HTA Austria
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Lecture notes: basics and principles of health technology assessment

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List of Abbreviations

AGES ..... Austrian Agency for Health and Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH)
AWMF ..... Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften)
AIHTA ..... Austrian Institute for Health Technology Assessment GmbH
ASVG ..... General Social Insurance Act (Allgemeines Sozialversicherungsgesetz)
ATMP ..... Advanced Therapy Medicinal Products
BIA ..... Budget Impact Analysis
B-KAG ..... Federal Hospitals Act (Bundeskrankenanstaltengesetz)
BMASGPK ..... Federal Ministry of Social Affairs, Health, Care and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz)
CBA ..... Cost-benefit analysis
CCA ..... Cost-consequence analysis
CEA ..... Cost-effectiveness analysis
CEESTAHC ..... Central and Eastern European Society of Technology Assessment in Health Care
CMA ..... Cost-minimisation analysis
CUA ..... Cost-utility analysis
DNVF ..... German Network for Health Services Research Association (Deutsches Netzwerk Versorgungforschung e.V.)
DRG ..... Diagnosis-Related Groups
DUK ..... University for Continuing Education Krems (Donau-Universität Krems)
DVSV ..... The Federation of Social Insurances (Dachverband der österreichischen Sozialversicherungen)
EBM ..... Evidence-based Medicine
EBPI ..... Evidence-based patient information
EBPH ..... Evidence-based Public Health
EC ..... European Commission
EU ..... European Union
ECAHI ..... European Assessment for Health Interventions
ECHTA ..... European Collaboration for Health Technology Assessment
EKO ..... Reimbursement code (Erstattungskodex)
EMA ..... European Medicines Agency
EP ..... European Parliament
EUnetHTA ..... European Network for Health Technology Assessment
FDA ..... Food and Drug Administration
FTE ..... Full-time employees
GDP ..... Gross Domestic Product
GÖG ..... Austrian Public Health Institute (Gesundheit Österreich GmbH)
GQG ..... Austrian Health Quality Act (Gesundheitsqualitätsgesetz)
HEE ..... Health economic evaluation
HEK ..... Commission for Evaluation of Pharmaceuticals (Heilmittel-Evaluierungs-kommission)
HEN ..... Health Evidence Network
HIA ..... Health Impact Assessment
HTA ..... Health Technology Assessment
HTAi ..... Health Technology Assessment International
HTAR ..... EU Regulation on health technology assessment (Verordnung (EU) 2021/2282)
IAMEV ..... Institute of general practice and evidence-based health services research (Institut für Allgemeinmedizin und evidenzbasierte Versorgungsforschung)
ICER ..... Incremental cost-effectiveness ratio

IMI ..... Institute of Medical Informatics, Statistics and Documentation (Institut für Medizinische Informatik, Statistik und Dokumentation)
INAHTA ..... International Network of Agencies for Health Technology Assessment
IPF ..... Institute for Pharmacoeconomic Research (Institut für pharmakoökonomische Forschung)
IQWiG ..... Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)
ISPOR ..... The Professional Society for Health Economics and Outcomes Research (formerly: International Society for Pharmacoeconomics and Outcomes Research)
ISTAHC ..... International Society of Technology Assessment in Health Care
LBI-HTA ..... Ludwig Boltzmann Institute for Health Technology Assessment (Ludwig Boltzmann Institut für Health Technology Assessment)
KAKuG ..... Hospitals and Health Resorts Act (Krankenanstalten- und Kuranstaltengesetz)
LKF ..... Procedure-oriented hospital financing/services catalogue/benefits catalogue, Austrian DRG system (Leistungsorientierte Krankenanstaltenfinanzierung)
MEL ..... Individual medical services (medizinische Einzelleistung)
MUW ..... Medical University of Vienna (Medizinische Universität Wien)
OTA ..... US Congress Office of Technology Assessment
POP ..... Planned and ongoing projects
QALY ..... Quality-adjusted life-years
RSS ..... Really Simple Syndication
RCT ..... Randomized controlled trial
RWD ..... Real-world data
RWE ..... Real-world evidence
TA ..... Technology assessment
VMDI ..... Contractual partner of medical service providers and innovation (Vertragspartner medizinische Dienstleister und Innovation)
WHO ..... World Health Organisation

