Dialogue with industry, methodological and conceptual frameworks for its development

Nora Ibargoyen Roteta
Osteba/BIOEF (Basque Foundation for Health Innovation and Research)

Bilbao, 9th November 2022

Osteba

bioef

1. Introduction

- In a proactive HTA, there are different activities that have been introduced into the routine of many HTA agencies and units.

- The connection with innovators and the advice or dialogue with them in terms of improving the quality of the product, alignment with systems' needs, and avoiding the valley of death in-product access to the market.

1. Introduction

EARLY DIALOGUE

SCIENTIFIC ADVICE

EARLY ADVICE

2. Aim

- To perform a systematic review of the activities named scientific advice (SA), early advice (EA), and early dialogue (ED).

Ibargoyen-Roteta N [1] , Benguria-Arrate G [1] , Galnares-Cordero L [1] , Guevara C [2] , De la Hoz Siegler I [2] , Chacon K [2] , Low E [2] , Otte M [3] , Dauben H [3] , Gutierrez-Ibarluzea I [1]

[1] Bioef-Osteba, Barakaldo Basque Country, Spain

[2] Keralty, Vitoria-Gasteiz Basque Country, Spain

[3] EuroScan-i-HTS, Cologne North Rhine-Westphalia, Germany

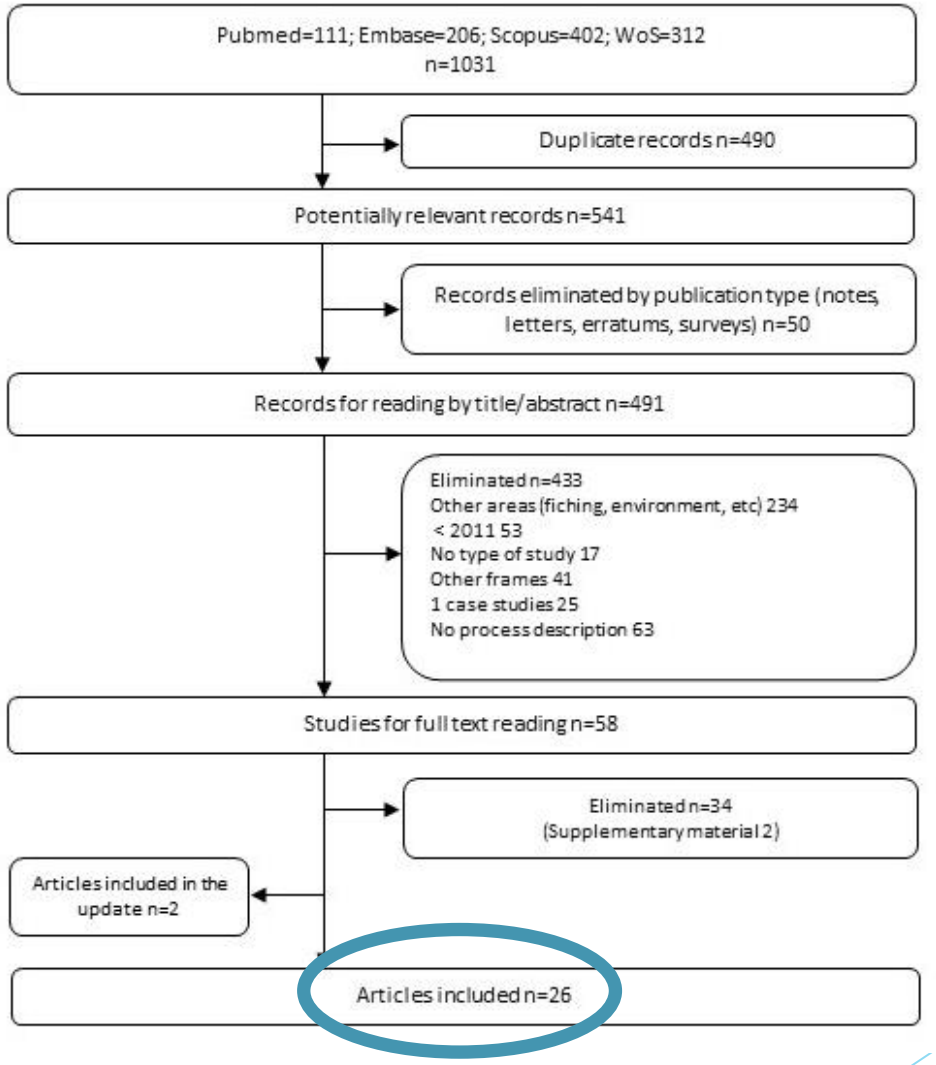
3. Methodology

- Major databases and HTA organizations' websites were explored.
  - Pubmed/ Embase/ Scopus/ WoS
  - HTA organization's websites identified in the included studies
  - Last update March 2022
- Protocol and search strategy published in PROSPERO (CRD42020219401)

3. Methodology

- Screening by pairs among six researchers
- Two researchers performed data extraction from all the included articles
- Information for each organization was structured in tables
- Any disagreement was resolved by consensus.

