

Health Technology Assessment: A Perspective from Germany

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Introduction

Health technology assessment (HTA) has been discussed in Germany since the late 1990s, closely related to the advent of evidence-based medicine. The idea of technology assessment was initially discussed in Germany by the “technology assessment office of the parliament.” This was further supported by a scientific project to evaluate the use and benefit of HTA in the German health-care setting at the Hanover Medical School [1]. The German Scientific Working Group Technology Assessment for Health Care was then founded in 1997 with the objectives to develop a database comprised of HTAs already available and improve the methodology for HTA. The project group consisted of university-based scientists and representatives of the various institutions within the statutory health insurance (SHI). The project was sponsored by the federal government and supervised by the German Institute for Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information [DIMDI]). The project was finished in 2001. HTA was formally established with the German Health Care Reform 2000. The reform included the assignment of the implementation of a database and a scientific working program on HTA within the remit of DIMDI. In the same year, the German Agency for Health Technology Assessment [DAHTA@DIMDI]. Based on the work done by the German Working Group Technology Assessment for Health Care, the principles and methods of HTA were continuously adopted by various decision-making bodies in Germany, such as the predecessors of the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA).

In Sections I and II of this paper, German organizations involved in HTA and their processes for conducting HTA are described. In Sections III and IV, current issues for the assessment and use of HTA are discussed. In Section V, HTA in Germany and lessons learned are presented.

SECTION I: GERMAN ORGANIZATIONS INVOLVED IN HTA

The most important bodies involved in HTA in Germany are the G-BA, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [IQWiG]), and the DIMDI. Others are the medical service of the head associations of the SHI (Medizinischer Dienst der Spitzenverbände [MDS]), the National Association of SHI Physicians (Kassenärztliche Bundesvereinigung [KBV]), and university-based institutes and others conducting HTAs in Germany.

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Federal Joint Committee (G-BA)

The G-BA is the supreme decision-making body of the so-called self-governing system in Germany. Physicians, dentists, hospitals, sickness funds, and patients are represented in the G-BA. The G-BA issues directives and, thus, determines the benefit package of the SHI covering about 70 million people. Finally, the G-BA is responsible for reimbursement decisions.

Like most other countries, in Germany, the parliament sets the legal framework for health-care provision and the G-BA issues standardized and binding directives to translate the legal framework into practice. The directives issued by the G-BA are legally binding for insured persons as well as for the providers and payers of health care: physicians, hospitals, and sickness funds. The directives define the provision and reimbursement of pharmaceuticals, diagnostic, and therapeutic procedures, medical devices, and nonmedical treatment.

One important area of responsibility of the G-BA is the assessment of new diagnostic and treatment methods (including medical devices, if part of the respective method). In outpatient care, each new treatment method needs the explicit approval of the G-BA. In inpatient care, each new treatment method can be used as long as the G-BA has not excluded the treatment method from being used within the SHI. The G-BA’s assessment of medical treatments and procedures follows a standardized procedure which is founded on the principles of evidence-based medicine. Hence, it is not only the IQWiG that conducts assessments but also the G-BA in its own capacity for new diagnostic and treatment methods. Based on the current state of medical knowledge, the effectiveness, quality, and economic viability of the treatment methods under examination are assessed. The process for this assessment of benefits is depicted in Figure 1.

The procedural rules for the assessment are described in the rules of procedure (Verfahrensordnung) of the G-BA. These assessments are pivotal for the development of the catalogue of benefits mainly in the area of diagnostics and medical treatment except pharmaceuticals. Nevertheless, the G-BA may commission an IQWiG assessment in those cases as well.

Institute for Quality and Efficiency in Health Care (IQWiG)

In 2004, the G-BA established the IQWiG as an independent scientific unit according to a new law (Gesetzliche Krankenversicherung [GKV]—Modernisierungsgesetz). On behalf of the G-BA or the Ministry of Health (MoH), the IQWiG assesses effectiveness, quality, and efficiency of diagnostic and therapeutic methods as well as pharmaceuticals. IQWiG’s technology assessments are used to inform the decision-making of the G-BA. Nevertheless, they do not determine the G-BA’s final decision.

