be assessed when taking the decision to disinvest in a technology?

2) Collection of ideas

Three rounds were undertaken per question, and each round was started by a different person. The experts were only allowed to present one of their proposals in each round, and, in the second or third round, if the ideas noted down by one of the participants had already been presented by another, they

were not repeated. To ensure transparency, the chairs transcribed the ideas in full view of all participants.

3) Discussion

The discussion was formatted to allow each of the proposed ideas (or several related ideas) to be discussed in detail, and to allow all the experts to express their opinion about them. Participants were allowed to intercede in order to clarify an idea or express a different point of view. The chairs reformulated some of the ideas based on the discussions.

4) Voting

Voting was conducted by e-mail. For each question, each member selected a maximum of 10 ideas that he or she considered to be the most important and ranked them from 1 to 10 (from the least to the most important).

5) Assessment

After voting, the scores were processed and the highest-scoring ideas were selected (in other words, those for which the highest consensus was found). Sufficient consensus was considered to have been reached when the proposal had at least 30 points, and half the experts had given a score of six points or more to the idea. All ideas/constructs selected by consensus were taken into consideration in the elaboration of the GuNFT Guideline. A feasibility study was conducted for those ideas which achieved 30 points but did not fulfil all the consensus criteria to decide if they should be considered when drafting the guideline. If half the experts considered a criterion to be feasible, it was taken into consideration.

IV.2. Preparation of the first version

All the ideas and contracts agreed upon by the nominal group, as well as the structure and contents of the GANT and GEN guidelines published by AETSA (Health Technology Assessment Agency of Andalusia), were taken into consideration when drafting the guideline (see Figure 1) (12;13).

Ideas selected by the nominal group

It was decided that those ideas obtaining a final score of 70 out of 100 or higher should always be taken into consideration when deciding whether to disinvest in existing technologies in hospitals.

These ideas were as follows:

Disinvestment in a technology should be considered when:

1. There is evidence that the technology causes an overall worsening of health, in other words, there is an imbalance between the side effects and benefits with regard to what was expected.
2. There is an unacceptable potential risk (for the patients, the environment, etc); in other words, the safety of the technology cannot be guaranteed.
3. The technology is, on balance, not acceptable to patients because it has a high level of discomfort or is very invasive compared to other technologies offering similar results.

In order to facilitate the acceptance of individual disinvestment decisions, it is necessary to:

1. Provide the patients with sufficient information regarding the reasons underpinning the decision.
2. Provide health professionals who use the technology with the reasons underpinning the decision.
3. Involve health professionals in the process of identifying and assessing whether a technology is suitable for disinvestment.

There was also good consensus on a number of other criteria concerning the patients and health professionals affected by the measure, the package of health services offered by the hospital, and the organisational, ethical and political implications, amongst others (ANNEX I). These criteria were also taken into consideration when drafting the guideline.

The New Technologies Acquisition Guideline (GANT) and the new genetic test acquisition Guideline (GEN)

The New Technologies Acquisition Guideline (GANT) and the new genetic test acquisition Guideline (GEN) were both used as a model around which to base the design of the GuNFT Guideline.

The GANT Guideline

The aim of the GANT Guideline is to provide a decision-making instrument to support the introduction of new technologies hospitals in the Spanish National Health System, thereby providing a method to facilitate their introduction and to foster contact between clinicians and managers when considering these decisions.

GANT was published in 1999, therefore there are already several years, experience regarding the use of this guideline in numerous health centres. The use of this guideline was included within the programme-contracts of the Health Service of Andalusia with its centres, and it has been updated following a process of analysis (14).

The GEN Guideline

The GEN Guideline is used for taking decisions on the incorporation of new genetic tests into the Spanish National Health System. This guideline aims to ensure that all key specific aspects are assessed explicitly, thereby facilitating the decision-making process concerning their inclusion into the health care services offered by the public health system.

This guideline is based on a prior review of the literature performed by the Health Technology Assessment Agency of Andalusia which led to a report entitled «Framework for the evaluation of genetic tests in the Public Health System of Andalusia» (15). This guideline states that the incorporation of new genetic tests into clinical practice should be based on the scientific evidence concerning the correct functioning of the test (analytical and clinical validity) and the health effects of the interventions and decisions taken with the information provided (clinical utility). The social, ethical, organisational and economic implications of its inclusion in the offer of care should also be estimated. A fundamental aspect when assessing a genetic test is the definition of the clinical situation in which its use is intended (indication) (16). Indeed, the conclusions reached following the evaluation process and the recommendations on using the test shall only be applicable to the indications for which it has been assessed.

In those cases where there was a prior alternative, the new test must provide clinically relevant advantages with respect to the aforementioned alternative. Finally, before a new genetic test can be used in clinical practice, all necessary care aspects must be provided in order to guarantee good results and its ethically acceptable use: quality control in laboratories, genetic counselling (including elements to guarantee the participation of individuals in the

decision to carry out the test and subsequent interventions) and the establishment of processes to treat and monitor patients and family members.

IV.3. Validation of the GuNFT Guideline

The first draft of the GuNFT document was reviewed by the members of the Nominal Group. The draft guideline was validated by external review. Two external experts in the area of health technology assessment in hospitals were selected and they proceeded to review the first draft version of the guideline. The suggestions made and the feasibility of carrying them out were assessed by the authors of the guideline.

Once the changes had been made, and after the reviewers' approval, the second draft was then translated into English. The translated guideline was then reviewed once again by two international experts in the area of disinvestment processes in health technologies. Their comments were also considered and incorporated to a greater or lesser extent into the guideline by the authors, thus resulting in the definitive first version of the GuNFT Guideline.

IV.4. Developments deriving from the GuNFT Guideline

The Basque Office for Health Technology Assessment is developing a software package for this guideline in order to speed up and facilitate the information flow amongst those who wish to disinvest in existing technologies, the assessment committee or organization and the management team or the decision-maker who will make the final decision regarding the proposal.

The aim of this software is to facilitate the creation of an *Observatory of existing, potentially non-fundable health technologies in the Autonomous Community of the Basque Country*. Similar organisations belonging to the Health Department or Health Technologies Assessment Agencies of the corresponding community or country, may also create a database to communicate those technologies for which disinvestment is under consideration.

The level of implementation of the procedure that is described in this guideline will depend on the aim of the stakeholders that are interested on it, although even when the technologies are only being considered at a hospital

level, it would nevertheless be of interest for the Observatory to have this information available. In addition, the software package that is currently being developed allows the application to be sent to the corresponding HTA Agency or Unit, automatically only when the organization considers the information to be relevant to send this. Moreover, if the health care centres that are using the aforementioned methodology do not have an Assessment Committee (or an HTA unit), it would be advisable that the corresponding HTA Agency to be able to take responsibility for the assessment process.