4. Results


Pubmed=111; Embase=206; Scopus=402; WoS=312
n=1031
Duplicate records n=490
Potentially relevant records n=541
Records eliminated by publication type (notes, letters, erratums, surveys) n=50
Records for reading by title/abstract n=491
Eliminated n=433
Other areas (fiching, environment, etc) 234
< 2011 53
No type of study 17
Other frames 41
1 case studies 25
No process description 63
Studies for full text reading n=58
Eliminated n=34
(Supplementary material 2)
Articles included in the update n=2
Articles included n=26

4. Results

- 26 documents selected:
  - 7 narrative reviews describing the approaches for ED/SA followed by different HTA organizations (4 conference abstracts)
  - 10 focused on SA by a single organization (NICE 4 references)
  - 9 articles about EUnetHTA ED services

4. Results

- 8 HTA bodies and the European Network offering SA/ED services

4. Results

- HTA bodies working on ED/SA are mostly based in Europe (NICE, HAS, GB-A…), followed by Canada (CADTH).
- Big HTA agencies (CADTH, NICE…) include EA or SA among their services, as well as the EUnetHTA network.

4. Results

- Type of activity, process, duration, purpose, and costs differ among HTA bodies.
- Most organizations not only had a national public service for ED/SA, but also participated in joint/parallel advice services with regulatory agencies, at a national or international level, or with other HTA organizations.

4. Results

HTA body	ED/SA	Technology	Weeks	ED/SA	Fees
NICE	•Standard SA •Express SA	•Drugs •Medtech (Metatool)	12-18	Individual or in Parallel with CADTH/ Regulatory EUnetHTA	£29,000 to 91,051
HTW (Wales)	SA (Metatool)	Non-medicine technologies	6-8	Individual	NR
CADTH	SA Early PSA	Drugs	18	Individual or in Parallel with NICE/Health Canada	65,000-100,000 CAN $
G-BA	Early/Late SA	Drugs	8	With National approval authorities EUnetHTA	2,000-10,000 €

HTA body	ED/SA	Technology	Weeks	ED/SA	Fees
HAS	ED Standard or Accelerated	Innovative Medicinal Products/ Medical devices	11-16	Individual EuneHTA	No fees.
ZIN	SA (written or oral advice)	Medicinal products	6-12	In parallel with MEB EUnetHTA	No additional fee to MEB
TLV	SA	Pharmaceuticals	8	In parallel with MPA EUnetHTA	No additional fee to MPA
AIFA	SA *Innovative meetings* (informal)	Pharmaceuticals	12	Individual EUnetHTA	10,000-40,000 €

