



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Healthcare Professional Involvement in Relative Effectiveness Assessments

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Healthcare Professional Involvement in Relative Effectiveness Assessments

Health Technology Assessments (HTA) are decision support tools that summarise information about medical, social, economic, organisational, ethical issues and patient perspectives in a transparent, systematic, and rigorous manner (1). Relative Effectiveness Assessments (REAs, synonym: Rapid REAs) compare a specific health technology to one or more relevant alternative interventions, using a limited subset of domains from the HTA Core Model® to focus on a technology's clinical effectiveness and safety. REAs are typically performed quicker than a complete HTA, which includes a larger set of Core Model® domains (2).

Aims

This document reports the development of recommendations for Healthcare Professionals (HCP) involvement in The European Network for Health Technology Assessment (EUnetHTA) Relative Effectiveness Assessments (REA) process within the Joint Action 3 (JA3 2016-2021, including prolongation). Our goals have been to describe:

1. *Goals for HCP involvement and preferred methods for engagement in REAs within JA3.*
2. *Definition of HCP.*
3. *Timeframe for HCP involvement.*
4. *Possible methods for HCP involvement.*
5. *How to make HCP involvement visible in the assessments.*
6. *Confidentiality issues, conflict of interest (COI), and compensation.*
7. *Evaluation of the HCP involvement process.*

Process

The EUnetHTA Secretariat established a Task Group, led by the EUnetHTA Senior Scientific Officer, on Patients and Consumers and Healthcare Professionals. The Task Group consisted of representatives from Work Package (WP) 1, WP2, WP4, WP5 and WP6 Lead Partners and Co-Lead Partners. The kick-off for the Task Group was in September 2017. The objective of the Task Group was to support the development of a process for Patient, Consumer, and Healthcare Professional involvement within WP4 assessments and WP5 early dialogues. The Task Group had weekly or bi-weekly e-meetings that included discussions of proposals and experiences with stakeholder involvement in the Joint and Collaborative Rapid Relative Effectiveness Assessments. Two face-to-face consulting meetings with HCP stakeholders took place, one where all stakeholders from the HTA Network Stakeholder Pool attended, and one primarily with HCP stakeholders.

In this document, the process regarding HCP involvement in REAs within JA3 is described. The document is primarily intended for those who design and conduct EUnetHTA REAs, although it may be informative for a wider audience of stakeholders such as healthcare professionals, patients, payers, industry, and regulatory agencies.

This recommendation document will be attached as a consented guidance document in the annex of all SOPs that describe processes related to HCP involvement in REAs. Several SOPs include process steps related to HCP involvement.

1. Goals for HCP involvement in REA within JA3

Input from HCP can provide important knowledge about the disease and insights into the treatment process, medical, surgical, dental, or other interventions, diagnostics or screening programmes that can support the assessment team's selection of relevant population, comparators and outcomes

measures. In addition, HCP involvement can provide valuable inputs from clinical practice to the draft project plan and draft assessment.

Goals for HCP involvement:

- *Gather expertise on clinical aspects regarding:*
 - o *the disease / condition;*
 - o *medical needs;*
 - o *available therapy/ies;*
 - o *the technology under assessment.*
- *Identify clinically relevant:*
 - o *patient population (and/or subgroups);*
 - o *comparators;*
 - o *thresholds for improvement.*
- *Gather information on clinically relevant outcomes including:*
 - o *possible neglected outcomes;*
 - o *gaining further information on importance of outcomes from a healthcare professional point of view.*

2. Definition of HCP

Healthcare professionals in this document are defined as clinical experts in a specific field with consolidated experience in clinical research and/or clinical practice, including general practitioners. Healthcare professionals working for agencies participating in an HTA assessment or at a manufacturer should not be defined as healthcare professionals within the meaning of this document.

3. Timeframe for HCP involvement

Ideally, the assessment team should be able to reach out to the HCP throughout the entire scoping and assessment phase.

In the scoping phase, the assessment teams specify the research question, develop and validate the project plan. During this phase, HCP may contribute with comments on the Patient, Intervention, Comparison and Outcome(s) (PICO).

During the assessment phase, inputs from HCP may be needed on various aspects, e.g. a description of the disease/condition, the place in therapy of a technology, or description of the comparators.

4. Possible methods for HCP involvement

During the process to reach consensus on possible methods for HCP involvement, national experiences and experiences in EUnetHTA with HCP involvement in the assessments of other technologies and pharmaceuticals were collected. Based on the experiences and discussions within the Task Group, involvement methods and recruitment process were identified. One method does not preclude the use of other methods. The preferred process for HCP involvement is through medical/clinical societies, and/or via direct individual expert input.

It is not necessary for HCP to have extensive knowledge about HTA process, since the aim is to consult with HCP on clinical questions regarding the intervention being assessed. However, HCP will receive key information before participation.