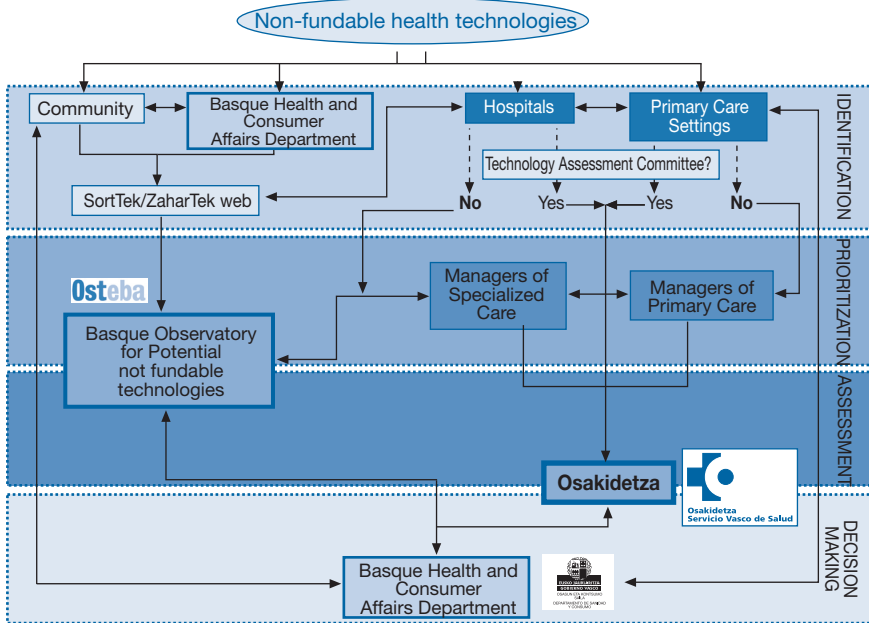
The ideal situation would be for assessment agencies, health departments, health services and hospitals to share information on those technologies whose financing is being reassessed. This will facilitate the assessment of technologies at a regional or national level that can not be taken into consideration in a local context. In those cases, the assessment would be the responsibility of the corresponding HTA Agency and the final decision would be taken by either the regional or national health service as the Department of Health, depending on case.

At a national level, further efforts are being made within the AUnETS collaboration to generate a repository of potentially obsolete technologies, defined as those technologies that have been superseded by other technologies in a significant way. It would therefore be of interest to have a connexion between this repository and the observatory of non-fundable health technologies as the former could be a very important source of data for the latter.

IV.5. Proposal to implement GuNFT in the Basque Country

A proposal to establish a disinvestment process in the Basque Country is outlined below (Figure 2), although all items contained therein should be discussed and analysed by all relevant stakeholders before its final implementation.

Figure 2. Possible proposal to implement the GuNFT Guideline in the Basque Country



V. References

1. Mitton C, Donaldson C. Priority setting Toolkit. A guide to the use of economics in healthcare decision making. 1st ed. London: BMJ Publishing Group; 2004.
2. Sixteenth World Health Assembly. Health Technologies. Report by the Secretariat. Provisional agenda item 12.19.A60/26. WHO; 22 March 2007. [Accessed 15 April 2008]. Available at: apps.who.int/gb/ebwha/pdf_files/WHA60/A60_26-en.pdf
3. Fifty-fifth World Health Assembly. Quality of care: patient safety. Agenda item 13.9. WHO; 18 May 2002. [Accessed 20 April 2008]. Available at: <http://www.who.int/en/>
4. Velasco-Garrido M, Busse R. Health technology assessment. An introduction to objectives, role of evidence, and structure in Europe. Brussels (Belgium): European Observatory on Health Systems and Policies, WHO, 2005.
5. Goodman CS. HTA 101: Introduction to Health Technology Assessment - The Lewin Group, Falls Church, Virginia, 2004
6. Elshaug A, Hiller JE, Tunis SR, Moss JR. Challenges in Australian policy processes for disinvestment from existing, ineffective health care practices. Aust New Zealand Health Policy 2007;4:23. <http://www.anzhealthpolicy.com/content/4/1/23>
7. Elshaug A, Hiller JE, Moss JR. Exploring policy-makers' perspectives on disinvestment from ineffective healthcare practices. Int J Technol Assess Health Care 2008;24(1):1-9.
8. Pearson S, Littlejohns P. Reallocating resources: how should the National Institute for Health and Clinical Excellence guide disinvestment efforts in the National Health Service? J Health Serv Res Policy 2007;12(3):160-5.
9. Asua, J, Gutiérrez Ibarluzea I, López de Argumedo, M. LA IDENTIFICACIÓN DE TECNOLOGÍAS SANITARIAS EMERGENTES. Documento de base para el funcionamiento de la red SorTek. Vitoria-Gasteiz. Departamento de Sanidad, Gobierno Vasco, 2002. Informe nº: Osteba D-00-02.

10. Ruano Raviña A, Velasco González M, Varela Lema L, Cerdá Mota T, Ibarгойen Roteta N, Gutiérrez Ibarluzea I, Blasco Amaro JA, Imaz Iglesias I et al. Identificación, priorización y evaluación de tecnologías obsoletas. Guía metodológica. Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Política Social, Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia; 2007. Informes de Evaluación de Tecnologías Sanitarias. avalia-t N.º 2007/01.
11. Peiró S, Portella E. El grupo nominal en el entorno sanitario. Quaderns de salut pública i administració de serveis de salut,1. Valencia: Escola Valenciana d'Estudis per a la Salut, 2003.
12. Briones Pérez de la Blanca E, Loscertales Abril M, Pérez Lozano MJ en nombre del Grupo GANT. Guía de adquisición de nuevas tecnologías en los centros sanitarios de Andalucía. Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, 1999.
13. Márquez Calderón Soledad, Castilla Alcalá Jose Antonio, Briones Pérez de la Blanca Eduardo, Carriazo Pérez de Guzmán Ana. Guía para la toma de decisiones sobre incorporación de nuevas pruebas genéticas en el Sistema Nacional de Salud (Guía GEN). Madrid: Plan Nacional para el SNS del MSC. Agencia de Evaluación de tecnologías Sanitarias de Andalucía; 2006. Informes de Evaluación de Tecnologías Sanitarias. AETSA 2006/04.
14. Cerezo Espinosa de los Monteros Juan Javier, Villegas Portero Román. Actualización de la Guía para la Adquisición de Nuevas Tecnologías (GANT). Madrid: Plan Nacional para el SNS del MSC. Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (AETSA);2006. Informes de Evaluación de Tecnologías Sanitarias. AETSA Nº2006/02.
15. Márquez Calderón S, Briones Pérez de la Blanca E. Marco para la evaluación de las pruebas genéticas en el Sistema Sanitario Público de Andalucía. Sevilla: Agencia de Evaluación de Tecnologías Sanitarias, 2005. Informe 2/2005.
16. Burke W, Atkins D, Gwinn H, Guttmacher A, Haddow J, Lau J et al. Genetic test evaluation: information needs of clinicians, policy makers and the public. Am J Epidemiol 2002;156:311-8.

VI. Annexes

Annex VI.1.

