Approaches to Economic Evaluation at German Agencies for HTA

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Overview

• Background
• HTA agencies in Germany
• IQWiG’s efficiency frontier approach
• Application of key HTA principles in Germany
European HTA Map 2000
European HTA Map 2008

UK: Total N=18
NL: Total: 8
DK: Total N>5
D: Total: 8
F: Total N>4
E: Total: 8

n = 73, not comprehensive

Schwarzer, ISPOR 2008
Background

• In Europe, Health Technology Assessment (HTA) is performed since the 1980s
• Countries with longest history: Sweden and The Netherlands
• Since mid 1990s, HTA plays an important role in German health policy
  – to inform the public
  – to support guidelines
  – to guide reimbursement or coverage decisions
German HTA Legislation

- 2000: SHI Health Care Reform Act
  - DRGs
  - Information System HTA by DAHTA@DIMDI

- 2003: Health Care Modernization Act
  - Initiation of IQWiG
  - 2004: Foundation of IQWiG; solely benefit assessments
  - 2010: Economic evaluations to determine maximum reimbursement rate
The German Agency for Health Technology Assessment (DAHTA) - Assessment of Health Relevant Procedures

The term Health Technology Assessment (HTA) specifies a process of systematically evaluating health relevant procedures and technologies with relation to the health care of the population. Since the middle of the 90's HTA plays an important role in German health policy. The German Agency for HTA at DIMDI was established in 2000. It runs the HTA information system and a programme for the production of HTA reports.

Basic Information Health Technology Assessment (PDF, 1.19 MB)

Search for HTA Reports

All HTA reports of the HTA series are available free of charge as full texts in the DAHTA database and at German Medical Science (gms).

Search for HTA reports »

HTA Programme

Circa 15 HTA reports are prepared yearly in the HTA programme. Anyone who is interested can propose questions for the reports. The questions are worked on according to their rank in the priority list. The next deadline for entering a question is 2010, May 31st!

more »

HTA Cooperations

National and international cooperation partners of DAHTA@DIMDI. more »

HTA Symposia

DAHTA@DIMDI organises a symposium yearly. The next meeting will take place in Cologne from March 18 to 19, 2010. more »
Step 1: The German HTA Project:

The *German Scientific Working Group Technology Assessment in Health Care*, a panel of ~40 HTA experts, developed framework for processes and methods; sufficient funding and time (6 years)

Step 2: DAHTA@DIMDI starts routine work
IQWiG is an independent scientific institute that investigates the benefits and harms of medical interventions for patients. We regularly provide information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions.

Women with breast cancer may benefit from autologous stem cell transplantation
Compared to conventional chemotherapy, autologous stem cell transplantation can extend "event-free survival" for breast cancer patients. Clinical trials provide proof of this for breast cancer with and without distant metastases. However, there are indications that this type of stem cell transplantation can more frequently give rise to severe complications affecting almost all organ systems. This is the conclusion of IQWiG's final report published on 16 December.

» Full text
Step 1: Foundation of IQWiG

Step 2: Development of framework:

a) IQWiG members developed guidelines for benefit assessment, expert review and hearings

b) *International Expert Panel* prepared draft of guidelines for cost-effectiveness evaluation based on legal restrictions, external review and hearings, several revisions and pilot studies
International Expert Panel

Members of the IQWiG International Expert Panel

Prof. Dr. Vincenzo Atella  “Tor Vergata” University, Rome  Italy
Prof. Dr. Jaime Caro, Chair  McGill University, Montreal  Canada
Prof. Dr. Gérard de Pouvourville  ESSEC Business School, Cergy  France
Prof. Dr. David Henry  University of Newcastle/ ICES  Australia
Prof. Dr. Maurice McGregor  McGill University, Montreal  Canada
Prof. Dr. Alistair McGuire  London School of Economics  England
Dr. Erik Nord  Norwegian Institute of Public Health, Oslo  Norway
Prof. Dr. Uwe Siebert  UMIT, Hall in Tirol  Austria
Legal Framework and Assignment of Tasks