1 Preface and structure of the lecture notes

The following document outlines the essential knowledge regarding:

- Understanding the necessity and complexity of decision-making in health care
- Defining key terms related to health technology assessment (HTA) terms
- Exploring approaches, perspectives, concepts, and theories underpinning HTA
- Examining the integration and scope of HTA within the healthcare system
- Reviewing the international landscape of HTA, including agencies, organisations, networks, expert associations, and funding mechanisms of HTA programmes
- Gaining insight into product development, legal market authorisation, and reimbursement of health technologies

Overview of Topics

The following topics are covered in the lecture notes:

- System context (Chapter 2) and HTA as decision-making support (Chapter 3)
- Implementation of HTA (Chapter 4)
- Globalisation and networking (Chapter 5) and HTA in Austria (Chapter 6)
- HTA throughout the health technology lifecycle (Chapter 7) and stakeholder involvement in the HTA process (Chapter 8)
- Dissemination and effects of HTA results (Chapter 9)

The following literature provided the foundation for the content:

Perleth, M et al. (2023). Health Technology Assessment. Konzepte, Methoden, Praxis für Wissenschaft und Entscheidungsfindung. 3rd ed. Berlin: Medizinisch Wissenschaftliche Verlagsgesellschaft.

Methodenhandbuch für Health Technology Assessment. Version 1.2012. (2012). Wien: Gesundheit Österreich GmbH.

Drummond, M. et al. (2015). Methods for the economic evaluation of health care programmes. Oxford: Oxford University Press.

Additionally, numerous other sources are cited; see references.

2 The system context

This chapter seeks to clarify the health policy framework for HTA implementation.

The objectives of this chapter are to:

- Identify the challenges in public healthcare financing
- Explain the rationale behind healthcare markets
- Highlight medical areas experiencing rapid innovation

All healthcare systems face the challenge of balancing the goal of providing the best medical care within the reality of limited resources (regardless of their amount). The available financial resources are determined by a political negotiation process. However, what criteria should guide the distribution of these funds? Resources must be allocated not only across different areas of healthcare (prevention, diagnostics, therapy, rehabilitation, nursing care), but also among groups of diseases (e.g., geriatrics and oncology) and medical products or procedures for specific indications (e.g., various cholesterol-lowering drugs).

In the past, these questions were not explicitly discussed. The need to use available resources as efficiently as possible was reinforced by the rapid increase in new, but often also extremely expensive, procedures; other demand-increasing developments (e.g., demographics); and the goal of funding effective services for all eligible individuals, with the help of a solidarity-based system, where necessary. This results in paying for services whose benefits outweigh potential harm and allocating the funds to maximise their (health) benefit relative to available resources, thereby bringing the criteria of “effectiveness” (How effective is a measure?) and costs (What is the relationship between effectiveness and costs?) more into focus.

New medical technologies or procedures, representing medical progress (“innovation”), are brought to the market daily. The launch of new products is often accompanied by superlatives in the media (e.g., “breakthrough in cancer therapy x” or “new drug makes cure for disease y possible”). This not only raises hopes among patients and their families but also generates demand for new products among service providers (such as hospitals, clinicians, and therapists). The economic term for this process is "supplier-induced demand". The possibility of potential harm (as with any health technology) remains unmentioned. Furthermore, when considering funding, not only benefit and risk are weighed, but also the price and associated costs. In other words, a “new” product does not inherently carry value or guarantee improvement for patients or population health, nor does it automatically provide greater benefits to the healthcare system relative to its costs.

There are numerous examples of "innovations" in healthcare – whether drugs, medical devices or diagnostic and treatment procedures – that later proved to be ineffective or even harmful, such as thalidomide for sleep disorders (the thalidomide scandal), endovascular stent grafting for abdominal aortic aneurysms or radical mastectomy for breast cancer [1]. New health technologies often provide only a marginal improvement over available alternatives. For example, antihypertensive drugs: The ALLHAT study [2] showed that the newer generation of antihypertensive drugs (ACE inhibitors, calcium channel blockers, alpha blockers) are more effective than the placebo but are less effective and more expensive than thiazide diuretics, which were already available on the market. In some cases, newer products have been associated with higher complication rates [1].