Criteria selected for the questions asked to the Nominal Group

Question no. 1:				
What are the characteristics that a technology must comply with for a hospital to consider that it should not be financed? (Example: scientific evidence of the lack of safety, ineffectiveness or obsolescence in one or several indications, etc.)				
Selected proposals	No. votes	No. votes \geq 6*	Total	Mean
There is evidence that the technology leads to an overall worsening of health, in other words, that there is a risk-benefit imbalance with regard to what was expected.	10	10	90	9
There is an unacceptable potential risk (patients, the environment, etc.). The safety of the procedure cannot be guaranteed.	10	9	88	10
There is no scientific evidence to show that the technology improves health (lack of evidence about efficacy and effectiveness)	9	6	64	7.5
New evidence on the inefficacy of the technology in one or more indications	8	7	54	7
The existence of an alternative technology that, with the same risk-benefit and direct costs, allows automation, lower staffing levels, shorter waiting times, etc.	7	5	41	6
Technology generally rejected by patients**	7	3	39	6
Question no. 2:				
What aspects relating to the package of health services offered by the hospital should be taken into consideration when assessing disinvestment in these technologies?				
Selected proposals	No. votes	No. votes \geq 6*	Total	Mean
Existence of exclusion criteria in the Package of Services (if the inclusion criteria are explicit these would help to define the exclusion criteria)	9	5	50	7
Possible «unnecessary» risk increase if the Hospital cannot deal with the complications that appear after applying the technology to the patient and he or she has to be transferred to another centre, with the increase in risk this involves.	6	5	44	9
Proof of a low level of need for the technology following its implementation (there is no demand, the expected numbers of patients are not treated, etc.)	6	5	44	8
Evidence of a very low acceptance level by patients, which may lead disinvestment in a technology to be considered	7	5	40	8

* Number of votes receiving 6 or more points

** Criteria not fulfilling all defined consensus criteria but considered as feasible

**Question no. 3:
What organisational implications must be considered when assessing the possibility of disinvesting in a technology?**

Selected proposals	No. votes	No. votes \geq 6*	Total	Mean
Impact of disinvestment on human resources (redistribution of staff, new staffing requirements, etc.)	9	6	61	7
Involvement of the different hierarchical levels of the hospital in decision-making (hospital management, medical management, etc.)	8	5	48	6
Workload differences of a substitutive technology compared with another alternative	6	5	42	8
Need for trained professionals to handle the technology	6	5	39	7

**Question no. 4:
What patient characteristics must be considered when assessing a decision to disinvest?**

Selected proposals	No. votes	No. votes \geq 6*	Total	Mean
The level of discomfort (pain, severe discomfort, etc.) produced by the technology or the negative repercussion produced by the degree of invasiveness of the technology on the patient	10	9	87	9
Reduction of the quality of life perceived by the patient	9	7	68	8
Ensure the possibility of treating those patients for which there is no alternative, even though the effectiveness of the treatment is low	8	6	53	7
The existence of an alternative technology that reduces indirect and non-quantifiable costs for the patient and his/her family.	8	6	50	7

**Question no. 5:
What are the alternatives and/or information that should be offered to the patients affected?)**

Selected proposals	No. votes	No. votes \geq 6*	Total	Mean
Existing evidence or reasons why the decision has been taken	10	10	92	9
Provide clear information regarding the benefits and risks that are eliminated in comparison with the possible alternative	7	6	58	9
The information received by the patient from all centres and professionals must be consistent, to avoid confusion	10	6	54	7
Assess the information needs of the patient (record of incidents, brochures, guidelines, etc.), defining who, where, when and how he/she is to be informed (a general campaign, the professional, etc.)	9	5	50	6.5
Channel the needs of patients so as not to create situations involving a lack of care, facilitating access to an alternative technology or to the technology used in other centres.	6	4	37	7

* Number of votes receiving 6 or more points

** Criteria not fulfilling all defined consensus criteria but considered as feasible

Question no. 6:
What barriers can be found among health professionals when implementing a decision to disinvest in a technology?

Selected proposals	No. votes	No. votes≥6*	Total	Mean
A lack of knowledge or information about the evidence on which the decision is based.	9	8	76	9.5
Fear or resistance to change (new learning curve for a new technology)	7	6	56	9.5
Pressure to which they are subjected by misinformed patients or those with false expectations	8	5	48	7

Question no. 7:
What measures would have to be adopted to secure the acceptance of health professional when implementing a decision to desinvest in a technology?

Selected proposals	No. votes	No. votes≥6*	Total	Mean
Involvement of professionals in the process	10	7	79	9
Suitable information policy regarding the explicit criteria taken into account in the decision-making process	9	7	66	9
Demonstrate through the study of indicators that there is an improvement with withdrawal of the technology and inclusion of the new one	8	7	61	8
Take a positive approach by focusing on the reinvestment rather than the disinvestment, without implying that the reinvestment has to be made in the service affected by the decision	7	7	50	7.5
Inform professionals about the scientific evidence that exists against the obsolete technology	4	4	40	10

Question no. 8:
What ethical, legal, social and political implications must be assessed when taking the decision to disinvest in a technology?

Selected proposals	No. votes	n.º votes≥6*	Total	Mean
Take into consideration the ethical implications associated with the patient (pain, hospital admissions, dependency)	9	7	68	9
The question of fairness resulting from the removal of the service must be taken into consideration (accessibility, cases that are left unprotected, absence of services and coverage of an area included in the Package of Services, etc.)	9	5	54	7
It is important to take into consideration the political implications and the importance of the mass media when disseminating the decision not to invest in the technology	10	6	50	6
Problems if there are inequalities in the Package of Services with regard to other services or communities (ethical, legal, social and political)	6	5	44	9

* Number of votes receiving 6 or more points

Annex VI.2.

**GuNFT Guideline:
Guideline for Not
Funding existing health
Technologies in health care
systems**

GuNFT Guideline Index

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1. General preliminary recommendations

The GuNFT Guideline is designed to be used within any health care system by a broad range of users, including all those who can identify a technology for which funds might be reduced or withdrawn (health professionals, patients or member of public), the committee which is to assess the application (the hospital technology Assessment Committee or the Agency for Health Technology Assessment (HTA)) and the management team or final decision-maker in the health system responsible for establishing the process and delivering the final decision about the identified health technologies.

The aim of this guideline is to provide a framework for the evaluation of all health technologies that may be suitable for disinvestment; in other words, all those technologies whose clinical benefit, safety or cost-effectiveness profiles might indicate they are candidates for disinvestment, rather than just those technologies that may have become obsolete (according to the definition agreed upon by the Spanish group- health technologies for one or several indications in use whose clinical benefit, safety or cost effectiveness have been significantly superseded by other available alternatives).

