EUnetHTA
European network for Health Technology Assessment

Convergence and Differentiation within the Framework of European Scientific and Technical Cooperation on HTA

University of Tokyo, October 24, 2013

Finn Børlum Kristensen
Adjunct professor, University of Southern Denmark
Secretariat Director, EUnetHTA Secretariat
Danish Health and Medicines Authority (EUnetHTA Coordinator), Copenhagen, Denmark
Participants in EUnetHTA

EUnetHTA Partners and Associates in JA2.

40 Partner organisations designated by Member States

Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA
Acceleration / deceleration of technology market access

- Basic research
- Applied research
- Experimental
- Investigational
- Nearly established
- Established Technology
- Obsolete???
Challenges in advancing HTA and the path toward a robust and efficient network

- Standardising where appropriate and quality assuring scientific and technical methodologies in HTA
- Harmonising approaches in HTA and relative effectiveness assessment (REA) across multiple jurisdictions
- Encouraging transparent open dialogue on medicinal assessment methods to improve decision-making in drug development
- Increasing collaboration between HTA authorities, industry, patient organisations and payers to ensure fair pricing and reimbursement
European initiatives in HTA to harmonise evidence requirements

- Early scientific advice to technology sponsors
- Additional data collection
- Guidelines on assessing outcomes
- Aligning HTA and regulatory needs
- Involving stakeholders in a shared process
European initiatives in HTA to harmonise evidence requirements

• The current European outcomes environment
• Early scientific advice to technology sponsors
• Additional data collection
• Guidelines on assessing outcomes
• Aligning HTA and regulatory needs
Article 15 of the Directive 2011/24/EU on cross-border health care

“The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States… That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations”
The timeline of reaching a sustainable and permanent HTA network in Europe

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>Call for project proposals</td>
</tr>
<tr>
<td>2006-2008</td>
<td>EUnetHTA Project</td>
</tr>
<tr>
<td>2009</td>
<td>Call for joint action</td>
</tr>
<tr>
<td>2010-2012</td>
<td>EUnetHTA Collaboration</td>
</tr>
<tr>
<td>2011-2015</td>
<td>EUnetHTA JA</td>
</tr>
<tr>
<td>2011-12</td>
<td>CBHC Directive now decided</td>
</tr>
<tr>
<td>2012-2015</td>
<td>EU Cooperation on HTA Implementing Decision</td>
</tr>
<tr>
<td>2013+</td>
<td>HTA Network</td>
</tr>
<tr>
<td>2013</td>
<td>EU Cooperation on HTA</td>
</tr>
<tr>
<td>2014-2020</td>
<td>Financial support HTA</td>
</tr>
<tr>
<td>2016-2020</td>
<td>EUnetHTA Scientific and technical cooperation</td>
</tr>
<tr>
<td>2011</td>
<td>FP7-Health</td>
</tr>
<tr>
<td>2012</td>
<td>Innovation-1</td>
</tr>
<tr>
<td>2011-2015</td>
<td>New methodologies for HTA</td>
</tr>
<tr>
<td>2014-2020</td>
<td>Horizon 2020 Calls</td>
</tr>
<tr>
<td>2016-2020</td>
<td>Health Care</td>
</tr>
</tbody>
</table>
Project → JA1 → JA2

- Establishment
- Putting into practice
- Strengthening practical application
Scope of EUnetHTA’s work
Health Technology

- **Healthcare technology** is defined as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained.
The Domains of the HTA Core Model®

**DOMAINS**

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects
Health Technology Life-cycle

Use of technology in health care

Time line of innovation

HTA / REA

Early scientific advice

Rapid REA

Additional data collection
EUnetHTA output
EUnetHTA Tools

- EUnetHTA HTA Core Model Online
- EUnetHTA Planned and Ongoing Projects Database (POP)
- EUnetHTA Evidence database on new technologies (EVIDENT)
- EUnetHTA Adaptation Toolkit
- EUnetHTA Contact Database
- EUnetHTA Intranet Groups
- EUnetHTA E-meeting facility
- EUnetHTA Document Repository
- EUnetHTA News Aggregator
The EVIDENT Database

Description
The EVIDENT Database enables sharing early information on evidence gaps identified during the production of HTA reports and consequent recommendations / requests for additional data collection.

It also contains information on reimbursement/coverage and assessment status of promising technologies in Europe.

Purpose
To reduce redundancy, promote generation of further evidence and facilitate European collaboration in the domain.
The EVIDENT Database
Online

Access to the EVIDENT Database:  https://evident.has-sante.fr/has/login.xhtml
9 Methodological Guidelines for Rapid REA

Development
9 Methodological Guidelines for Rapid REA of Pharmaceuticals developed in JA1 by WP5.

Content
Guidelines on methodological challenges that are encountered by health technology assessors while performing a rapid relative effectiveness assessment of pharmaceuticals.

Primary Aim
To help the assessors of evidence interpret and process the data that are presented to them as part of a REA
9 Methodological Guidelines for Rapid REA

Endpoints used for REA of pharmaceuticals
1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life

Comparators and comparisons
6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison

Levels of evidence
8. Internal validity
9. Applicability of evidence in the context of a relative effectiveness assessment

Link to the guidelines
http://www.eunethta.eu/outputs/methodological-guideline-rea-pharmaceuticals-clinical-endpoints
The HTA Core Model®

**Description**
The HTA Core Model® is a methodological framework for shared production and sharing of HTA information.

**Purpose**
To enable production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information.
The Structure of the HTA Core Model®

ONTOLOGY
Questions that an HTA should answer

METHODOLOGICAL GUIDANCE
How to answer the questions

Common reporting structure that enables standardised reporting of HTAs. Results are presented as collections of result cards. The theme of each result card is outlined by the assessment element cards.
EUnetHTA output and national HTA work
HTA is context specific

Globalize the evidence, localize the decision

J.M. Eisenberg
Core HTA Structure

Pool of structured HTA Information

Collections
Serve also as project platforms

Official EUnetHTA
- Core HTA
- Rapid HTA

Other
- Full domain
- Free set (≥ 1)
- My collection

Local products
- Primarily EUnetHTA
- Primarily national

Local Tools
- Primarily EUnetHTA
- Primarily local

HTA Core Model
Online Tool & Service
Submission template of evidence requirements from HTA organisations in that reflects the HTA Core Model

Current national evidence requirements vary!!!

- Specific vs general
- Size/ quantity
- Content
- How much guidance given
- How safety and clinical effectiveness are considered
- Interpretation / conclusion
- Domain 1+2: similar to CORE model
- Domain 3+4: different from the CORE model
EUnetHTA Joint Action 2 (2012-2015)

Objectives

- To strengthen the practical application of tools and approaches to cross-border HTA collaboration

- To achieve a better understanding for the European Commission and Member States of ways to establish a sustainable structure for HTA work in the EU

- To produce recommendations regarding the design and management of the future EU HTA cooperation

Total budget: € 9,428,550
- To strengthen the practical application of tools and approaches to cross-border HTA collaboration

• At least 28 pilot exercises
  • Joint assessments applying full or rapid HTA Core Model
  • Early dialogues, methodological guidelines, submission template
  • Trainings in tools and approaches (provided to staff of HTA agencies and to stakeholders (patients and providers)
• At least 40 national HTA reports with the use of tools and information from Joint Action 2
• External co-operation
  • R&I FP 7 research projects
  • EU JAs (PARENT JA)
  • EMA – EUnetHTA co-operation
- To achieve a better understanding for the European Commission and Member States of ways to establish a sustainable structure for HTA work in the EU
- To produce recommendations regarding the design and management of the future EU HTA cooperation

Recommendations will be built on EUnetHTA’s experience from field testing of:

- tools, methods, approaches in EU co-operation on HTA including national use of EUnetHTA output
- involvement of stakeholders
Stakeholder involvement
Composition of the EUnetHTA Stakeholder Forum

- Payers
- Patients/Consumers
- Industry
- Providers
Purpose of the Stakeholder Forum

To provide stakeholders with the opportunity

- to participate as stakeholder representatives in the EUnetHTA Joint Actions

- to observe and comment on the EUnetHTA Joint Action work

- to provide advice to overarching governance questions in the Joint Actions, and

- to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Actions
Purpose of the Stakeholder Advisory Groups (SAGs)

Representatives from Stakeholder organisations participate in WP activities via SAGs to
- represent Stakeholder views
- provide perspectives and knowledge on the EUnetHTA work in progress
- Help WPs to improve the basis of their deliberations
- Examples of participation:
  - Commenting on the scope of the project / selected methodologies
  - Commenting on draft reports in preparation of final draft documents before public consultation
External Collaboration
EUnetHTA-EMA Collaboration

- To identify opportunities for and undertake specific steps to improve the efficiency of the process and conditions for patients’ timely access to an effective medicine.
EUnetHTA-EMA Collaboration

- Scientific advice/early dialogues involving regulators and HTAs
- Scientific and methodological guideline development
- Post-licensing (post-authorisation) data generation
- Availability of clinical study data
- Orphan medicinal products
- Cooperation in specific pilot projects of EUnetHTA JA2
- Conferences, workshops and seminars/meetings
Thank you for your attention

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme.
HTA 2.0 Europe

EUnetHTA Conference, Rome, October 30 – 31 2014

Teaming up for Value