EUnetHTA

Criteria to select and prioritize health technologies for additional evidence generation

WORK PACKAGE 7

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Description of Criteria to select and prioritize health technologies for additional evidence generation

was developed by

Work Package 7: “New technologies”

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ABBREVIATIONS

ADC: ADDITIONAL DATA COLLECTION

DALY: DISABILITY-ADJUSTED LIFE YEAR

EUNETHTA: EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

HAS: FRENCH NATIONAL AUTHORITY FOR HEALTH

HTA: HEALTH TECHNOLOGY ASSESSMENT

QALY: QUALITY ADJUSTED LIFE YEAR

BACKGROUND

Evidence gaps identified during health technology assessment are one of the major obstacles to ensuring timely access to new health technologies. Several countries have therefore developed policy frameworks and mechanisms, called Access with evidence generation[1] mechanisms, which allow temporary access to these technologies while concurrently requesting the generation of additional evidence to reduce uncertainty.

However, these mechanisms imply setting up studies, or any kind of Additional data collection (ADC), that are resource and time consuming. The process for selecting the most valuable technologies for further research is often informal and varies from one health care system to another.

Therefore Strand A of the EUnetHTA Joint Action 2010-2012 Work package 7 focused on developing a set of selection/prioritization criteria that should help **HTA doers, funders and other stakeholders to select technologies for which complementary studies are really worth performing.**
Developed criteria may have a broader application than in the context of Access with evidence generation mechanisms and be used to select technologies that are already covered and diffused but for which additional data on their effective impact in current practice is needed.

[1] Different terms are used locally to refer to the Access with evidence generation systems, like “Conditionally funded field evaluation” in Ontario, Canada, “Monitored use” in Spain, “Interim funding” in Australia, “ Coverage with evidence development” in the United States, “Only in research” in the United Kingdom, “Still in research” in France.

PRESENTATION OF THE SELECTION / PRIORITIZATION CRITERIA

Developed selection/prioritization criteria are presented as a list (cf. box 1), that is followed by more detailed explanations of each criterion (cf. following pages).

Selection criteria are split into two categories:

- Primary criteria determine the eligibility of the technology for ADC. All five primary criteria should be fulfilled; **if the answer is NO for any of the primary criteria, technology is not eligible for ADC and is excluded from the further selection.**

- Secondary criteria should be applied for further selection/prioritization once the eligibility of the technology has been determined. The importance of each secondary criterion may vary according to national/regional context. It would be hard and risky to establish a common prioritizing system on European level given the differences in health care systems.

Box 1. Selection/prioritization criteria

Primary criteria: eligibility for ADC?

1. Did you identify any critical evidence gaps during HTA? *(yes, no)*
2. Is the research question explicitly defined? *(yes, no)*
3. Is ADC feasible (especially in terms of timeframe, type of study, population and costs)? *(yes, no)*
4. Is this study necessary taking into account similar planned/ongoing studies?
    a) *Yes*, because there is no similar planned/ongoing study elsewhere.
    b) *Yes*, because even though there is a similar planned/ongoing study elsewhere, there is an additional value of performing this one too.
    c) *No*, because the similar planned/ongoing study will bring sufficient information.
5. Will the additional data to be collected bring a significant added value for the subsequent HTA and decision making? *(yes, no)*

Secondary criteria: further selection and prioritization

1. Burden of target disease (mortality, morbidity prevalence, incidence, DALYs, QALYs)
2. Expected benefit of the technology (on the burden of disease/on the management of disease/economical benefit/organisational/social benefit)
3. Potential of the technology to cover unmet health care needs or to substantially improve the health care compared to existing alternatives
4. Importance of ADC for confirming expected benefit and/or monitoring/optimizing the conditions of use.

- Developed criteria represent a common and general decision making tool for all technologies. Their interpretation and application might however differ between different types of health technologies.
- Almost all the information elements needed to respond to the criteria are in general available in the HTA report.
- These criteria should represent a common **scientific basis** for decision making. If needed, the final decision could be adjusted according to local political imperatives.

Primary criteria: eligibility for ADC?