Possible methods for HCP involvement are as follow:

Meetings:

- *Scoping e-meeting without manufacturers (MAH).*

Reviewing drafts:

- Review of preliminary PICO.
- Review of draft project plan.
- Review of draft assessment report.

Contact during the scoping and assessment phase:

- Pre-defined set of questions for scoping phase,
- Pre-defined set of questions for assessment phase.
- Question and answer (Q&A) approach.

Choice of method for HCP involvement:

The choice of method depends on the timelines of the assessment. For assessments with short timelines, the Q&A approach is the preferred method.

Recruitment procedures:

The following recruitment strategies:

- o HCP organisations can be recruited through direct emails to the organisations either at the EU or national level.
- o The HTA Network Stakeholder Pool can be used to identify HCP organisations ([here](#)).
- o Direct contact with relevant HCP, e.g. from the EUnetHTA stakeholder list or other.

5. How to make HCP involvement visible in assessments

Recommended presentation of HCP involvement is to:

- Describe the method of HCP involvement in the method section of the report.
- Specify specialist field and organisational affiliation (if applicable) and country for each HCP in the preface of the report.

If HCP review and comment the draft project plan or the draft assessment, this should be published, for transparency, as a separate document together with the final assessment report.

6. Confidentiality, conflict of interest, and compensation

Questions regarding confidentiality, conflict of interest, and compensation must be in agreement with the Declaration of Interest (DOI) guidance ([here](#)):

- The EUnetHTA Declaration of Interest (DOI) and EUnetHTA Confidentiality Agreement (CA) forms need to be completed and signed by every HCP representative who participates in the REA.
- Declaration of Interest forms must be approved by the EUnetHTA Conflict of Interest Committee prior to involvement.

Compensation procedures are outlined in the SOP "Compensation of External Parties in Joint Action 3". The payment of the expert is dependent on the practice of the organisation responsible for the payment.

7. Evaluation of the HCP involvement

The development of the HCP involvement in the EUnetHTA REAs will be revised in light of its use. A formal evaluation of the involvement process is required to ascertain if the objectives of the process are being reached. In this sense, a questionnaire to be filled by the HCP after their participation in the assessment will be developed, including questions about recruitment, clarification of responsibilities before participation, dialogue and interaction with involved parties, and general satisfaction with the assessment process. The results of the questionnaires will be used to further refine this document and the related SOPs.

Summary

The goal for HCP involvement in REAs is to gain further understanding of the indication, type of healthcare, and circumstances in which the healthcare is provided, during both the scoping and assessment phases. The Task Group identified possible methods for HCP involvement in REAs. Participation in (e-) meetings, reviewing of drafts, and direct contact (Q&A) during all phases of the assessment are recommended methods. For assessments with short timelines, the Q&A approach is the preferred method. All contributors need to fill out the Declaration of Interest and Confidentiality Agreement forms. Table 1 gives an overview of contributions, compensation, and confidentiality issues for possible methods of HCP involvement in REAs.

Table 1. Possible methods for HCP involvement in REAs within JA3

Approach	Participants	Description of contribution & deliverables	HCP investment and compensation	Conflict of interest and confidentiality issues
(E-)meetings	HCP will have access to PICO and information publicly available, no additional confidential data will be shared.	General feedback on research question (PICO)	No travel costs if done via phone; compensation is outlined in the SOP for compensation of external parties	Declaration of conflict of interest to be completed, any risk of conflict of interest will need to be assessed by the COI Committee before HCP engagement
Reviewing of drafts	HCP will have access to information publicly available and draft project plans and reports developed by EUnetHTA*. The submission dossier will not be shared with HCP.	General feedback on drafts by use of checklists via comments forms	Compensation is outlined in the SOP for compensation of external parties	Declaration of conflict of interest to be completed, any risk of conflict of interest will need to be assessed by the COI Committee before HCP engagement
Direct contact during all phases of the assessment	HCP will have access to information publicly available, no additional confidential data will be shared.	Feedback on questions from assessment teams	Compensation is outlined in the SOP for compensation of external parties	Declaration of conflict of interest to be completed, any risk of conflict of interest will need to be assessed by the COI Committee before HCP engagement

HCP = healthcare professionals, *: HCP will only receive draft documents developed by EUnetHTA, once the Conflict of Interest Committee has approved the Declaration of Interest and Confidentiality Agreement forms.

References

1. European Network for Health Technology Assessment (EUnetHTA). What is health technology assessment (HTA)? [cited 09.04.18]. Available from: <https://www.eunetha.eu/services/submission-guidelines/submissions-faq/>
2. European Network for Health Technology Assessment (EUnetHTA). HTA Core Model [cited 11.12.18]. Available from: <https://www.eunetha.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf>