



A HEALTHY MARKET?

Health Technology Assessment in the UK and Germany

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STOCKHOLM NETWORK

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Executive Summary

This paper examines the role and operation of Health Technology Assessment (or HTA) in the UK and in Germany. In both countries, health expenditure is constantly rising, yet tax revenues cannot be increased without the likelihood of incurring harmful economic side-effects. Within the given political consensus, which views health care as a public good, prioritising the use and reimbursement of medicines and treatments through HTA appears to be a non-arbitrary alternative to rationing by political bodies.

In this context, in 1999, the UK set up the National Institute for Clinical Excellence (NICE), now renamed the National Institute for Health and Clinical Excellence. Germany followed suit in 2004 with the Institute for Quality and Efficiency in Health Care (IQWiG). Both institutions pursue different strategies with different outcomes. NICE has generally portrayed itself as a technical evaluation body, IQWiG as a counterweight aimed at limiting the influence of the pharmaceutical industry. NICE has a wider scope than IQWiG, greater responsibilities, and tools for implementing its findings in practice.

Both institutions have aroused controversies. IQWiG has often been accused by producers and doctors' groups of using an arbitrary methodology. NICE has been criticised for focussing excessively on cost cutting, but some professionals have also demanded it should be endowed with much wider powers. Both countries have chosen intermediate positions between the two theoretical polar opposites of health care policies either entirely run by politicians, or conversely health care policies solely run by an autonomous professional body.

Operational issues of scientific rigour, methodological soundness and transparency can be improved, and most likely they will be addressed to some extent in Germany, in the course of the latest health care reform. But even the best implementation cannot alter the fact that HTA is a very rough tool. It is necessarily based on average values, standardisation and generalisation. It should be used much more flexibly, but within a public health care monopoly this can be done only in a very imperfect way.

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Introduction

Can there be such a thing as an “evidence-based health care policy”? Can health care policy be removed from the sphere of party politics, election campaigns, emotional debates and vested interests, and instead be performed on the basis of scientific evidence, professionalism and objective facts? This appears to be the premise behind the growing importance of the public use of Health Technology Assessment (HTA) throughout the developed world.

In the introductory paper to the Stockholm Network’s series of papers on HTA, Pugatch and Ficai (2007) explained what HTA is and why it has evolved, and pointed to the gap that exists between HTA-theory and its actual performance. The authors defined HTA as the generation of “evidence-based tools for prioritising health care treatments in terms of their utility, efficiency and cost-effectiveness”. They describe its evolution as motivated both by phenomena exogenous to the configuration of health care systems, namely “the rapid growth of medical technology and the increasing volume of new knowledge”, but also as “a logical policy tool [...] [a]ssuming a state-centric approach and within publicly funded health systems”. In the subsequent paper of the series, Pugatch and Davison (2007) found that the role and design of HTA bodies is largely a function of the institutional environments of the health systems they operate in. Particularly, they found that in health systems which are almost exclusively under state control, HTA bodies were set up earlier and had wider powers than in more decentralised systems.

This paper will build on these findings by comparing the main HTA institutions in two countries with very different health systems, and, accordingly, two very different HTA bodies. Britain’s National Institute for Health and Clinical Excellence (NICE) was set up in 1999, in the context of a strongly centralised health system where government is the prime funder and a key provider of health care. The German Institute for Quality and Efficiency in the Health Care System (IQWiG) was set up in 2004 in an environment in which key actors in the health system are organised around the principle of self-government. Both institutes have been subject to criticism, which is not surprising given the often unpopular nature of the recommendations they

have to make. But NICE has also won much support from professional societies, which IQWiG has largely been lacking.

A Brief History of the Financing of Health Care Systems in the UK and Germany

Historically, health care systems have evolved very differently in Germany and the UK. Until the late 19th century, the funding of health care in both countries was mainly performed by cooperatives, trade union schemes and out-of-pocket payment. Germany took a different road as early as 1883, when the public sickness fund system was created and existing institutions were gradually absorbed. At the outbreak of World War I, half of the population were already covered by a public sickness fund, a proportion which increased to 85% - 90% until the early 1960s and has remained at these levels since then¹. About 10% of the population are fully privately insured.

In Britain, comprehensive public funding of health care began much later, but was enacted more quickly. The National Health Service (NHS) was founded in 1948 and quickly became the main funder of most health care services. There are important differences in the organisation of health care in both countries. While the NHS is tax-financed and access is universal (a so-called 'Beveridgean System'), German sickness funds are financed from wage-related contributions and bear some similarity to insurance companies (a so-called 'Bismarckian System'). The funds do not own any facilities but only reimburse, while the NHS runs most British hospitals. Therefore, there is a full separation of funding and provision in Germany, and a partial integration of both in Britain.

Health care spending as a proportion of GDP has traditionally been very high in Germany and comparatively low in the UK. The gap has become narrower in recent years, with an increased priority put on health care spending in the UK since 1997. Today, spending amounts to 10.7%

¹ Oberender et al (2002) p. 28

(Germany) and 8.3% (UK) of respective GDP², of which 77% and 87% respectively come from public spending.³

Both countries have a number of common features. Despite differences in the overall level of health spending, both display a long-term rise in health care expenditure. Both countries are experiencing a rising old-age dependency ratio (the number of retirees to the working population) while their health systems did not set up reserves.

In both countries, health care services are free or almost free at the point of use. That changes the behaviour of customers and thus of providers. Not only is there a general incentive for an overconsumption of medical services, but also a reduced incentive to replace a given medical product, service or organisational pattern with a lower-cost alternative⁴. In other economic sectors, innovation drives up costs by adding new products and services to established ones. But it also lowers costs, by substituting established products and services with more efficient ones. Health care, in contrast, appears as “free” from an individual’s perspective, so there is little reason for demanding lower-cost technologies or procedures. Consequently, fewer of them are introduced. Providers compete less on price, but rather in terms of modern equipment, so most innovation has been additive, not substitutive.⁵

The trend toward rising costs is exacerbated by the scarcity of competition in health care provision and funding in both countries. On the provision side, most British and German hospitals are state-owned and do not compete for patients. On the funding side, the NHS is a monopoly/monopsony organisation⁶, and German sickness funds only compete in a very limited

² OECD Health Data (2007) Chart 3

³ OECD Health Data (2007) Chart 5

⁴ A notable exception is the replacement of branded by generic drugs. But drug usage is nonetheless no general exception to the tendency described above. Practices like negotiating allowances with producers are underdeveloped in both countries.

⁵ Oberender et al (2002) p. 56 & 135

Breyer et al (2005) p. 509-517

⁶ The NHS is a monopoly from the perspective of its patients who cannot switch to a “rival NHS”. It is a monopsony from the perspective of medical providers, who cannot sell their services to a “rival NHS” instead. In general, the only way to exercise choice is to go outside the system altogether and into the private market.

sense. They negotiate collective contracts with all doctors, hospitals, and producers of pharmaceuticals, medical technologies and devices. There is thus no competition over efficient purchasing of medical products and services.

In the UK, as in Germany, simply accepting this tendency towards rising health expenditure and adapting to it by increasing revenue is not an option, or is only possible to a limited degree. Being financed by wage-related contributions and/or taxes, increases in rates directly affect the cost of labour and thus employment, which form the systems' financing base. Raising rates can lead to higher unemployment and thus decrease revenue instead of raising it. As a result, health policy in both countries has increasingly focused on cost containment. Costs can be contained in various ways. One could be a stronger reliance on the private sector and competition to increase efficiency, which has been the rationale between measures like the “purchaser-provider-split”⁷ in the UK and the easing of switching between sickness funds in Germany. But these approaches have been limited because in both countries, there is a strong belief that health care should not be bought and sold on markets like other goods. Another possibility would be a freezing of budgets and/or an exclusion of expensive treatments by deliberate political decisions. But that would mean the introduction of random rationing, based on other criteria than objective evidence.⁸ In this context, HTA appears to be a non-arbitrary means of limiting expenditure within the given political consensus.

Other arguments for strengthening HTA, more pronounced in the UK than in Germany, have been widespread and systematic geographical variations in the use of medical technology and pharmaceuticals (sometimes labelled “postcode prescribing”⁹).

⁷ The term purchaser-provider-split describes the situation which occurs when a service paid for by the NHS, but provided by a private medical supplier.

⁸ Maynard et al (2004)

⁹ for example Cookson et al (2001) p. 744

HTA in the UK and Germany

HTA became important much earlier in the UK than in Germany, and still plays a greater role in terms of funding and scope. NICE, founded in 1999, has 240 employees and an annual budget of about £20m.¹⁰ IQWiG was founded in 2004, has 60 employees and a budget of £8m.¹¹ Both receive their assignments from their respective ministries of health. NICE and IQWiG are not the only institutions carrying out HTA-related research. In the UK, the Department of Health, the NHS and the Medical Research Council also run their own HTA research programmes.¹² NICE is a part of the NHS, and is mainly active in England and Wales. Scotland has an HTA body of its own, the Scottish Intercollegiate Guidelines Network (SIGN). The German Institute of Medical Documentation and Information (DIMDI), a downstream agency of the Ministry of Health, operates an agency for HTA (DAHTA@DIMDI) which commissions external experts with studies and documents the findings in public databases. IQWiG can be a constituent of DAHTA.¹³ There are other smaller HTA-bodies, and some observers have criticised the lack of coordination between them.¹⁴

Apart from the larger budget and personnel, NICE receives greater media coverage and is far more widely known than IQWiG. According to one survey, 34% of the British people know about NICE¹⁵, a fairly high rate for a technical body. Similar surveys are, to the author's knowledge, not available for the German case, but one could expect the number of people who have ever heard of IQWiG would be much lower. Of the bigger newspapers, the *Frankfurter Allgemeine Zeitung* has mentioned IQWiG in 30 articles from 2004 to this date, the *WELT* in 16, the *Sueddeutsche Zeitung* in 3 and the *Frankfurter Rundschau* on only one occasion.¹⁶

¹⁰ NICE (2004) p. 3

¹¹ IQWiG (2007) p. 24

¹² Sainfort (2005) p. 27/28

¹³ DIMDI (2007)

¹⁴ AvaMed (2005) p. 6

¹⁵ NICE (2007)

¹⁶ www.faz.net, www.welt.de, www.sueddeutsche.de, www.fr-online.de (2007)

The Rationales of NICE and of IQWiG

Internationally, the reasoning behind the adoption of HTA is a perceived lack of evidence-basing and scientific rigour in medical decisions, both at the policy and the practice level. This does not automatically mean that there is a general overuse of new medical means, but rather a random diffusion. According to this definition, there could be simultaneous underuse of some and overuse of other medical technologies.¹⁷ However, as Pugatch and Davison point out, HTA institutions often focus on the cost-containing aspects¹⁸, which contradicts the theoretical intuition on which they are based.