The pace of innovation across different areas of healthcare changes over time. Currently, particularly dynamic areas include genetic diagnostics and gene therapy, diagnostic imaging, e-health and m-health applications within the framework of digital technologies, and new developments in oncology [1]. For example, in oncology, the European Medicines Agency (EMA) approves yearly some 20 to 25 new cancer therapies or indication extensions for existing therapies, including new, complex therapeutic approaches such as immunotherapies, cell and gene therapies [3]. However, as noted above, an authorised product is not automatically funded publicly, nor is it immediately and simultaneously available in all European countries, even though patients, service providers, and manufacturers often expect it. These expectations arise from differing interests: for manufacturers, it is profit maximisation; for patients, hope for life extension or improved quality of life. Therefore, health payers determine whether new services should or can be

funded for specific patients, and at what price, within the framework of a solidarity-based system, and which new services cannot be covered.

However, there are various underserved areas in healthcare ("supply gaps") and diseases that receive little attention from the industry ("unmet medical needs"). For these areas, new products are rarely introduced to the market, because they are not profitable or require less high-technology (e.g. the use of medical technology or complex medical devices) or drug therapies, but focus on, for example, counselling or psychotherapeutic and psychosocial interventions instead. This includes child and adolescent psychiatric care or the development of new antibiotics in response to the growing threat of antibiotic resistance. Thus, the funding of services should be determined to prevent overuse, underuse, or misuse as much as possible and to address the actual needs of society, which are constantly evolving (e.g., due to demographic changes).

3 HTA as decision support

This chapter describes key terms and core principles of HTA and explains various definitions of HTA. The objectives of this chapter are to:

- Explain the purpose of HTA
- Identify key characteristics of HTA
- Distinguish HTA from related research areas
- Outline the historical development of HTA

3.1 HTA's intention

Due to the rapid increase of knowledge about health technologies, as described in Chapter 2, it is not feasible for decision-makers to base their choices on a comprehensive understanding and thorough quality assessment of all available health technologies and their potential consequences. Despite this challenge, objective and informed decision-making remains essential, particularly regarding issues like reimbursement. Therefore, HTA aims to support decisions based on scientific findings and is considered a vital instrument for scientific policy counselling (bridging the gap between science and politics) [1]. An introductory video by the Austrian Institute for HTA (AIHTA GmbH) explains the key characteristics of HTA (https://bit.ly/33QAUfd).

- HTA is particularly important when:
- There is a high burden of disease is,
- An intervention is used frequently and/or is costly,
- A cost-effective therapeutic standard ("gold standard") is available,
- There is high variability in the clinical application,
- The potential effectiveness is significant, but considerable uncertainties remain.

However, recently, therapies for rare diseases (orphan drugs) have been increasingly the subject of HTA assessments, as they have no previously available treatment options and are often costly (e.g., Spinraza® for the treatment of spinal muscular atrophy). For example, drug therapies for very rare diseases in some paediatric units amount to more than 90 per cent of the pharmaceutical budget [3]. Reasons for high prices are small patient populations, lack of treatment alternatives and monopolies of suppliers [4, 5].

3.2 Definition of HTA

Early HTA studies (1970s) regarded HTA as a form of policy research that examined short- and long-term consequences of medical technologies. The aim was to provide policymakers with policy alternatives [4].

Later, Goodman [5] defined HTA as the systematic evaluation of the properties, effects or broader impacts of medical technologies with the purpose of informing policy decisions related to medical technologies.

In recent years, the definition used can be found in the HTA glossary (http://www.htaglossary.net), which is a collaboration between the International HTA Network (INAHTA), HTA international (HTAi) and other partner organisations. They defined HTA as: "the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision-making regarding health technologies. Note: HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods."