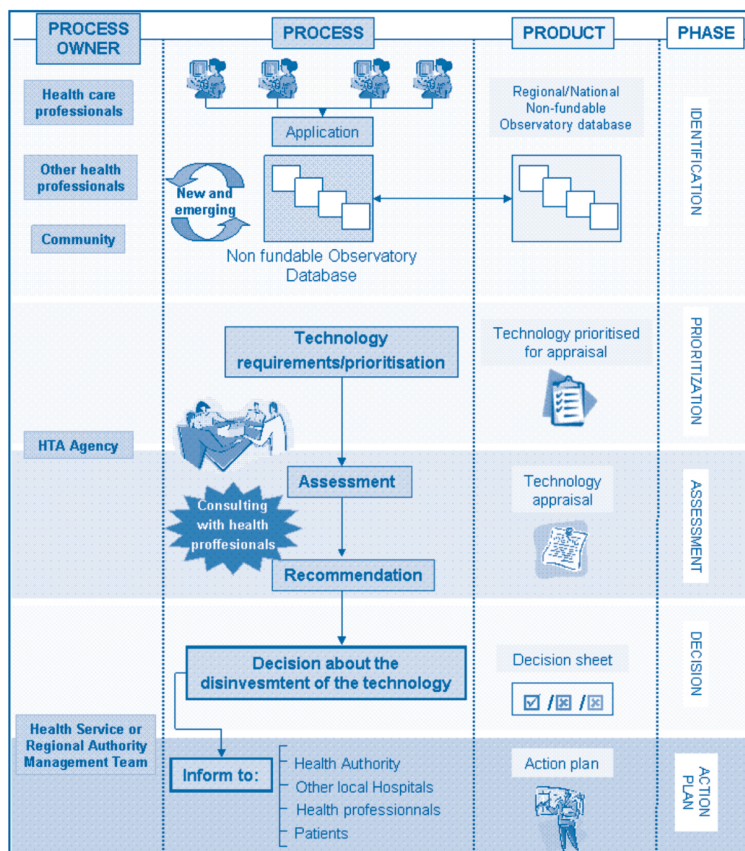
The successful implementation of the framework described in this guideline depends, in turn, on a number of different factors that must be taken into consideration:

- The use of this guideline at a regional-national level would ensure that those technologies for which disinvestment can not be considered at a local level (due to the complexity of the technology or its coverage) are also considered. Nevertheless, it should be noted that this guideline can also be used at a hospital level, where it could assist the assessment of locally used technologies, thereby allowing the hospital to reorganize its resources.
- It would be advisable to integrate this process with that used to identify new and emerging technologies and that used to monitor technologies in use (if they exist) in order to combine processes that are to some extent complementary.
- If there is no existing health technology assessment committee or similar group responsible for this task, one should be established. Written rules should specify the method by which consensus is going to be reached and the Committees, level of authority.
- Participation of health professionals with the appropriate knowledge (EBM, statistics, HTA, management or health economics), skills and aptitudes in this process must be encouraged, bearing in mind that they must have sufficient time to dedicate to this task.

- It is essential to establish a formal obligatory working procedure that is familiar to all the professionals in the health organization, and that this method is accepted by the centre's management team or the final decision-maker.
- As defined in the GANT Guideline, it is advisable that this procedure be undertaken electronically, for example, by making the instructions, forms and other documents required to formulate GuNFT applications available on the internet. The process would be most efficient if the internet could also be used to send applications to the assessment committee and for the committee to issue its decision, as this would speed up the administrative procedures and allow waiting times to be reduced. The organisation should also commit to minimising the time that elapses between the request, the recommendation of the committee and the management team's final decision. All these factors are important in order to reduce health professionals' negative perception of bureaucratic barriers.
- Once the decision to disinvest in a specific technology has been taken, an «action plan» should be designed to ensure that the process is followed in the most suitable manner, stressing the importance of informing health professionals and the patients affected about the decision taken, the reasons that have led to it and the actions that are going to be performed.

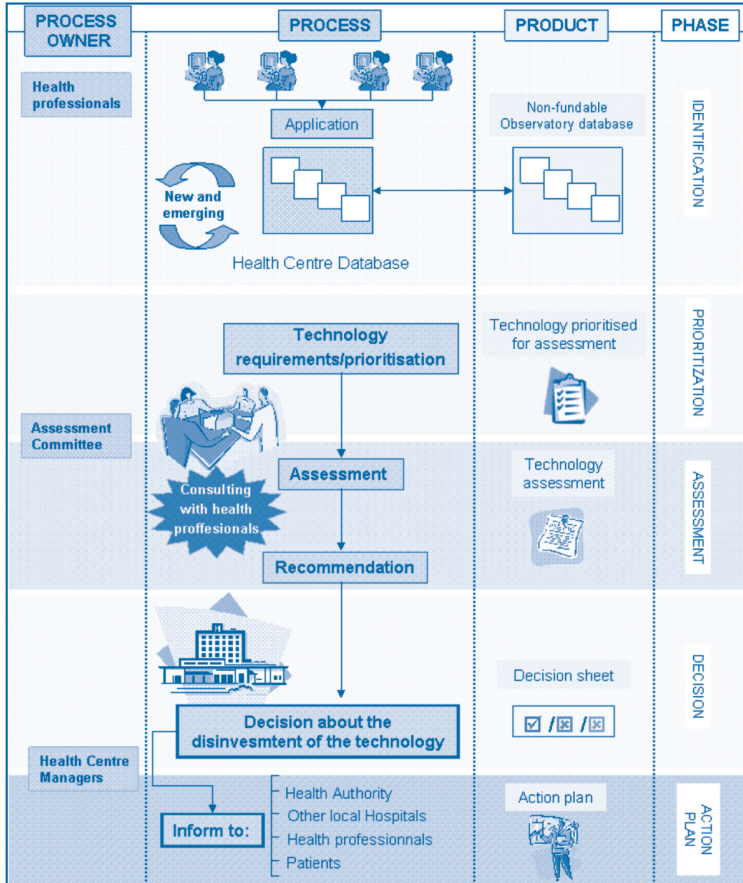
The process that could be followed to implement the GuNFT Guideline at a regional or national level is presented in Figure 1.

Figure 1. Process to disinvest in existing health technologies at a regional or national level



The process that could be followed at a local level is presented in Figure 2:

Figure 2. Process to disinvest in existing health technologies at a local level



The main stages into which this process should be divided are: a) identification b) validation of applications; c) prioritization (if necessary), d) assessment of applications, e) decision making, f) development of an the action plan and g) diffusion of the decision, the reasons why it has been taken and the action plan to achieve disinvestment (Table 1).

Table 1. Actions, methods and people responsible for each stage of the procedure

Action	Method	Responsibility
a) Application	GuNFT Guideline: Application form (ANNEX I)	Any health professional working in a Health Care Centre
b) Checking applications	GuNFT Guideline: Proposal checklist (ANNEX II)	Technology Assessment Committee or similar
c) Prioritising applications	Possible use of the criteria proposed in the «Guideline for identifying, prioritising and assessing obsolete health technologies» of Avalia-t or those proposed by Elshaug et al, 2009	
d) Assessing the proposal	GuNFT Guideline: Final proposal and assessment report (ANNEX III)	
e) Decision making	GuNFT Guideline: ANNEX IV	Hospital Management Team or multidisciplinary group consisting of the people involved in the process (Management Team, Assessment Committee, health professionals involved, patients, etc.)
f) Activities plan	Design of the strategy to be followed (see page 10 of the GuNFT guideline)	

2. Completing the application

Prior technological requirements

A health technology must comply with the following requirements in order for it to be proposed for disinvestment assessment:

- The proposed technology should be used in the Centre or place where the application is made.
- The status/situation of the technology in the Centres in that region is known to the applicant.
- There should be an alternative treatment option to the technology (availability of a cost-effective alternative treatment), except when the decision to disinvest is based on matters of safety or high risk (negative balance between risks and benefits), when there is strong evidence of a high rate of rejection by patients or when the technology is ineffective.
- Disinvestment in the specific technology will not give rise to an absence of care in the available Health Care Services Package or, if

appropriate, the needs of affected patients who do not now receive the technology will be taken into consideration in order not to create situations in which no care is provided.