The tendency towards cost-containment has clearly been visible in Germany, whereas in the British case it is less clear. As the Department of Health declares, one of the factors behind the creation of NICE was the “slow and inconsistent uptake of new treatment”¹⁹, so NICE has not been directly set up as a cost-cutting agency. The fact that NICE recommendations are automatically binding for NHS organisations when they are positive, but not so when they are negative, is a further argument against viewing NICE as a pure cost-cutter. Of the 86 recommendations NICE gave between 1999 and 2005, 19% have been classified by the British Medical Journal as an unequivocal “no”, 32% as a “yes, but with major restrictions”, 26% as a “yes, but with minor restrictions”, and 23% as an unequivocal “yes”. Of the “no” recommendations, about two thirds were justified by insufficient medical evidence whilst one third of the negative decisions were based on consideration of their cost-effectiveness ratio. Restrictions in the recommendations, when given, were mostly aimed at changing utilisation practices in such a way as to raise cost-effectiveness.²⁰

IQWiG only began to assess cost-effectiveness in April 2007, in the course of Germany’s most recent health reform. Before then, its official duty was to compare various interventions with one another, without addressing cost issues. Chairman Peter Sawicki explicitly outlined this

¹⁷ OECD (2005) p. 19

¹⁸ Pugatch & Davison (2007) p. 15,16

¹⁹ Department of Health (2007)

²⁰ Raftery (2006)

feature in order to distinguish IQWiG from NICE: “Contrary to the British NICE, IQWiG’s prime concern is quality. Costs only come into focus when two methods or two drugs lead to the same result and are equally good.”²¹ Critics of IQWiG such as the health economist Harald Schweim have expressed strong doubts about this self-portrayal. In IQWiG’s legal statutes, the appraisal of “drugs that are administrable for the first time and contain patent-protected agents”²² is especially highlighted. Schweim criticises the fact that these two features of a drug (being new and patented) have nothing to do with its quality, but are rather associated with high costs. IQWiG-chairman Peter Sawicki has also stressed in an interview that “in any case, the number of drugs is too high”²³, which is a very different outlook to the possibility of simultaneous over- and underuse.

The Strategies: Cooperation or Confrontation?

NICE generally portrays itself as a technical body, not as a political one. It does not pursue an explicit agenda. Therefore, even if its relationship with the pharmaceutical industry is not necessarily a harmonious one, NICE can still endorse a cooperative style. For example, industry representatives are regularly invited to its workshops preceding an appraisal, where participants agree on a methodology before the actual process begins.²⁴

The relationship between IQWiG and the pharmaceutical industry (as well as with some medical associations as will be explained below) has been a much tenser one. IQWiG has endorsed a very confrontational style. Chairman Sawicki has repeatedly made clear in media interviews that he regards most medical innovation as useless²⁵, existing information sources as biased, and that he views the role of his institute as to correct this flaw. According to Sawicki, “the pharmaceutical industry views Germany as a self-service outlet”²⁶ and “the pharmaceutical

²¹ Sawicki quoted in Schweim (2005), translation mine

²² German Code of Social Law (SGB), §139b para. 1&2

²³ Sawicki quoted in Schweim (2005) p. 14, translation mine

²⁴ Aerztezeitung (2007)

²⁵ Sawicki exact statement was that at most one third of all new approved drugs worldwide were true innovation, see Wirtschaftswoche February 21st 2007

²⁶ Wirtschaftswoche, February 21st 2007

industry is always present in the doctor-patient-relationship. It influences almost every prescription”²⁷. In another interview, Sawicki stated: “Also the internet, where patients search through Google for a lot of things nowadays, mainly delivers pharma-driven information. People just don’t always realise that.” In the focus of his criticism are so-called “me-too-products” that, in his view, companies develop not because they represent an improvement over the predecessor, but because the predecessor’s patent expires and its profitability subsequently falls.

Producers and the medical community have criticised the occasions when these premises have influenced IQWiG’s strategy. When IQWiG was commissioned with appraising anti-dementia drugs, Sawicki described them as “useless” in a media interview even before the appraisal had begun.²⁸ What producers found especially frustrating were Sawicki’s statements about Vioxx, an anti-rheumatic drug that its producing company had taken off the market after discovering heavier side-effects than expected. Sawicki speculated that it had caused at least 2,700 strokes, thrombosis and heart attacks, and that many of these patients had certainly died. But exact numbers on Vioxx were never available, and as such it was unknowable which medication people would have taken and how they would have reacted under different circumstances.²⁹ The doctors’ journal *Aerztepost* goes as far as reckoning that IQWiG’s true purpose was not scientific assessment but “a crusade against modern pharmaceuticals and their producers”.³⁰

Implementation: Does HTA Matter?

While funding for HTA research is growing in most OECD countries³¹, the volume and scope of such activities tells us little about their actual impact. Results from studies and surveys about the importance of HTA in health care decision-making are ambiguous. As a report of the OECD Health Project has pointed out, some studies suggest that there are countries in which

²⁷ Sawicki quoted in Schweim (2005) p. 15, translation mine

²⁸ Schweim (2007)

²⁹ Schweim (2005) p. 19

³⁰ Kron, quoted in Schweim (2006) p. 15, translation mine

³¹ OECD (2005) p. 48

lots of HTA information is produced, but little of it is ever made use of.³² This is true at the micro-level (e.g. hospitals), but the authors also mention that “the rate of diffusion of technology in itself [will not] necessarily be of great interest to policy makers”.³³

The UK and Germany differ from one another in this regard. Consistent with its greater overall emphasis on HTA, the UK has gone farther in giving NICE concrete tools for implementation. Foremost, since 2002, NHS organisations have to provide funding for drugs and procedures that NICE has recommended. When a NICE approval has been published, the NHS has three months to adapt its practice.³⁴ NICE also runs its own implementation programme to boost compliance. IQWiG’s findings, in contrast, are not binding on anyone. Decision power over reimbursement lies with the federal joint committee (GBA), which commissions IQWiG and considers its recommendation, but IQWiG has no tools on hand to take this forward.

Not much, but some empirical evidence on the implementation of HTA results is available. Sheldon et al (2004)³⁵ have examined the impact of NICE recommendations on medical practice. For interventions that have been appraised by NICE, the authors have looked at whether there was trend in their performance numbers and checked whether the publication of the NICE report has been followed by a break in this series.³⁶ Where NICE recommendations were not simply a “yes” or “no” but rather referred to a specific use, the authors have questioned senior medical staff and patients and thus derived the proportion of treatments that followed NICE recommendations. Sheldon et al find mixed results. There have been cases where medical practice differed from the NICE recommendation, or where it has been in accordance but probably not so **because** of the NICE recommendation. For example, there has been a decline in the number of wisdom teeth removals just as the NICE report recommended, but that merely continued a trend which had set in well before the publication

³² OECD (2005) p. 38-40. Other studies find that HTA-recommendations did have a large impact in Sweden, Canada and the UK.