The Professional Society for Health Economics and Outcomes Research (formerly known as the International Society for Pharmacoeconomics and Outcomes Research, ISPOR), the World Health Organisation (WHO) and regional HTA networks (e.g., the European network for HTA, EUnetHTA) have published their own definitions of HTA.

In spring 2020, a collaboration of various international HTA networks and organisations published a new definition of HTA that can be found in the HTA glossary mentioned above, describing it as "a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system" [4].

Four additional remarks were made [4, 6]:

- Note 1: “Health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. Note 1: The intervention can be a test, device, medicine, vaccine, procedure, program or system.” (a definition of "health technology" from the HTA glossary (http://htaglossary.net/).
- Note 2: The process is formal, systematic and transparent, utilising methods that comply with current scientific standards to consider the best available evidence.
- Note 3: Assessing the intended and unintended consequences of using a health technology compared to existing alternatives allows examination of its value dimensions. These dimensions often include clinical effectiveness; safety; cost and economic implications; ethical, social, cultural and legal issues; organisational and environmental aspects; and impacts on patients and their families, caregivers and the population. The overall assessment of value depends on the perspective, involved stakeholders and the context of decision-making.
- Note 4: HTA can be conducted in different stages of the health technology’s life cycle, i.e., before market launch, during market approval, after-market launch or disinvestment of a health technology.

The updated definition from spring 2020 addressed criticisms that previous definitions were relatively technical, used terms that were difficult to translate, and lacked memorability. Furthermore, the entire international HTA community recognises the definition, which experts developed using a participatory approach [4].

All definitions state that the evaluation of health technologies must be comprehensive, focusing on efficacy, safety, and economic implications of a medical procedure. However, as stated in the additional remarks, the most recent definition includes further evaluation dimensions, including ethical, organisational, legal and cultural implications; and more recently, the effects on the environment or climate have (sometimes) also been considered.

The first remark from the most recent definition shows that the term "technology" in "health technology assessment" is a broad concept, as it can refer to technology, devices, tools, computer programmes, systems or procedures. The former Office of Health Technology Assessment (OTA), which served the U.S. Congress, defined medical technologies as "...drugs, devices, and medical and surgical procedures used in medical care, and the organisational and supportive system within which such care is provided" [7]. Therefore, scientists can conduct an HTA for any intervention used in healthcare (e.g. pharmaceuticals, health promotion measures, prevention programmes, diagnostic or non-pharmacological measures).

"Health Technology Assessment" is also widely used in other languages.

3.3 Classification of medical technologies

There are different classifications of medical technologies. The OTA, for example, based the categorisation on the use of the medical technology: prevention, diagnostics, therapy, rehabilitation, patient support, and administration [7]. Thomas (1971) [8] used an alternative classification:

1. Nontechnology: The non-technological supportive role of medical and nursing care providers (e.g. counselling). The actual methodology used generally does not change the natural mechanisms of disease.
2. Halfway technology: Interventions that identify and manage disease. It may help extend life, but cannot cure disease (e.g. diagnostic procedures, symptomatic treatment).
3. Definite technology (high technology): Fundamental scientific knowledge enables the prevention or cure of illness, which requires an understanding of the pathogenesis (e.g., mechanisms that trigger cancer). An example of "high technology" are cancer drugs or vaccinations.

According to Perleth et al. [1] a difference in practice can be observed between new and established technologies. New technologies encompass innovations (e.g., gene therapies), modifications of existing technologies (e.g., advancements in computer tomography), or changes in the frequency of use. The latter is "new" in terms of the impact on healthcare (i.e., regulatory changes).

Regulatory authorities can also categorise technologies to their regulatory framework. In Austria, for instance, distinct regulatory structures exist for pharmaceuticals, medical devices (such as implants), preventive interventions (e.g., vaccinations, screening) and rehabilitation by law. HTA rarely evaluate management or organisational structures. Perleth et al. [1] provided an example from Germany assessing the effectiveness of the organisational structure relating to specialist consultation in nursing homes.

