Methods
for Assessment of the Relation of Benefits to Costs in the German Statutory Health Care System

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Methods Document

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- 2 Basis for Economic Evaluation
  - 2.1 Introduction
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    » Concept
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  - 2.4 Decision Zones
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- Technical Papers
  - Details of EF, Modeling, Cost estimation.
Legal requirements embedded in the German legislation according to § 35b SGB V (Social Code Book V)

Purpose: Provide information to G-BA for the setting of ceiling price at which a superior health technology in a given therapeutic area should continue to be reimbursed

Follow international standards of health economics

No uniformly accepted international standard for doing so
  – Arbitrary - price cuts
  – Price controls
  – Profit controls
  – Value-based pricing.
Fixed expenditure limits have not been set in the German system
IQWIG’s mandate is to address benefits relative to costs for a given indication, not to set funding priorities across the health care system.
No Fixed Budget
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IMPLICATIONS
Approved health technologies adopted initially regardless of price
Evaluation takes place after health technology is already on the market
No basis for priority setting across therapeutic areas – concern is efficiency within a particular indication
Method takes a pragmatic approach aimed at setting ceiling prices in each intervention area.
This ceiling price represents the maximum that the Spitzenverband Bund der Krankenkassen (the national umbrella organization for the statutory health insurance funds) should pay for the benefits produced.

**IMPLICATIONS**

- Assessments primarily from the perspective of the community of **citizens** insured by Statutory Health Insurance (SHI)
  - Only costs born by citizens
    » by fees for the SHI or
    » directly
  - Out-of-pocket costs may be incorporated
- Citizens insured by the SHI must judge whether any additional expenditures are reasonable.
Health benefits to be considered in the economic assessment have been estimated already by IQWiG following its published EBM Methods

Only address health technologies judged superior

**IMPLICATIONS:**
- New “inferior” therapies have no place (even if less expensive than existing ones)
- New “equivalent” therapies not assessed – price equivalence
- Effectiveness component must reflect IQWiG estimates.
An efficiency frontier should be constructed for each therapeutic area as the basis for economic evaluation of relevant health technologies
- Reflects the “going rate” for benefits in a specific therapeutic area
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Efficiency Frontier

- Long history of use in economics (~1950’s) - Markowitz
Efficiency Frontier

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Efficiency Frontier

- Long history of use in economics (~1950's)
  - idea first introduced in finance
    » Markowitz Efficient Frontier is set of all portfolios that give highest expected return for given level of risk (Capital Asset Pricing Model)
    » becoming increasingly popular for evaluating relative performance in not-for-profit entities, hospitals, etc.

- Standard, accepted method
  - Underlies incremental economic evaluation
    » Cost-utility analysis
  - WHO Guidelines
  - PHARMAC (NZ) is considering an approach based on efficiency frontier framework
  - NICE (2005) recommends a similar method for prioritization
  - Oxfordshire Health Authority (UK) uses similar method.
**Figure 2** Efficiency frontier for lipid-lowering therapies: effectiveness measured using percentage reduction in LDL-C level. LDL-C, low density lipoprotein cholesterol; N, niacin (2.5 mg); CO, colestipol (4, 10, 15, 16, 20 mg); CH, cholestyramine (24 mg); F, fluvastatin (20, 40 mg); S, simvastatin (5, 10, 20, 40 mg); P, pravastatin (10, 20, 40, 80 mg); A, atorvastatin (10, 20, 40, 80 mg); L, lovastatin (20, 40, 80 mg).
Figure 3. Results of 10,000 Monte Carlo simulation evaluations of the gastroesophageal reflux disease (GERD) model presented on the cost-effectiveness plane. PPI = proton pump inhibitor; $H_{2}$RA = $H_{2}$-receptor antagonist; PA = prokinetic agent.
The efficiency frontier plot should be constructed so that it reflects the relevant health technologies in a given therapeutic area. This involves:

- Full, detailed specification of the therapeutic area at issue. This may include:
  - the specific disease,
  - the conditions of treatment (e.g., in hospital),
  - the intended patient population,
  - the therapeutic sequence (first, second, etc.),
  - whether it is mono- or combination therapy
- Establishing the costs of existing interventions and the value of the health improvement (“benefit”)
- Locating interventions on a coordinate system with the value of the benefits on the vertical axis and costs on the horizontal
- Drawing the efficiency frontier.
Absolute vs Extended Dominance