³³ OECD (2005) p. 42

³⁴ NICE (2005) p. 9

³⁵ Sheldon et al (2004)

³⁶ More precisely, Sheldon et al have modelled the number of interventions as an Autoregressive Integrated Moving Average (ARIMA) process with the publication of the NICE report as a dummy variable.

of the report. There were, however, cases where NICE recommendations seemed to have had a visible impact. The authors conclude that NICE guidance has been most successful when it was widely approved within the medical community. It also made a difference whether recommendations were straightforward and easy to implement, or whether they referred to more complex procedures involving, for example, a larger network of practitioners. But still, the study shows that HTA sometimes has an impact on health care decision making in the UK, albeit perhaps not as much as intended by NICE. Roughly speaking, NICE has an impact on the prescription of drugs, limited impact on the use of technologies, and little impact on the use of devices and procedures.

There is less evidence for the German case. A DAHTA@DIMDI (2005)³⁷ review of several studies argues that medical practice often matched HTA evidence, but it does not specifically refer to HTA by IQWiG. DAHTA also cautions against believing that “accordance” means that an HTA-report must have contributed to a particular outcome. It could be that a change in medical practice occurred for other reasons, while an HTA report advocating the same changes just happened to be issued at the same time. DAHTA judges the reliability of the studies in estimating the factors enhancing or hindering the use of HTA as weak. They would reflect the observations of the studies’ authors and not scientific assessment. But at least as starting points for further investigation, they adhere that the reputation of the HTA-agency with regard to independence, scientific robustness and non-partisanship could be one of the key factors. Involvement of relevant groups in the appraisal process could also promote its implementation.

³⁷ Gerhardus & Dintsios (2005)

The scope

According to the theoretical assumptions on which HTA is based, it has the potential not only to act as an additional gate keeper to the diffusion of new technologies³⁸, but also to screen the stock of existing technologies for poor performers. Under these assumptions, putting all interventions to test could detect underperformers, eliminate them, and transfer the resources saved to places where they can be employed with greater effect. If there were no theoretical problems with HTA, one could even imagine a “welfare maximising” health policy that would employ HTA resources for screening for as long as the resources saved through HTA are greater than the costs.³⁹

Evaluation methods are only tools; it is determined outside the HTA-agency what they are used for. The UK and Germany answer this question differently in so far as NICE has a wider focus than IQWiG. It consists of three different centres, two of them occupied with the traditional realm of HTA (the Centre for Health Technology Evaluation and the Centre for Clinical Practice), and one outside of it. The Centre for Public Health Excellence is concerned with the public health effects of lifestyle issues such as alcohol and tobacco consumption.⁴⁰ So far, IQWiG has not been commissioned with the evaluation of lifestyle-related treatments, as these are less relevant for health policy than in many other countries. For example, the sickness fund system does not cover nicotine replacement therapies for smokers who try to quit, although from a pure HTA-perspective they would be likely to be considered as “cost-effective”.⁴¹

The trade-off between appraising new and already existing interventions is also answered differently. In the case of Germany, the situation is clearer. The code of social law (SGB) limits

³⁸ Before drugs can make it to the market, they must pass a comprehensive set of safety tests. But when a drug passes all these tests, it is only established that it is not dangerous, not that it is beneficial, let alone that it provides “value for money”. HTA is meant to find out whether the incremental benefit a drug provides over existing ones justify its incremental costs, given that it is safe.

³⁹ In economic terms, there would be an optimum in which the marginal (present) value of HTA equals its marginal costs. The “marginal present value” of HTA is the present value of the costs saved by eliminating “useless” interventions.

⁴⁰ NICE (2005) p. 11-13

⁴¹ Valesco-Garrido & Busse (2005) p. 16

the focus of IQWiG to drugs reimbursable for the first time⁴². NICE, in contrast, also has the explicit mission of putting conventional interventions to test, and has sometimes been criticised for factually focussing too narrowly on new ones.⁴³ Linden et al (2007) have classified all NICE appraisals issued between March 2000 and June 2006, be they of drugs, of equipment, of medical devices or of procedures, in this regard. They have found that 64% of all evaluated interventions had been launched in the UK more than one year ago. In 47% of all cases, more than three years had passed since launch, and in 33%, it was more than five years. So there is an emphasis on new products, but it is not NICE's exclusive focus. Drugs tend to be tested closer to launch than other treatments: of all drugs tested, only 38% were older than three years.⁴⁴ NICE reports on drugs tended to have larger media coverage than other reports, which might explain the perception that NICE was exclusively concerned with new products.

The process⁴⁵

IQWiG's methodology has recently been overhauled in the course of the latest health care reform. The process of appraisal now works relatively similarly in the UK and in Germany. In both countries, it begins with the Ministry of Health selecting a topic for appraisal. In Germany, the topic can also come from the Joint Federal Committee (GBA). Then, the HTA body specifies the questions. For example, it identifies the target variables to be examined and the criteria for the inclusion or exclusion of studies. In this process, stakeholders such as patient and expert groups become involved. NICE compiles the results into a "draft scope" and sends it to all involved representatives, who have 20 days to hand in their comments. They are then invited to a scoping workshop, where these findings can be discussed. IQWiG computes an "examination report" (*Berichtsplan*) and publishes it. Stakeholders can respond within four weeks. In both countries, the commissioner of the study has to agree to the scoping report.