Another consideration is distinguishing procedures under evaluation from other areas of care (such as nursing and care outside the healthcare sector, which is financed differently, namely through the social sector). Normally, nursing interventions, even in home environments (e.g., fall prevention) or within the social sector (e.g., psychosocial counselling), can be assessed using the same methodology (see Chapter 4.4). However, in some welfare states (including Austria), these measures fall outside of the influence of the healthcare system, causing the term "***health*** technology assessment" to be somewhat misleading.

3.4 Key principles of HTA

While the scope and dimensions addressed in an HTA can vary considerably, there are several key principles underlying any quality HTA:

1. Maximum transparency: Authors must present the methodological steps in an HTA transparently, enabling readers to understand how they reached the results, conclusions, and possible recommendations. This applies to topic selection, formulating the research question, conducting the literature search, and synthesising the literature. Any subsequent review or comment procedures must be transparent.
2. Interdisciplinarity: Because an HTA considers different perspectives of a health technology (such as efficacy, safety, and organisational implications), experts from multiple disciplines participate in the assessment, ranging from medical practitioners, public health experts and other health researchers to health economists, ethicists, lawyers, and social and natural scientists.
3. Neutrality / objectivity: HTA is committed to independence from various interest groups and to conducting research and presenting the results in the assessment as objectively as possible. This requires disclosure of the methodological approach in advance, justification for any deviations from methodological standards or predetermined report plans, rules for stakeholder involvement in the HTA process (e.g., disclosure of conflicts of interest), transparency regarding the client and financing of the HTA report, and quality assurance through external review (peer review).

3.5 HTA and related research areas

3.5.1 Technology Assessment

The roots of HTA lie in technology assessment (TA). However, while TA typically evaluates newer areas of development broadly (e.g., pharmacogenetics, preimplantation diagnostics), HTA focuses on individual health technologies within the emerging fields (e.g., genetic testing for familial hypercholesterolaemia).

Unlike TA, which primarily focuses on societal implications as a whole, HTA focuses more methodologically on clinical benefits and the economic impact on the healthcare system, relying mainly on published scientific data. TA seeks to identify the needs for political and societal action and examines the perspectives, interests, and values of different social groups and making greater use of qualitative methods and empirical social research instruments. In contrast, HTA relies more heavily on epidemiological and quantitative methods, adopting different perspectives (e.g., payers, service providers, etc.) depending on the decision-making context.

Ideally, TA and HTA complement each other. Perleth et al. [1] illustrate this using the example of telemedicine, where HTA examines diffusion dynamics into the healthcare system, health outcomes, organisational effects, and costs. At the same time, TA addresses aspects such as patient privacy or data protection. In German-speaking countries, TA has been established for many years, for example at the Institute of Technology Assessment at the Austrian Academy of Sciences (Institut für Technikfolgen-Abschätzung der Österreichischen Akademie der Wissenschaften) (https://www.oeaw.ac.at/ita/home/) and at the Office of Technology Assessment at the German Federal Parliament (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag).

3.5.2 Evidence-based medicine, guideline development and evidence-based patient information

The term "evidence" refers to information from scientific studies and systematically compiled experiences that confirm or refute facts [1]. Compared to English-speaking countries, decision-making in the healthcare system based on scientific findings has a relatively short history in Austria. Within the culture of evidence-based decision-making, several trends have developed: evidence-based medicine (EBM), clinical practice guidelines, evidence-based patient information and HTA.

Evidence-based medicine (EBM) [9] is the conscientious, explicit and rational use of the best available external scientific evidence for decision-making in the medical care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external evidence from systematic research. EBM is based on three pillars: individual clinical experience, patients' values and wishes, and the actual status of clinical research.

The approach of EBM is based on five steps:

1. Formulating the clinical problem as a research question that can be answered through scientific investigation
2. Systematic literature search for suitable studies
3. Critical evaluation of evidence from all identified studies
4. Application of the findings obtained concerning the specific clinical situation
5. Evaluation and, where applicable, adjustment of the current approach

Guidelines are developed systematically to help practitioners and patients make decisions about appropriate health care for specific clinical circumstances. Guidelines are intended to provide external scientific evidence as a local standard at the level of a specific group of patients (if possible, taking into account further aspects such as age, gender, comorbidity, setting and cost-effectiveness), established through a defined and transparent consensus process involving experts and stakeholders; in justified cases, it is permitted or even necessary to deviate from this standard [1].

Evidence-based patient information (EBPI) aims to convey medical knowledge to patients in an objective and comprehensible manner, enabling informed decision-making. High-quality patient information

presents the benefits and harms of interventions and communicates risks appropriately. To identify high-quality patient information the DISCERN assessment tool is used (www.discern.de). A reliable source of patient information is the "patient information" section at the Institute for Quality and Efficiency in Health Care (IQWiG) (www.gesundheitsinformation.de).

In contrast, as previously mentioned, HTA primarily functions as decision support at the health system level, focusing on population groups or the entire population rather than individual patients. HTA is more multidisciplinary, including the qualifications of the authors, than EBM or guideline development, which clinical expertise strongly supports (see Table 3-1).

Table 3-1: Differences between EBM and HTA

	EBM	HTA
Target group	Medical practitioners	Decision maker in the health system
Target population	Individual patients	Population / demographic groups
Context of application	Clinical decision-making	Cost coverage/reimbursement investments, regulation
Methods	E.g., systematic reviews, meta-analyses	E.g., systematic reviews; meta-analyses; clinical studies; economic evaluations; political, ethical and sociological analyses

Source: [10]

Table 3-2 provides an example of HPV vaccination at the time it entered the market to illustrate the differences between clinical decision-making and HTA. From a clinical perspective, clinicians base the decision to vaccinate on the benefit-risk ratio, evaluating it according to the individual patient's values, preferences, risk behaviours and other factors. In contrast, HTA focuses on population health, providing insights into the current epidemiological situation, outlook, and economic considerations.

For example:

- How often does the disease that the vaccination aims to prevent (cervical cancer) occur compared to other diseases?
- How does the incidence of cervical cancer change after vaccinating the entire population?
- Are there cheaper alternatives that also achieve the same outcome (reducing cervical cancer mortality and morbidity)?

Table 3-2: Differences between EBM and HTA: The example of HPV vaccination[a]

Clinical Perspective	Population Perspective
Effectiveness/safety: ■ With the vaccine, 3 out of 1,000 women contract or 1 die from cervical cancer; without the vaccine, 10 or 2 ■ Reduces the incidence of precancerous stages (30–40% reduction, independent of virus type) ■ To date, researchers have not identified any serious safety concerns. ■ However, some issues remain unresolved, such as the necessity of booster shots and the potential for long-term adverse events. ■ **Key question**: Does the benefit outweigh the potential harm?	Epidemiology, benefits and costs ■ 2011: cervical cancer ~400 new cases, 150 deaths (ranked 14th) ■ Total cancer cases among women: ~17,500 new cases, 10,000 deaths among women ■ Annual vaccination costs: €4–6 million ■ Max. benefit in Austria in 100 years ■ Effective alternative (somewhat less optimal): Screening ■ **Key questions:** What health outcomes and costs can be expected compared to screening? What services CANNOT receive funding because resources are allocated to the HPV vaccination? (opportunity costs!) Could the vaccination budget be used more effectively to achieve a broader health impact?

a: Based on the information available before the decision to provide reimbursement

As shown in Table 3-1, these two perspectives have similarities. For example, guideline developers, EBPI experts, and HTA teams often conduct systematic reviews, synthesising and critically assessing identified primary studies according to defined criteria. They may use either a narrative or quantitative approach (e.g., meta-analysis) for this process (see Chapter 4.4).

3.5.3 HTA and health services research

Health services research is a multidisciplinary approach that examines the implementation of scientific findings in healthcare practice, focusing on their impact on quality and efficiency from both individual and socio-economic perspectives [11]. This definition demonstrates that HTA and health services research share content and methodological links, such as a multidisciplinary approach.

