IMPROVING ADDITIONAL EVIDENCE GENERATION FOR HEALTH TECHNOLOGIES

Evidence gaps are often identified at the time of an initial Health Technology Assessment for new technologies. In order to reduce uncertainty, HTA bodies can make recommendations/requests for Additional Evidence Generation (AEG), which may include trials, observational studies, registries, data on appropriateness of use, etc.

Work Package 7 / Subgroup 2

Background

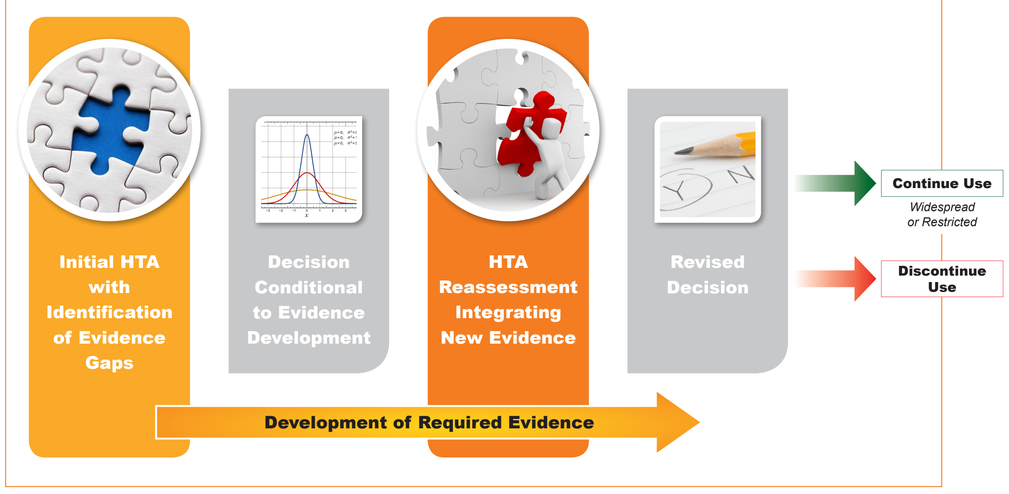
Improving collaboration among HTA bodies in the field of AEG has been one of EUnetHTA's priorities since 2010.

Following the developments in Joint Action 1 (JA1):

- **EVIDENT database** to share information on AEG recommendations/requests
- **Criteria** to prioritize research needs

JA2 is focusing **on developing and testing a methodological basis for European cooperation** in this field.

Importance of Additional Evidence Generation for Health Technologies



Objectives

- Help HTA doers define more specific research recommendations, that may better serve decision maker and researcher needs, by addressing the following two questions (**two EUnetHTA position papers**):
  - how to formulate a **research question**;
  - how to decide on the appropriate **study design**.
- Reduce multiple uncoordinated study requests and favor the collection of more robust data through a **pilot of a common core study protocol**.

  The final deliverable will be the core protocol, not a study conduct, since study funding or implementation is not within scope of this work.

Methods

- Literature review and survey of EUnetHTA partners to:
  - Reach a more in-depth understanding of HTA body practices in the domain of AEG;
  - Explore possibilities and conditions for performing harmonized data collection in different countries.
- Development of 3 deliverables by EUnetHTA partners (two authoring agencies per deliverable plus reviewers).
- Consultation of stakeholders and key people in the field of AEG (involved in the scoping phase and review of the documents).
- Collaboration with the European Medicines Agency (EMA) and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).
  - Regular, mutual updates on the developments in the area of post-licensing (post-authorization) evidence generation;
  - Exploring coordinated approaches on post-authorization evidence generation, such as possible parallel advice;
  - Exploring the possibility of developing and testing methodology relevant to regulatory and HTA activities in this field.

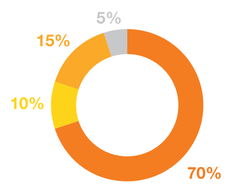
Results

- ***The analysis of the survey on AEG practices, performed in 2013 among EUnetHTA partners, confirmed the need to work on structuring and harmonizing AEG recommendations/requests across Europe. Main results are presented in Figures 1-7.***
- ***The position paper on how to best formulate the research questions is focused on improving their presentation and providing a structured approach for identification and prioritization of research gaps.***
- ***The position paper on how to decide on the appropriate study design discusses the role of the HTA author/systematic reviewer in specifying the study design – whether this should be attempted at all, and if so what needs to be taken into consideration. Both position papers are currently being drafted and should be published in 2015.***
- ***Finally, the feasibility of coordinating an AEG request in Europe will be tested through the pilot of a common core protocol, with the objective of elaborating a core study protocol that could be used in different countries. The protocol should be completed in summer 2015.***

Main Survey Results

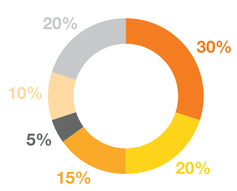
General information on AEG (fig.1-2)

Which technologies?



- Both new and those already used/on the market
- Only new
- NA
- Only for those already on the market and in the context of multiple HTA

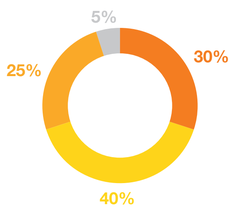
Which sources of funding?



- HTA Body + Public/Private Funding
- Public
- NA
- HTA Body alone
- Private
- Public/Private Partnership

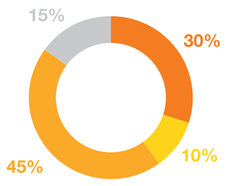
Level of standardization of research recommendations (fig.3-4)

How are research recommendations formulated in the HTA report?



- In a detailed manner
- With some indications on AEG (research question, study design...)
- Without any detail
- Not in the HTA report

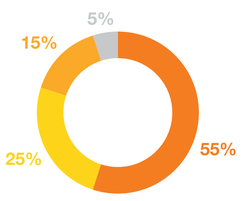
Is there a standardized format for the research recommendation/ question?



- Yes (PICO; EPICOT)
- No, but "guidance" exists
- No
- NA

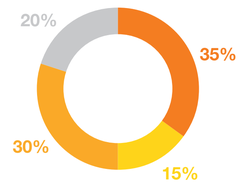
HTA bodies' involvement in the definition of the research question and the protocol (fig.5-6)

Are HTA doers involved in the definition of the research question?



- Yes (Sometimes together with external institutions)
- No
- NA
- Appraisal comitee

Who designs the protocol?



- HTA body with other professionals
- HTA body
- Other professionals (* Manufacturers)
- NA

Real life experiences with AEG (fig.7)

According to the respondents, the most often used design is a study in real life settings.

Seventy five percent (75%) of responding agencies make 1-10 research recommendations/requests per year.

Only 30% of HTA bodies are involved in the final decision on whether to perform the additional research. It is the Ministry of Health that most often makes the final decision.

Only 20% of agencies stated that almost all of their recommendations/requests are really carried out, while 30% think that less than 10% of their recommendations/requests are really carried out.

* Twenty agencies having an experience with AEG responded to the survey.

Key Elements for Success

- **Information Sharing - EVIDENT database.**
- **Coordination of Partners - EUnetHTA and external partnerships.**
- **Prioritization - JA1 criteria.**
- **Scientific and Pragmatic Guidance - JA2 deliverables.**
- **Funding for Data Collection and Analysis.**

Poster developed by The French National Authority for Health (HAS).
Content on SG2 Additional Evidence Generation (Lead by HAS) as part of EUnetHTA Work Package 7 (HAS as Lead and IQWIG as Co-Lead)

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