Comparative cost-benefit: Germany goes IQWiG style

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Delegation = State only defines legal framework

Ambulatory

Inpatient

Physician

17 (Regional) Physicians’ Associations

Federal Parliament

Federal Ministry of Health

Proposals for health policy actions

State Ministries responsible for health

Federal Assembly (Bundestag)

Federal Council (Bundesrat)

Federalism

Sectorisation

Federal Joint Committee (since 2004)

Federal Office for Quality Assurance

Institute for Quality and Efficiency (IQWiG)

Statutory health insurance early 2007
But regulatory institutions and programmes become trans-sectoral …

Members: 9 sickness funds
9 providers
3 neutral
+ 9 patients (no voting rights)

Members (1.7.08):
5 sickness funds
5 providers
3 neutral
+ 5 patients (no voting rights)
### Criteria for Assessment and Decision-Making

**Criteria**

| Criteria                                | A | T | U | B | E | C | A | H | E | D | F | I | R | N | H | O | N | Z | S | E | U | K |
| Therapeutic benefit                    | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Patient benefit                        | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Cost-effectiveness                     | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Budget impact                          | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Pharmacological/innovative characteristics | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Availability of therapeutic alternatives | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Equity considerations                  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Community need                         | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Public health impact                   | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| R&D                                    | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Government priorities                  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

Since 1 April 2007

Zentner/Velasco Garrido/Busse 2005
Legal requirements embedded in the German legislation according to § 35b SGB V (Social Code Book V)

Purpose: Provide information to Federal Joint Committee for the setting of ceiling price (actually: reimbursement rate) at which a superior health technology in a given therapeutic area should continue to be reimbursed

Follow international standards of health economics

But: no uniformly accepted international standard for doing so

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

IMPLICATIONS

Approved health technologies covered initially regardless of price

Evaluation takes place after 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 sickness 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 contributions to SHI or
    - directly
  - Out-of-pocket costs may be incorporated
- Citizens insured by 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.

**IMPLICATIONS:**
- New “inferior” therapies have no place (even if less expensive than existing ones)
- New “equivalent” therapies not assessed – reimbursement equivalence
- Effectiveness component must reflect IQWiG estimates.
Recommendations - 1

- 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

![Efficiency Frontier Diagram]

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.
Efficiency Frontier (Markowitz)

WHO
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

Existing Therapies

• Physiology
• Events (e.g. Premature deaths prevented)
• Duration (disease-free time)
• Function
• QOL
• % Responder
• Score (incl. QALYs)

CAVE: Cardinal Scale
### Recommendations - 4

- 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 SHI *(not: “theoretical ones such as ill-defined ‘society’”)*
  - 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.

### Estimation of costs

- Insured costs (“direct medical”) should be the main type of expense considered in economic evaluation carried out on behalf of IQWiG
- Health care costs not covered by insurance (“direct non-medical”) can be included if they are a major component in a particular therapeutic area
- Indirect costs should not be included (at least not as “costs”)
- Identifying the resources that are to be included in the costs requires specifying the perspective, selecting a time frame for the analysis and determining the cost centres. Expert opinion may be valuable in these tasks.
- Quantification of consumption of resources must be based on actual data that are credible and relevant. Expert opinion is not to be used for this task.
- Either micro-costing or a top-down approach can be used to value resources but the choice must be carefully justified given the therapeutic area. …
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, if efficiency:
  - [A] better than all existing ones, continue to be reimbursed at the prevailing price (if judged affordable).
  - [B] less than the lowest efficiency, price should be reassessed.
  - [C] in between, prevailing pricing may be appropriate.
Decision Zones

- **Superior**

Total Cost (/patient)

Value

- **Existing Therapies**

### Process

- Efficiency frontier proposal was elaborated by IQWiG with the help of an international advisory board (and especially its chair, Jaime Caro)
- German health economists were alienated by this and strongly opposed proposal when it was published in early 2008
- They are supported by pharmaceutical industry, both pointing to “missing orientation along international standard” (actually they seem to mean NICE’s procedure)
  - > founding of German Society of Health Economics (with strong industry involvement)
  - > IQWiG has invited some German health economists to a new advisory board
International experts advising IQWiG

Vincenzo Atella  University “Tor Vergata”, Rome
Gérard de Pouyourville  ESSEC Business School, Cergy
David Henry  University of Newcastle/ ICES
Maurice McGregor  McGill University, Montreal
Alistair McGuire  London School of Economics
Erik Nord  Norwegian Institute of Public Health, Oslo
Uwe Siebert  UMIT, Hall in Tirol
Jaime Caro  UBC, Concord (CHAIR)

The IQWiG Supermarket
Purchasing Cheese at IQWiG Supermarket

How much?

Only 10% more!

The NICE Supermarket

CALories

€/CAL
Current challenges

Proof is in the pudding

- Quantification & valuation of benefit (including existing technologies)
- Dealing with different outcome dimensions (especially if cost-benefit ratios differ)
- Actual vs theoretical benefits & costs (merging study with actual data)
- Differing uses/indications and populations
- Feasibility, costs, expertise ...
- Role of data provided by industry?