Health services research examines how the concept of healthcare – its organisation, management and funding – affects access to care, its quality, safety and costs, and ultimately the health and well-being of citizens [12]. Health services research emerged from the understanding that changes in the healthcare system require planning or, at the very least, evaluation based on scientific evidence. Therefore, health services research aims to support change processes with scientific findings. Furthermore, health services research is less about researching the system and more about deliberately involving different stakeholders. While health services research is in its relatively recent stages in German-speaking countries (particularly in Germany through dedicated and very well-funded research funding programmes) [13], it has a much longer history in English-speaking countries.

Health services research adopts approaches from empirical social research and clinical research. Literature and secondary data analyses play a crucial role in connecting health services research with HTA. Health services researchers frequently incorporate results from HTA, for example, the evaluation of complex interventions (e.g., screening, disease management programme), integrating the benefits of individual programme components into the evaluation. HTA often also uses health services research findings, for example, when describing the background of health technologies, formulating the HTA research question, and incorporating epidemiological evidence. Other healthcare-relevant data (e.g., the frequency of use of services based on administrative data) are also frequently used in HTA reports to describe the context of health technologies.

Compared to HTA, health services research is not linked to decision-making (as much). Although health services research projects come from an information need, they are typically not directly linked to decision-making. While both research areas are interested in the effectiveness of a technology in the real-world setting, HTA primarily relies on published literature, whereas health services research also collects primary data. However, the boundaries between the fields often overlap. Furthermore, the extent of the incorporation of health services research into HTA varies by institution. At the Austrian Institute for Health Technology Assessment (AIHTA GmbH) (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**), for example, numerous projects have a health services research focus because research questions sometimes require a methodological approach that extends beyond the systematic reviews.

Both research areas complement each other in analysing ethical and social implications of health technologies, with health services research offering contextual insights that enhance the understanding of ethical and social implications highlighted in the HTA report [1].

3.5.4 HTA and health impact assessment

Health impact assessment (HIA) is a multidisciplinary approach aimed at improving population health by evaluating (and potentially improving) health-related consequences of various (political) measures, laws, and other projects that may extend beyond the healthcare sector [14, 15]. Practitioners conduct HIAs in various areas, including industry (such as the construction or expansion of factories); infrastructure and transportation (such as road construction); and health policies and laws (such as smoking regulations, COVID-19 measures) [16, 17].

The HIA process adheres to the fundamental principles of democracy, equity, sustainable development, and ethical use of evidence [14]. HIAs typically start with screening potential (health) impacts of an intervention, essentially mapping all potential health impacts of a particular programme or project. The

scoping process follows, during which practitioners assess the extent of the HIA. During the scoping process, direct and indirect health impacts (including impacts on specific population groups) are assessed. Additionally, appropriate methods, resources, participants, and timeframes of the HIA (and its implementation) are selected [14]. Based on the outcome of the scoping process, practitioners choose the appropriate type of HIA: rapid health impact appraisals, health impact analyses, or health impact reviews, which differ in terms of resources and time required [14].

When comparing similarities and differences between HIA and HTA, experts identify the following as true: Both HIA [14, 15] and HTA [1] aim to support decision-making based on scientific evidence (linking research to policy). However, while HTA [1, 18] primarily aims to evaluate medical and health-related interventions, such as their efficacy and safety, HIA [14, 15] examines health-related consequences of more complex interventions that are not necessarily health-focused.

3.6 Historical development of HTA

The term HTA originates from the Office of Technology Assessment (OTA) of the U.S. Congress, which established the first HTA programme in 1976. Initially, its purpose was to provide policy support on technology development in healthcare (focusing on e.g., whether the introduction of new procedures was sufficiently planned and controlled). Early methodological approaches emphasised social effects rather than technology effectiveness. One of the first assessments examined computer tomography and challenges related to diffusion and control.

