

Approaches to Economic Evaluation at German Agencies for HTA

Uwe Siebert, MD, MPH, MSc, ScD

Dept. of Public Health, Medical Decision Making and HTA
UMIT - University for Health Sciences, Medical Informatics and
Technology, Hall i.T., Austria

Center for Health Decision Science
Department of Health Policy and Management
Harvard School of Public Health, Boston, MA

Contact Data:

Uwe Siebert, MD, MPH, MSc, ScD

Professor of Public Health (UMIT)

Adjunct Prof. of Health Policy and Management (Harvard Univ.)

Chair, Dept. of Public Health, Medical Decision Making and HTA

UMIT - University for Health Sciences, Medical Informatics and
Technology

Eduard Wallnoefer Center I, A-6060 Hall i.T., AUSTRIA

Tel.: +43-50-8648-3930, Fax: +43-50-8648-673931

Email: public-health@umit.at

Overview

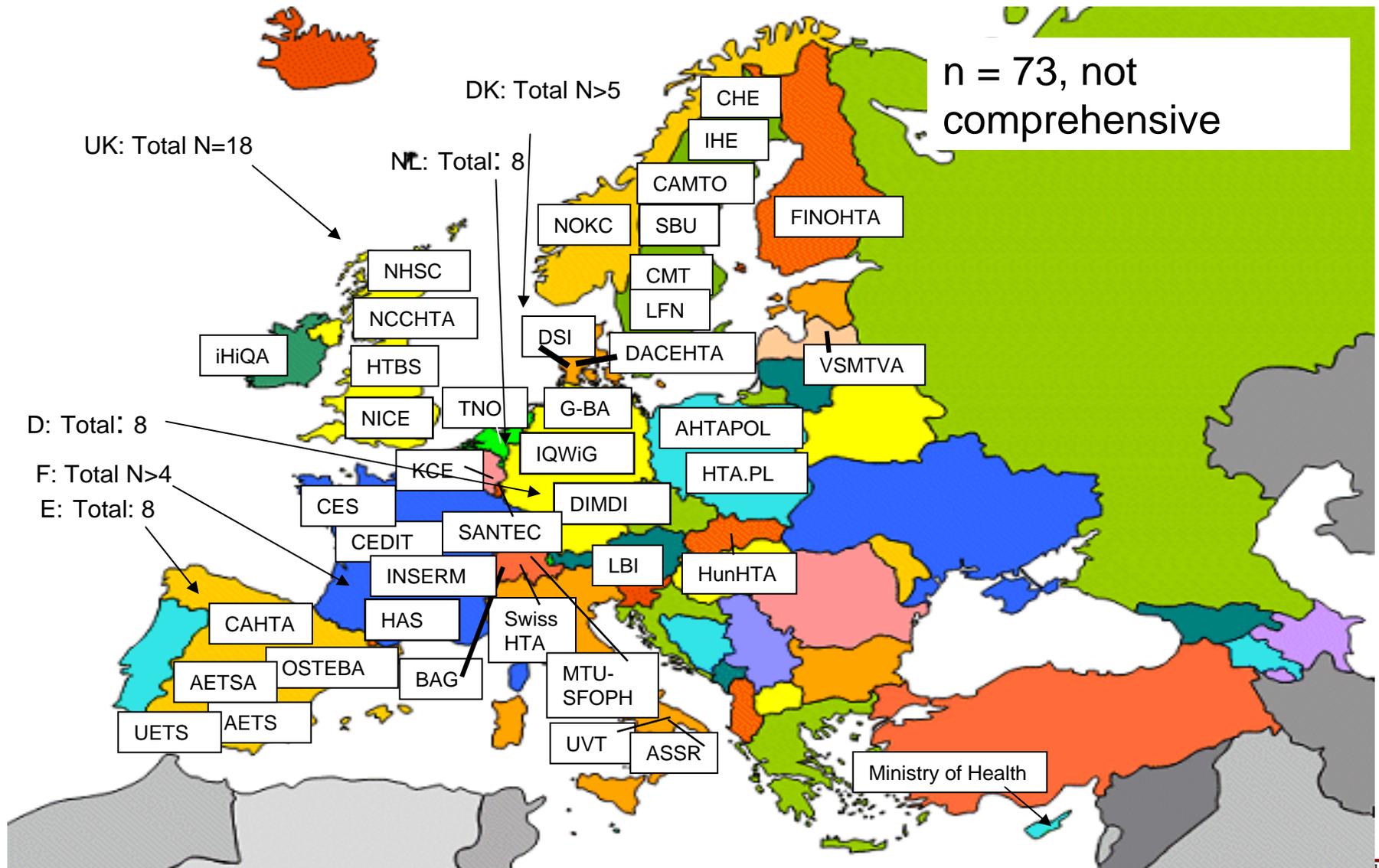
- Background
- HTA agencies in Germany
- IQWiG's efficiency frontier approach
- Application of key HTA principles in Germany



European HTA Map 2000



European HTA Map 2008



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

HTA Agencies in Germany



www.dimdi.de

German Agency for Health Technology Assessment at DIMDI



www.iqwig.de

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

DAHTA@DIMDI

DIMDI
40 years medical knowledge
German Institute of Medical
Documentation and Information

Deutsch Sitemap | Press | Imprint | Contact Search: enter search term go

Your position: [Homepage](#) » [HTA](#)

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 Symposia

DAHTA@DIMDI organises a symposium yearly. The next meeting will take place in Cologne from **March 18 to 19, 2010**. [more »](#)

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 »](#)

Database Query

enter search term go

Database Preselection
 Database Selection

[Premium-Login](#)

Servicelinks

- News
- Subscribe Newsletter
- [DIMDI](#) Webshop
- [gms](#) e-journal

Quicklinks

- [HTA](#) Reports
- Submit Topics
- Symposium

Your position: [Homepage](#) » [HTA](#)

© DIMDI 1995-2010 last modified: 12/2/09 swefre

DAHTA@DIMDI

The screenshot shows the DIMDI website interface. The top left features the DIMDI logo with the text "40 years medical knowledge German Institute of Medical Documentation and Information". The top navigation bar includes "Deutsch", "Sitemap | Press | Imprint | Contact", and a search bar. The left sidebar lists various categories, with "HTA" highlighted in orange. The main content area is partially obscured by a large green box containing text. At the bottom, there is a footer with copyright information and a date.

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

Your position: [Homepage](#) » HTA

© DIMDI 1995-2010 last modified: 12/2/09 swefre



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.



Search:

[OK](#)

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](#)

Award of commissions

Commissions and projects currently advertised

informedhealthonline

The German Institute for Quality and Efficiency in Health Care

LATEST TOPIC

New medications for depression [»](#)

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

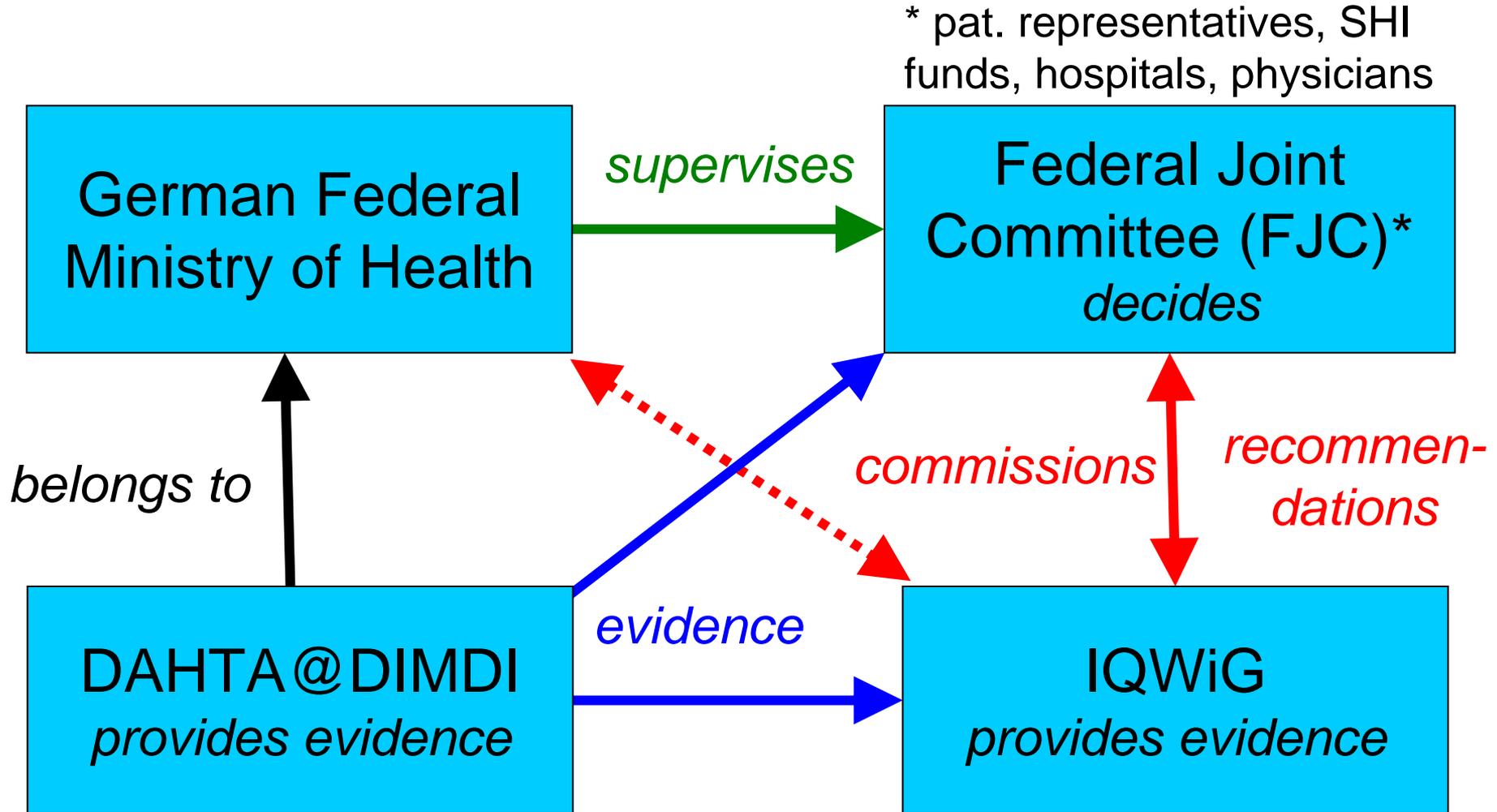
International Expert Panel

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	UNIT, Hall in Tirol	Austria

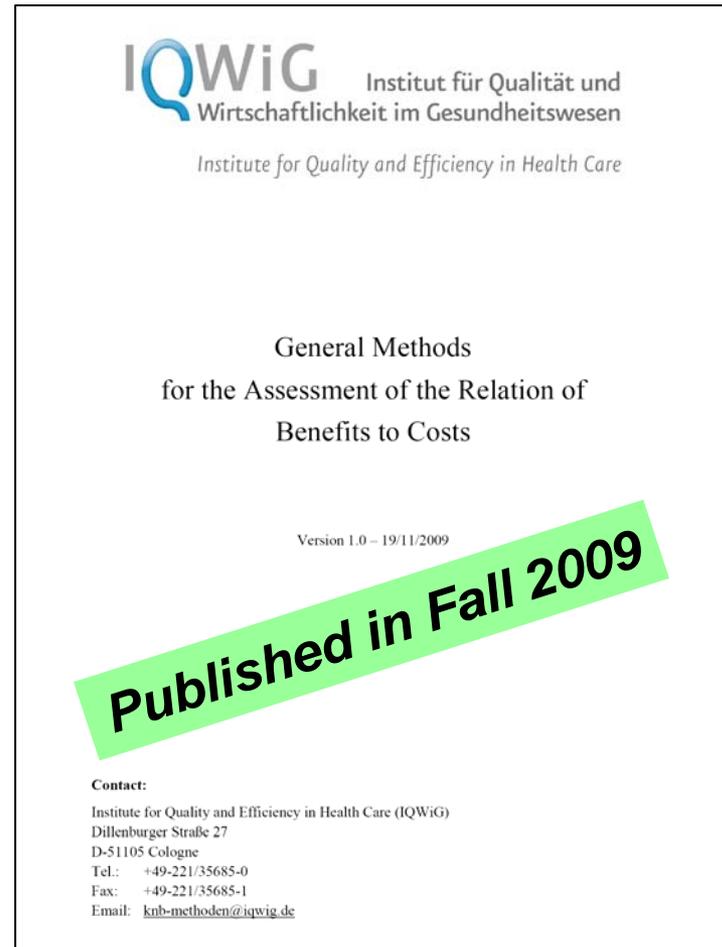


Legal Framework and Assignment of Tasks



IQWiG: Efficiency Frontier Approach

- Comparison within indication area
- Generate efficiency frontier and compare costs and benefits of new technology to efficiency frontier



