

# Das deutsche Beispiel IQWiG: Modifikation der Standardverfahren The German Example IQWiG: Modifying the Standard Approach to Health Economic Evaluation

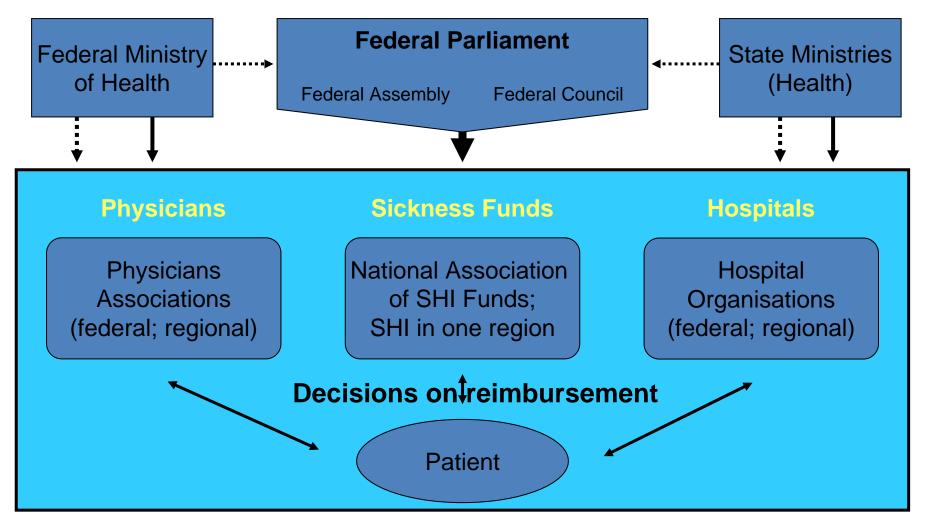
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November 5th, 2010

#### **Topics**

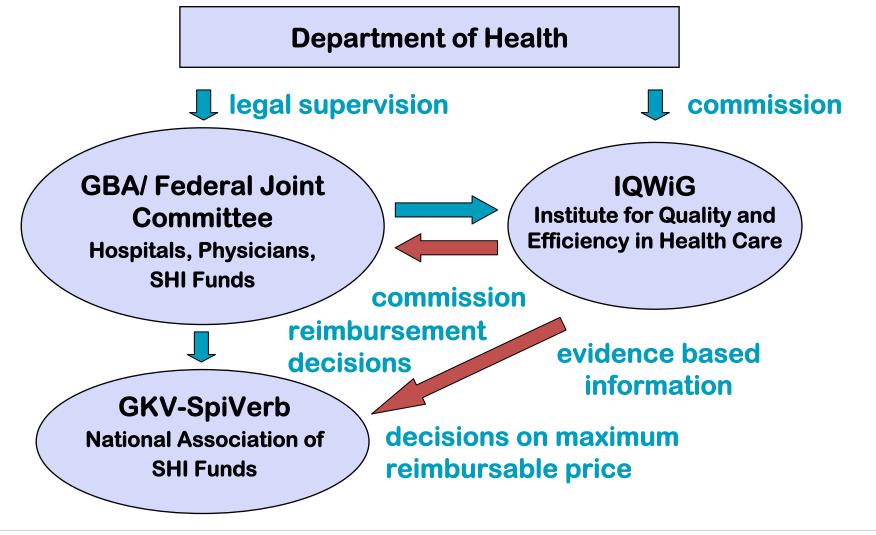
- Legal context of health economic evaluation in Statutory Health Insurance (SHI)
- IQWiG's benefit assessment
- Consequences for health economic evaluation
- IQWiG's method of the efficiency frontier and its implications

#### **Self Governance**



Adapted from Health Care systems in transition: European observatory on health care systems, WHO

#### Self governance in the German SHI





# Maximum reimbursable prices and reference groups in Germany

- After approval by the EMA or the national drug authority (BfArM), drugs are automatically reimbursed by the SHI at the price set by the pharmaceutical industry
- After the drug is on the market, the Federal Joint Committee can decide to include a drug in a reference price group
- Reference price groups comprise drugs with identical or comparable agents, or with comparable therapeutic effects, eg statins, proton pump inhibitors
- Reference price groups define reimbursement prices