⁴² German Code of Social Law (SGB), §139b para. 1&2

⁴³ see, for example, Maynard et al (2004)

⁴⁴ Linden et al (2007)

⁴⁵ Unless otherwise specified, the information in this subchapter is from NICE (2004) p. 1-18 and IQWiG (2006) p. 101-104

In both countries, the HTA body then begins the actual evaluation process. It is divided into two parts. First, the existing literature is reviewed, and the data of clinical trials handed in by producers is analysed. An intermediary report is developed, to which stakeholders can respond. In the second part, the comments and objections of stakeholders are included. If their pleas are not included, this decision has to be justified. In the case of NICE, the division into two stages takes a more explicit form by labelling the first one “assessment” and the second one “appraisal”. The first stage leads to launch of the Appraisal Consultation Document (ACD), which does not yet give recommendations. The whole process finally leads to a Final Appraisal Determination (FAD), with a clear recommendation. Similarly, IQWiG computes the preliminary report (*Vorbericht*) and has to give stakeholders at least four weeks to respond to it. The final report (*Abschlussbericht*) should reflect these additional inputs.

While these procedures are similar, there are also important differences. While neither NICE nor IQWiG use an explicit upper limit on how much a Quality Adjusted Life Year (QALY)⁴⁶ may cost, NICE has established a practice that oscillates around such a frontier, or better, an interval. If an intervention costs less than £20,000 per QALY saved, NICE recommends using it without much further consideration. If it costs between £20,000 and £30,000, NICE recommends to use it contingently, but to consider additional factors such as data certainty or wider societal costs of a disease. If it costs more than £30,000, additional factors in favour of a

⁴⁶ The QALY is the standard calculation unit in health economics. Its rationale is to make very heterogeneous states of health comparable. Medical units can measure, for example, the effect of an intervention on blood pressure for someone suffering from hypertension, or the level of blood sugar for a diabetic. But with these numbers, the health statuses of those two persons could not sensibly be compared with one another. It would be a step further to measure the success of an intervention by the number of additional life years that it brings. That outcome measure could be used regardless of the way it is achieved, be it by lowering the blood pressure of a hypertonic or by lowering the level of blood sugar of a diabetic. But it is still too rough a measure, because some diseases do not necessarily lead to earlier death but still decrease the quality of life (for example, painful rheumatics). So the number of life years is further adjusted for the quality of life. Surveys reveal how patients “value” different types of limitations of their health status, on average. Based on these outcomes, an “exchange rate” is derived by which life-years lived with an illness can be converted into a smaller number of life-years lived with full health, in such a way that patients would be indifferent between both options if they had the choice. For example, if patients indicate that they are indifferent between living 4 years in full health or 5 years with pain in the back, then the equivalent of 5 years with pain in the back is 4 QALYs.

treatment must be very strong.⁴⁷ ⁴⁸ IQWiG does not use numerical values. As Peter Sawicki said, “that would be unimaginable in Germany”.⁴⁹

Another important procedural difference is that a NICE recommendation can be appealed. IQWiG recommendations cannot. In about a third of all NICE appraisals, that possibility has been employed. The ratio of upheld to dismissed appeals has been about 2:3.⁵⁰

NICE, IQWiG and the Medical Communities

IQWiG has had serious conflicts with many of the German medical associations, who perceived its methodology in using evidence as arbitrary and the institute’s style of dealing with criticism as inappropriate. NICE has rather been criticised for its focus on cost containment which critics have perceived as excessive. The institute has, at the same time, found ardent supporters within the professional community.

What does “evidence” mean in medical terms? Health economists typically distinguish between different evidence-classes, which are thought of as a hierarchy. The first class of evidence is derived from a so-called ‘randomised controlled trial’ (RCT), which is basically a controlled clinical experiment with a largely homogeneous group to eliminate the bias of other influences. It is based on Evidence Ia, which is a meta-analysis of several RCTs already conducted, and Evidence Ib, which is the conduct of one or more RCTs. Evidence falls under class II when it comes from controlled, but not randomised (not controlled with a placebo group) experiments, or a treatment so well monitored that it comes close to an experiment (IIb). Class III Evidence consists of non-experimental studies, and Class IV of expert opinion or experience.⁵¹

⁴⁷ NICE (2007)

⁴⁸ Raftery (2006) p. 1266

⁴⁹ Wirtschaftswoche (2007)

⁵⁰ NICE (2007)

⁵¹ Rychlik (2005) p. 13

It must be noted that the above ranking applies to scientific purposes. Its applicability to decisions about actual treatment can differ. What RCTs cannot capture is the actual compliance of patients under real-world conditions. They show the effect of a drug, a treatment or a device in a controlled experiment, but people behave differently in a controlled experiment than in their everyday lives. When drug intake is difficult to integrate into daily routine, an innovation which facilitates it may enhance its actual effectiveness, but a RCT would not reflect that. This has been the background behind some disputes between IQWiG and various medical professional bodies.⁵²

For example, IQWiG has recommended that sickness funds should not reimburse insulin-analoga with short-term efficacy (a possible alternative to insulin), on the grounds that they had shown no improvement over conventional insulin in RCTs.⁵³ But the main difference between these treatments is that short-term analoga can be used flexibly, while conventional insulin requires a strict adherence rhythm. The results of a RCT might therefore not be reproducible under everyday conditions. The alternatives therefore had a market share of more than 70% in neighbouring countries, compared to 43% in Germany.⁵⁴ The German Diabetes Federation (DDB) was strongly in favour of this type of drugs, but found itself unable to have this position reflected in the appraisal procedure. DDB-chairman Manfred Woelfert described IQWiG as unresponsive to external objections.⁵⁵ In the screening-process -the selection of which existing studies should be included in the appraisal- 1012 of 1017 studies were declared as “irrelevant” because they were not based on RCTs.⁵⁶

A similar case was IQWiG’s recommendation against fixed combinations of agents in an inhalation therapy for asthmatics, compared to the standard treatment of inhaling them separately. Heinrich Worth, chairman of the German Airway League, credited the use of fixed combinations with a fall in emergency treatments. According to Worth, patients often leave