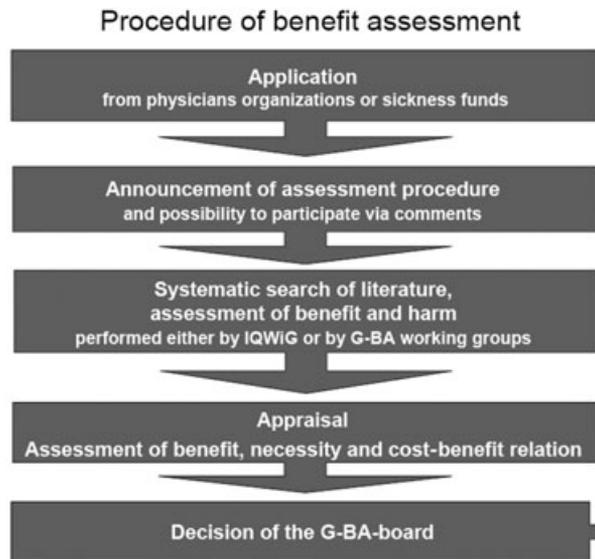


Figure 1 Assessment of Benefits by the Gemeinsamer Bundesausschuss (G-BA) [2]. IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen.

German Institute for Medical Documentation and Information (DIMDI)

DAHTA@DIMDI develops and implements information systems, specialized databases, and produces HTA reports. The reports are designed to inform health policy and not primarily to shape the catalogue of benefits. Nevertheless, IQWiG may commission DIMDI, but the benefit assessment by the IQWiG differs from the HTAs commissioned by DIMDI.

Because of limited budget and based on input by all partners within the German health-care system, scientific topics are

selected and prioritized to be included in the HTA development program. The procedure for identification of topics is outlined in Figure 2. The HTA Board of Trustees (composed of insurance companies, hospitals, and physicians, complemented by representatives of nursing, patients, or consumers, as well as observer representatives from the IQWiG and the industry) sets priorities and determines the topics for future reports in a multilevel procedure.

MDS

HTA reports are also issued by other groups within the SHI, such as the group for evidence-based medicine at the medical service of the head associations of the SHI, MDS, which serves sickness funds within the SHI and prepares reviews and HTA reports to inform sickness fund decisions. These assessments are based on internal standard procedures, which are not publicly available. HTAs issued by the MDS can be viewed as guidance for the regional medical services of the sickness funds and for sickness fund decisions, e.g., in cases of individual funding applications for diagnostic or treatment methods not covered by the catalogue of benefits.

National Association of SHI Physicians (KBV)

The assessment of innovative diagnostic or treatment devices has been a prerequisite for the admission of these devices to the catalogue of benefits for many years. This assessment was driven by the National Association of SHI Physicians (KBV) since 1996, even before the government had introduced HTA officially. This group is now the KBV department dealing with innovation and the benefit assessment of medical services. The KBV runs its own assessments to support internal decisions or to contribute to the work of the G-BA as one of its members.

Other Organizations

Both groups, at the MDS and the KBV, can be seen as pioneers of HTA in Germany and they still exist. There are other groups



Figure 2 The health technology assessment (HTA) process at DIMDI [3]. DAHTA, Deutsche Agentur für Health Technology Assessment im Deutschen Institut für Medizinische Dokumentation und Information.

dealing with assessment issues within the German health-care system. Just to name a few, among them are the National Association of Physicians (Bundesärztekammer), the scientific institute of the Allgemeine Ortskrankenkassen (Wissenschaftliches Institut der Ortskrankenkassen), and the scientific institute of the Techniker Krankenkasse. Nevertheless, they do not play an official role in HTA.

Increasingly, universities engage in HTA. Their focus is mainly on the development of methodologies and training for those who develop and apply HTA. In addition, scientific associations dealing with evidence-based medicine, epidemiology, social medicine, or public health have set up working groups or special interest groups for HTA. They focus on the interdisciplinary approach of HTA and the methodological issues in this area as well. Relevant players in the field are the German Association for Social Medicine and Prevention (Deutsche Gesellschaft für Sozialmedizin und Prävention [DGSM]), the German Network for Evidence-based Medicine (Deutsches Netzwerk für Evidenzbasierte Medizin [DNEbM]), and the German Association for Medical Informatics, Biometrics, and Epidemiology (GMDS).

All of these groups may have an impact on the decision-making of the G-BA. Nevertheless, decisions are taken by the G-BA based on its own assessments (diagnostic, medical devices) or based on assessments by the IQWiG (mainly drugs) serving the SHI and its constituencies. In contrast, DAHTA@DIMDI serves the broader public and is not subject to those rules that G-BA and IQWiG need to adhere to.