The image shows the cover of a report from IQWiG. At the top left is the IQWiG logo, which consists of the letters 'IQWiG' in a blue, sans-serif font. To the right of the logo is the text 'Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen' in a smaller, black, sans-serif font. Below this is the English translation 'Institute for Quality and Efficiency in Health Care' in an italicized, black, sans-serif font. In the center of the page, the title 'General Methods for the Assessment of the Relation of Benefits to Costs' is written in a black, sans-serif font. Below the title, the version information 'Version 1.0 – 19/11/2009' is printed. A prominent green diagonal banner with the text 'Published in Fall 2009' in black, bold, sans-serif font is overlaid on the lower right portion of the cover. At the bottom left, under the heading 'Contact:', the following information is provided: 'Institute for Quality and Efficiency in Health Care (IQWiG)', 'Dillenburgstraße 27', 'D-51105 Cologne', 'Tel.: +49-221/35685-0', 'Fax: +49-221/35685-1', and 'Email: knb-methoden@iqwig.de'.

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

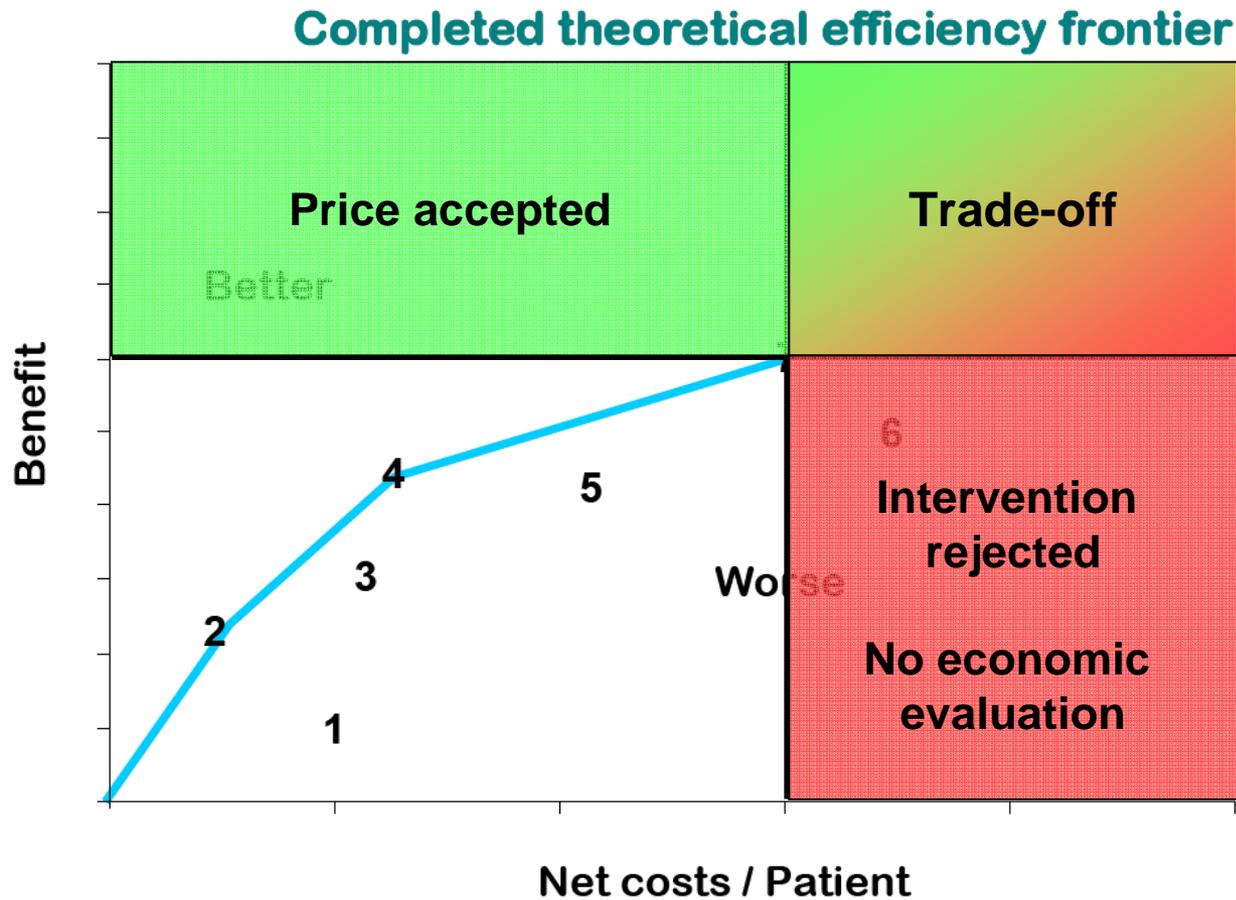
General Methods
for the Assessment of the Relation of
Benefits to Costs

