European Network for Health Technology Assessment (EUnetHTA) Joint Action 3

Zoe Garrett,
Senior Technical Adviser
Lead WP7 National Implementation and Impact
National Institute for Health and Care Excellence (NICE)
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Overview of EUnetHTA JA3
Timeline of EUenetHTA

2006

EUnetHTA Collaboration

EUnetHTA Project

Joint Action 1

Inception

Putting into practice

Joint Action 2

Strengthening practical application

Joint Action 3

Turning pilots into standard practice

2016
EUnetHTA Joint Action 3 (2016-2020)

• Aims to contribute to a sustainable model for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe in close collaboration with stakeholders and the European Commission

• Specific objectives:
  • To increase production of high quality HTA joint work
  • To increase uptake and implementation of joint HTA work at the national, regional and local level
  • To support evidence-based, sustainable and equitable choices in healthcare and health technologies

• **81 partners of 29 countries**, consisting of national, regional and non-for-profit agencies that produce or contribute to HTA
Context

• Work of EUnetHTA JA3 is contextualised within the EC proposals for developing a sustainable model of HTA cooperation in the EU

• Specifically, the possible legislative framework for HTA cooperation
  • Shared use of tools and methodologies
  • Joint production of relative effectiveness assessment
  • Collaborative horizon scanning
  • Joint early dialogues

• For pharmaceuticals and also other technologies
Work packages in EUnetHTA JA3

**Work package 1** Coordination (NL)

- **Work package 4** Joint production (NO, NL, AT)
- **Work package 5** Evidence generation (FR, DE)
- **Work package 6** Quality management (DE, BE)
- **Work package 7** Implementation (UK, IT)

**Work package 2** Dissemination (ES)

**Work package 3** Evaluation (SE)
Summary of activities in EUnetHTA JA3

- **WP4 Joint Production**
  - To produce 37 rapid REA on pharmaceutical and 43 on other technologies
  - To provide a system for topic selection and prioritization, e.g. horizon scanning

- **WP5 Evidence Generation**
  - To support additional evidence generation along the technology lifecycle:
    - Joint Early Dialogues (joint HTA or parallel/joint with regulators)
    - Post-launch evidence generation, particularly the use of registries as a data source

- **WP6 Quality Management**
  - To provide quality management for EUnetHTA joint products
  - To further develop methodologies and tools for joint work

- **WP7 National Implementation**
  - To facilitate the reuse and implementation of joint products
  - To support development of a model of sustainable HTA cooperation
WP5: Early Dialogues
Early Dialogues organisational structure

- HAS (France) provides organizational coordination through JA3 (EUnetHTA ED Secretariat)
- Rotating project coordination for each early dialogue from HAS (France) and G-BA (Germany)
- Consistency and rigour across projects maintained by an Early Dialogues Working Party (EDWP)
  - Includes HTA bodies with experience in EDs and commitment to participate in EUnetHTA EDs
  - Current composition:
    - Full seats for HAS (FR), G-BA (DE), NICE (UK), AIFA (IT), NIPN (HU);
    - Shared seat between ZIN (NL) and RIZIV INAMI (BE)
    - Alternate institution tested in IT (RER, Emilia Romagna)
Early Dialogues Procedures
Timelines for one Early Dialogue

1. **Feedback on prioritization criteria**
   - **D -16**
     - By EUnetHTA ED Secretariat

2. **Written Request for Clarification**
   - **D -16**
     - Compiled by EDC Scientific Coordinator

3. **Draft Written Positions and Issues**
   - **D +25**
     - Compiled by EDC Scientific Coordinator

4. **Draft Written Recommendations**
   - **D +48**
     - Compiled by EDC Rapporteur, validated by EDC Scientific Coordinator

5. **Final Written Recommendations**
   - **D +67**
     - Compiled by EDC Rapporteur, validated by EDC Scientific Coordinator

6. **Comments to Compiled Final Written Recommendations**
   - **D +70**
     - Compiled by EDC Rapporteur, validated by EDC Scientific Coordinator

7. **Compiled Draft Written Request for Clarification**
   - **D -15**
     - Compiled by EDC Scientific Coordinator

8. **Compiled Draft Written Positions**
   - **D +25**
     - Compiled by EDC Scientific Coordinator

9. **Compiled Draft Written Recommendations**
   - **D +50**
     - Compiled by EDC Scientific Coordinator

10. **Compiled Final Written Recommendations**
    - **D +67**
      - Compiled by EDC Scientific Coordinator

11. **Final Consolidated HTA ED Written Answers**
    - **D +75**
      - Compiled by EDC Scientific Coordinator

12. **Final Consolidated HTA ED Written Answers**
    - **D +475**
      - Compiled by EDC Scientific Coordinator

**Output**

**Input from partners**

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Only in case of PCC or Multi-HTA Early Dialogue
Early Dialogues in JA3 so far

• 1 ED (multi-HTA) in Y1
  – New model of patient participation tested
• 10 ED (1 multi-HTA, 9 PC) since June ’17
• Anticipate having 3 to 4 PC requests per month
• Continuous improvement needed
  – Interaction with partners, EMA, industry
  – Rotating partners for each ED
  – Participation of patients (various models to be tested)
• Funding mechanism in development to make it sustainable
WP5: Post launch evidence generation standards for registries
Improving the quality of registers – standards for their use in HTA

• Project leads: HAS (France), NICE (UK), NIPH (Croatia)
• Pilot sites: Avalia-t (MedTech), INFARMED (Pharma), AQuAS (MedTech)