SECTION II: GERMAN PROCESSES FOR CONDUCTING HTA

With the development of HTA and the increase in quality and quantity of those conducting HTA in Germany, there is a need to ensure the quality of HTA in Germany, thus the development of HTA guidelines. HTA guidelines and review processes for conducting HTAs by DIMDI, IQWiG, and the G-BA follow.

DIMDI HTA Process

DIMDI commissions HTAs based on the above-mentioned prioritization process. The HTAs are conducted by DIMDI contractors according to HTA methodology defined by DIMDI. The methods are summarized in a document issued by the DIMDI which is called “Handbuch für Autoren zur Erstellung von HTA-Berichten” [4]. It is updated on a regular basis. The collection of methods deals with the required content, the layout of the document, as well as the HTA process, reporting, and details of the elements of the final HTA report. Interim and final reports are reviewed by internal and external HTA experts. The internal review is conducted by employees of DAHTA@DIMDI to ensure plausibility of the report structure and content as well as consistency with the defined HTA methodology. The external review is conducted by experts from scientific associations, universities, and other institutions with expertise in the field of the research question and HTA methodology. The objective of the external review is the assessment of the content and the methods of the respective HTA. Usually, there will be two external experts. Based on internal and external reviews, the reports are revised and finalized. The final version is published on the DIMDI website.

IQWiG HTA Process

IQWiG assessments need to adhere to the “General methods” on benefit assessments and the “Methods for Assessment of the Relation of Benefits to Costs in the German Statutory Health

Care System” abbreviated here as cost–benefit assessment methods. IQWiG defined and published its working methods at the end of February 2005 in a general methods paper for the first time. In January 2008, the institute published its cost–benefit assessment methods. The methods must be followed by IQWiG and third parties working on behalf of the IQWiG. Furthermore, any evidence submitted to IQWiG is assessed in the light of these methods. IQWiG’s methods are updated and revised annually to accommodate current requirements and developments in health-care research and the health-care system [5].

The cost–benefit assessment methods were developed with the support of a group of external experts and the institute’s scientific advisory board. Nevertheless, the cost–benefit assessment methods were not finalized in 2008. In 2009, public debate on the methods will continue and pilot assessments will be run before issuing the first final version, expected in the second quarter 2009 according to IQWiG.

Assessments on behalf of the IQWiG are subject to internal reviews. In addition, IQWiG conducts hearings after publication of the draft report plan and after publication of the draft report itself. These hearings may have an impact on the final version of the assessment. Hearings are usually based on written comments. An additional oral discussion is optional. The production process used by IQWiG is depicted in Figure 3.

G-BA HTA Process

The assessments by the G-BA are based on its rules of procedure (Verfahrensordnung). The rules aim to provide a transparent and sound legal basis for G-BA decisions [7]. The rules are applied to decisions of the G-BA, benefit assessments, and the collaboration with IQWiG [7]. Products and services affected are innovative diagnostic or treatment methods, remedies like logotherapy, physiotherapy, diagnostic or treatment methods already performed on behalf of the SHI if requested by a member of the G-BA. The differentiation between outpatient and inpatient care is only relevant with regard to the implications of the assessment as already described above.

Criteria for the assessment include efficacy, benefit–risk ratio, outcomes, additional benefit of an option compared to the alternative, cost–benefit assessment, budget impact, and evidence levels of the evidence collected or submitted [7]. Furthermore, the G-BA can commission the IQWiG. The implications of a benefit assessment are depicted in Figure 4.

SECTION III: CURRENT ISSUES FOR ASSESSING HEALTH TECHNOLOGY

There are a number of issues related to HTA currently discussed [8]. Among these are the transparency of assessments, the difference between relative therapeutic value and relative efficacy, the data related to the values of resource items, the relevance of quality-adjusted life-year (QALY) thresholds, the questions on uncertainty, the transferability of economic information, and the relevance of real-world data.

Because in Germany assessments are performed by different groups and none of these assessments are mandatory in the sense that their submission by industry is required to achieve reimbursement, the discussion of these issues is related to the respective institution conducting or affected by the assessments. Hence, the discussion should focus on the view of the G-BA and IQWiG conducting assessments on behalf of the G-BA, as well as on the view of DIMDI, if there are statements on the respective issue in DIMDI’s manual for authors. Its manual deals with the structure, the required content, and the formal aspects of HTA reports [4].