⁵² Aerztezeitung, March 14th 2007

⁵³ Aerztezeitung, March 22nd 2007

⁵⁴ Sickmueller (2006) p. 6-9

⁵⁵ Aerztezeitung, March 3rd 2007

⁵⁶ Sickmueller (2006) p. 12

important substances out when inhaling separately. Asthma experts pointed this out in hearings at IQWiG after the release of the preliminary report.⁵⁷ Mark Fladrich, CEO of fixed-combination producer AstraZeneca, criticised the fact that four relevant studies had been excluded because they did not fit into the RCT pattern.⁵⁸

IQWiG also clashed with the German Society for Urology (DGU) when it recommended against the usage of non-medicinal treatments for Benign Prostatic Hyperplasia. Klaus Hoefner of the DGU's working committee on the topic spoke of "severe shortcomings in methodology", because expert knowledge of urologists had not been included. The report's conclusion was therefore "wrong and grossly misleading".⁵⁹

Perhaps the most severe dispute IQWiG faced was its row with the German Society for Haematology and Oncology (DGHO). IQWiG had disapproved of a treatment practice given to patients with acute leukaemia. When chemo-therapies failed, patients could undergo a transplantation of stem cells from a close relative. When no such close relative was available, the cells could also come from a stranger. According to IQWiG, there was no proof that stem cell transplantation from a non-familial donor was superior to a standard chemo-therapy. DGHO-president Gerhard Ehninger countered that there was evidence, only that it was not directly comparing those two. But he saw it as proven that a transplantation of stem cells from a non-kin donor was just as effective as transplantation from a relative. So the superiority over chemo therapies could be derived by indirect comparison. Indirect comparison, however, does not classify as class I evidence. Ehninger also criticised shortcomings in the handling of information. Data which the DGHO had handed in after the publication of IQWiG's interim report had not been included in the final report. A second hearing of DGHO members, which had been agreed with IQWiG, had not taken place.⁶⁰

⁵⁷ Aerztezeitung June 13th 2007

⁵⁸ Aerztezeitung June 13th 2007

⁵⁹ Aerztezeitung May 11th 2007, translation mine

⁶⁰ Aerztezeitung, June 19th 2007

In the course of the latest German health care reform, the rules and regulations governing IQWiG have changed profoundly. The new statutes that have been in effect since April 1st 2007 oblige IQWiG to adhere to international appraisal standards, and involve patient representatives and pharmaceutical producers. IQWiG is now also explicitly commissioned with cost-effectiveness-analyses. The general theme of these changes is to expand IQWiG's responsibilities, but also to make it more transparent and less discretionary. Before, IQWiG had a large leeway in defining its methods itself.⁶¹ It remains to be seen, however, whether the lessons from past difficulties have really been learned.

NICE, too, has been subject to severe criticism. When it recommended against the use of inhaled insulin, producers called the decision “perverse and short-sighted”. They stated that a reduction in diabetes complications such as heart disease, amputations, blindness and kidney failure would now be foregone.⁶² When it recommended against a treatment for mild Alzheimer's, producers spotlighted “Alzheimer's patients betrayed by NICE”⁶³, and when it recommended against the use of two novel brain tumour treatments, it was argued that the institute was “poised to deny potentially life-prolonging new treatments”.⁶⁴ However, these criticisms do not necessarily attack NICE's methodology, but instead reproach the institute as being too narrowly focused on costs. Like IQWiG, NICE has a strong preference for RCT-studies, and for direct “head-to-head” comparisons between treatments. They regard other sources of evidence as much more vulnerable to bias. However, when direct comparisons are not available, NICE cautiously resorts to indirect ones. They also take it into account whether a treatment has a high patient drop-out rate. When RCT evidence is seen as too limited, for example because it only refers to a very small group, non-RCT evidence is carefully taken into account. NICE would then move down the ladder of the evidence hierarchy to the next-highest available alternative.⁶⁵

⁶¹ Rychlik p. 11

⁶² Pfizer Press Releases (2006)

⁶³ Pfizer Press Releases (2006a)

⁶⁴ Link Pharmaceuticals Press Releases (2006)

⁶⁵ NICE (2004) p. 11

While NICE has been strongly criticised, there has also been strong support from parts of the medical community. Various authors in the *British Medical Journal* (BMJ) have regularly taken a pro-NICE position. Some of them have demanded that NICE be provided with enormous powers. It is interesting to note that while German critics of IQWiG have often portrayed it as a camouflage organisation for politicians' desire to ration health care, British NICE supporters regard it as a means to de-politicise health care. Their common rationale is that each health care spending decision entails a foregone alternative; each pound spent on one form of health care use is no longer available for another. The authors assume that if spending is not based on evidence, it will be based on lobbying and political power games. Ferner et al (2006) explain how public health care systems are subject to the "tragedy of the commons": as health care services are perceived as "free", excessive use is rational from each individual's perspective. But as no society can spend its entire wealth on health care only, some restriction mechanism must eventually be found, for example a rationing body. But it will be, as the authors show, under permanent pressure. Pharmaceutical companies want to maximise profits, patient groups want to maximise their specific share of the health care budget, the media is interested in highly emotional headlines and stories (such as those about NICE denying the use of a drug), and politicians like to portray themselves as warm-hearted people. The authors thus argue that a strong independent body is needed to make tough "rational" decisions.⁶⁶

Cookson et al (2001) go into greater detail. According to them, "NICE needs to become a national health care rationing agency".⁶⁷ They want evidence-basing to be effectively enforced. NICE should have a notional budget and allocate it to all potential new drugs and treatments. This would mean that NICE would not only appraise technologies when commissioned, and that its recommendations would be binding. Cookson et al's proposal would create an automatic process by which no new technology could enter into practice without being approved by NICE. In effect, this means that over time, all health care spending decisions would become based on NICE evidence. Health care policies would be shifted from political bodies to a professional body. Maynard et al (2004) have gone even further. They state that "[t]he issue is

⁶⁶ Ferner et al (2006)

⁶⁷ Cookson et al (2001) p. 744

not whether but how to ration”, and that “the government should make it impossible for the NHS to adopt expensive new technologies until they are approved by NICE”. But instead of simply maximising the number of QALYs saved through the given resources, they want NICE to make judgments about who should get these years: “[E]verybody is entitled to a "normal" span of health.”⁶⁸ To implement these ideas, they suggest either fixing a maximum value for how much a (quality-adjusted) year of life may cost⁶⁹, or giving NICE a notional budget, or, as the authors’ preferred solution, giving NICE a real budget and requiring it to finance all its recommendations from that budget.