Recommendations for completing the application

- The application (ANNEX I) will have more weight if there is a high degree of agreement among the health professionals who use the nominated technology, or when experts support the proposal.
- It is not necessary to complete all the information requested on the application form, although those fields indicated as mandatory must be filled in (fields marked with an*). The Assessment Committee may request, if appropriate, the assistance of the applicant in order to gather any further information on this matter.
- The application form may be submitted on paper and in an electronic version, but it is recommended to complete the electronic version to ensure optimum legibility. All the sections in the questionnaire must be clearly and completely filled out, providing all relevant details. The application must indicate those patients who would be affected by the measure and whether disinvesting would involve one, several or all the indications of the technology.
- If it is considered that there are relevant aspects (such as «special circumstances») that should be taken into account to make the assessment and to take a decision on disinvesting in the proposed technology, and there is no place on the questionnaire to include them, a separate sheet may be added or these comments may be included in the suggestions or notes box that can be found at the end of the application presented in the GuNFT Guideline.
- All the supporting bibliography that is considered relevant to take a decision on disinvesting in an already established health technology should be enclosed, including any recommendations established in relevant clinical practice guidelines, at both national and international levels.

3. Checking and prioritising applications

Depending on the level of implementation of this guideline, the corresponding organization will determine who is going to validate and, if necessary, prioritise the evaluation of the applications submitted. In a local context, it would be advisable to designate the Health Care Centre's Technology As-

assessment Committee. Where this does not exist, the local reference Health Technology Assessment Agency should be nominated to guide the process. In the case of a global implementation, the HTA Agency or similar organization should be the responsible for prioritisation and assessment.

Upon receipt, all applications should be reviewed by the Assessment Committee in order to ensure that they comply with the preliminary requirements specified in section 2 and ANNEX II of this guideline.

When the number of technologies to be assessed is considered high, a prioritisation system should be established. This system could be based on the criteria defined in the «Guideline on the identification, prioritising and evaluation of obsolete technologies» currently developed by Avalia-t¹. The guideline contains a tool designed to help in the work of prioritising the obsolete technologies identified for evaluation according to: a) the characteristics of the population/users in which this technology is employed, b) the balance between risks and benefits of the technology and c) costs, organisational aspects and other implications linked to the technologies to be prioritised. These criteria are however, defined for obsolete technologies, which are those that have been superseded by other technologies. Therefore, prioritisation criteria could be defined depending on the local context under consideration. A recent study² concerning the identification of existing health care services that do not provide value for money, listed criteria that could be used to prioritize candidates for detailed review after identification (Figure 3). These criteria could also be used to determine which nominations should be tested first.

¹ Ruano Raviña A, Velasco González M, Varela Lema L, Cerdá Mota T, Ibarгойen Roteta N, Gutiérrez Ibarluzea I, Blasco Amaro JA, Imaz Iglesias I, et al. Identificación, priorización y evaluación de tecnologías obsoletas. Guía metodológica. Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Política Social. Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia; 2007. Informes de Evaluación de Tecnoloxías Sanitarias; avalia-t. Nº 2007/01.

² Elshaug AG, Moss JR, Littlejohns P et al. Identifying existing health care services that do not provide value for money. *Med J Aust* 2009;190(5):269.

Figure 3. Criteria to inform the prioritisation of candidates for detailed review after identification (Reproduced with permission from Elshaug A et al, Med J Aust 2009)

4 Criteria to inform the prioritisation of candidates for detailed review after identification*

Cost of service: High cost per procedure (eg, high item cost on the Medicare Benefits Schedule or Pharmaceutical Benefits Scheme), high cost by volume, or an aggregate measure of these.

Potential impact:

- Likely health impact (eg, crude estimate of quality-adjusted life-years lost per patient).
- Likely cost effects (eg, crude estimate of cost savings per patient; liberation of additional resources, including downstream costs such as theatre time required for corrective procedures, and sunk costs of human and physical capital, including costs of retraining, and costs associated with length of hospital stay).
- Overall assessment relating to the maintenance of equity in care should this health care intervention be displaced (eg, access by patient subgroups).

Cost-effective alternative: When a cheaper but more, or equally, effective alternative exists, is identified or emerges. See also Box 3 item *Assess new intervention — displace old*.

Disease burden: Conditions associated with low degrees of disability or morbidity or low rates of mortality (but excluding orphan conditions) may influence priority differentially to those with high degrees or rates. “Low” may reduce the potential for controversy; “high” may represent greater scope for reinvestment/reallocation of resources.

Sufficient evidence available: Rigorous assessment requires robust evidence on which decisions can be made. While evidence is rarely 100% conclusive, it should be available and adequate to offer decision-making utility.

Scope for time-limited funding with “pay for evidence” or “only in research” provisions: If there is not new, adequate or sufficient evidence, but other criteria are met and/or there is a moderate indication of (cost-)ineffectiveness within existing evidence, then there should be scope for “(time-limited) funding with evidence generation” to assist decision making. Time-limited funding (standard subsidy) is conditional on patients being enrolled in a controlled clinical trial. Internationally, this is known as “pay for evidence”, “only in research” or “coverage with evidence development”.²¹ The need or extent of new evidence required to meet “sufficient evidence” (item above) might inform prioritisation.

Futility: An intervention that is highly unlikely to result in “meaningful survival” or benefit.²² For example, life-saving treatments for the seriously demented (especially those who have given advance directives); procedures that require multiple stages to which patients have poor adherence due to pain or side effects; and treatments with high relapse rates.

* It is likely that points of identification would be incorporated in parallel into assessments of prioritisation, as determined by decisionmakers. ◆

4. Assessing applications

As stated, the Assessment Committee or the HTA Agency of reference should be responsible for completing the assessment of all health technologies proposed for disinvestment.

An assessment system similar to that described in the GANT Guideline has been developed to assess the application. This system considers the assessment on the basis of three fundamental criteria: a) The Centre's Health Care Services Package and strategic objectives of the Centre, b) the balance between the advantages and disadvantages of adopting the proposal and c) the ability of the Centre or Health Care Setting to assume the proposal. A document to facilitate the assessment of the proposal is provided in ANNEX III.

If, at the beginning of the process, information is found to be missing from some of the non-mandatory fields in the application, the Assessment Committee or equivalent should search for this information, with the help of input from the health professionals who made the proposal or other professionals from specialties involved in the proposed technology. In addition to securing a higher level of acceptance of the process, this may increase the level of knowledge and training of the interdisciplinary group responsible for the process, as well as the health professionals themselves.

Those responsible for conducting the assessment (not the applicant), should carry out a further systematic literature search on the subject in order to find relevant, high quality scientific studies to aid the decision-making process or, where appropriate, provide the sources from which any data presented has been obtained (for example, from hospital records, from the hospital's Patient Care Service, etc.).

Questions A1-A4 will be used to assess the first criteria, questions B1-B4 to assess the second criteria, and questions C1-C4 to assess the third criteria (see ANNEX III of this guideline).

