The Potential and Challenges of Health Technology Assessment: Insights from Experience in Europe

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WHY need for HTA?
Technology drive & information overload

Doubts about effectiveness, appropriate use, cost-effectiveness; large variation in utilization...

Information: publication etc.

New technologies (and their costs)

(One role of) HTA

Health budgets (ca. GNP + 1%)

Needs (demography, morbidity)

GNP
Inappropriateness

**Sources:** Chassin et al., 1988; Winslow et al., 1988

Figure 21. Examples of Proportion of Procedures Studied that are Inappropriate or Uncertain
Small-area variation

What is “Technology”? 

• Greek: technologia
• Techni - "art/craft/skill"
• Logia - "saying/be about something"

• Narrower: material objects, hardware, devices
• Wider: systems, organization methods, techniques
What is Health Technology Assessment?

• MTA (Medical technology assessment) → HCTA (Healthcare technology assessment) → HTA

• INAHTA (International Network of Agencies for HTA):
  – 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.
  – Technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

• EUnetHTA (European network for HTA):
  – Health technology is the application of scientific knowledge in health care and prevention.
  – Health technology assessment is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.
The goal of HTA is to provide input to decision making in policy and practice” (Henshall et al. 1997)
Health Technology Assessment (HTA)

[...] a form of policy research that systematically examines short- and long-term consequences—in terms of health and ressource use—of the application of a health technology [...] 

The goal of HTA is to provide input to decision making in policy and practice.

(Henshall et al. 1997)
The **interventions** (drugs, procedures, complex multidisciplinary activities) which can be provided / reimbursed within the system when **delivering health services**

The **interventions** applied to the system to **organize service** delivery, access, financing, payment of providers, etc.
An example

Practical Purpose
„improving survival after myocardial infarction“

Technologies
Aspirin
Stent
Early rehabilitation

Disease Management Programme
Payment for Performance
Use of HTA

Health Technology Assessment /HTA

Clinical research

Assessment

Scientific documentation:
- Clinical effect
- Cost-use

Consequences:
- Organization
- Patient perspective
- Ethics/Law
- Resources/Costs
- Education

Appraisal

Politics

Benefits package/Reimbursement

Guidelines

Priority

Clinical practice
Those involved in HTA

Health Technology Assessment / HTA

Clinical research

Assessment

Appraisal

Industry
Health care-systems
Clinicians
Scientists
Innovators
Patients

Scientists
HTA-Agencies
Universities

HTA-Agencies/Decision-making bodies

Governments

Politics

Benefits package/Reimbursement

Guidelines

Priority

Clinical practice

Policy makers
Regulators
HC Professionals
Governments
Industry
Journalists, Patients
Layers of questions when deciding upon health technologies

How should we do it here?

Should we do it here?

Can it work here?

Can it work?

Technical Performance (devices)/ « Quality » (drugs)

Effectiveness

Efficacy

Applicability

Implementation

Health Technology Assessment

Regulation on Market Access
HTA in a chain of knowledge creation

- **Research**
- **Synthesis**
- **Appraisal**
- **Decision**
- **Dissemination**
- **Utilization**
- **Evaluation**

### (Primary) Research Innovation
- Evidence synthesis/assessment (Systematic reviews) *global*

### Impact & applicability appraisal *local*

### Decision making

### Dissemination Utilization

### Evaluation Monitoring
HTA in a chain of knowledge creation

HTA

Research
Synthesis
Appraisal
Decision
Dissemination
Utilization
Evaluation

(Primary) Research Innovation
Evidence synthesis/assessment (Systematic reviews) (global)
Impact & applicability appraisal (local)
Decision making
Dissemination Utilization
Evaluation Monitoring

Potential and Challenges of HTA: Experience in Europe
What is the “evidence” in an assessment?

“Evidence” is understood as the product of systematic observation or experiment and it is inseparable from the notion of data.

The idea to base decisions on the “best available evidence” implies a “hierarchy” of the evidence.
Hierarchy of research designs for evidence-based medicine

- In-vitro ("test-tube") research
- Animal research
- Ideas, opinions
- Single case reports
- Case series
- Case-control studies
- Cohort studies
- RCT
BEST PRACTICE IN UNDERTAKING AND REPORTING HEALTH TECHNOLOGY ASSESSMENTS

Working Group 4 Report

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Request for and in close collaboration with the working group by Reinald Busse, Marcel Velasco, Matthias Perleth, and Jacques Orvalin. The authors are indebted to Wendy Williams (Dartmouth Observatory on Health Care Systems) for providing English language editing.

RCTs other types of evidence

global local

Conducting the assessment

Definition of the Policy question(s)

Elaboration of HTA protocol

Collecting background information/Determination of the status of the technology

Definition of the research questions

Safety Efficacy Effectiveness Psychological Social Professional Economic


Draft elaboration of discussion, conclusions, and recommendations

External review

Publishing of FINAL HTA REPORT and summary report

14 November 2012

Potential and Challenges of HTA: Experience in Europe
Project planning (the “HTA protocol”)

• Scoping, i.e. what will be studied?
  – Extensive technology-oriented HTAs: one technology or few technologies, many or all uses of it/them (e.g. "Hyperbaric oxygen therapy")
  – Limited technology-oriented HTAs: one technology or few technologies in a specific setting (e.g. "Hyperbaric oxygen therapy for diving accidents")
    PICO: patients, intervention, control, outcomes
  – Health problem oriented HTAs: one or few health problem(s) and all (or most) technologies used for it (e.g. "Decompression sickness")

• How fast are results needed?
  – Full HTAs (1-2 years)
  – Rapid HTAs/ reviews (3-6 months) -> concentration on one/ a few dimensions
    – Ultra-rapid reviews (1-12 weeks)

• What will be included in the review?
  – Original studies, or only review of reviews?
  – Data provided by industry? -> only publicly available? confidentiality?
HTA dimensions in theory and reality

<table>
<thead>
<tr>
<th>Safety</th>
<th>Efficacy</th>
<th>Social</th>
<th>Ethical</th>
<th>Organisational/professional</th>
<th>Economic</th>
</tr>
</thead>
</table>

Depth of analysis

Ideally

Methodological standards

In reality

14 November 2012  Potential and Challenges of HTA: Experience in Europe  21
### Table 2. Main Aspects and Dimensions Assessed in the Sample (n = 433)

<table>
<thead>
<tr>
<th>Main aspect</th>
<th>Dimensions assessed</th>
<th>Frequency</th>
<th>% of total sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Efficacy</td>
<td>259</td>
<td>59.8</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>304</td>
<td>70.2</td>
</tr>
<tr>
<td></td>
<td>Effectiveness</td>
<td>325</td>
<td>75.1</td>
</tr>
<tr>
<td></td>
<td>Other outcomes</td>
<td>136</td>
<td>31.4</td>
</tr>
<tr>
<td></td>
<td>Indications</td>
<td>409</td>
<td>94.5</td>
</tr>
<tr>
<td></td>
<td>Population affected</td>
<td>323</td>
<td>74.6</td>
</tr>
<tr>
<td>Economic</td>
<td>Efficiency</td>
<td>57</td>
<td>13.2</td>
</tr>
<tr>
<td></td>
<td>Costs</td>
<td>231</td>
<td>53.3</td>
</tr>
<tr>
<td></td>
<td>Cost-effectiveness</td>
<td>158</td>
<td>36.5</td>
</tr>
<tr>
<td></td>
<td>Cost utility</td>
<td>81</td>
<td>18.7</td>
</tr>
<tr>
<td></td>
<td>Cost benefit</td>
<td>19</td>
<td>4.4</td>
</tr>
<tr>
<td>Patient-related</td>
<td>Social Impact</td>
<td>86</td>
<td>19.9</td>
</tr>
<tr>
<td></td>
<td>Ethics</td>
<td>52</td>
<td>12.0</td>
</tr>
<tr>
<td></td>
<td>Acceptability</td>
<td>106</td>
<td>24.5</td>
</tr>
<tr>
<td></td>
<td>Psychological reactions</td>
<td>115</td>
<td>26.6</td>
</tr>
<tr>
<td></td>
<td>Other patient parameters</td>
<td>89</td>
<td>20.6</td>
</tr>
<tr>
<td>Organizational</td>
<td>Diffusion</td>
<td>77</td>
<td>17.8</td>
</tr>
<tr>
<td></td>
<td>Centralization/decentral.</td>
<td>94</td>
<td>21.7</td>
</tr>
<tr>
<td></td>
<td>Utilization</td>
<td>49</td>
<td>11.3</td>
</tr>
<tr>
<td></td>
<td>Accessibility</td>
<td>63</td>
<td>14.5</td>
</tr>
<tr>
<td></td>
<td>Skills—routines</td>
<td>118</td>
<td>27.3</td>
</tr>
<tr>
<td></td>
<td>Education—training</td>
<td>118</td>
<td>27.3</td>
</tr>
<tr>
<td></td>
<td>Other organizations</td>
<td>14</td>
<td>3.2</td>
</tr>
</tbody>
</table>

