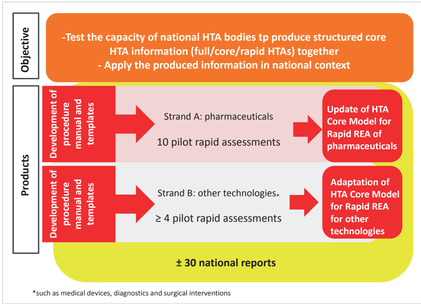
RAPID HTA: PRODUCING JOINT ASSESSMENTS ON NON PHARMACEUTICAL TECHNOLOGIES

WP 5 STRAND B

Objective, Products and Outputs



Topics

Non-pharmaceutical technologies comprise:

- medical and surgical interventions,
- diagnostic technologies,
- screening technologies.

Two main models for identifying suitable topics for rapid assessments have been defined:

Model 1: **"Call for collaboration"** (active brokering) to find partners:

Authoring organisations or institutions have identified relevant topics out of their own work-programmes. Members are asked to express their interest in acting as co-authors or reviewers.

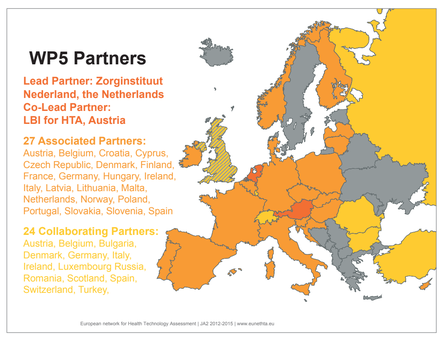
Model 2: Contacting partners with similar work programmes individually based on the **"Planned and Ongoing Projects"** (POP) database:

Topics for collaboration could be identified via the POP database or based on spontaneous reactions to POP-alerts on similar work programmes between several agencies.

Who

Different models of collaboration have been employed primarily differing due to the different responsibilities of the co-authors. However, an assessment team always consists of:

- 1 main author
- 1 – 2 co-authors
- about 3 – 5 dedicated reviewers
- The coordination team



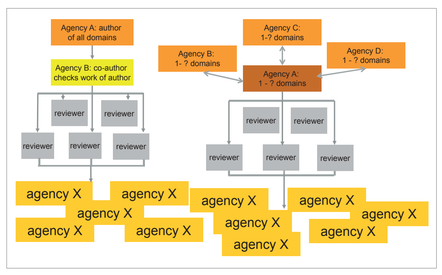


Figure 1: Modes of collaboration

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Tools

The main tools used for the production of standardised and high quality assessments encompass the "HTA Core Model for Rapid Relative Effectiveness of Pharmaceuticals". The HTA Core Model for Rapid is currently being updated to cover also the needs of assessors of other technologies.

Since specific questions may need to be addressed when assessing non-pharmaceuticals, authors of rapid assessments are encouraged to consider relevant generic questions of other applications of the HTA Core Model, including those on screening and diagnostic technologies as well as on medical and surgical interventions.

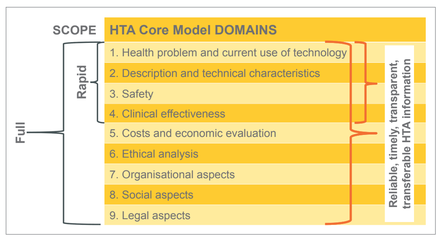

Figure 2: "Chapters" (i.e. domains) of the Full HTA Core Model and the HTA Core Model for Rapid Relative Effectiveness

In addition, 9 Guidelines have been developed on specific methodological issues. These are:

1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life
6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison
8. Internal validity
9. Applicability.

Further, a submission file template for medical devices will be used for the assessments and authors can find further guidance in a "Procedure Manual" and templates for the project plan and assessments.

Production process

Four main phases can be distinguished during the rapid assessment production process: project planning (protocol), assessment, review and consultation.

