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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 HTA was established within DIMDI (Deutsche Agentur für 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.

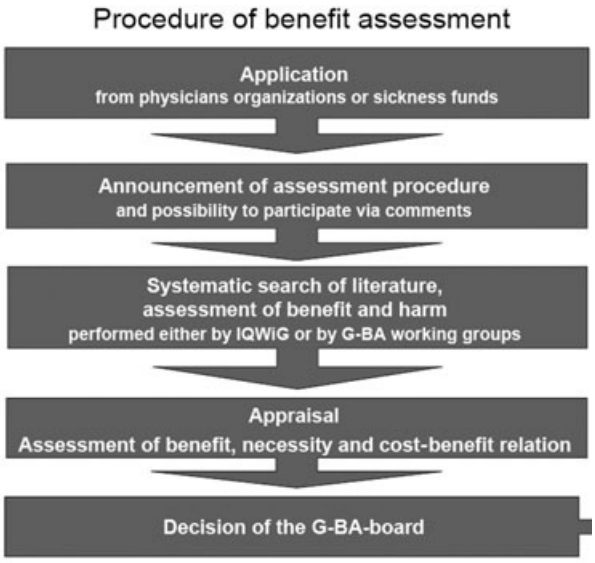

Figure 1 Assessment of Benefits by the Gemeinsamer Bundesausschuss (G-BA) [2]. IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen.

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

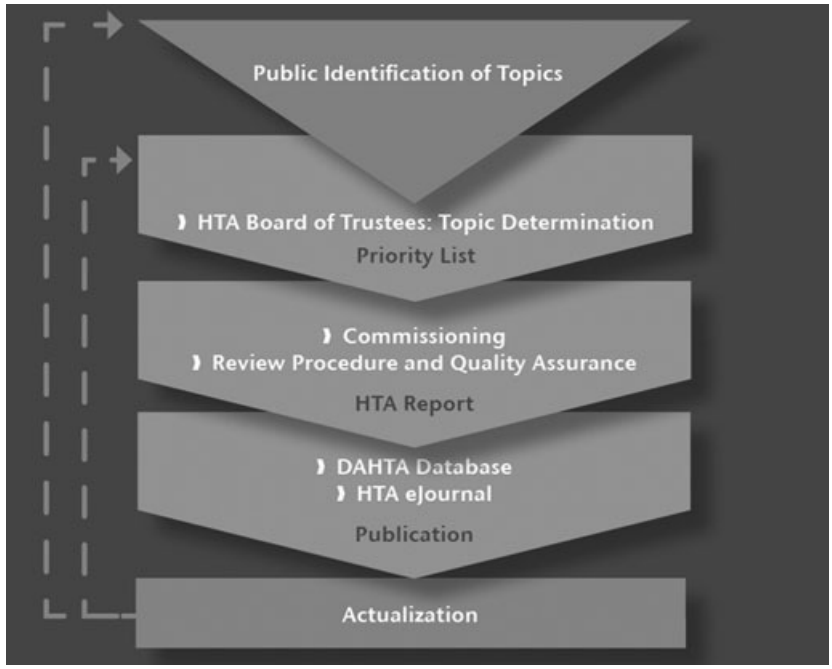

Figure 2 The health technology assessment (HTA) process at DIMDI [3]. DAHTA, Deutsche Agentur für Health Technology Assessment im Deutschen Institut für Medizinische Dokumentation und Information.