#### **Decisions of the Federal Joint Committee**

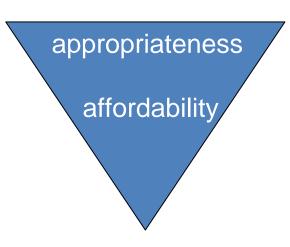
If a superior health technology cannot be included in a reference price group: The National Association of SHI Funds will decide about the maximum reimbursable price (CAVE: according to current law, changes with the new bill to reorganize the pharmaceutical market will come)

§35 b: IQWiG to provide the Federal Joint Committee (G-BA) with evidence based information to be used to decide on a maximum reimbursable price at which a health technology with additional benefit in a given therapeutic area should be reimbursed



#### **Balance Medicine, Ethics, and Economics**

SHI as constituency of insurees paying contributions



Pharmaceutical manufacturer(s)

Persons that are in need of a specific therapy/ drug (legal entitlement)

#### The resulting question/problem

- How can you warrant medical treatment for people who depend on it, and finance it
- lest the paying insurees should be overburdened with increasing contributions
- while at the same time a pharmaceutical manufacturer should be reimbursed an appropriate maximum reimbursable price (on the basis of the market situation in that therapeutic field)?
- Question/problem is not about allocation per se

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#### Patient-Relevant Trial Outcomes (Benefit and Harm)

- life expectancy (mortality)
- complaints and complications (morbidity)
- health-related quality of life
- intervention-related burden
- patient satisfaction

#### Aims of IQWiG's benefit assessment

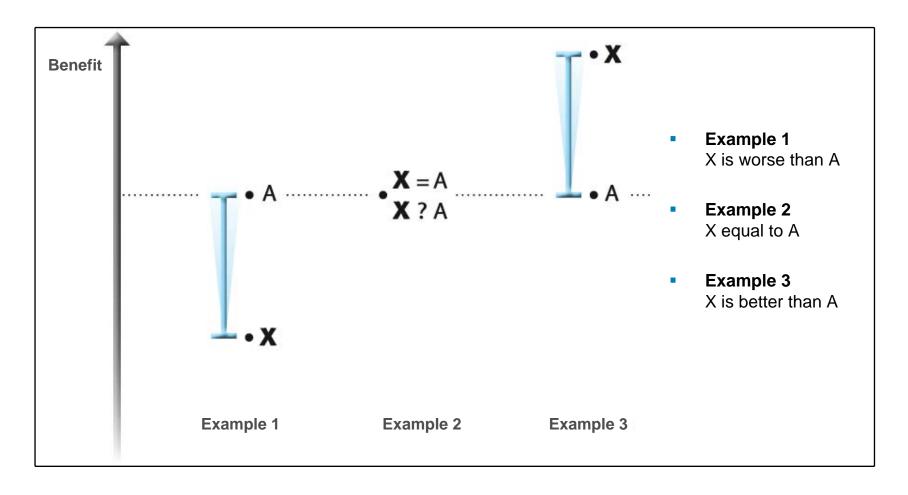
Comparison of an intervention with

- Placebo if no treatment is available
- Best available therapy currently on the market

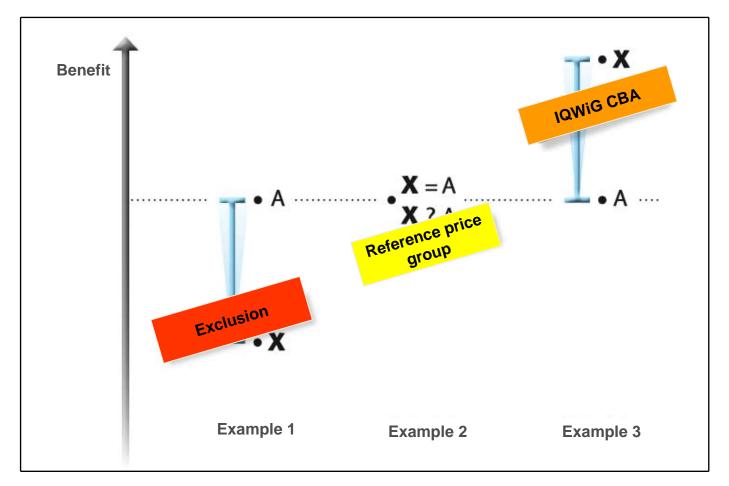
The benefit assessment has to follow the standards of evidence based medicine (§139a SGB V)