Version 1.0 – 19/11/2009

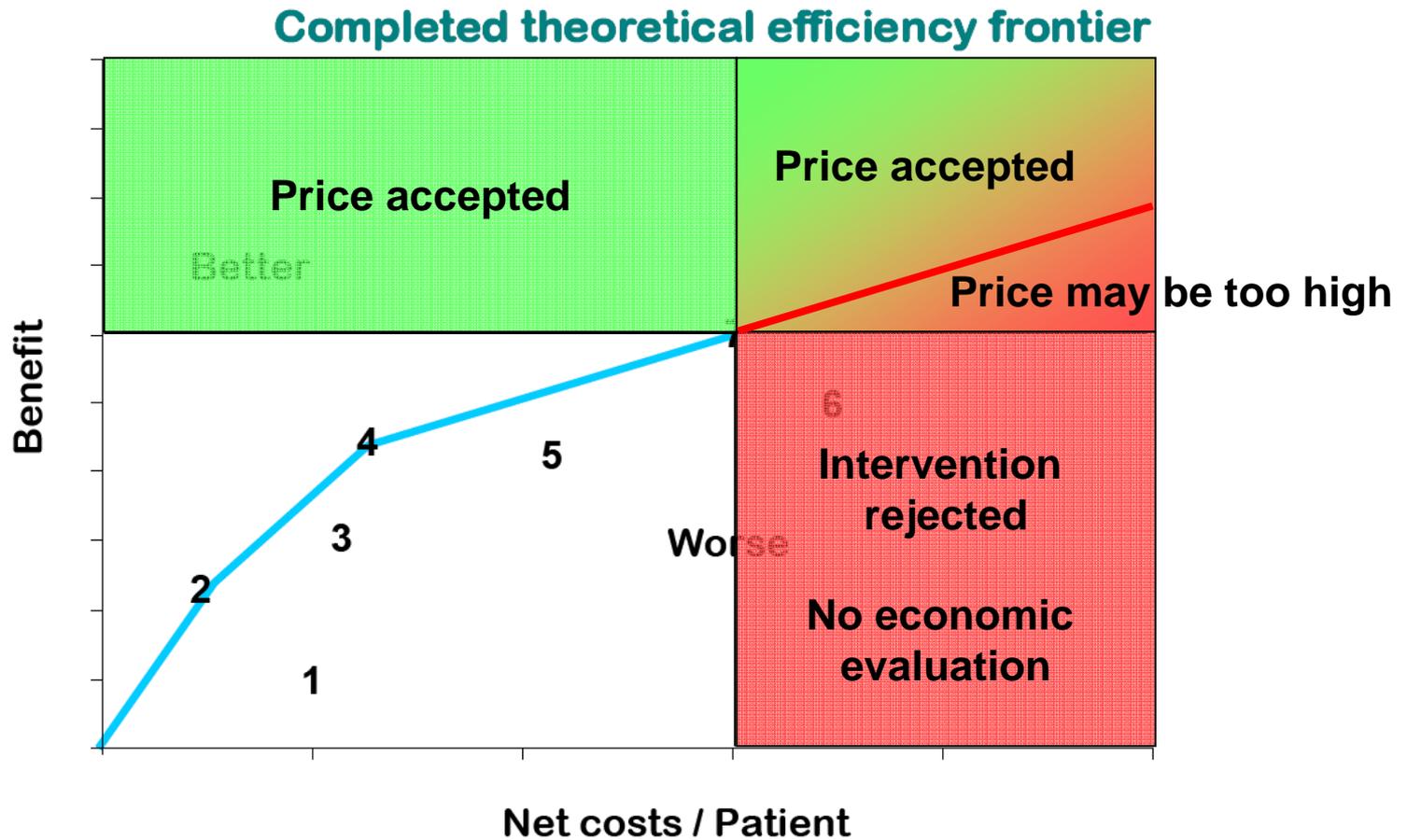
Published in Fall 2009

Contact:
Institute for Quality and Efficiency in Health Care (IQWiG)
Dillenburgstraße 27
D-51105 Cologne
Tel.: +49-221/35685-0
Fax: +49-221/35685-1
Email: knb-methoden@iqwig.de