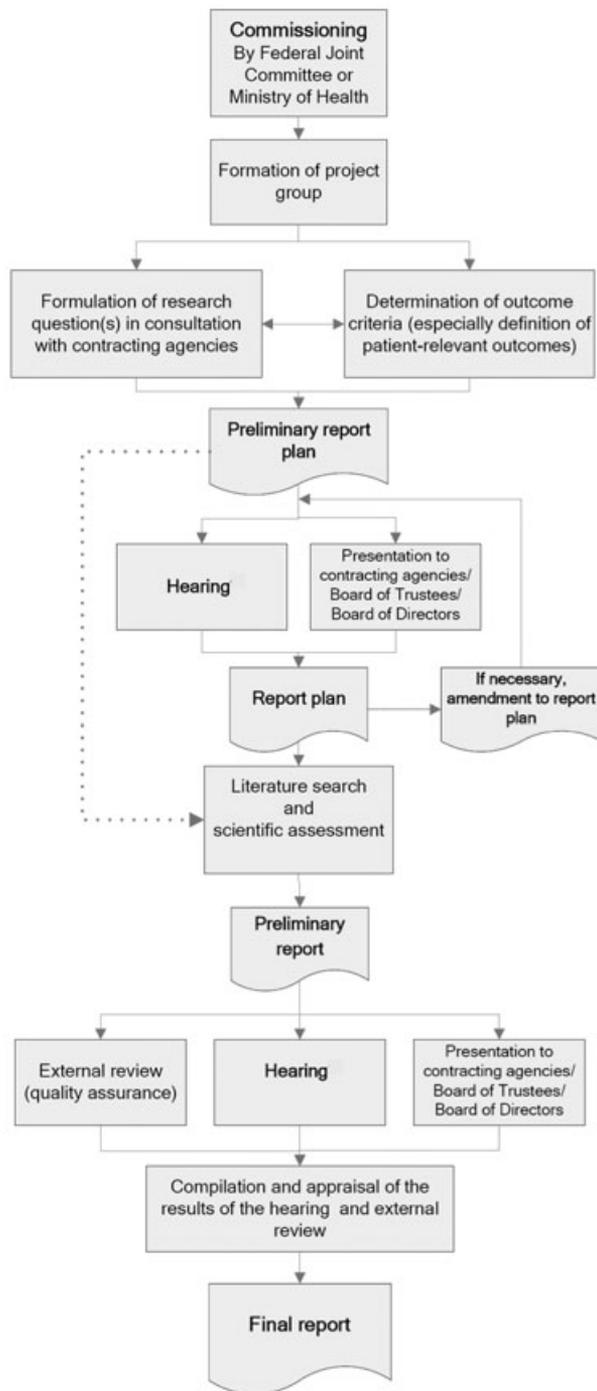


Figure 3 Production process for an IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) assessment [6].

Because these institutions are closest to any decision-making processes, at least from a formal point of view, their views on the above-mentioned issues will be taken into consideration.

Transparency of Assessments

There are different aspects of transparency involved in HTA. There is the transparency of the assessment itself. Guidelines are

aiming to secure transparency of assessments as much as possible, meaning that there is a plausible link between the evidence depicted and the conclusions drawn. Furthermore, the use of HTA in health-care decision-making should be transparent, meaning that the link between the assessment and related decisions is plausible. If an assessment should have any impact on decision-making, transparency is required with regard to both aspects of the process [9].

The DIMDI manual ensures a common approach and structure of HTAs as well as transparency [4]. There is no formal process to take into account DIMDI HTAs in policy decisions. Hence, DIMDI HTAs do not have immediate outcomes except the report itself.

This is different with regard to IQWiG assessments usually not denoted as HTAs but as benefit assessments (Nutzenbewertung). Because of the specific methodologies for the assessment, they are characterized as benefit assessments or as cost-benefit assessments. IQWiG assessments are conducted on behalf of the G-BA and initiated to inform G-BA decisions. Nevertheless, the IQWiG does not conduct assessments on its own. The IQWiG commissions assessments from its supplier base. Hence, based on the specific method papers of the IQWiG, the general methods paper, and the methods paper on the assessment of the cost-benefit relation of health-care interventions, the IQWiG tries to ensure the transparency of the assessments conducted on its behalf by its methods papers. The ultimate decision is taken by the G-BA. The decision process should be as transparent as possible, including the assessment itself, to minimize the probability of being legally challenged.