What these authors essentially propose is health care policies entirely run by a professional body with autonomous discretionary powers, much like monetary policies are run by a central bank and not by the ministry of finance. The authors of the related OECD study have asked: “Can democracy and technocracy co-exist peacefully?”⁷⁰ One could add another question: Would such coexistence be desirable?

Concluding remarks: A “Central Bank for Health Care”?

In many respects, the difference between NICE and IQWiG is the difference between an established, well-known institution with a clear role and responsibility, and an infant institution which still has to find its proper role. Public HTA is associated with a number of difficulties, some of which have to do with implementation and some of which are intrinsic. The comparison of NICE and IQWiG can help to distinguish between those two.

Some critics use the term “HTA” as a synonym for “rationing”, or rationing through the back door. This criticism is not valid. HTA is neither automatically the same as rationing, nor does it come through the back door. HTA is the alignment of health care decisions according to a specific standardised evaluation method. In a narrower sense, it measures the outcomes of health interventions in special measurement units, mostly the QALY. In a wider sense, it

⁶⁸ Maynard et al (2004)

⁶⁹ The authors propose £12,000-£15,000

⁷⁰ OECD (2005) p. 43

measures the cost per QALY of an intervention. Whether that leads to a rationing of health care or not simply depends on the upper limit for how much a QALY may cost. NICE uses an approximate threshold of £30,000. If it used £60,000, HTA would lead to a greater diffusion of medical technologies; if it used £5,000, it would lead to massive rationing. But determining this limit is outside the scope of the field of HTA, HTA-methods themselves cannot provide an answer to that. In other words, HTA is a mechanism to allocate a given health care budget, not to determine that budget itself. Therefore, HTA is not automatically the same as rationing.

From a Public Choice perspective⁷¹, it might of course be objected that politicians would not set up an HTA body (or at least not act according to its recommendations) if they had any other intentions than to cut costs. In the end, strict compliance with HTA means subordinating decisions to a fixed set of rules, which decreases the discretionary leeway. Why should a political institution do that if not in order to delegate unpopular decisions to a separate entity, or an “objective” mechanism? While this objection would be consistent with political economic analysis, it does not factor in the argument that HTA is neither sufficient nor necessary for rationing. Access to health care is always restricted in one way or another. Long before HTA even existed as a clearly defined concept, governments engaged in “silent rationing” by restricting access to the medical profession, delaying the approval of new pharmaceuticals, setting maximum spending budgets, controlling prices or by under-investing in public hospitals.⁷² From a political economy perspective, an HTA body would thus have a desirable property even if it acted as a pure cost-cutter: it would partially replace silent rationing by an open rationing. The decisions of NICE and IQWiG at least spark public controversies; if a technology is simply not introduced, patients would perhaps not even know it exists.

⁷¹ The Public Choice School is a strand of economics that analyses political decisions with economic methodology. In contrast to traditional Welfare Economics, which assumes government acts like a “benevolent dictator” exclusively interested in the citizenry’s wellbeing, the Public Choice School assumes that public institutions are composed of individuals that have self-interests, just like private individuals. If it can be assumed that private households and companies maximise their economic rent (income, profit, leisure), then individuals that form public institutions maximise their political rent (popularity, influence, power).

⁷² For the history of cost-containment measures in Germany, see Oberender et al (2002) p. 65-99. In the UK, the process is simpler as government decides about spending directly.

The above description holds only if an HTA body really adheres to an internationally established state of the art methodology (and adheres to fixed rules of expanding given methods where no best practice exists). Further, it must contract external experts on a basis comparable to public tendering procedures. In as far as it gains the reputation of pursuing a political or ideological agenda, its acceptance in the medical community shrinks, which will lessen its influence. That has been a problem especially for IQWiG. The only way to sidestep this problem would be to give the HTA body wide powers to implement its own findings, which would limit the therapeutic autonomy of doctors.

To gain a standing of scientific rigour, an HTA body must adhere to methodological soundness, transparency and involvement of stakeholders, and abstain from political and ideological battles and lurid media campaigns. In these respects, NICE is relatively far advanced, while IQWiG has gambled away some of its credibility. However, the changes introduced in the course of the latest health care reform suggest that lessons have been learned from these initial struggles, and that IQWiG may end up following a similar course to the one NICE has taken in the UK.

But even if all of these shortcomings of implementation are resolved, and a best-practice HTA body evolves, some basic dilemmas remain unsolved. In a public health system, decisions can either be made by a political body -directly or indirectly accountable to government- or by an autonomous professional body. In the first case, decision-making is subject to the usual weaknesses which the Public Choice School has proven countless times. It will be biased in favour of well-organised interest groups, administrative bodies willing to maximise their own sphere of influence, and will follow political cycles around elections. The second case, as has been explained, has been advocated by a number of authors in the *British Medical Journal*. An unaccountable technocratic body would assume wide powers over decisions of life and death. In a way, this proposal would carry the rationale of HTA to its logical final conclusion. If we have an expert-run monetary policy, should we not have an expert-run health policy as well? Should NICE, and eventually IQWiG, become “central banks for health policy”?