• Draft standards tool developed based on guideline from the PARENT JA
Structure of the standard

- Records methodological information about the research methodology and how the information was collected
- HTA agency gathers information about the research conducted by the registry in a structured way
- Essential standards: minimum requirements for every registry
  - Universal and essential elements of good practice and evidence quality
  - Unless all criteria met HTA agency will not use registry in HTA
- Additional requirements: elements of good practice and evidence quality that are not always practical or feasible to achieve but useful to consider
  - HTA agency judges whether the level of evidence given is enough to meet the agency requirements
Contents of the standard

- Methodological information includes:
  - aims, description of the technology, area covered, dates of data collection, population, number, coverage, follow up methods, design

- 8 essential standards including:
  - Protocol availability, governance structure, financial plan, minimum dataset, data dictionary, standard definitions, security, consent

- 13 additional requirements including:
  - Financial sources, data sharing, data collection, source data, data providers, quality control plan, control for confounding, missing data plan

- For all essential standards and additional requirements there is a minimum requirement, explanation and scoring criteria
Timeline for Pilots of Post-Launch Evidence Generation Standards Tool

Register
Established (if not already)

Register Selection

PLEG data collection protocol agreed with register

Baseline standards assessment
End 2017

Possible interim assessment
Mid-2018

May use standards to guide

Data transfer

Final standards assessment
End 2018

Final standards assessment
End 2018

Feedback on usage of standards tool
Jan 2019

HTA produces technology evaluation report

Timeline
WP6: The HTA Core Model
Overview

The HTA Core Model:

• Is a methodological framework for the production and sharing of HTA information
• Was developed by EUnetHTA in 2006-2008 and updated during EUnetHTA JA1 and JA2
• Used by EUnetHTA for ‘full’ and ‘REA’ assessments
• Has been tested by the industry
• Has been used in the context of non-EUnetHTA assessments
Structure
The HTA Core Model consists of three main components:

1. The *HTA ontology* contains a list of generic questions that can be asked in an HTA. The ontology also identifies relations between the questions.

2. *Methodological guidance* helps researchers in finding answers to the questions defined by the ontology.

3. The *common reporting structure* provides a standard format for the output of HTA projects.
# The ontology - example

## Domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Health problem and current use of technology (CUR)</td>
</tr>
<tr>
<td>2.</td>
<td>Description and technical characteristics of technology (TEC)</td>
</tr>
<tr>
<td>3.</td>
<td>Safety (SAF)</td>
</tr>
<tr>
<td>4.</td>
<td>Clinical effectiveness (EFF)</td>
</tr>
<tr>
<td>5.</td>
<td>Costs and economic evaluation (ECO)</td>
</tr>
<tr>
<td>6.</td>
<td>Ethical analysis (ETH)</td>
</tr>
<tr>
<td>7.</td>
<td>Organisational aspects (ORG)</td>
</tr>
<tr>
<td>8.</td>
<td>Patient and Social aspects (SOC)</td>
</tr>
<tr>
<td>9.</td>
<td>Legal aspects (LEG)</td>
</tr>
</tbody>
</table>

## Topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Mortality</td>
<td></td>
</tr>
<tr>
<td>Morbidity</td>
<td></td>
</tr>
<tr>
<td>Function</td>
<td>Health-related quality of life</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
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<tr>
<td>Patient satisfaction</td>
<td></td>
</tr>
<tr>
<td>Test-treatment chain</td>
<td></td>
</tr>
<tr>
<td>Test accuracy</td>
<td></td>
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<tr>
<td>Patient safety</td>
<td></td>
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<tr>
<td>Change-in-management</td>
<td></td>
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<tr>
<td>Benefit-harm balance</td>
<td></td>
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</tbody>
</table>

## Issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D0011</td>
<td>What is the effect of the technology on patients’ body functions?</td>
</tr>
<tr>
<td>D0014</td>
<td>What is the effect of the technology on work ability?</td>
</tr>
<tr>
<td>D0015</td>
<td>What is the effect of the technology on return to previous living conditions?</td>
</tr>
<tr>
<td>D0016</td>
<td>How does the use of the technology affect activities of daily living?</td>
</tr>
</tbody>
</table>

The issues are the generic questions that should be considered when assessing health technologies.
WP6: Methodological guidance and tools to support HTA
Methodological guidance

EUnetHTA provides different documents to guide researchers

• The HTA Core Model user guide
• Procedure manuals that guide the production of different types of EUnetHTA assessment
• 14 scientific guidelines that focus on methodological issues commonly encountered while performing HTA
EUnetHTA tools

• The **EUnetHTA Evidence Submission templates** can be adapted by HTA agencies and used to request evidence from companies to support their HTA and reimbursement processes

• The **EUnetHTA POP Database** allows HTA agencies to share information with each other on planned and ongoing projects

• The **EVIDENT Database** allows sharing and storage of information about reimbursement decisions and requests or recommendations for additional studies arising from HTA

• The **EUnetHTA adaptation toolkit** helps HTA agencies to adapt HTA reports from other countries, regions or settings for their own use
EUnetHTA JA3 developments

**Quality Management**
- Processes and Process Flows
- Quality Management Concept
- SOPs (incl. Checklists and Templates)
- Training Activities

**Scientific Guidance and Tools**
- HTA Core Model, Methodological Guidelines
- Practical Tools
- Tools Handbook
- Training Activities

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**EUnetHTA Companion Guide (web-based)**
Thank you

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme.