EUnetHTA Joint Action involvement of health care providers – expert level involvement

March 21, 2019 - Brussels

Clinical expert involvement in REAs

WP4 Lead Partner | Norwegian Institute of Public Health

WP4 CoLead Partner Pharma | Dutch National Healthcare Institute

WP4 CoLead Partner Other Technologies | Ludwig Bolzmann Institute for Health Technology Assessment

Goals for clinical expert involvement

- To ensure EUnetHTA assessments are clinically relevant

- Elicit Health Care Providers' views on aspects regarding the disease/condition and available therapy/ies
  - to identify clinically relevant patient population (e.g. subgroups)
  - to identify clinically relevant comparators
  - to identify clinically relevant thresholds

- Gather information on clinically relevant outcomes
  - to identify possible neglected outcomes
  - to gain further information on importance of outcomes
  - to ensure inclusion of patient relevant outcomes

Clinical expert involvement in EUnetHTA Assessments

Identification

- Contacting medical/clinical societies, individual experts
- Evaluate *conflict of interest*
- Define method of involvement

Scoping

- Specify research question, develop & validate protocol
- Involvement of external experts in scoping: commenting on population, intervention, comparator, outcome (PICO)!

Assessment

- Identify, select and evaluate articles. Data extraction and synthesis. Writing and validating report
- Involvement of external experts during the assessment phase

Experiences and preferred methods

Current involvement methods applied

Health care professionals

Pharmaceuticals

- 2/7: reviewing report
- 2/7: Q&A approach
- 2/7: ongoing identification
- 1/7: not successful

Other Technologies

- 5/18: participation in scoping (e)meeting
- 18/18: reviewing project plan/PICO
- 18/18: reviewing report
- 18/18: Q&A approach allowed

Experiences so far...

- Limited response from medical societies to help identify experts
- Conflict of Interest limits involvement of experts

- Review of draft assessment not ideal
  - High burden for expert
    - Workload and time limitations to perform the review
  - Review is too late in the process
  - Limited feedback/comments from involved experts
- Useful involvements
  - During scoping phase
  - Throughout interactive Q&A approach
  - In specific cases: interaction in the scoping e-meeting

Considerations for selecting a method

- Timelines have to be considered
  - in PT very tight timelines
  - Strict timelines for the clinical expert involvement
- Burden of work for the expert

- Level of Conflict of Interest
- Knowledge in HTA may be required

- Expert‘s comments are discussed within the team
  - No consensus on implementation has to be found with the expert

Preferred methods for involvement

Phase	Method of involvement	Considerations	Conflict of interest
Throughout assessment	Continuous Q&A approach	Limited burden of work for the expert; ensure relevant interaction when needed. Low risk of conflict of interest	Low risk
Depending on topic/team/timelines/expert (e.g. willingness and COI) this can be complemented with one of the following methods			
Scoping phase – development of PICO	Review of preliminary PICO	Very early interaction, ensure PICO is clinically relevant. Experts have influence on the scope of the assessment.	High risk
	Pre-defined set of (disease specific) questions	Very early interaction, ensure PICO is clinically relevant	Lower risk
	Review of project plan	Early interaction, ensure PICO is relevant. More burdensome approach for experts	High risk
	Attending scoping e-meeting (without manufacturer)	Interactive engagement with the expert, allowing for follow-up or clarifying questions during the meeting. Resource intense for expert. Confidential data may be discussed	High risk –
Assessment phase	Review of the draft assessment by means of a list of pre-defined questions	Ensures critical quality assurance prior to publication. High burden of work for expert. May require that the expert has HTA knowledge. Draft document has to be shared, which may contain confidential information.	High risk

Recruitment of clinical experts

Recruitment - current strategy

- Ideally at least 2 experts are involved
  - European and national perspective should be represented

- HTA Network stakeholder pool
- **European** medical/clinical societies
  - Use stakeholder pool from European Medicines Agency (pharma)
- **National** medical/clinical societies
- Suggestions from EUnetHTA (participated in previous assessments, collaborated in national assessments etc.)
- Google search for individual experts

Recruitment – future framework?

- EUnetHTA plans to establish a **European database** of experts
  - Linked to COI information
  - Info on specific expertise
  - Ensure up-to-dateness

- **Individual** expert, or expert speaking **on behalf of society**? National/European?

- **Open call** for experts
  - General announcement on the EUnetHTA website to register with us
  - Assessment specific announcement on the EUnetHTA website

Need your support!

We need strong commitment from medical/clinical societies

Suggestions:

- **Inform** your membership about HTA and of importance of participating in EUnetHTA assessments as experts
- **Add** to your membership database a tick box where members can state specific expertise and willingness to participate as expert in a HTA
- Soon: **Encourage** your membership to register with planned European database of experts
- Other suggestions?

Certificate of involvement

Incentives?

- Your opinions about creating a certificate showing expert participation in EUnetHTA assessments?
- Any other ideas for providing (non-monetary) incentives in participating as an external expert?

Next steps

Next steps

- Further testing of involvement methods
  - especially pre-defined questions
- Develop recommendations on HCP involvement in EUnetHTA assessments
- Testing of open call for recruitment
- Establishment of European database of experts

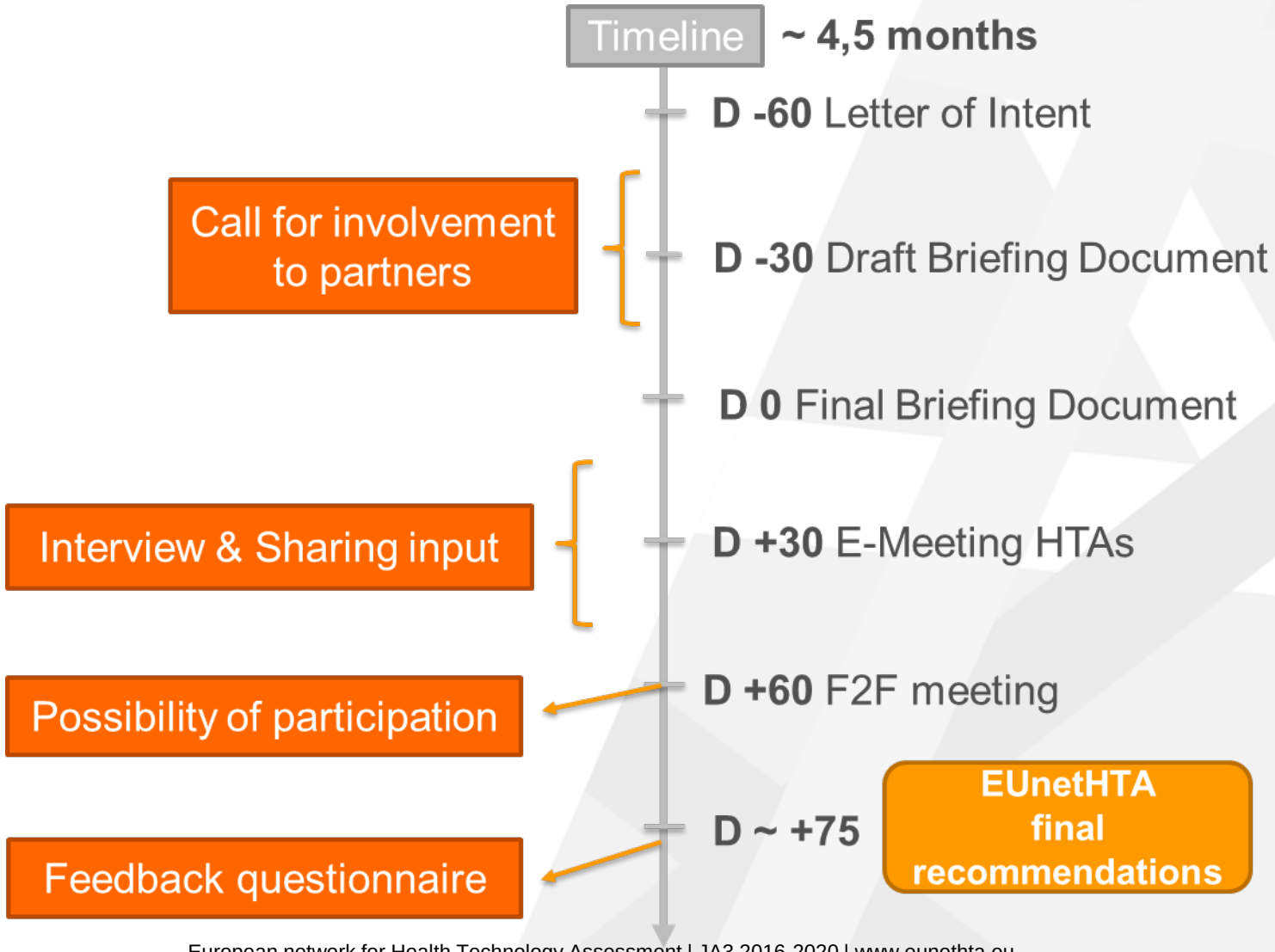
Methods of involvement in early dialogues

Project Manager WP5A, HAS
Project Manager WP5A, G-BA

Goals for Health Care Professionals (HCP) involvement

- Feedback on the disease and current disease management
  - Identify specific unmet needs/patient subgroups
  - Current standard of care
  - Hurdles to diagnosis and treatment access…
- Study design
- Study feasibility

Current stakeholder involvement – Early Dialogues (Pharma & MD)



Context of HCP involvement in EUnetHTA Early Dialogues

- First focus was on patients as many HTAB did not include them at all in their national/regional processes
- Much “informal” involvement of Health Care Professionals (HCP) in Early Dialogues (ED) to date, particularly for orphan drugs and innovative products (e.g. ATMP)
- A few instances of more formal involvement (NICE)
- Currently surveying partners to learn where they have consulted HCP
- Working to develop a “EUnetHTA” approach for EDs, similar to that used for patient involvement

