

## **IQWiG: an opportunity lost?**

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There is a need for more and better information for private and public decisions about health technology. The development of health technology assessment (HTA) and economic evaluation are responses to this. Most European countries have established institutions to meet this need, but with few exceptions their impact on the allocation of resources has been limited. One of the reasons for this is that the economic aspects have been neglected in the studies that have been conducted.

Germany is a good example of this. Health policy, when it comes to the economic aspects, has since decades been dominated by cost-containment acts with limited, and sometimes dysfunctional, effect on resource allocation. The German agency for HTA at DIMDI (<http://www.dimdi.de>), established in 2000, has produced many reports but with limited policy impact. The creation of the Institute for Quality and Efficiency in Health Care (IQWiG; <http://www.iqwig.de>) in 2004 was timely and welcome for several reasons. First because it was part of a new legislation aimed at improving the efficiency in the health care system. The purpose of the creation of IQWiG was to provide information for decisions about what should be funded within the statutory health insurance system, covering 90 per cent of the German population. Second, IQWiG was created as an independent body, which made it possible to give unbiased advice to the decision makers. Third, the mandate covered all health technologies, not only drugs. However, for some reason it was decided in the law that drugs should be assessed for benefits only and not cost-benefit. The drawbacks of this exception became

obvious with the publication of the first methods paper (1), and the law was readily changed. The revised legislation, the German health care reform effective, 1 April 2007, also stated that the methods for cost-benefit analysis (“kosten–nutzen analyse”) should be based on “international standards”.

For the revision of the methods paper IQWiG commissioned an international group of experts, under leadership of a consultant from the US. While this was a rather surprising step, taking into account the number of qualified health economists that can be found in Germany, you would at least expect that the resulting publication would reflect the international standard in the field. The publication of the new guidelines is therefore a great disappointment (2). Not only because the document fails to give any guidance for the use of economic evaluation to support health policy decisions in Germany, but also because it pictures health economics, and economic evaluation in particular, as a subject totally void of theory and method.

It is initially stated that there is no health care budget in Germany. That may be correct or incorrect dependent on the perspective, but it is simply irrelevant for the role of economic evaluation for health policy. The important introductory statement is that resources for health technologies are scarce in Germany as in all other countries, regardless of how the health care system is organized and financed. What is important in the German situation, similar to other countries with health insurance systems, is that it is not any more possible to increase contributions from employers, and that an increasing part of health care financing comes from general taxation. The methods paper thus fails to educate the payers, providers and patients about the choices they face and the potential contribution of health economics to achieve value for money.

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The guideline document also states that the purpose is to set “ceiling prices” for drugs. If economic evaluation should be used for setting prices, it should be done for all inputs in the production of health, hospital stays, doctors fees, etc, and not only drugs. But there is great confusion as to what is meant by ceiling prices. One interpretation is that it is reference prices, over which the patients has to pay the extra cost. This would create great inequalities, for example for access to new cancer drugs. Another interpretation is that the ceiling price represents the willingness to pay by the Statutory Health Insurance for a specific treatment. But the WTP varies with the quantity (indication). Different prices will give different distributions of consumer and producer surplus; i.e. the value above the price paid and the difference between price and cost, respectively. A lower price increases the consumer surplus, but also reduces the producer surplus. The price will therefore also impact incentives for innovation. There are a growing number of studies aimed at estimating the distribution between consumer and producer surplus of new drug innovations. These studies indicate that the producer only gets a small part of the total consumer surplus generated by pharmaceutical innovation. It would be ambitious if this was the purpose of setting ceiling prices for drugs in Germany, and probably not what the authors mean.

Economic evaluation is neither sufficient nor necessary for setting prices. The managers of the insurance system who see their role as “setting ceiling prices” will only see the guidelines and the information provided according to them as an unnecessary distraction. The authors have thus, probably without understanding it, given its clients (the G-BA, the health Insurers, and the Federal Ministry of Health) good arguments against using economic evaluations as guidance for reimbursement decisions. Economic evaluations can provide information about value for money, and thus effect how resources are allocated. This may have an influence on prices, but most important, also on the quantities.

The guidelines focus on assessment within defined indications. This is correct but presented as if it was something new. A drug or other health technology can never be cost-effective in itself; only within a specific indication in relation to a specific alternative.

Also the concept “efficiency frontier” from portfolio theory is an unnecessary and confusing introduction to the methods. This concept was used by Markowitz to define portfolios of assets that give the highest return for each level of risk. It was essential for the development of the Capital Asset Pricing Model, which is used to determine the value or price of an asset when added to an already well diversified portfolio. While this represents pioneering work in theory of financial economics, and Markowitz, Miller

and Sharpe were awarded the Nobel Memorial Prize in Economics in 1990, the relevance of this concept for reimbursement decisions is not obvious and never developed in the methods paper.

Instead, the concept is used in the methods paper as a production or cost function to sort out inefficient alternatives; i.e. alternatives where you can find other treatments with better outcomes for the same level of input or cost. This is always included in an economic evaluation. When comparing several alternatives, those that are dominated by others will be sorted out and there are defined decision rules for that (3). The problem is that the guidelines are written in a way that they indicate that the valuation of the incremental benefits can be restricted to and undertaken within a specific indication. Someone with only limited knowledge in the methods of economic evaluation will be tempted to calculate average cost-effectiveness ratios on clinical measures and make conclusions, most often misleading, from them.

There are several other confusing components of the guidelines, for example the definition of indirect costs and the absence of a clear standing on the important issue that a social perspective is relevant in Germany where the statutory health insurance covers both health care and income losses. The law also states that it is the consequences for the insured population that should be considered, not only their “insured costs”. While some of these mistakes can be corrected in future revisions, the leadership from IQWiG and its international methods group is lost.

The IQWiG approach to using economic evaluation to improve decisions about reimbursement and funding of health technologies invites some conclusions. The first is that economic evaluation in Germany is still not seen as a valuable instrument by decision makers. If there is no demand for relevant high quality studies, no such studies will be undertaken. The pharmaceutical industry and other innovators are left in uncertainty what studies to undertake. A lot of money will be spent on meaningless studies which try to find out “what IQWiG wants”, and there will be a consultancy market for guideline economics, but no real improvements in method and data. But most important, an opportunity for improving quality, outcome and efficiency in the in the German health care system is lost.

Seen in a European perspective the most important conclusion is that a potential leadership from Germany is lost at a time when important decisions must be made on how to coordinate regulatory and reimbursement decisions in the European Union, in order to continue the development towards a common health care market. Apart from the important goal of creating equal access to treatments in Europe, such coordination is also important for the future

of the European industry. Common efforts are now made in basic research through the funding by the EU of a common technology platform, but at the same time we can observe that clinical trials are moving to Asia. More clinical research, including assessment of impact of new technologies for patients and health care systems in Europe is needed for the development of both the health industry and the health care systems, but without rational and supportive decisions on reimbursement and funding this will not happen.

1. IQWiG Methoden, version 2.0, 2006. English translation 22 January 2007 (<http://www.iqwig.de>)
2. IQWiG Methods for Assessment of the Relation of Benefits and Costs in the German Statutory Health Care System, version 1.0, 2008 (<http://www.iqwig.de>)
3. Karlsson, G., Johannesson, M.: The decision rules of cost-effectiveness analysis. *Pharmacoeconomics*. **9**(2), 113–120 (1996)

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