- German Federal Ministry of Health
- DAHTA@DIMDI provides evidence
- IQWiG provides evidence
- Federal Joint Committee (FJC)* decides
  - supervises
  - commissions
  - *pat. representatives, SHI funds, hospitals, physicians

- belongs to
- evidence

IQWiG

DAHTA@DIMDI

German Federal Ministry of Health

Federal Joint Committee (FJC)*

* pat. representatives, SHI funds, hospitals, physicians
IQWiG: Efficiency Frontier Approach

• Comparison within indication area

• Generate efficiency frontier and compare costs and benefits of new technology to efficiency frontier

Published in Fall 2009

IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Institute for Quality and Efficiency in Health Care

General Methods for the Assessment of the Relation of Benefits to Costs

Version 1.0 – 19/11/2009

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Efficiency Frontier

- **Completed theoretical efficiency frontier**
  - Price accepted
  - Trade-off
  - Intervention rejected
  - No economic evaluation

- **Axes:**
  - Benefit
  - Net costs / Patient

- **Points:**
  - 1
  - 2
  - 3
  - 4
  - 5
  - Worse
  - Better
Efficiency Frontier

Completed theoretical efficiency frontier

Price accepted

Better

Price accepted

Net costs / Patient

Price may be too high

Worse

Intervention rejected

No economic evaluation

No economic evaluation

UMIT

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Comparing IQWiG and DIMDI along Key Principles for HTA

Drummond et al., IJTAHC, 2008

KEY PRINCIPLES FOR THE IMPROVED CONDUCT OF HEALTH TECHNOLOGY ASSESSMENTS FOR RESOURCE ALLOCATION DECISIONS

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Bryan R. Luce
United BioSource Corporation

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University of Washington

Health technology assessment (HTA) is a dynamic, rapidly evolving process, embracing different types of assessments that inform real-world decisions about the value (i.e., benefits, risks, and costs) of new and existing technologies. Historically, most HTA agencies have focused on producing high quality assessment reports that can be used by a range of decision makers. However, increasingly organizations are undertaking or commissioning HTAs to inform a particular resource allocation decision, such as listing a drug on a national or local formulary, defining the range of coverage under insurance plans, or issuing mandatory guidance on the use of health technologies in a particular healthcare system. A set of fifteen principles that can be used in assessing existing or establishing new HTA activities is proposed, providing examples from existing HTA programs. The principal focus is on those HTA activities that are linked to, or include, a particular resource allocation decision. In these HTAs, the consideration of both costs and benefits, in an economic evaluation, is critical. It is also important to consider the link between the HTA and the decision that will follow. The principles are organized into four sections: (i) “Structure” of HTA programs; (ii) “Methods” of HTA; (iii) “Processes for Conduct” of HTA; and (iv) “Use of HTAs in Decision Making.”

The authors are members of The International Group for HTA Advancement.
Key HTA Principles

**STRUCUTURE OF HTA**
1. Goal and scope explicit & relevant
2. Unbiased & transparent
3. All relevant technologies
4. Clear priority setting for topics

**METHODS OF HTA**
5. Approp. cost & benefit methods
6. Wide range evidence & outcomes
7. Full societal perspective
8. Explicitly characterize uncertainty
9. Generalizability & Transferability

**PROCESSES FOR CONDUCT**
10. Engage all stakeholders
11. Seek all available data
12. Monitor implementation of findings

**USE IN DECISION MAKING**
13. Should be timely
14. Appropriate communication
15. Clear link HTA–decision making

*Drummond et al., Int J Technol Assessment Health Care, 2008*
Support and Use of Key HTA Principles

Policies

Are Key Principles for improved health technology assessment supported and used by health technology assessment organizations?