The Assessment Committee or similar should submit a recommendation to the final decision-maker, based on one of the numerous approaches designed for this purpose (from SIGN to Oxford or GRADE). The approach would depend on the methodology that each Assessing Committee applies, and this stage is not mandatory, although it could provide additional help for the decision-maker.

5. Taking the final decision

ANNEX IV of this guideline should be followed to draw up the report containing the final decision about the proposal.

Table 2 (ANNEX IV) will be consulted to take the final decision concerning the proposal, which will be reached based on the following process:

A. Disinvestment of the technology in the proposed indication(s) according to the terms put forward in the proposal is approved (*First scenario*).

B. Disinvestment is not approved, but could take place in the future if:

a. The health organization considers that even though the proposal can not currently be approved, it could be approved in the future (for example, when funding can be secured to purchase the technology that is to replace the existing one) (*Second scenario*).

b. New evidence in favour of the proposal for disinvestment appears, such that the recommendation can be revised to endorse the proposal (*Fourth scenario*).

c. Another reason:

C. Financing of the technology in the proposed indication(s) is to continue. Reasons:

a. It is not possible to disinvest the technology in the proposed indication(s), as it would need to be replaced by another technology that cannot currently be financed (with the exception of those technologies that involve serious risks for the patient) (*Third scenario*).

b. There is evidence against the proposal for disinvestment (*Fifth scenario*).

c. It is not possible to disinvest the technology because a gap of care is created (*Seventh scenario*).

d. Another reason:

Table 2. Establishing the recommendation on the proposal

SCENARIO	SECTION A Services Package and strategic objectives	SECTION B Balance between advantages and disadvantages	SECTION C Ability of the Centre	RECOMMENDED FINAL DECISION
First	☺	☺	☺	☑
Second	☺	☺	☹*	☒ ¹
Third	☺	☺	☹	☒
Fourth	☺	☹**	☺	☒ ²
Fifth	☺	☹	☺	☒
Sixth	☺	☹	☹	☒
Seventh	☹	☺	☺	☒
Eighth	☹	☺	☹	☒
Ninth	☹	☹	☺	☒
Tenth	☹	☹	☹	☒

☺: in favour of the proposal; ☹: against the proposal; ☹*: against the proposal but modifiable in the future; ☹**: against the proposal because of a lack of evidence but modifiable in the future; ☑: proposal recommended; ☒: proposal not recommended; ☒¹: proposal not recommended but that decision may be reconsidered once the capacity of the Centre has been revised; ☒²: proposal not recommended but modifiable if new evidence becomes available.

The decision-maker should be able to interpret the evidence found concerning the proposed technology in an appropriate manner and it is recommended to consult any of the guidance or manuals regarding the elaboration of systematic reviews or, the elaboration of recommendations, such as the SIGN's guideline³ (at an international level) or those proposed by «Guía Salud»⁴ or the Spanish Agency for Health Technology Assessment⁵ (at a national level).

³ Scottish Intercollegiate Guidelines Network. SIGN 50: A guideline developer's handbook. Available at: <http://www.sign.ac.uk>.

⁴ Grupo de trabajo sobre GPC. Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud. Manual Metodológico. Madrid: Plan Nacional para el SNS del MSC. Instituto Aragonés de Ciencias de la Salud-I+CS; 2007. Guías de Práctica Clínica en el SNS: I+CS.Nº 2006/OI.

⁵ Agencia de Evaluación de Tecnologías Sanitarias (AETS). Instituto de Salud Carlos III - Ministerio de Sanidad y Consumo «Guía para la Elaboración de Informes de Evaluación de Tecnologías Sanitarias». Madrid: AETS - Instituto de Salud Carlos III, Junio de 1999.

6. Action plan

Once the decision to disinvest has been taken, the management team must develop an implementation strategy. The final success of the entire process may depend largely on this last stage, therefore it is necessary to undertake the following actions:

- To inform the applicants and any other health professionals affected of the decision that has been taken. These individuals should work together with the different hierarchic levels of the hospital/setting, involved in the design of the plan to implement the decision. The aim of this process is to avoid any fears or resistance to the change, to promote transparent, consistent information and to ensure that health professionals are provided with support, should they be subjected to any pressure from affected patients or negative reactions from other healthcare professionals.
- To inform patients about the decision taken, the reasons that have led to the decision and the plan that has been designed in order to implement the decision.
- To develop a system in order to confirm, using indicators, that withdrawal of the technology actually represents an improvement and, when indicated, to observe also the effect of the new technology implemented as a replacement. An approach similar to that proposed by Avalia-t with regard to the surveillance of new health technologies introduced into the system could be used⁶.
- Take a positive approach, focussing on reinvestment rather than disinvestment. Care should be taken not to imply that the reinvestment will be made in the service affected by the decision.
- Forecast the impact of the decision with regard to the services offered by other hospitals or communities.
- Take into consideration the question of fairness resulting from the withdrawal of a service (accessibility, unprotected cases, absence of services or coverage of any area included in the Package of Services), considering, when appropriate, the needs of the patients affected to avoid lack-of-care-situations.

⁶ Varela Lema L, Ruano Raviña A, Cerdá Mota T, Blasco Amaro A, Gutiérrez Ibarluzea I, Ibarгойen Roteta N et al. Observación post-introducción de tecnologías sanitarias. Guía metodológica. Plan de Calidad del Sistema Nacional de Salud del Ministerio de Sanidad y Política Social. Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia; 2007. Informe de Evaluación de Tecnoloxías Sanitarias: avalia-t; 2007. N° 2007/02.

- Consider the need to simultaneously inform the media about the decision to disinvest in an established technology. This will ensure journalists have timely access to correct information and reduce the potencial for adverse publicity, which might complicate the implementation of the measure.
- Design, when necessary, an effective plan to withdraw the affected technology.

In all cases, it is recommended that, irrespective of the decision, a detailed explanation should be given to both the health professionals involved and the affected patients regarding the specific reasons that have led to the decision. With regard to this last point, the HTA Agency of Andalusia is working on a manual to adapt Health Technologies Assessment Reports to the public⁷ although there are other documents at an international level, such as those published by HAS (Haute Autorité de Santé), which propose recommendations for carrying out this task⁸.

⁷ Hermosilla Gago T y Grupo de expertos AETSE. Manual para adaptar informes de evaluación de tecnologías sanitarias a los ciudadanos (MADETSCI). Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; 2009. (Ministerio de Sanidad y Política Social. Informes, Estudios e Investigación: AETSA 2007/18) en prensa.

⁸ HAS. Élaboration d'un document écrit d'information à l'intention des patients et des usagers du système de santé. Guide methodologique. Service des bonnes pratiques professionnelles. Juin 2008.