The assessment process as laid out by the rules of procedure by the G-BA seems, on the surface, to be clear. Nevertheless, the devil is in the details. Hence, the G-BA itself is looking for measures to improve the transparency and comprehensibility of the assessment process and its implications [2]. Admittedly, because of the fact that the G-BA process and decisions can be legally challenged, the G-BA process is most probably the most transparent process in Germany.

Relative Therapeutic Value versus Relative Efficacy

Relative therapeutic value and relative efficacy are outcome measures that relate to different concepts and are composite measures. The relative therapeutic value can be composed of differences in morbidity, mortality, and quality of life compared to current standard of care. Within the DIMDI manual on HTA,

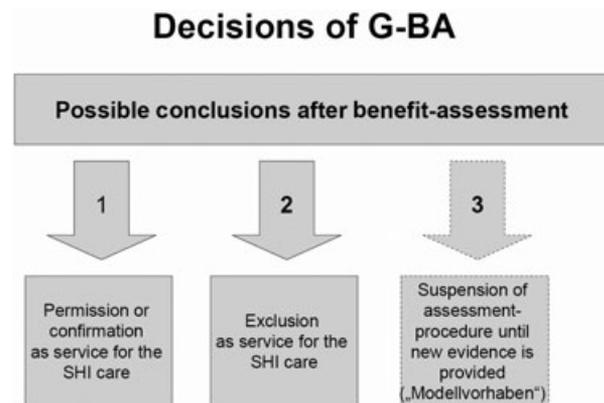


Figure 4 Implications of Gemeinsamer Bundesausschuss (G-BA) assessments [2]. SHI, statutory health insurance.

there are no explicit requests with regard to outcomes measures. Indirectly, DIMDI is emphasizing the acceptance of a technology by service providers, payers, and patients [4].

This is different with IQWiG, where patient-related outcomes are the relevant parameters for IQWiG assessments. Relative efficacy of new health-care technologies plays a role only if causally linked to patient-related outcomes or relative therapeutic value. Surrogate parameters without a causal relationship to patient-relevant outcomes are not accepted by the IQWiG [3]. The IQWiG position is in line with the G-BA point of view. If the G-BA commissions IQWiG according to the rules of procedure, IQWiG needs to observe the rules [7].

Head-to-head comparisons of drugs will become the standard of the future in Germany and this is independent from the institution dealing with or using HTA in decision-making.

Value Related Data

There are no limitations with regard to the values for the valuation of resource use data when it comes to DIMDI HTAs. With regard to benefit assessments, this is not an issue either. Nevertheless, currently, there is heated debate on the valuation of resource use when it comes to cost–benefit assessments. The debate is rooted in the relevant perspective for assessments, and the discussion is between the payers’ perspective and the societal perspective.

DIMDI does not take a stand in this discussion. Its manual is dealing with the structure and formal aspects of HTA reports only. For cost–benefit assessments, IQWiG has argued for a combined perspective of the payers and the insured. This so-called “*Perspektive der Versichertengemeinschaft*” should focus on the “citizens insured by the SHI in Germany” [10]. IQWiG admits that there are health technologies that should be analyzed using a different perspective due to their impact on health outcomes, i.e., the outcomes of drug treatment for Alzheimer’s disease might not only benefit the SHI but also social security related to long-term care. For budget impact analyses, IQWiG clearly votes for the budget holder perspective, which is the perspective of the sickness funds including the patients [21].

In addition, the most recent publication of the technical documents or annexes to the “*Methods for Assessment of the Relation of Benefits to Costs*” digs into these issues more deeply and discusses the perspective of the citizens insured by the SHI as being ambiguous ranging from the SHI perspective to the societal perspective [11].

Having decided on the perspective, the question remains: What is the right approach with regard to the valuation of health-care services? The IQWiG technical document on cost estimation favors societal opportunity costs. Nevertheless, due to imperfect health-care markets, the technical document argues for a microcosting approach based on resource utilization multiplied by resource prices, if available [11]. Adjustments to better estimate opportunity costs should be taken into account under specific circumstances as discussed in the document.

Nevertheless, this is not an easy approach because resource prices are often not publicly available and the size of the adjustments to reflect opportunity costs can be argued and used strategically. From a pragmatic point of view, valuation of health-care services from the SHI perspective should take resource costs into account as absorbed by the SHI.