Fair comparison of alternatives in prospective randomized controlled trials

## Benefit assessment: comparison X vs. A



# Benefit assessment: comparison X vs. A



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#### Consequences for health economic evaluation

#### Health economic evaluation

- is for superior health technologies (proof of additional benefit by EBM methods in IQWiG's benefit assessment)
- takes place after the health technology is already on the market
- is aimed to optimize treatment in each therapeutic area
- meaning that it is performed solely within an indication
- is primarily aimed to support decisions around a maximum reimbursable price

New inferior therapies have no place in the system



#### Consequences for health economic evaluation

#### Health economic evaluation

- is performed primarily from the perspective of the community of the SHI insurees
- includes primarily costs that the community of the SHI insurees bear (directly, by fees for SHI)
- appropriateness and reasonableness of additional expenditures might be judged by a budget impact analysis (BIA)



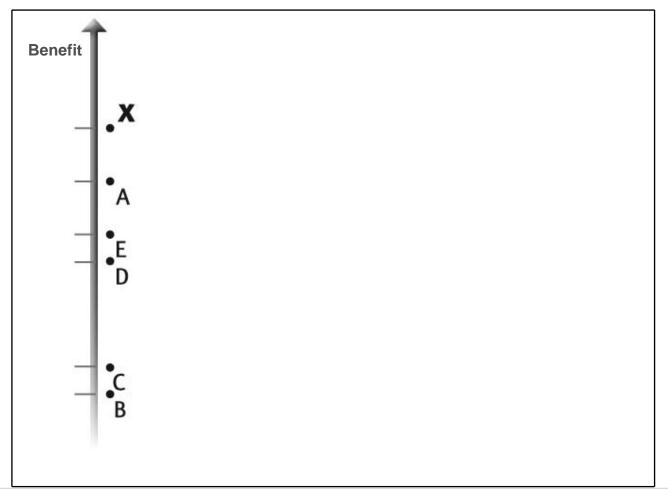
## Why not the QALY?

- No comparison across indications necessary
- Conceptual weakness of the QALY approach
- Can be one method for aggregation of different endpoints
- Could be presented in addition if requested by the decision makers
- However, the efficiency frontier per se is compatible with the QALY

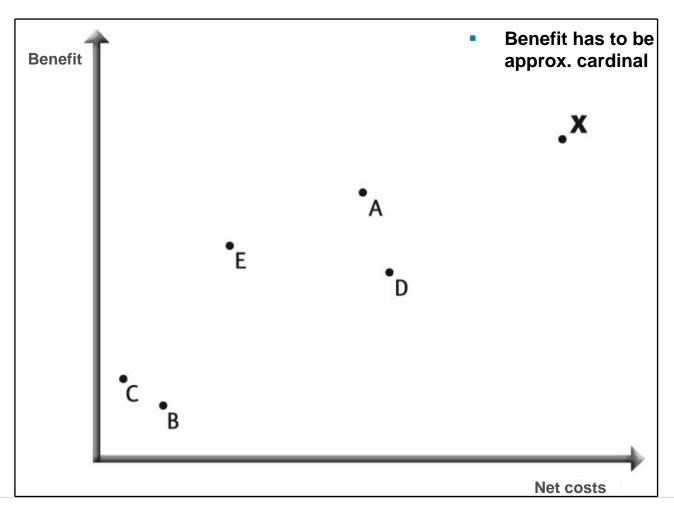
#### **Topics**

- Legal context of health economic evaluation in SHI
- IQWiG's benefit assessment
- Consequences for health economic evaluation
- Methodology of the efficiency frontier and implications