The International Working Group for HTA Advancement

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Previously, our group—the International Working Group for HTA Advancement—proposed a set of fifteen Key Principles that could be applied to health technology assessment (HTA) programs in different jurisdictions and across a range of organizations and perspectives. In this commentary, we investigate the extent to which these principles are supported and

Neumann et al., IJTAHC, 2010
## Key Principles and German HTA Agencies

<table>
<thead>
<tr>
<th>Year of Inception</th>
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<th>Washington Medicaid/ DERP (US)(^b)</th>
<th>WellPoint (US)</th>
<th>BCBS TEC (US)</th>
<th>NICE (UK)</th>
<th>IQWiG (Germany)</th>
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### Key Principle

**Structure of HTA program**

1. The goal and scope of the HTA should be explicit and relevant to its use
   - CMS: ++
   - Washington Medicaid/ DERP: ++
   - WellPoint: ++
   - BCBS TEC: ++
   - NICE: ++
   - IQWiG: ++
   - DAHTA@ DIMDI: ++
   - TLV: ++

2. HTA should be an unbiased and transparent exercise
   - CMS: ++
   - Washington Medicaid/ DERP: ++
   - WellPoint: ++
   - BCBS TEC: ++
   - NICE: ++
   - IQWiG: ++
   - DAHTA@ DIMDI: +
   - TLV: +

3. HTA should include all relevant technologies
   - CMS: ++
   - Washington Medicaid/ DERP: ++
   - WellPoint: ++
   - BCBS TEC: ++
   - NICE: ++
   - IQWiG: ++
   - DAHTA@ DIMDI: ++
   - TLV: +

4. A clear system for setting priorities for HTA should exist
   - CMS: +
   - Washington Medicaid/ DERP: +
   - WellPoint: ++
   - BCBS TEC: +
   - NICE: ++
   - IQWiG: +
   - DAHTA@ DIMDI: ++
   - TLV: +

**Methods of HTA**

5. HTA should incorporate appropriate methods for assessing costs and
   - CMS: +
   - Washington Medicaid/ DERP: ++
   - WellPoint: +
   - BCBS TEC: ++
   - NICE: +
   - IQWiG: ++
   - DAHTA@ DIMDI: ++
   - TLV: ++

\(^a\) CMS (US) and DERP (US): Center for Medicare & Medicaid Services (US) and Department of Employment, Retirement, and Population (US)

\(^b\) Washington Medicaid: Washington State Medicaid Program

\(^d\) + implies a strong agreement or endorsement, - implies a weak agreement or endorsement.
Structure of HTA

**DAHTA@DIMDI**
- Part of GFMH, HTAs for public information
- No *by default* link to decision maker
- All types of technologies. Many examples for prevention, screening, diagnostics, devices, etc.
- Prioritization by Board of Trustees (Delphi)

**IQWiG**
- Part of independent foundation, HTAs for FJC
- Reports mainly commissioned by FJC
- All types of technologies. Focus on new expensive drugs or special problems
- Collection and prioritization by FJC, not open to public

NUTRITION ≠ typical drug intervention
Methods

**DAHTA@DIMDI**
- Assessment of both benefits and costs
- Approach depends on research question, based on international and national standards
- Full societal perspective
- Comparisons across health care system
- CEA: most models report EUR/QALY

**IQWiG**
- 2-step approach: first benefits then costs (using same benefit measure)
- Efficiency frontier approach / “Benefit and economic assessment according to internationally recognized standards (EbM, economic)” (SCB V §139a)
- Perspective of community of German citizens insured by SHI (includes out-of-pocket costs etc.)
- Comparison only within indication
- CEA: Cost per clinical benefit

**NUTRITION**: examples for benefit outcomes: kg reduced, MI avoided, diabetes prevented
Processes for Conduct of HTA

DAHTA@DIMDI
- Stakeholders involved regularly in topic collection
- Not responsible for monitoring implementation