QALY Thresholds

QALYs are not accepted in the German assessment debate [24]. Hence, QALY thresholds are not accepted either. IQWiG does not perceive a justification to focus on QALYs because of its

mandate by the MoH and based on the comments of the MoH on QALYs. Therefore, threshold discussions are currently irrelevant with regard to the German context.

Dealing with Uncertainty

The IQWiG methods paper on cost–benefit assessments does not deal with uncertainty explicitly. The issue is mentioned several times in the document, but the reader is mainly referred to the technical document on uncertainty [13]. The technical document deals with uncertainty in terms of an estimate of the true value of a parameter and uncertainty in terms of the confidence intervals around this estimate.

Transferability of Economic Information

The transferability of economic information from one country to another is dealt with in the technical document on cost estimation [11]. The document points to factors influencing transferability of cost data, key determinants influenced, efforts to check correspondence between studied and target country, and adjustments to improve transferability to the context of the target country.

As to the document, there are “knock-out criteria” that preclude transferability of cost data, for example, the intervention to be analyzed is not relevant to the target country, the study quality does not meet methodological standards of the target country, and other issues. Modeling adjustments might be required with regard to differences in epidemiology, health-care standards (health-care processes and resource utilization), and relative prices. If currency conversion is required, this should be done using purchasing power parities.

Generating and Using Real-World Data

In HTAs, among others, the following categories of data are involved: data on outcomes, resource use, and the values of resources used. The discussion on real-world data concerns outcomes and, potentially, resource use. Values of resources used depend on the perspective of the analysis and the costing approach [11].

With regard to outcomes data, IQWiG focuses on randomized controlled trials (RCTs) in its general methods because of their internal validity, which is to demonstrate causal relationships [6]. This raises questions on the external validity of the respective study results. For IQWiG, the most important elements for internally valid study results are randomization, an unbiased assessment, summarization, and publication of study results to achieve a high degree of certainty of results.

Furthermore, IQWiG does not perceive a contradictory relationship between internal and external validity because external validity depends on the research questions and “the intelligent combination of study type, design, and conduct” [6]. The institute refers to the discussion on pragmatic trials and views RCTs as feasible means to generate real-world data, depending on the appropriate trial design. Hence, with regard to the benefit assessment as a precursor for the cost–benefit-assessment, IQWiG is confined to RCTs if available but flexible with regard to the proximity of the trial design to routine care conditions. Real-world data generated by study designs other than the RCT are only taken into account by the institute if there is no alternative [6].

SECTION IV: CURRENT ISSUES WITH THE USE OF HTA

The ultimate purpose of HTA is to inform health-care decision-making. See Henshall et al. for an European overview on HTA in

policy and practice [14]. Health-care decision-making occurs at the level of parliament and the MoH responsible for setting the frame for health care in Germany. Health-care decision-making also occurs at the level of the G-BA responsible for implementing health-care services in specific terms [15].

As a basis for decision-making, HTAs need to be initiated in advance. The G-BA or the ministry can commission IQWiG for an assessment of any particular research question that they want to resolve. Nevertheless, there is no explicit prioritization compared to DIMDI, as described above.

For example, the DIMDI topics of priority for 2008 were as follows [16]:

1. What medical and economic benefit has the examination of the *Helicobacter pylori* population via urea respiratory test in primary diagnostics compared to invasive and non-invasive methods?
2. What medications for the treatment of hypertension do support diabetes mellitus, type 2? What medications are, in the long run, cost-effective?
3. What efficacy has interventions for preventing falls on the mobility of the persons concerned, their fall rate, and fall consequences? What efficiency has the preventive measures with regard to falls and the associated treatment and follow-up costs?
4. What are the medical pros and cons of endoprosthesis registers? What are the international experiences? How is the efficiency? What are the judicial, ethical, and social implications?
5. What are the efficacy and efficiency of nonmedical secondary prevention of patients with coronary heart disease in Germany? In comparison to conservative methods, what is the value to physicians, patients, and the funding bodies?

The assessments of the IQWiG are used by the G-BA for their decision-making. Whether the HTAs commissioned by DAHTA@DIMDI inform health policy is not so clear and there is no evidence available on that. Nevertheless, various institutions within the German health-care system are very active in HTA. At least, they perceive a benefit in undertaking these activities.

The issues regarding the use of HTA include transparency in decision-making, the independence of assessments, health policy versus politics, silo budgeting, parallel trade, patient and provider choice, and the effect of HTA on budgets, reimbursement, and access.