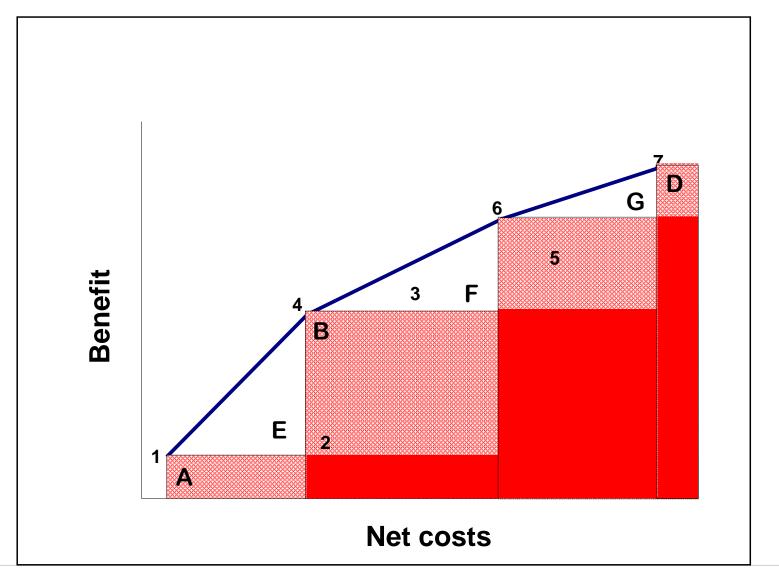
# **Example: Results of benefit assessment**



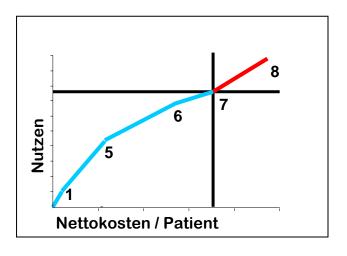
#### ... and additional evaluation with costs

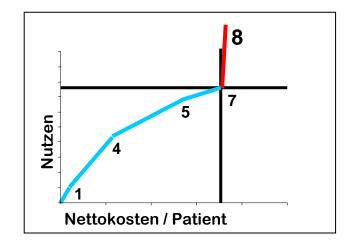


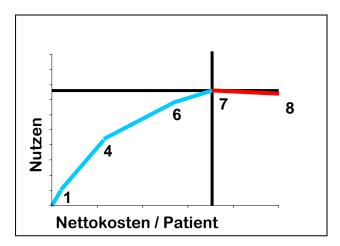
## **Absolute vs. Extended Dominance**



### **Various Efficiency Frontiers**

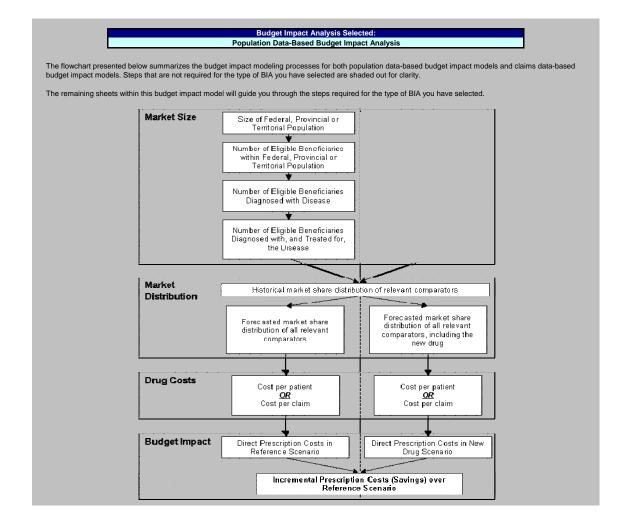






#### Three efficiency frontiers:

- Response
- Remission
- Health related quality of life





#### Take home messages: Strengths of the EF approach

- Value-based pricing: appropriate price
- Overview of the drugs in an indication with regard to cost-effectiveness
- Market like approach
- Highly transparent as aggregation follows upon plotting individual efficiency frontiers
- Combination with BIA allows to assess affordability of appropriate price



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