1. Project planning phase: includes scoping, searching for information, formulating research questions, and planning methodologies. The objective of this phase is to develop a final project plan, including timelines, a list of all relevant questions to be answered and methodologies intended to be used in the assessment.
2. Assessment phase: includes finding answers to the questions using the outputs of the protocol phase, the methodological guidance in the HTA Core Model for Rapid Relative Effectiveness, and the guidelines.
3. Internal review phase: includes review of the assessment. The objective of this phase is to collect and address comments and suggestions for changes from dedicated reviewers.
4. External review and consultation phase: includes consultation of the assessment with EUnetHTA members, at least 2 clinical experts, the manufacturer(s) and other potential stakeholders (e.g., patients). The objective of this phase is to collect and address comments and opinions from these parties.

No Recommendations

It is important to note, that the assessments do not contain specific recommendations. Decisions on Reimbursement have to be made at the local level.

Published and ongoing rapid assessments

2 assessments have been published on the EUnetHTA website:

1. Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus.
2. Renal denervation systems for treatment-resistant hypertension.

Two further assessments are ongoing:

1. Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction.
2. Biodegradable stents for benign refractory esophageal stenosis.

The call for collaboration is ongoing for the fifth pilot.

Local/National usage of Rapid Assessments

Examples of usage include:

1. Translation of the whole rapid assessment into national language and the format of local/national HTA agencies.
2. Direct use of the Rapid HTA: Using the rapid HTA directly to inform discussions on the use of the technology.

More EUnetHTA members are or will be using already published assessments in their own local/national context. However, only until the end of 2015 more precise information on the actual usage and thus on efficiency gains will be available.

Stakeholder involvement

To ensure the quality and the relevance of the assessments, a variety of different stakeholders are involved during the production of the assessments.

These are:

- Stakeholder Forum: EUnetHTA's Stakeholder Forum is composed out of representatives from industry, patients/consumers, providers and payers. They are invited to comment on the draft project plan.
- Stakeholder Advisory Group: a subset of the Stakeholder Forum specifically interested in the production of rapid assessments is also invited to comment on the draft project plan and they are also asked to provide information about manufacturers producing the technology under assessment and to suggest suitable patient representatives or medical experts.
- Medical experts: at least two medical experts support the pilot team. Ideally, they are already involved in the scoping phase and help identifying suitable outcomes and comparators. In addition, they are asked to review the assessment prior to publication.
- Patients/Consumer representatives: patients ideally assist the pilot team in the selection of outcomes relevant for patients. Furthermore, they are asked to comment on the assessment prior to publication.