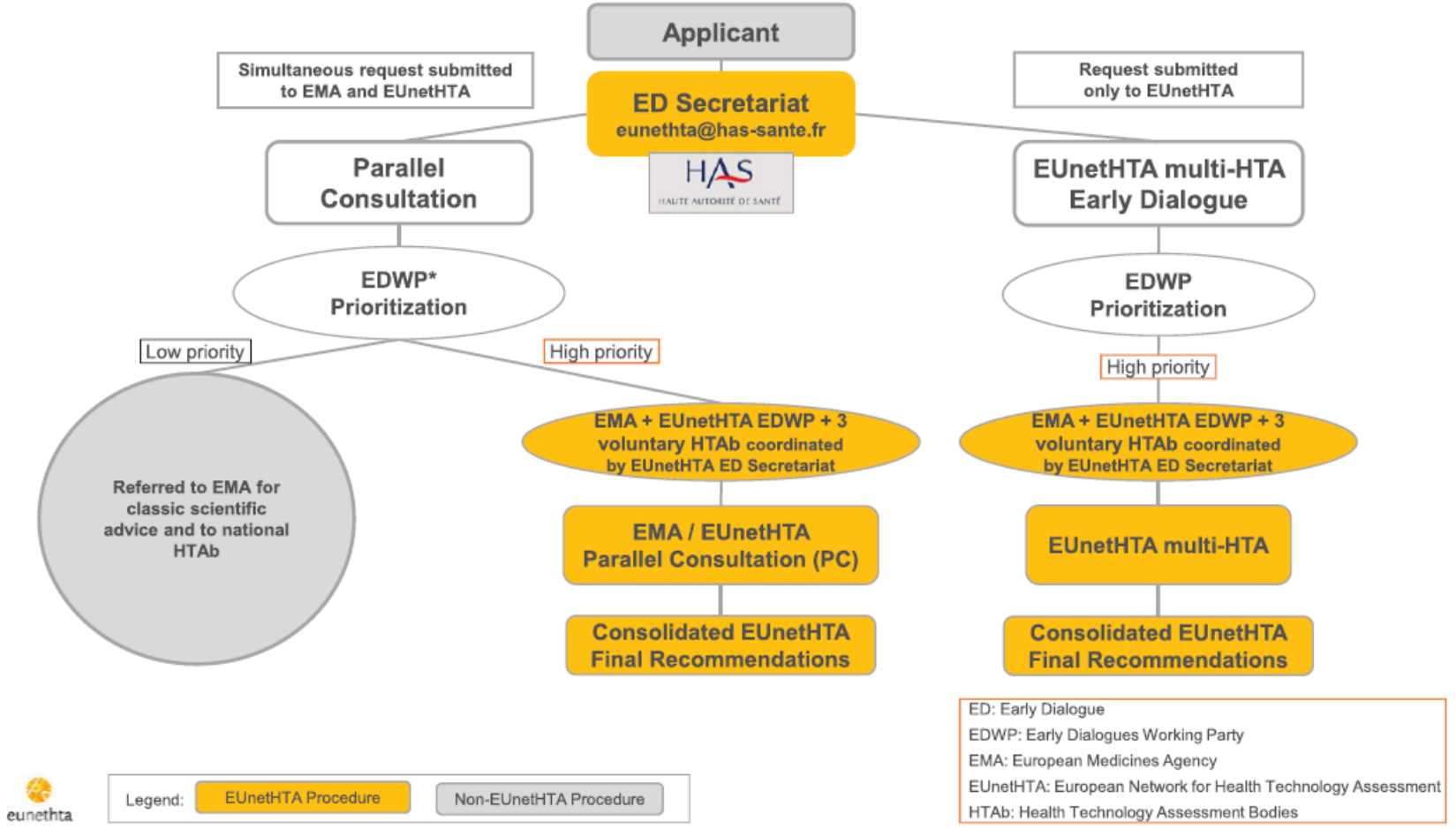


Figure 1. European Network for Health Technology Assessment Early Dialogue request process and outcome based on request type and Early Dialogues Working Party prioritization.

Galbraith M, Guilhaume C, Bélorgey C. Early Dialogues for Pharmaceutical Products in European Network for Health Technology Assessment Joint Action 3: What Was Done and Where to Go in the Future. Int J Technol Assess Health Care. 2022;38(1):e30.

Medtech Early Technical Assessment (META) Tool

Medtech

Proof of concept, prototype phase

Get an early insight into building an evidence base to demonstrate the value of your technology and meet the needs of HTA bodies, commissioners and payers with our META Tool©.

Evidence generation phase

Identify any gaps in your evidence generation plans and receive information on the next steps using our META Tool©.

Optimise your clinical trial/study plans by getting answers to your questions and receiving key insights through our advisory services.

Adoption phase

Identify any gaps in the existing evidence base for your technology and receive information on the next steps with the META Tool©.

Pharmaceuticals

Pre-clinical / Phase 1

Initiate early dialogue with us when your technology does not fit the conventional development paradigm and there is uncertainty around your evidence generation plans.

Phase 2 and 3

Optimise your clinical trial/study plans by getting answers to your questions and receiving key insights through our advisory services.

Post phase 3, pre-authorisation

Optimise your economic strategy and/or any additional clinical trial/study plans by getting answers to your questions and receiving key insights through our advisory services.

Seek expert technical advice on the structure, transparency and overall suitability of your economic model with our PRIMA service.

Post-authorisation

Optimise any further clinical trial/study plans by getting answers to your questions and receiving key insights through our advisory services.

Seek expert technical advice on the structure, transparency and overall suitability of your economic model with our PRIMA service.