1. Did you identify any critical evidence gaps during HTA? (yes, no)

Evidence gaps can be grouped into three categories (clinical, economical and organisational evidence gaps). **The criterion is considered met if evidence gaps are found in at least one category.**

Only critical evidence gaps are taken into account in the selection process. What makes an evidence gap critical can be context dependent and therefore the criticality should be determined on national/regional level. [2]

2. Is the research question explicitly defined? (yes, no)

In order to clearly focus ADC it is needed to define a research question filling in the critical evidence gaps. **A complete protocol is not always available and is not needed at this stage.** Instead, defining the objectives of the study in the PICO format would be useful.

3. Is ADC feasible (especially in terms of timeframe, type of study, population and costs)? (yes, no)

The feasibility of ADC is a major information element, since it is useless to propose an ADC that cannot be performed.
This criterion takes into account if an appropriate study could be set to answer the defined research question. The elements that should be particularly taken into account are the timeframe, the type, the population and the cost[3] of the study.
For example studies demanding an enormous number of patients or having a very long follow-up (several years) are likely to be less feasible.

4. Is this study necessary, taking into account similar planned/ongoing studies?

a) Yes, because there is no similar planned/ongoing study elsewhere.

b) Yes, because even though there is a similar planned/ongoing study elsewhere, there is an additional value of performing this one too.

c) No, because the similar planned/ongoing study will bring sufficient information.

The absence of similar ADC confirms the need of generating required new evidence not available elsewhere.
If similar planned/ongoing ADC is identified elsewhere, the possibility to cooperate and to collect data of common interest should be investigated.

Therefore, a technology should be selected for ADC if **no planned or ongoing similar stud**y has been identified, **or** if **there is an additional value of performing this one in addition to other similar study/ies** (collaboration etc).

5. Will the additional data to be collected bring a significant added value for the subsequent HTA and decision making? (yes, no)

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[2] GRADE system could represent a common basis to judge the quality of available clinical evidence. However, the 'criticality' of an evidence gap may depend not only on the quality of available data, but also on the nature and relevant importance of missing data etc. Therefore, this document will provide no further guidance and the criticality should be determined on national/regional level.

[3] or an idea of the magnitude of the cost, if the precise cost is not known at the moment of selection making.

This criterion should serve to estimate the potential of additional information to influence the conclusions of the reassessment and future decision making. If the study could not deliver results that would be relevant for the reassessment or decision making, the ADC is not worth performing.

! Reminder: If the answer is NO for any of the primary criteria, technology is not eligible for ADC!

Secondary criteria: further selection and prioritization

1. Burden of target disease (mortality, morbidity prevalence, incidence, DALYs, QALYs)

The burden of the target disease can be determined by the overall prevalence/incidence of the target disease(s), by the associated mortality, morbidity and disability, or by using DALYs or QALYs.
The relative importance of the disease, expressed by the burden of the target disease, can be context dependent. ADC is more required if the target disease represents a local priority.

2. Expected benefit of the technology (on the burden of disease/on the management of disease/economical benefit/organisational/social benefit)

The benefit of the technology can be expected at the clinical level, on burden or management of the disease, or at the economical, organisational or social level. The importance of the benefit depends on its nature and magnitude, and may be context dependent.

3. Potential of the technology to cover unmet health care needs or to substantially improve the health care compared to existing alternatives.

The absence of diagnostic/therapeutic alternatives reflects the existence of unmet health care needs. The fact that the technology is the only one available for a particular condition makes necessary to document its consequences on individuals and on the health care system very carefully, thus justifying the requirement of ADC.
On the other hand, existence of several alternatives may indicate that the health care needs are covered and the given ADC would be less required in that case.

4. Importance of ADC for confirming expected benefit and/or monitoring/optimizing the conditions of use.

This criterion estimates the relevance of ADC through its potential:

a) to confirm the expected benefit of the technology (in terms of safety, efficacy, effectiveness or cost-effectiveness) and/or

b) to monitor or optimize the diffusion of a technology in 2 situations: significant potential misuse/off label use by health care professionals and patients and/or major financial or organisational impact on the health care system.