Transparency in Decision-Making

The DIMDI process is transparent, but there is no immediate decision-making based on DIMDI HTAs.

With regard to IQWiG, decision-making during the assessment process is based on the draft report plan, which is publicly discussed with different stakeholders in writing and during a hearing. The reasons for decisions during the assessment process are not depicted in the public domain. Because IQWiG is a private institute established as an institution of the Foundation for Quality and Efficiency in Health Care to undertake commissions from the G-BA and the MoH, it is responsible only to the foundation and its representatives.

Decision-making of the G-BA based on IQWiG assessments, again, is transparent, meaning that the final decision will be coded as a directive and the reasons for the respective decision are given in writing. In addition, the decisions of the G-BA can be legally challenged. This holds true for the assessment activities of the G-BA itself as well.

Independence of Assessments

IQWiG awards scientific commissions to external experts to fulfill its commitments toward the G-BA. These commissions are subject to the regulation of public procurement law. External experts need to adhere to the following requirements:

1. consideration of the methods papers of the institute;
2. disclosure of potential conflicts of interest pertaining to the assignment;
3. command of German language;
4. specification of medical/professional references; and
5. proof of medical/professional experience pertaining to the assignment.

The external experts are acting on behalf of the IQWiG. Their assessment is not independent. Whether the assessment delivered by the IQWiG can be perceived as independent, that is, at least, questionable and will be answered differently in Germany, depending on the individual perspective because the IQWiG is serving the interests of its founders.

This is easier with regard to DAHTA@DIMDI: Because the manual of DAHTA is less prescriptive with regard to the content of the assessment but with a clear structure of the content of the HTA, the independence of the working groups conducting the assessments is less biased.

Health Policy versus Politics

Evidence and assessments are not the only factors influencing decision-making of the G-BA or the ministry. Among other factors are the need for cost containment in a health-care system, a culture in favor of evidence, lobbying activities of stakeholders in favor of or against specific health technologies, transparency in decision-making, expertise in applying HTA, changes in the political system, change in personnel conducting the HTA, tedious decision-making processes, and lack of a coordinating office collecting and providing HTAs centrally [9]. In addition to these factors, the reputation of the working group or agency conducting HTA, involvement of stakeholders during the assessment process, congruence between the HTA sponsor and the ultimate decision-maker, innovativeness and expensiveness of the assessed health technology, and the role of emotions related to the health technologies discussed impact the final decision.

There is only limited evidence available on the relevance of these factors compared to the evidence, and a quantitative approach to measure the impact still needs to be developed [17].

Silo Budgeting

The German health-care system is financed via a system of budgets and comparable means and even funding and reimbursement access is handled differently depending on the features of the health technology. Funding and reimbursement of drugs is regulated mainly via the G-BA; for medical devices used by the patient directly prescribed in outpatient care, the approval by the head association of the sickness funds and the admission to the official list of aids are required. For medical devices used as part of a medical service in outpatient care, the G-BA needs to approve the service with the device after an assessment of the benefits of the service based on the "Verfahrensordnung" of the G-BA. This is different if the device is used for inpatients [18]. Hence, there is no common assessment process or set of criteria independent from the technology to be assessed.

These assessments are similar but conducted by different institutions and they rarely take the societal perspective into account. Therefore, health technologies with additional costs for

the health-care system, but with benefits accruing to other organizations within the social security system, can be denied for SHI patients.

Parallel Trade

Parallel trade in Germany is supported by law and office-based pharmacists are required to dispense at least 5% of their total drug dispensation as parallel imported drugs. This is due to cost containment measures and the aim of lowering the drug expenditure in Germany. Nevertheless, there is no discussion on parallel trade pertaining to HTA. There is little discussion of drug safety issues related to parallel trade.

Patient and Provider Choice

Provider choice can relate to sickness funds as well as physicians or hospitals using formularies. Hospitals use formularies in Germany on a regular basis. Physicians do not use formularies explicitly but have a range of products they prescribe regularly. Physicians organized in integrated care networks and other organizations may set up their own formularies. Sickness funds are just starting discussions on sickness funds' individual formularies based on current discount negotiations between sickness funds and the pharmaceutical industry in Germany.

Nevertheless, sickness funds' individual formularies still need a long way to go until they become implemented in the German system. Currently, sickness funds have no direct means to influence physicians' drug prescriptions.