Value

Costs
Absolute vs Extended Dominance

Value

Costs

UBC
Absolute vs Extended Dominance

Value

Costs

A
B
C
D

1
2
3
4
5
6
7
Absolute vs Extended Dominance

Costs

Value

A

B

C

D

1

2

3

4

5

6

7
Absolute vs Extended Dominance
Absolute vs Extended Dominance

Value

Costs

A

B

C

D

1

2

3

4

5

6

7

Absolute vs Extended Dominance
Absolute vs Extended Dominance

- **Value**
  - A
  - B
  - C
  - D
  - E
  - F
  - G

- **Costs**
  - 1
  - 2
  - 3
  - 4
  - 5
  - 6
  - 7

- **Legend**
  - A
  - B
  - C
  - D
  - E
  - F
  - G
Interpreting the Slopes

Value

Cost

Positive Efficiency

1 2 3 4 5 6 7
Interpreting the Slopes

Value

Cost

Infinite Efficiency

Positive Efficiency

1

2

3

4

5

6

7

UBC
Interpreting the Slopes

- Positive Efficiency
- Infinite Efficiency
- No efficiency

Value vs. Cost graph with points labeled 1 to 7.
Interpreting the Slopes

Value

Cost

Infinite Efficiency

Positive Efficiency

Negative Efficiency

No efficiency

1

2

3

4

5

6

7

UBC
Recommendations - 3

- The vertical axis should reflect the health benefits assessed by IQWiG
  - The benefits should be parameterized in terms of the actual clinical measures
    » which may include quality of life scores, or
    » the likelihood of benefiting, or
    » a score integrating the consequences
  - The benefit must be transferred to the vertical axis measured on a cardinal scale that reflects how valuable that benefit is
  - This transfer may involve prognostic modeling to address the (longer) time horizon required for economic analysis and proper capturing of the full value produced.
Benefit vs Value

- New treatment for cancer
  - Increases time-to-progression from 6 months to 12 months
  - Is this benefit twice as valuable?

- New diagnostic test for inherited anomaly
  - Doubles the True Positive rate
  - Is this benefit twice as valuable?

- New vaccine to prevent severe infectious illness
  - Immunogenicity is doubled
  - Is this benefit twice as valuable?

- New therapy for chronic illness
  - Decreases the symptom score by 20 units compared to 10
  - Is this benefit twice as valuable?
Constructing the Frontier

IQWiGopathy

- Physiology
- Events (e.g. Premature deaths prevented)
- Duration (disease-free time)
- Function
- QOL
- Responder
- Score
Constructing the Frontier

IQWiGoPathy

Existing Therapies

Benefit
Constructing the Frontier

IQWiGopathy

Benefit

Existing Therapies

Superior
Total net costs per patient should be plotted on the horizontal axis

- The costs should be estimated from the perspective of the community of German citizens insured by the SHI
- The time horizon should be sufficient to cover the majority of relevant costs
- The costs should be the actual ones that are expected to accrue.
Constructing the Frontier

IQWiGopathy

Value

Total Cost (/pt)

Existing Therapies

1 2 3 4

5 6 7
Constructing the Frontier

IQWiGopathy

Value

Existing Therapies

Total Cost (/pt)
Constructing the Frontier

IQWiGopathy

Incremental

Value

Existing Therapies

Total Cost (/pt)
The area of superiority is demarcated by the horizontal line intersecting the point of the intervention that gives the most value.

The area of higher costs is demarcated by the vertical line that intersects the most expensive therapy.

- In the decision zone indicating superiority, prices that yield costs lower than the highest prevailing one should continue to be reimbursed at the prevailing price (and they redefine the efficiency frontier).
- Prices that indicate higher costs, efficiency:
  - better than all existing ones, continue to be reimbursed at the prevailing price (if judged affordable).
  - less than the lowest efficiency, price should be reassessed.
  - in between, prevailing pricing may be appropriate.
Decision Zones

Total Cost (/pt)

Value

Existing Therapies

Superior
Decision Zones

Existing Therapies

Total Cost (/pt)

Value

Superior
Supermarket
Purchasing Cheese

We have a new Cheese

Is it Better?
Purchasing Cheese

Very superior – twice as good!

How much?
Purchasing Cheese

We have a new Cheese. Is it better? Very superior – twice as good!

How much? Only 10% more!
The NICE Supermarket

CALI

€/CALI
The NICE Supermarket
Define Therapeutic Area ➔ Select Interventions ➔ Identify Consequences ➔ Estimate Benefits

Translate Benefits to Good ➔ Benefit on Cardinal scale?

Vertical Axis ➔ Plot Efficiency Frontier

Economic Evaluation ➔ Estimate Costs ➔ Horizontal Axis
Some Criticisms

- Does not follow established economic methods
  - “Where’s the QALY”?  
- No comparison across intervention areas
  - May lead to “inconsistencies” across areas
- Two step approach with benefit measurement first is inappropriate
  - EBM limits Benefit (e.g., compliance)
  - Superiority not essential
- Accepts historical funding decisions
- Perspective should be “societal”
- Not “incremental” approach
- Uncertainty not addressed
- Doesn’t provide an incentive for pharma to invest.
External Willingness to Pay

Value vs. Total Cost (/pt)
Challenges

- Quantification & valuation of benefit
- Actual vs theoretical benefits & costs
- Differing uses and populations
- Non-linear expansion paths
- Feasibility.