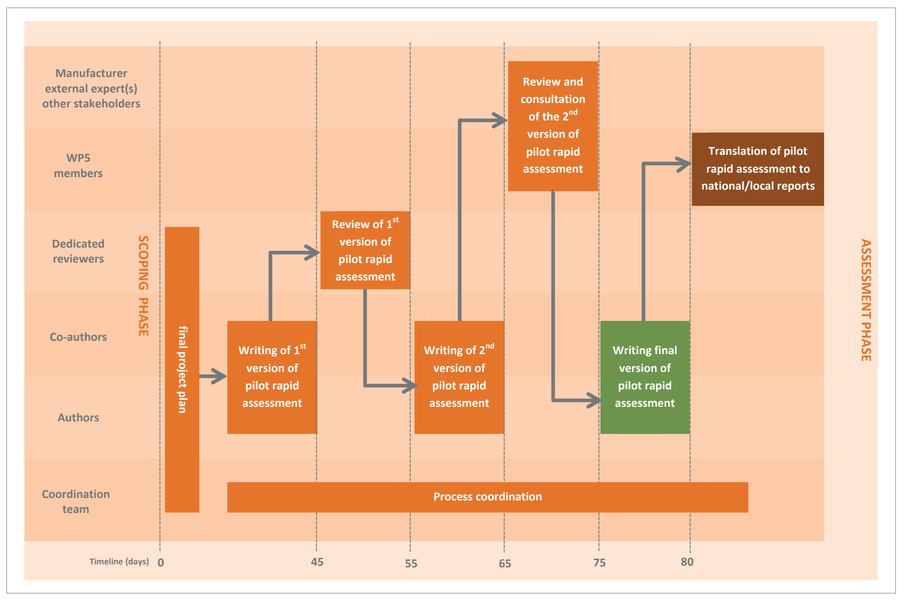

Figure 3: Overview on assessment phase

	Duodenal-jejunal bypass sleeve for the treatment of obesity with or without type II Diabetes mellitus	Renal denervation for treatment resistant hypertension	Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dsyfunction	Biodegradable stents for benign refractory esophageal stenosis
Duration	January 2013 – August 2013	April 2013 – December 2013	April 2014 – December 2014	April 2014 – to be confirmed
Pilot team agencies, n	8	8	5	5
(Co-)Authoring HTA bodies	LBI-HTA (Austria) AAZ (Croatia)	NOKC (Norway) Avalia-t (Spain) CFK (Denmark)	FinOHTA/THL HIQA (Ireland)	ISCIII (Spain) SAGEM (Turkey)
Dedicated reviewing HTA bodies	GYMEZSI (Hungary) HIQA (Ireland) HVB (Austria) ISCIII (Spain) NOKC (Norway) Charles University Prague (Czech Republic)	HIS (UK) FinOHTA/THL (Finland) AHTAPol (Poland) GYMEZSI (Hungary) IQWiG (Germany)	GYMEZSI (Hungary) HVB (Austria) AHTAPol (Poland)	VASPVT (Lithuania) Slovak Ministry of Health (Slovakia) LBI-HTA (Austria)

Table 1: Overview on Rapid assessments

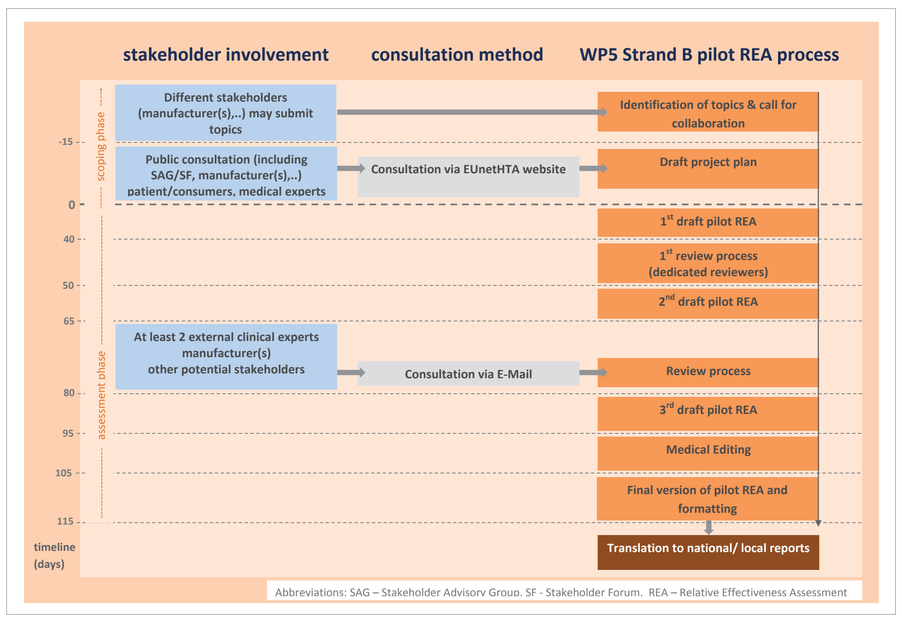

Figure 4: Overview on stakeholder involvement during assessment production

- Manufacturers: producers of technologies under assessment are involved at various levels. They are approached early in the scoping phase, inquiring information on the product itself, competitors, available evidence and reimbursement status of the technology.

  They are then invited to comment on the project plan and they will receive the assessment prior to its finalisation.

  In the future, manufacturers will also be asked to provide more detailed information via a submission file for medical devices.
- Public: since the draft project plan is publicly available on the EUnetHTA Homepage for a period of 15 days, the public is also welcomed to comment on the scope of the assessment.

Outlook

The updated version of the HTA Core Model for Rapid Relative Effectiveness is currently under review by EUnetHTA members. The Scientific Advisory Group and the Public will get the opportunity to comment on the draft version prior to its finalisation. The planned date for these activities is in summer 2015.

Further information

Procedure Manual of Strand B: http://www.eunethta.eu/outputs/wp5-strand-b-procedure-manual-v3

Published assessments: http://www.eunethta.eu/

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