7. Guideline annexes

Annex I

APPLICATION FORM FOR DISINVESTMENT IN TECHNOLOGIES (Administrative details and mandatory fields to be filled in by the applicant and to be completed, if necessary, by the Assessment Committee or similar)

ADMINISTRATIVE DETAILS OF THE APPLICANT

Name and surname of the applicant:

Date of the application:

Service in which the applicant works:

Position:

Place of work:

Please indicate, the level of agreement reached for the proposal to disinvest in this technology, especially when related to a hospital context:

- Request submitted by one individual
- The proposal has been agreed upon with other colleagues in the service
- The proposal has been agreed upon with other services involved

Contact telephone:

E-mail:

Signature of the applicant:

MAIN DETAILS OF THE PROPOSAL (mandatory fields marked with*)

- 1. Title of the proposal*** (should contain the technology and the patients to whom the proposal applies):

- 2. Name of the technology*:**

- 3. Indication(s) for which disinvestment is proposed*:**

One

Details:

Several

Details:

Total withdrawal of financing for all the indications

- 4. Reason(s) for proposing withdrawal of financing (select one or several)*:**

Evidence or suspicion of lack of safety

Unacceptable potential risk:

Environmental

For the patient

For the health professional

Evidence or suspicion of ineffectiveness

The technology reduces his/her perceived quality of life, with the result that this technology is not generally accepted by patients (discomfort or invasiveness, even though this may be more effective than alternatives or even when there is no alternative)

Its financing does not represent a benefit for the patient's health (e.g.: technologies that generate information without modifying the decision on the handling of patients)

- Obsolete technology for which there is an approved and available alternative (including more (cost)effective alternatives)**

In this case, is new investment required in the alternative technology?

- Yes No (it is already provided in the Health Services Package)

What would the alternative technology be?

- The technology proposed is not accepted by the health professional (non-acceptance of the procedure, awkward use, learning curve, etc.)**

5. Sponsor(s)*:

6. Health care centres currently using the technology*:

- Tertiary hospital
 General hospital or out-patient surgery
 Primary or community care
 Information not available
 Other Please specify:

7. Year implemented in the health system (may be approximate)*:

8. Is this technology being used in Centres in the Autonomous Community in which you are working?* No Yes I don't know

Details of Centres:

Is/Are this/these Centre(s) considering the possibility of disinvesting in this technology?

No Yes I don't know

9. Are there any relevant recommendations in high-quality clinical practice guidelines or those from a scientific society? If yes, please, provide details*.

10. What is the prevalence and/or incidence of the indication(s) for which the proposed technology is employed?

Incidence:

Prevalence:

Burden of the disease (morbidity, mortality...):

11. Are there qualitative studies or data from the centre itself or from other centres that indicate the opinion of patients about the proposed technology?

No Yes

If yes, please provide relevant details

12. What is the cost of the technology? (per unit, maintenance cost, direct and indirect costs...) (may be approximate).

13. Is this technology being used in other indications?

No Yes

If the answer is affirmative, might it be necessary to continue financing the technology for these other indications?

No Yes I don't know

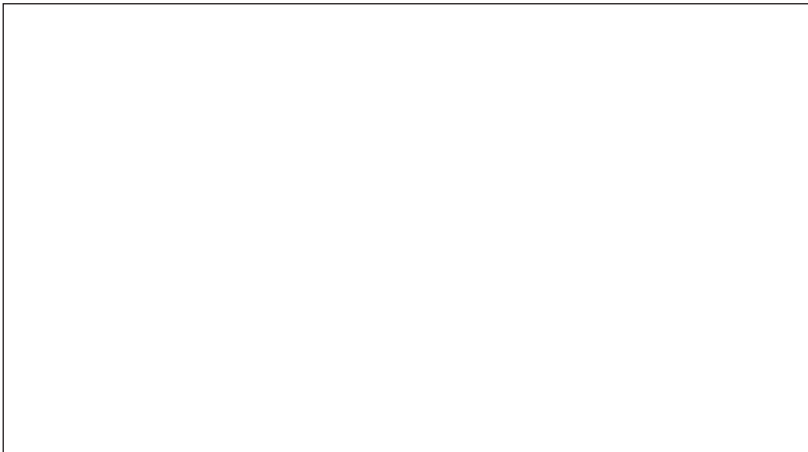
14. For how many patients (or how many procedures if there is more than one per patient) is this technology used per year in the Centre?

- < 15
- Between 15 and 25
- Between 25 and 100
- >100
- > 500

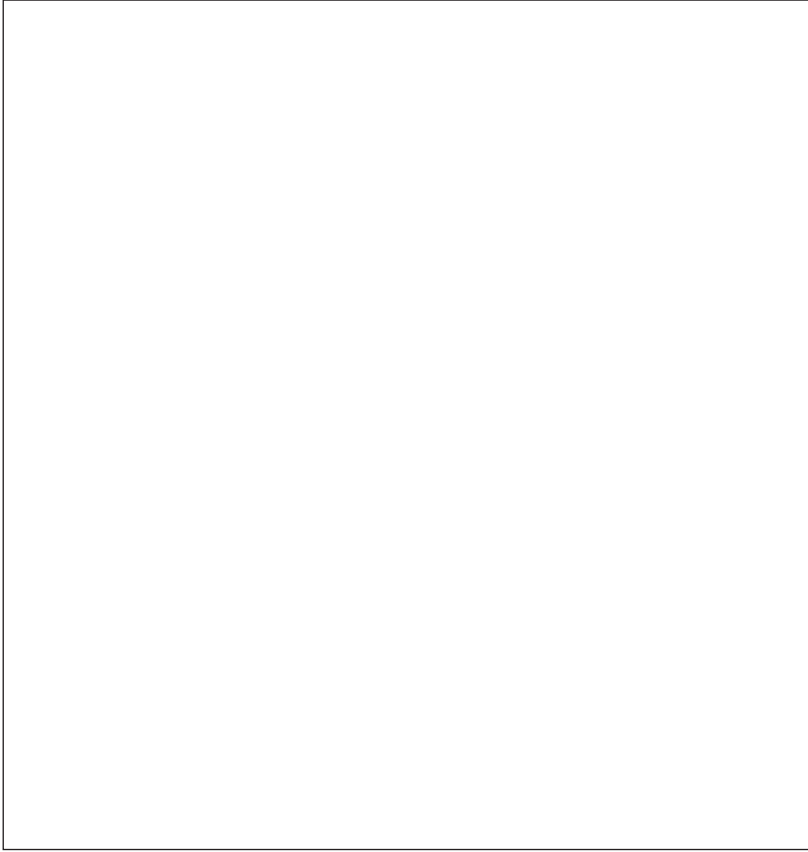
15. What evidence is there to support the proposal to withdraw the technology?



16. Provide details of the most relevant references (articles, reports, records (including audit) of the hospital itself, etc.)



SUGGESTIONS OR NOTES:

A large, empty rectangular box with a thin black border, intended for providing suggestions or notes. The box is currently blank.