Efficiency Frontier



Efficiency Frontier



Comparing IQWiG and DIMDI along Key Principles for HTA

Drummond et al., IJTAHC, 2008

UMIT

International Journal of Technology Assessment in Health Care, 24:3 (2008), 244–258.
Copyright © 2008 Cambridge University Press. Printed in the U.S.A.
doi:10.1017/S0266462308080343

Key principles for the improved conduct of health technology assessments for resource allocation decisions

Michael F. Drummond

University of York

J. Sanford Schwartz

University of Pennsylvania

Bengt Jönsson

Stockholm School of Economics

Bryan R. Luce

United BioSource Corporation

Peter J. Neumann

Tufts University

Uwe Siebert

UMIT—University for Health Sciences, Medical Informatics and Technology

Sean D. Sullivan

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

STRUCTURE 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

Neumann et al., IJTAHC, 2010

UMIT

International Journal of Technology Assessment in Health Care, 26:1 (2010), 71–78.
Copyright © Cambridge University Press, 2010
doi:10.1017/S0266462309990833

POLICIES

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

The International Working Group for HTA Advancement

Peter J. Neumann

Tufts Medical Center

Michael F. Drummond

University of York

Bengt Jönsson

Stockholm School of Economics

Bryan R. Luce

United BioSource Corporation

J. Sanford Schwartz

University of Pennsylvania

Uwe Siebert

University for Health Sciences, Medical Informatics and Technology

Sean D. Sullivan

University of Washington

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

The International Working Group for HTA Advancement was established in July 2007 with unrestricted funding from the Schering Plough Corporation. The mission of the Working Group is to provide scientifically based leadership to facilitate significant continuous improvement in the development and implementation of practical, rigorous methods into formal health technology assessment (HTA) systems and processes, by facilitating development and adoption of high quality, scientifically driven, objective, and trusted HTA to improve patient outcomes, the health of the public and overall healthcare quality and efficiency. We are grateful to Andrew Mitchell, Jill Sanders, Tony Tam, and Bong-Min Yang for providing feedback on selected HTA organizational practices. The evaluations and views expressed in this study are those of the authors and do not necessarily reflect the opinions of any of these individuals or their organizations. We are also grateful to Hannah Auerbach for excellent research assistance and to the anonymous referees for constructive comments on an earlier draft.



Key Principles and German HTA Agencies

	CMS (US) ^a	Washington Medicaid/ DERP (US) ^b	WellPoint (US)	BCBS TEC (US)	NICE (UK)	IQWiG (Germany)	DAHTA@ DIMDI (Germany)	TLV (Swede)
Year of inception	1999	2003	2009	1985	1999	2004	2000	2002
Key Principle								
<i>Structure of HTA program</i>								
1 The goal and scope of the HTA should be explicit and relevant to its use	++	++	++	++	++	++ ^d	+	+
2 HTA should be an unbiased and transparent exercise	++	++		++	++	++	++	++
3 HTA should include all relevant technologies	++		++		++	++	++	
4 A clear system for setting priorities for HTA should exist	+	+			++	+	++	+
<i>Methods of HTA</i>								
5 HTA should incorporate appropriate methods for assessing costs and			+		++	+ ^d	++	++



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 \neq 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*

QALYs in Germany: IQWiG Guidelines

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

Assessment within disease;
Overall threshold does not exist

NICE

IQWiG

Overall ICER
threshold across
all diseases;
Use of QALYs

Increased ICERs
for some cancers

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 utilit*).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

- Richards DM, Deeks JJ, Sheldon TA, Shaffer JL. Home parenteral nutrition: a systematic review. Health Technology Assessment 1997;1(1):1-59.
- 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).
- The Netherlands Organization for Health Research Development (ZonMw). Cost-effectiveness of nutritional screening and intervention in elderly subjects after hip fracture, 2006(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
- First economic evaluations starting in 2010
- Nutrition interventions not yet assessed in Germany