The broad understanding of technologies and the chain of knowledge creation

**Fig. 8.2** Different levels of health-care technologies/interventions

<table>
<thead>
<tr>
<th>Health system interventions</th>
<th>Research</th>
<th>Synthesis</th>
<th>Appraisal</th>
<th>Decision</th>
<th>Utilization</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational interventions</td>
<td>Research</td>
<td>Synthesis</td>
<td>Appraisal</td>
<td>Decision</td>
<td>Utilization</td>
<td>Evaluation</td>
</tr>
<tr>
<td>Population interventions (public health)</td>
<td>Research</td>
<td>Synthesis</td>
<td>Appraisal</td>
<td>Decision</td>
<td>Utilization</td>
<td>Evaluation</td>
</tr>
<tr>
<td>Individual interventions (clinical practice)</td>
<td>Research</td>
<td>Synthesis</td>
<td>Appraisal</td>
<td>Decision</td>
<td>Utilization</td>
<td>Evaluation</td>
</tr>
<tr>
<td>Technologies (drugs, devices etc.)</td>
<td>Research</td>
<td>Synthesis</td>
<td>Appraisal</td>
<td>Decision</td>
<td>Utilization</td>
<td>Evaluation</td>
</tr>
</tbody>
</table>
Figure 3. Types of HT assessed in HTA organisations (N=41)*

Topics

- Drugs 28%
- Devices 22%
- Diagnostics 16%
- Surgery 7%
- Other clinical 24%
- Public health 5%
- Delivery 15%
- Financial 2%
- Governance 3%

* Multiple choice question which allows to select more than one correct answer to be selected.

EUnetHTA WP8, 2008

(223 HTAs from Canada, USA, England and Denmark)
Institutions undertaking HTA

**Non-drug HTA**
- CAHTA
- NCCHTA
- DIHTA
- FinOHTA
- SMM
- DAHTA
- UETS

**Drug HTA**
- PBAC
- PMPRB
- CFH
- PPB
- PHARMAC
- NoMA
- HEK
- EAK
- CT
- PBB
- CEDAC

**Broad HTA**
- DACEHTA
- NOKC
- KCE
- IQWiG
- „New“

- SBU
- 1987, 89, 91/92, 93, 94, 95, 96, 97, 98, 99, 2000, 01, 02, 03, 04, 05
Merging HTA agency into a broader institution

01.01.2004

Ministry of Health: Mandate and budget

Directorate for Health and Social Affairs

Norwegian Knowledge Centre for the Health Services

Suggestions
- Ministries
- Hospitals
- Clinicians
- Patients

Products:
- HTA reports
- Early warning reports
- Systematic reviews (Cochrane)
- Electronic health library
- Performance Indicators
- Clinical indicators
- Quality improvement advice
- Patient safety
- Priority setting (secretariat)

Monitoring quality

Governmental centre
HAS’ structure consists of an executive Board (chaired by Professor Laurent Degos), specialist Committees, a director and departments.

1. **THE BOARD ("COLLEGE")**

Board members are appointed for a 6-year term, renewable once. Half the Board is renewed every 3 years.

2. **THE SPECIALIST COMMITTEES AND THEIR MISSIONS**

There are seven specialist committees (see Box 1). In addition to the Transparency Committee (article R. 163-15 of the Social Security Code) and the Committee for the Assessment of Devices and Health Technologies (CEPP) (article R. 165-18 of the Social Security Code), five other committees were created by the Board, which decided their composition and their common rules of operation. Each Committee is chaired by a member of the Board and has its own internal regulations. Each Committee Chair is supported by a corresponding head of department, who reports directly to the director.

**Box 1. 7 specialist Committees**

- Transparency Committee (assessment of medicinal products)
- Committee for the Assessment of Devices and Health Technologies
- Committee for the Assessment of Diagnostic and Therapeutic Procedures
- Committee for Healthcare Cover for Chronic Conditions
- Committee for Practice Guidelines and Practice Improvement
- Committee for Medical Information Quality and Dissemination
- Committee for Accreditation ("certification" in French) of Healthcare Organisations.
HTA and the broader quality agenda

“... quality of care is that component of the difference between efficacy and effectiveness that can be attributed to care providers, taking account of the environment in which they work”

(Brook & Lohr 1985)
Layers of questions when deciding upon health technologies

- **Effectiveness**: Can it work here?
- **Efficacy**: Can it work?
- **Technical Performance (devices)/ « Quality » (drugs)**
- **Applicability**: Should we do it here?
- **Implementation**: How should we do it here?

**Regulation on Market Access**

Health Technology Assessment

14 November 2012  
Potential and Challenges of HTA: Experience in Europe
<table>
<thead>
<tr>
<th><strong>Efficacy</strong></th>
<th><strong>Effectiveness</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• explanatory trials</td>
<td>• pragmatic trials</td>
</tr>
<tr>
<td>• highly selected populations</td>
<td>• few exclusions</td>
</tr>
<tr>
<td>• comparator: placebo</td>
<td>• comparator: ‘current (best) practice’</td>
</tr>
<tr>
<td>• outcomes: clinical, morbidity, mortality, adverse effects</td>
<td>• outcomes: patient-focused, down-stream resources</td>
</tr>
<tr>
<td>• ‘what it says on the packet’</td>
<td>• ‘the real life effect’</td>
</tr>
</tbody>
</table>
Efficacy

- explanatory trials
- highly selected populations
- comparator: placebo
- outcomes: clinical, morbidity, mortality, adverse effects
- ‘what it says on the packet’

Effectiveness

- pragmatic trials
- few exclusions
- comparator: ‘current (best) practice’
- outcomes: patient-focused, down-stream resources
- ‘the real life effect’
<table>
<thead>
<tr>
<th>Final outcomes</th>
<th>versus</th>
<th>surrogate parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary thrombosis (thrombolysis)</td>
<td>Quality-adjusted survival</td>
<td>Number surviving</td>
</tr>
<tr>
<td>Unstable angina (various interventions)</td>
<td>Quality-adjusted survival</td>
<td>Number surviving</td>
</tr>
<tr>
<td>Stable angina (various interventions)</td>
<td>Quality-adjusted survival</td>
<td>Number with acceptable quality of life</td>
</tr>
<tr>
<td>Asthma (various drugs)</td>
<td>Quality-adjusted survival</td>
<td>Number surviving</td>
</tr>
<tr>
<td>Depression (various drugs)</td>
<td>Quality-adjusted survival</td>
<td>Number avoiding suicide</td>
</tr>
<tr>
<td>Hypertension (various drugs)</td>
<td>Quality-adjusted survival</td>
<td>Number avoiding stroke</td>
</tr>
</tbody>
</table>

*source: PBAC*
No erection: 89% (Medicare Follow-up) vs. 60% (Metanalysis of RCTs)
Incontinence: 47% (Medicare Follow-up) vs. 27% (Metanalysis of RCTs)
Reoccurrence after 1 yr.: 6% (Medicare Follow-up) vs. 3% (Metanalysis of RCTs)


Two possibilities for differences: (1) selection criteria for RCTs, (2) bad quality under routine conditions.
RCT selection → RCT participation

Based on: McKee M et al. BMJ 1999;319:312-315

On average, only 15% of actual patients meet RCT inclusion criteria.

To what degree can we generalize results to the other 85%?

Based on: McKee M et al. BMJ 1999;319:312-315
Preferred study designs (in 11 countries doing drug HTA)

• preferably “head-to-head” randomized controlled trials (direct comparisons)
• majority favours final outcome parameters (change in mortality, morbidity, quality of life) and studies in “natural” and country specific setting
• But: available are often 24-week RCTs against placebo with highly selected patients and providers conducted in a mixture of countries
<table>
<thead>
<tr>
<th>Trial conditions</th>
<th>Quality</th>
<th>Safety</th>
<th>Efficacy/effectiveness</th>
<th>Benefit</th>
<th>Additional benefit</th>
<th>Ethical, social, organisational etc. implications</th>
<th>Costs and Cost-effectiveness / benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Authorization</td>
<td>Clinical endpoints (vs. placebo)</td>
<td>Typical 24 week-market authorization</td>
<td>Expansion of market authorization criteria?</td>
<td>RCTs with cost data</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Real world conditions

- Effectiveness
  - "real" patients (incl. children, women, elderly, with co- and multi-morbidity) pragmatic RCTs/observational studies
  - "real" setting (e.g. unselected providers) pragmatic RCTs/observational studies
  - relevant subgroups pragmatic RCTs/observational studies
  - Longer time horizon
  - Other data sources (e.g. routine data, modelling)

- Relative/comparative effectiveness
  - Other data sources (e.g. routine data with utilization and costs), modelling

**HEALTH TECHNOLOGY ASSESSMENT**
<table>
<thead>
<tr>
<th>Trial conditions</th>
<th>MARKET AUTHORIZATION</th>
<th>Typical 24 week-market authorization</th>
<th>RCT → Efficacy</th>
<th>Expansion of market authorization criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real world conditions</td>
<td></td>
<td></td>
<td></td>
<td>RCTs with cost data</td>
</tr>
</tbody>
</table>

**HEALTH TECHNOLOGY ASSESSMENT**

**Country-specific context**
(values, budget, priorities, health care delivery system)

**Transferability of results**
Health Technology Assessment / HTA

Clinical research:
- Industry
- Health care systems
- Clinicians
- Scientists
- Innovators
- Patients

Assessment:
- Scientists
- HTA-Agencies
- Universities

Appraisal:
- HTA-Agencies/Decision-making bodies
- Governments

Politics
- Benefits package/Reimbursement
- Guidelines
- Priority
- Clinical practice

Policy makers
- Regulators
- HC Professionals
- Governments
- Industry
- Journalists, Patients
The benefits package – a model

Possible Health Benefits

Core Benefits
- e.g. “screening”, “pre-natal care”

Actually Covered Benefits
- e.g. cervical cancer screening with Papanicolaou Test;
  - toxoplasma serology in the first trimester
Possible Health Benefits

Core Benefits

Actual Benefits

Representative Institutions, e.g. Parliaments (Law)

Planning Bodies
Coverage Commissions
HTA

Third-party Payers

Advisory bodies

(Social) Courts

Criteria
HTA direct after market launch
(currently existing mainly for drugs)

New drug/ device/ intervention
→ „single technology assessment“:
Important input = structured information (dossier of manufacturer/ promoter)

With price (e.g. Sweden)  Without price (e.g. France)

Need (disease burden) & Effectiveness
(also for patient sub-groups and selected indications)

Additional benefit/ comparative effectiveness
(also for patient sub-groups and selected indications)

Cost-benefit
(comparative, sub-groups …)

- price determined by manufacturer (if additional benefit large)
- price negotiated (trend → value-based pricing & volume-price)
- price regulated

not reimbursable
reimbursable only for selected indications or providers, second line … (“optimised“)
reimbursable
only in research
(to generate additional data)
More than YES or NO:
Decision Options (e.g. in Switzerland)

<table>
<thead>
<tr>
<th>Coverage (reimbursement)</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>reimbursement without conditions</td>
</tr>
<tr>
<td>Yes</td>
<td>reimbursement for specific indications</td>
</tr>
<tr>
<td>Yes</td>
<td>in centers which have to fulfil certain</td>
</tr>
<tr>
<td></td>
<td>requirements</td>
</tr>
<tr>
<td>Yes</td>
<td>in centers + evaluation registers</td>
</tr>
<tr>
<td>Yes</td>
<td>in evaluation (by benefit commission)</td>
</tr>
<tr>
<td>No</td>
<td>in evaluation (by applicant)</td>
</tr>
<tr>
<td>No</td>
<td>refusal</td>
</tr>
</tbody>
</table>

Source: Swiss Federal Office for Social Security (SFOSS)
### More than YES or NO:

**Actual decisions in England**

<table>
<thead>
<tr>
<th>Decision</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrestricted</td>
<td>98</td>
<td>29%</td>
</tr>
<tr>
<td>Optimised</td>
<td>188</td>
<td>55%</td>
</tr>
<tr>
<td>Only in Research</td>
<td>21</td>
<td>6%</td>
</tr>
<tr>
<td>Not recommended</td>
<td>31</td>
<td>9%</td>
</tr>
<tr>
<td>Non-submission</td>
<td>4</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>342</td>
<td>100%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Number</th>
<th>% of opt. rec.</th>
</tr>
</thead>
<tbody>
<tr>
<td>By patient group</td>
<td>158</td>
</tr>
<tr>
<td>By price</td>
<td>53</td>
</tr>
<tr>
<td>By continuation rule</td>
<td>34</td>
</tr>
<tr>
<td>By regimen</td>
<td>7</td>
</tr>
<tr>
<td>By setting</td>
<td>4</td>
</tr>
</tbody>
</table>

342 individual recommendations in 166 technology appraisals
France: Clinical Added Value (ASMR)

<table>
<thead>
<tr>
<th>ASMR I</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASMR II</td>
<td>Important</td>
</tr>
<tr>
<td>ASMR III</td>
<td>Moderate</td>
</tr>
<tr>
<td>ASMR IV</td>
<td>Minor</td>
</tr>
<tr>
<td>ASMR V</td>
<td>No</td>
</tr>
</tbody>
</table>

30.7% 34.3% 38.5% 13.4% 17.5%

2005 2006 2007 2008 2009 (Jan-Oct)

Major Important Moderate

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Potential and Challenges of HTA: Experience in Europe
The background for EU action:

The HTA article in the EU Patients’ Rights Directive

**Article 15**

**Cooperation on health technology assessment**

1. 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. The members of the network shall participate and contribute to the network’s activities according to the legislation of the Member State where they are established.

2. The objective of the Union support referred to in paragraph 1 shall be:
   
   (a) to support Member States in their cooperation through the national authorities or bodies referred to in paragraph 1;

   (b) and to support Member States in the provision of objective, reliable, timely, transparent and transferable scientific information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between the national authorities or bodies.
3. In order to implement paragraph 2, the network on health technology assessment may receive Union aid. Aid may be given in order to:

(a) contribute to the financing of administrative and technical support;

(b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;

(e) facilitate the consultation of stakeholders on the work of the network.
Two problems acknowledged:

HTA implemented differently across Europe
→ Reduced applicability of foreign reports

Varying structure of reports
→ Extraction of data from reports is often difficult

Aim: Attempt to define and standardise elements of an HTA to facilitate shared understanding of HTA and promote the international use of HTA results
## Domains of HTA

- Identified in previous EU projects, particularly EUR-ASSESS and ECHTA/ECAHI
- Promote the multidisciplinary nature of HTA

<table>
<thead>
<tr>
<th>Health problem and current use of technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical characteristics</td>
</tr>
<tr>
<td>Safety</td>
</tr>
<tr>
<td>Clinical effectiveness</td>
</tr>
<tr>
<td>Costs and economic evaluation</td>
</tr>
<tr>
<td>Ethical analysis</td>
</tr>
<tr>
<td>Organisational aspects</td>
</tr>
<tr>
<td>Social aspects</td>
</tr>
<tr>
<td>Legal aspects</td>
</tr>
</tbody>
</table>
Topics

Clinical effectiveness

Topic 1: Mortality

Issue 1: What is the effect of the intervention on overall mortality?

Issue 2: What is the effect of the intervention on mortality caused by the target disease?

Issue 3: etc…

Table:

- Health problem and current use of technology
- Technical characteristics
- Safety
- Costs and economic evaluation
- Ethical analysis
- Organisational aspects
- Social aspects
- Legal aspects
Assessment elements

- Combination of domain-topic-issue
- The basic unit of the model. It defines a piece of information that describes the technology or the consequences or implications of its use, or the patients and the disease for which it is applied.
- Nature of elements may vary across domains, since the consequences and implications are understood and studied differently
- The common denominator for all elements is that they outline a set of information that may be useful when deciding on the use or non-use of technology
The Core HTA Structure

i.e. HTA Core Model, Core HTAs and local reports

Pool of Structured HTA Information

HTA Core Model

Domain 1

Domain 2

Domain 3

Domain 4

CORE HTA

Summary of key findings, no recommendation on technology use

LOCAL REPORT

Takes into account local epidemiology, resources, values, etc.

AE = assessment element

AE = Core element

AE = Non-core element

INFO = Locally produced information that does not follow HTA Core model structure

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• Policy processes and HTA
• Health systems, health policy and HTA
• HTA producers
• Impact of HTA
• Needs and demands of policy-makers
• Future challenges for HTA in Europe