That does not mean that patients can choose their drugs on their own. Drug prescriptions are mainly driven by physicians based on the directives of the G-BA regulating the prescribability of drugs (Verordnungsfähigkeit). Without going into details, regulation by the G-BA impacts on drug prices, utilization, and quality by deploying reference prices, negative lists, exclusions from prescribability, individual physician budgets (Richtgrößen), and other measures. Cassel and Wille list 18 measures impacting on drug prices, utilization, and quality [19]. Patients within the SHI are free to choose drugs only if the respective drugs are available without a prescription (over-the-counter drugs).

Patients with private health insurances can choose drugs provided that the respective drug is prescribed by a physician.

With regard to technical aids, for SHI-patients, prescribed aids need to be listed on the official list of aids. Within that range, patients can choose together with their physicians. If medical devices are used as part of a medical service, there is rarely a choice for the patient.

Effect on Budgets, Reimbursement, and Access

HTA is only one factor influencing budgets, reimbursement, and access. The other factors, like the above-mentioned measures to guide drug prescriptions, are still of far more importance in Germany. There are prominent examples like the short-acting insulin analogues where the IQWiG assessment led to discount contracts between sickness funds and the affected pharmaceutical companies, and hence impacted on access for patients, reimbursement, and budget. Nevertheless, looking at the complete picture of drug expenditure and related regulation, the impact of regulation is much stronger than the impact of HTAs. The impact of regulation sometimes conflicts with rational prescribing behavior. Hence, those conflicts need to be resolved before HTA really makes a difference.

SECTION V: HTA IN GERMANY— LESSONS LEARNED

HTA is increasingly used in Germany to inform health-care decision-making, but there is no systematic and prospective evidence on the impact of HTA [9].

The assessment of pharmaceuticals is mainly done by the IQWiG on behalf of the G-BA. Hence, IQWiG assessments, as a specific or modified form of HTA, are becoming more and more important. HTAs driven by DAHTA@DIMDI rarely play a role in funding and reimbursement. Nevertheless, they could play a role for health policy decisions by the parliament and for independent patient information which is not biased towards the goals of the members of the foundation of the IQWiG, but this does not seem to be the case.

HTA is mainly used by the G-BA, IQWiG, sickness funds, statutory physicians' associations (subsequent to IQWiG or G-BA activities), and others dealing with the catalogue of benefits and its composition. It is mainly directed to shaping and updating the catalogue of benefits. But does that help the health-care budget?

In Germany, there is no single health-care budget. There are various measures to contain health-care costs and some of those are budgets, but there is not one single budget figure. With regard to drugs alone, and as mentioned above, there are about 18 measures to steer drug expenditure according to Cassel and Wille [18]. On the contrary, because of the current use of HTA in Germany, assessments impact on the health-care budget and on access to health care. The adoption of innovative treatment methods potentially increases the pressure on health-care expenditure due to the increase of available treatment because the adoption of innovative treatments is rarely linked to the exclusion of existing treatments from the catalogue of benefits. Because the decisions by the G-BA are legally binding not only for sickness funds and statutory physicians but for the insured as well, HTA impacts on access as well.

The G-BA adoption requirement for innovative treatment methods for outpatient care and the power to exclude treatments from inpatient care defines the regular pathway for innovation into the German system: Innovative treatments very often enter the system via inpatient care and run into outpatient care after the adoption by the G-BA. This is even the case if the treatments are designed for outpatient care. Assessments take time and delay the access of innovative treatments in outpatient care. Whether this is positive or negative is debated not only in Germany. With regard to drugs, this discussion has led to the request that there should be a fourth hurdle for drugs, and the immediate funding and reimbursement of new drugs after market authorization should be abolished. The differences in market access for drugs, medical devices used in medical services, technical aids, and diagnostics should be questioned and health policy should think about a common approach for the admission of new technologies to the German health-care system based on HTA. Nevertheless, this discussion is just at the beginning.

The increasing popularity and use of HTA by different stakeholders in the German health-care system has led to the professionalization of the HTA business not only at the G-BA, IQWiG, DIMDI, MDS, KBV and other institutions already mentioned above but also in the industry. The health-care industry in Germany has adopted the requirement to support innovative products by explaining the value of those products in comparison to the state of the art. Industry uses HTA to assess and demonstrate the value of their products. Hence, HTA seems to be emerging as the common gateway for innovation into the German health-care system.

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