IQWiG
- Scoping hearing or written comments (3x)
- No mandate for monitoring implementation (in contrast to NICE or HAS)

NUTRITION: Which specific stakeholders? Schools, drug stores, …
Use of HTA in Decision-Making

**DAHTA@DIMDI**
- **Timeliness:** 12-18 months for full reports
- **Multiple decision makers** (health care professionals, FJC, sickness funds, public)
- **Linked as supportive information provider; DIMDI recommends, other parties decide**

**IQWiG**
- **Timeliness:**
  - Benefit reports: 9-24 months,
  - Economic reports: ~18 months
- **Multiple decision makers, mainly FJC**
- **Direct link to reimbursement decisions (FJC); IQWiG recommends, FJC decides**

NUTRITION: Link to which entities?
Decision-Analytic Modeling at DIMDI and IQWiG

- **DIMDI** encourages modeling
  - for both costs and health outcomes
  - for reporting cost/QALY gained
  - no explicit threshold
  - uncertainty assessment: sensitivity analyses (type not specified)

- **IQWiG** encourages modeling
  - to extrapolate cost beyond clinical trials to relevant time horizon
  - to consider prognostic implications (benefit and harm)
  - QALY can be used to summarize multidim. benefits & harms
  - uncertainty assessment: sensitivity analyses (multiple 1-way deterministic, multi-way probabilistic)
  - Value-of-information analysis?
ICER Threshold in Germany

Federal Ministry of Health Statement:

*The approach of excluding drugs with costs above a **fixed uniform threshold** value from reimbursement is not compatible with legal regulations in Germany*
Another way of representing the benefit [...] is to aggregate different benefits into one single measure [...] Since health economic evaluation in Germany should not be performed across indications, but only within individual therapeutic areas, single indication-specific aggregated measures can be employed. It is not necessary to use primarily aggregated measures which can be applied across indications. The use of such measures, e.g. the QALY, can however be reasonable for the comparison of interventions within a therapeutic area [...]. The indication-specific use of QALYs can be particularly useful with new drugs whose life-extending effect is considerably offset by the reduction of quality of life caused by side effects. In this case, the ethical and methodological problems surrounding the equity of QALYs would not apply.
Converging Approaches

Assessment across diseases; Fixed threshold assumed

NICE

Overall ICER threshold across all diseases; Use of QALYs

Increased ICERs for some cancers

IQWiG

Assessment within disease; Overall threshold does not exist

Low cost/QALY considered necessary intervention; Use of QALY within disease

Indication-specific ICERs, No QALYs mentioned
European HTAs with Nutritional Interventions

• Simple Literature Search
• Databases: NHS-EED, CDSR, EbM-Reviews-HTA
• Search Syntax:
  – (nutrition*.ti,ab. OR diet*.ti,ab.) AND (cost-effectiveness or cost effectiveness or cost-effectiv* or cost-utilit* or cost utilis*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
  – Exclusion criteria: type of intervention, study type (not a full economic evaluation)
• Hits N=101: CDSR 43, NHSEED 53, HTA 5
• 4 European HTAs, 0 in Germany
European HTAs with Nutritional Interventions


- NICE. Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation – guideline, 2001(1).

- NICE. Clinical and cost effectiveness of rimonabant within its licensed indications as an adjunct to diet and exercise for the treatment of obese and overweight patients, HTA ref 07/14/01, 2007(1).

Conclusions

- Germany has two agencies with different processes, methods and scopes
  - DIMDI informs the public on benefits, risks and cost-effectiveness
  - IQWiG informs the FJC regarding maximum reimbursement rates
- IQWiG suggests modeling for costs and long-term health outcomes
- IQWiG has a 2-step approach for benefit and efficiency assessment and primarily compares efficiency within diseases
- However QALYs and cost/QALY can be used for interventions affecting multiple attributes
- Fist economic evaluations starting in 2010
- Nutrition interventions not yet assessed in Germany