The short answer is no. There are important flaws in the proposals of the BMJ authors, because there are differences between health care and areas where expert rule are applicable, like monetary policy. First of all, monetary policy does not have to take account of diversity. In the longer run, everybody loses from excessive inflation. In contrast, people respond very differently to medical treatments. HTA can take account of such differences only as long as they are related to systematically distinguishable groups. It can appraise a treatment separately for men and women, or for people over and under a certain age. But if the differences are not related to such systematic factors, HTA cannot identify them. It will lump together different outcomes into one single average. Secondly, even if the anatomy of everybody was the same, the valuations of a particular health status would not be. The concept of QALYs is not really comparable to measures of the quantity of money, or the Consumer Price Index. In monetary policy, there are no reasons to assume that some individuals may prefer a high rate of inflation and others a low rate. In health care, a reduction in motor skills may be terrible for a passionate sportsman, but bearable to someone who enjoys quiet activities. A QALY is essentially an average of such diverse valuations. Whenever there are large deviations from this average, the QALY concept becomes an inappropriate measurement for many individuals.

Policy Recommendations

In the absence of market prices, individuals have little incentive to use scarce resources cautiously and thoughtfully. One could interpret public HTA as an attempt to enforce rational behaviour in an environment in which “natural” incentives to behave rationally have been deliberately eliminated. To go to the root of this dilemma, it is perfectly legitimate to think of a free market health care system in which such behaviour was in every actor’s self interest, and where an artificial imposition was wholly unnecessary. So, is any government intervention in health care justifiable at all? Is there any type of ‘market failure’ in health care?

Yes, there is. Without any government activity, some people (for example, those with a very low income or a severe chronic disease) could probably not afford the insurance premium even for a basic health insurance package. But if state intervention is to be justified on the grounds of

this failure, it can only go so far as to eliminate this failure – and no further. The acknowledged failure only concerns the demand side of the health market, and on the demand side, it only concerns a clearly definable group. It does not concern the supply side, and it does not concern the vast majority of the demand side. The only derivable state intervention is thus to subsidise the health insurance premium of those people who could otherwise not afford it. The acknowledged market failure does not provide a case for the existence of state-run insurance companies, let alone state-run hospitals, regulation of doctor's wages, pharmaceutical prices, pharmacies' profits, or any other intervention that goes beyond enforcing the rules of the game. In such a system, it would be up to the insurance companies to purchase medical technologies in an efficient way and to provide their clients with incentives to use their entitlements intelligently. To discover what "efficient purchase" and "intelligent use" mean precisely, HTA would most certainly be a useful tool. But its use would be consumer-driven and diverse, not imposed from above and monolithic.

However, within the given climate of opinion on health care, moves in such a direction are unlikely for the time being. 62% of Germans and 69% of Britons would like to see their health care systems improved through increased spending⁷³, not liberalisation. "Pragmatic" recommendations, departing from the status quo instead of a *tabula rasa* perspective, are more likely to exercise a medium-term impact. Nevertheless, some insights from the above paragraph can be used as a guideline for policy proposals within the logic of a publicly funded health care system. First, HTA must be used in a much more flexible way than it is currently. Second, incentives should be introduced so that people have a self interest in using health care resources cautiously. In such a case, HTA would be much more effective, because it would be more in line with people's interests. To make HTA more effective and flexible, proposals for both the UK and Germany will now be presented.

⁷³ Stockholm Network (2004) p. 33 & p. 93

UK

- HTA should not lead to a black and white 'yes or no' decision. When NICE decides that the incremental benefit of a new technology over the established treatment does not justify its incremental costs, this should not mean that it becomes completely unavailable. Patients should still be able to use it, but should only be reimbursed with the amount that the standard therapy would have cost.⁷⁴ If they are willing to pay the incremental cost out of their own pocket, the option should always be available. This would alleviate the weakness that an HTA report that recommends against the use of a treatment may be 'correct' for the majority of the population, but still 'wrong' for some people.
- A proportional co-payment, in the form of a fixed percentage rate, should be introduced for all medical consumption. It should apply for all out-patient and in-patient services, drugs and medical devices. Welfare recipients could be exempted, an annual cap could part-exempt the chronically ill. People themselves would start asking whether a lower-cost alternative is available that leads to the same outcome. They would be more reluctant to demand treatments with marginally higher benefits and substantially higher costs. This greater scrutiny would affect all treatments, be they new or established, fully re-reimbursable or not. In some cases, people could even begin to use HTA-information themselves to make decisions.
- Private co-insurance should be facilitated. With increasing rationing, private co-insurances could emerge to cover treatments that the NHS rules out as too costly. Currently, private co-insurances have to employ medical staff and facilities of their own. This means that they have to create parallel health care systems, a very inefficient solution. It duplicates fixed costs and creates an entry barrier for the private sector. If the NHS decides not to reimburse the costs of a particular treatment, people should still have the option to receive the treatment using NHS-facilities and have their private insurance company cover the costs.

⁷⁴ Where various standard treatments are relevant, the most expensive one reimbursable could be the point of reference.

Germany

- For the same reason as in the case of the UK, IQWiG recommendations should not lead to a yes or no decision. At most, it should help by setting a reimbursement limit at the cost of the standard therapy, and leave patients the option to cover the extra costs out of their own pocket or through private top-up insurance. This option already exists sometimes for drugs. It should be extended to all medical consumption.
- For the same reasons as explained above, a proportional co-payment in the form of a fixed percentage rate should be introduced for all medical consumption.
- IQWiG should not set the reimbursement limit for particular treatments (see point I) itself, but only publish the cost per QALY. Sickness funds should be free to decide what they make of this information, that is, what maximum cost per QALY they accept. There could be 'innovation funds' with a very high cost threshold, but these would have to charge high contribution rates. At the same time, there could be 'standard funds' demanding stricter cost-effectiveness. They could offer a low contribution rate, but their clients would have to accept the risk of not always receiving the newest treatment available.
- Sickness funds should be able to conduct their own HTA, or syndicate to do so, if they find IQWiG's methodology inappropriate. Competing HTA's could evolve.

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