Graduated approach to stakeholder involvement – Early Dialogues (Pharma & MD)

Approach	Patient deliverables	Health Care Professional (HCP) deliverables
Approach 1: Individual patient/HCP - interviewed regarding the disease and their experience	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant)	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 3: Expert; Approach 1 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the applicant	• Minutes of the interview • Share final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire

New approaches tested in 1st ED for a Medical Device

- 4 of 8 participating HTAb included a **clinical expert**; 1 clinical expert participated in the closed HTAb meeting the morning of the F2F
  - 2 did not share the briefing book with the expert (corresponds to approach 1)
  - 2 shared the briefing book with the expert (corresponds to approach 2/3)
- Expert advice collected from each HTAb shared with other participating HTAb
- Expert contribution not included in the final recommendations

Graduated approach to stakeholder involvement – Early Dialogues (Pharma & MD)

Approach	Health Care Professional (HCP) deliverables	Current Status
Approach 1: Individual patient/HCP - interviewed regarding the disease and their experience	• Minutes of the interview • Feedback questionnaire	• Done in 1st EDMD • Unofficially done in pharma ED • For pharma, lacking transparency and needs further reflection on inclusion in final recommendations
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant)	• Minutes of the interview • Feedback questionnaire	• Done in 1st EDMD • Will be tested in a current pharma ED • To be further developed • For pharma, lacking transparency and needs further reflection on inclusion in final recommendations
Approach 3: Expert; Approach 1 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the applicant	• Minutes of the interview • Feedback questionnaire	• Done in 1st EDMD • To be further developed • For pharma in particular, lacking transparency and needs further reflection on inclusion in final recommendations

Challenges identified from first experience

1. Human resources
   - Transcription and translation of interview
   - Training/explanation of procedure/collection of feedback
2. Transparency
   - Management of Conflict of Interest
   - Risk of confusion between the expert opinion and the final HTAB recommendations
   - Sharing opinions of national experts
3. Experts involved by the company

HCP involvement in reviewing WP5 procedure/Tools

June-July 2018: Public consultation on the procedure and briefing book template for Early Dialogues on Medical Devices

- Official launch March 2019

November-December 2018: Consultation on Registry Quality Standards tool and Vision paper

- Update REQueST and Vision paper using stakeholder comments then out to wide public consultation in early 2019.

Further Consultations to come…

Strand A: Early Dialogues	
Updated ED Procedures for pharmaceutical products	Q4 2019 Multi-stakeholder consultation
Updated ED Briefing Book Template	Q4 2019 Industry consultation
Guidance documents for patients and HCP contribution for ED	Q3 2019 Multi-stakeholder consultation
Strand B: Post-Launch Evidence Generation	
Update REQueST	Q2 2019 Multi-stakeholder

Conflict of interest

EUnetHTA Secretariat, Dutch National Healthcare Institute

Handling conflict of interest within JA3 activities: main features

- Based on an inclusive and pragmatic approach, taking into account different policies for handling conflict of interest implemented by HTA bodies at the national level.
- Aims to assist in decision-making on the involvement of individuals into EUnetHTA JA3 activities (e.g. assessors, experts, patients)
- Definition of criteria for the assessment of potential conflict of interest in a transparent and consistent way
- Definition of a EUnetHTA committee for the assessment of potential conflicts of interest

Handling conflict of interest within JA3 activities: situations of major conflict leading to exclusion

1. PI for a industry-sponsored study evaluating the technology under assessment, a comparator, or a relevant technology under development.

2. Paid or unpaid advisory/consultancy services to a company producing the technology under assessment, a comparator, or a relevant technology under development.

3. Employment at a company/consultancy/CRO producing the technology under assessment, a comparator, or a relevant technology under development;

4. Being member of an association (patient or HCP organization) funded mainly by the industry (>40 % of association budget)

Handling conflict of interest within JA3 activities: situations of major conflict leading to exclusion (cont'd)

5. Currently receiving funds for research activities related specifically to the technology under assessment, a comparator, or a relevant technology under development.

6. Having a current financial interest (e.g. holding shares or the like) in the industry producing the technology under assessment, a comparator, or a relevant technology under development or a financial interest in industrial sector funds.

7. Travel costs/honorarium for delivering a presentation on a topic specific to the technology under assessment, a comparator, a relevant technology under development or for attending meetings sponsored by only one company producing either the technology under assessment, a comparator, or a relevant technology under development.

Handling conflict of interest within JA3 activities: prior interests and special circumstances

- An individual can still be included in a EUnetHTA task, if interests related to funds for research activities and financial interests (point 5 and 6) occurred in the past and are no longer existing.

- Possibility under exceptional circumstances (e.g. lack of available experts for a rare/ultra-rare disease), to seek the expert opinion of an individual with an existing CoI. However, in such cases the expert shall not have access to any document requiring confidentiality and should only give advice on a predefined set of questions posed by the assessment team/EDC.

Thank you

Any questions?