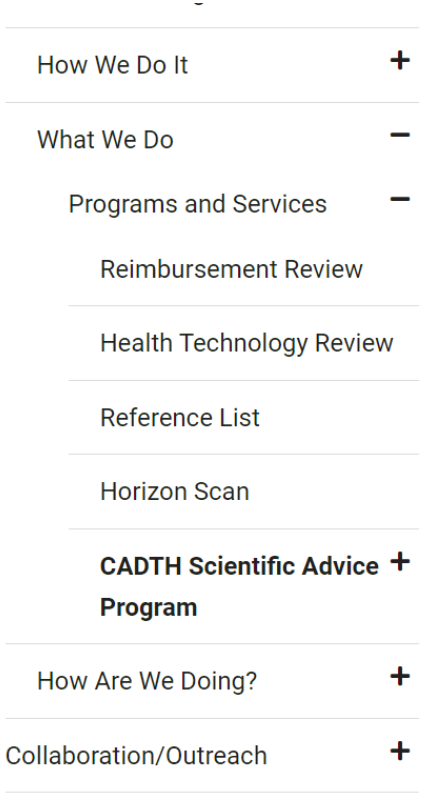
https://www.nice.org.uk/about/what-we-do/life-sciences/scientific-advice

Early dialogue/Scientific advice impact

How it has been measured?

- Description of type of services given, type of questions received….
- Changes made by the industry to the pivotal trials designs (implementation of given recommendations (from Regulatory or HTA bodies))
- Reimbursment/appraisal results of technologies with a given ED/SA
- Manufacturers' satisfaction with the advice given (was it useful?...)

- HTA ED/SA processes are quite new services, and updates are common



Latest News

CADTH Expands Scientific Advice Program to Include Advice on Real-World Evidence

CADTH is expanding its Scientific Advice program to include applications for advice on real-world evidence (RWE) generation plans after protocols for pivotal trials have been finalized. This is an opportunity for pharmaceutical companies to enhance their engagement with CADTH regarding RWE.

The expanded program will run for a 1-year learning period and requests will be considered until March 31, 2023. Any request must include questions related to RWE generation plans; questions on economic modelling may also be included. Priority will be given to rare diseases; however, all requests will be considered based on availability of meeting dates. Advice will continue to be offered from CADTH alone or in parallel with Health Canada or the National Institute for Health and Care Excellence (NICE). The established scientific advice processes will be followed.

Early CADTH Scientific Advice services prior to finalization of pivotal trial protocols still plays an important role and continues to be offered. Questions related to RWE planning are also accepted at this earlier stage.

To discuss potential applications for CADTH Scientific Advice, please contact **scientificadvice@cadth.ca**.

Published : April 27, 2022

https://www.cadth.ca/scientific-advice

5. Conclusions

- Heterogeneity of activities framed under the same nomenclature
- Need to define what SA, ED, and EA are.
- With the results of this SR and lessons learned, a framework for ED/EA/SA processes will be proposed.

frontiers | Frontiers in Public Health

TYPE Systematic Review
PUBLISHED 06 October 2022
DOI 10.3389/fpubh.2022.942230

OPEN ACCESS

EDITED BY
Georgi Iskrov,
Plovdiv Medical University, Bulgaria

REVIEWED BY
Maria Stefanova Kamusheva,
Medical University of Sofia, Bulgaria
Anastasia Chalkidou,
National Institute for Health and Care Excellence, United Kingdom
Chiara de Waure,
University of Perugia, Italy
Anna Nachtnebel,
Hauptverband der österreichischen Sozialversicherungsträger, Austria

*CORRESPONDENCE
Nora Ibargoyen-Roteta
nibargoyen@bioef.eus

SPECIALTY SECTION
This article was submitted to Public Health Policy,
a section of the journal

A systematic review of the early dialogue frameworks used within health technology assessment and their actual adoption from HTA agencies

Nora Ibargoyen-Roteta[1]*, Lorea Galnares-Cordero[1], Gaizka Benguria-Arrate[1], Kelly Rocío Chacón-Acevedo[2], María Paula Gutiérrez-Sepulveda[2], Eduardo Low-Padilla[2], Ilich Herbert De La Hoz-Siegler[2], Claudia Isabel Guevara-Pérez[2], Ángel del Pozo-Pérez[3], Marta Suárez[3], Hans Peter Dauben[4], Maximilian Otte[5] and Iñaki Gutiérrez-Ibarluzea[1,6]

And what’s next?

Thank you!