Annex II

CHECKLIST FOR APPLICATIONS (By the Assessment Committee or similar)

ADMINISTRATIVE DETAILS

File Number:

Name and surname of the applicant:

Date of the application:

Service in which the applicant works:

Position:

Contact telephone:

E-mail:

ON THE BASIC REQUIREMENTS OF THE APPLICATION

- 1. Has the title of the proposal and the name of the proposed technology been specified correctly?**
(Items 1 and 2 of the application) Yes No
- 2. Have the indication(s) in which it is requested to disinvest in the technology been specified? (Item 3)** Yes No
- 3. Have the reason(s) for which the disinvestment application is being made been defined? (Item 4)** Yes No
- 4. Have been the sponsor(s) of the technology been specified? (Item 5)** Yes No
- 5. Have the type of health care centres in which the technology is used and the date of introduction been specified? (Items 6 and 7)** Yes No
- 6. Has the situation of nearby hospitals or centres with regard to the proposed technology been identified? (Item 8 of the application)** Yes No
- 7. Have the recommendations of the clinical practice or scientific society guidelines with reference to the indication specified for the proposed technology been detailed? (Item 9)** Yes No

Annex III

APPLICATION ASSESSMENT (By the Assessment Committee or similar)

FILE NUMBER:

DATE OF REPORT:

NAME OF THE PROPOSAL:

A) HEALTH SERVICES PACKAGE

A1. Description of the technology proposed for disinvestment. Name, components, operation.

A2. Has the proposal been agreed upon with colleagues in the service(s) that will be affected? Yes No

In this case, which are the reasons?

A3. Will the proposal involve the creation of a care gap in the Health Services Package? Have measures been considered to counter this? What measures?

A4. Does the proposal help to improve the quality of the services offered and make progress in line with the strategic plan defined by the organization? Is there any proposal regarding how to measure this improvement (shorter waiting times, reduction in the adverse effects recorded) and the plan of activities in order to carry out the proposal?

B) SUMMARY OF ADVANTAGES AND DISADVANTAGES OF THE PROPOSAL

B1. What reasons are given to endorse the application to disinvest in the technology in this/these indication(s)?

B2. What are the advantages of withdrawing the technology (e.g.: reduction in the waiting lists by eliminating its use in non-approved indications, facilitate reinvestment in efficient and safer technologies for patients, etc.)?

B3. What are the disadvantages of withdrawing the technology? For example, the need to channel patients to other centres due to low demand or the need for funding to finance the new technology that might «restrict» the financing of other technologies, etc.

B4. What scientific evidence has been provided to corroborate the responses provided to the last three questions?

C) ABILITY TO CARRY OUT THE PROPOSAL

C1. What is the likely impact on healthcare professionals of any decision to disinvest? For example, relocation of staff, need for training due to the replacement of the technology or less work due to the high level of automation in the replacement technology, fewer hazards in the workplace by withdrawing the technology, etc.

C2. What are the main changes to be made in the organisation of the health centre in order to conduct disinvestment in the technology? (Regarding the number of consultations, number of admissions, number of diagnostic tests, readmission rates, average stays in hospital, waiting lists)

C3. From an economic point of view, does the proposal compare favourably with existing alternatives? Initial costs, maintenance costs, need for accessories or additional consumable material, cost-effectiveness studies, cost-benefit and utility cost, etc.

C4. Will a decision to disinvest create controversy with nearby Centres? (For example, with centres that continue to invest in a specific technology, etc.)

Annex IV

GuNFT GUIDELINE: FINAL DECISION REPORT OF THE PROPOSAL (by the management team or final decision-maker)

FILE NUMBER:

DATE OF REPORT:

NAME OF THE PROPOSAL:

HEALTH SERVICES PACKAGE AND STRATEGIC OBJECTIVES

The proposal has been agreed upon at least with colleagues in the Service; the aims of the proposal are relevant for the organization and its results are quantifiable; the proposal matches the characteristics of the specific hospital and there will be no vacuum of appropriate and quality care in its Health Services Package.

Health Services Package and strategic objectives:

- Favourable assessment
- Unfavourable assessment
- Lack of information

Details

SUMMARY OF THE PROPOSAL'S ADVANTAGES AND DISADVANTAGES

Withdrawal of the technology may involve an improvement in the safety, health or quality of life of the patients indicated (and family members); or, if appropriate, without affecting the results with regard to health, improve the efficiency of the Service offered by the Centre by eliminating the technology's use in unapproved and inefficient indications, or by reinvesting the capital «saved» in more efficient technologies for these or other indications, for the benefit of patients. There must be evidence or data from the hospital itself to backup the potential advantages described.

Balance between advantages and disadvantages:

- Favourable assessment
- Unfavourable assessment
- Lack of information

Details

ABILITY OF THE CENTRE TO ACCEPT AND ENACT THE PROPOSAL

The organization is capable of implementing the proposal: it has the support of health professionals and sufficient resources to carry out the strategic plan. The proposal does not represent a major inconsistency with the offer of care of other Health Centres or Health Care Systems. There have been complaints from patients of the Centre regarding the technology in which it is wished to disinvest, in support of the decision of the Centre to make the proposal. The investment/reinvestment in the action plan to be followed represents an improvement over the technology for which disinvestment has been requested, taking into account not only the cost per unit and maintenance, but also the additional costs in terms of adverse effects on patients, associated indirect costs, more expenditure on staff, etc., and by securing resources from disinvestments, the plan can be financed totally or in part.

Ability of the Centre to accept the proposal

- Favourable assessment
- Unfavourable assessment
- Lack of information

Details

GUIDANCE FOR TAKING THE FINAL DECISION

SCENARIO	SECTION A Services Package and strategic objectives	SECTION B Balance between advantages and disadvantages	SECTION C Ability of the Centre	RECOMMENDED FINAL DECISION
First	☺	☺	☺	☑
Second	☺	☺	☹*	☒ ¹
Third	☺	☺	☹	☒
Fourth	☺	☹**	☺	☒ ²
Fifth	☺	☹	☺	☒
Sixth	☺	☹	☹	☒
Seventh	☹	☺	☺	☒
Eighth	☹	☺	☹	☒
Ninth	☹	☹	☺	☒
Tenth	☹	☹	☹	☒

☺: in favour of the proposal; ☹: against the proposal; ☹*: against the proposal but modifiable in the future; ☹**: against the proposal because of a lack of evidence but modifiable in the future; ☑: proposal recommended; ☒: proposal not recommended; ☒¹: proposal not recommended but that decision may be reconsidered once the capacity of the Centre has been revised; ☒²: proposal not recommended but modifiable should new evidence become available.

FINAL DECISION ABOUT THE PROPOSAL

Consult the enclosed information about the possible decisions that could come up:

FINAL DECISION POSSIBILITIES

A. Disinvestment of the technology in the proposed indication(s) according to the terms put forward in the proposal is approved (*First scenario*).

B. Disinvestment is not approved at present, but it could take place when:

- The hospital/health care setting considers that although the proposal can not be adopted in the present, it could be approved in a future (for example, when funding can be secured to purchase the technology that is to replace the existing one) (*Second scenario*).
- New evidence in favour of the proposal becomes available, so the recommendation can be revised to endorse the proposal (*Fourth scenario*).
- Another reason:

C. Financing of the technology in the proposed indication(s) should continue. Reasons:

- The hospital/health system cannot disinvest in the technology in the proposed indication(s), as it must replace this technology with another that it cannot currently afford to finance (with the exception of those technologies that involve serious risks for the patient). (*Third scenario*).
- There is evidence against the proposal (*Fifth scenario*).
- A gap of care is created which cannot be covered by other hospitals/centres of the health system, as this would involve an increase in their care load, thereby worsening the situation for other centres (*Seventh scenario*).
- Another reason (*Eight, ninth and tenth scenarios*):

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