The shift toward clinical evaluation was in the 1980s. The Institute of Medicine (an institution of the American National Academy of Sciences) published "Assessing Medical Technologies" [19] in 1985 that identified essential components of HTA, including safety; efficacy; feasibility; indication; costs and cost-effectiveness; and social, economic and ethical implications. While TA examines societal consequences of technologies (such as environmental and cultural impact), HTA primarily focuses on the healthcare sector (see Chapter 3.5.1). No other TA area (except for HIA) has developed its methodology and established its institutions in the same way as HTA. Perleth et al. [1] note that the issues addressed by the OTA report remain relevant today (e.g., standardisation of methodology). The U.S. pioneered cost-reimbursement decisions based on HTA; however, unlike Europe, the HTA audience was primarily private insurance.

In Europe, HTA-based reimbursement decision-making developed later, in the mid-1980s. As a result, numerous organisations that initially focused on expensive and complex procedures, such as the fragmentation of kidney stones, were established. Many countries have established publicly funded national HTA programmes (including those in the Nordic countries, Great Britain, Switzerland, France, Spain, and Italy), with some also developing regional programmes (e.g., Spain and Italy). The methods, processes, organisational structures, alignments, dissemination strategies, implementation approaches, and impact of HTA have in some cases been very heterogeneous [20].

Since the mid-1990s, there has been an increase in methodological standardisations and developments. The systematic literature review (see Chapter 4.4.1) became the standard methodological approach. Additionally, due to the increased need for global cooperation and cross-national standardisation of methodology, efforts to improve HTA comparability and transferability to other countries have become more critical.

Organisational framework of HTA institutions in Europe

An overview published by the European Commission (EC) in 2017 [21] showed that 56 organisations in 27 EU Member States and Norway were involved in the process of HTA development at the national level for decision support, and 15 countries maintained one national institute, while in twelve countries operated two or more national HTA bodies. Currently, there are more than 90 European HTA organisations [1].

The HTA organisations employ a multidisciplinary team, primarily with backgrounds in pharmacy, medicine, health economics, information specialists, statistics or epidemiology. However, they can also collaborate with other related fields, such as sociology, nursing science, nutritional science, and sports science.

Most institutions commission external experts to conduct HTAs or specific work components (e.g., external reviews and statistical analyses) in addition to their in-house staff.

According to EU studies, HTA primarily informs reimbursement and pricing decisions, most frequently for the reimbursement of pharmaceuticals (in 24 EU countries and Norway), but also for the reimbursement of medical devices (19 countries). Nine EU countries use HTA for pricing decisions. The integration of HTA into the respective decision-making processes varies significantly across countries (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** for the integration of HTA in Austria).

There are differences between European countries in the way medicines are assessed after approval for reimbursement decisions, for example, in the assessment scope, comparison standard, or decision-making timeframe. This is due to differences in the healthcare systems, funding and legal frameworks of the individual countries. To promote the quality and efficiency of benefit assessment within the EU Member States, Regulation (EU) 2021/2282 [22, 23] established a legal framework for joint clinical assessments. This Regulation forms the basis for European cooperation in the field of HTA (see Chapter 5.2).

4 Implementation of HTA

This chapter explains the process of HTA and outlines the methodological approach for its implementation. The objectives of this chapter are:

- Understand the essential processes and work steps of HTA.
- Gain an overview of the possible contents of an assessment.
- Identify methods used in HTA and describe two of them in detail.
- Recognise the key methodological manuals that provide an in-depth explanation of all methods discussed.

4.1 HTA steps

HTA involves several steps beyond merely creating the assessment (the evaluation of health technologies):

- Identifying the assessment topic (health technology/use of medical technology), which can involve using early alert systems ("horizon scanning")
- Prioritising HTA topics
- Implementation of the HTA: Identifying and synthesising scientific evidence (e.g., related to benefits, safety, cost-effectiveness, organisational implications) using standardised methods (see a course on methodology of HTA reports and Chapter 4.4)
- Conclusions, and possibly recommendations to relevant decision-makers (potentially further dissemination, see Chapter 0)
- Communicating and implementing results to healthcare practice
- Impact assessment (see Chapter 9)
- However, not every assessment includes all the listed steps. Furthermore, a selection or prioritisation of topics is necessary because the HTA system does not have the capacity to assess all health technologies. The prioritisation processes are not standardised. For example, in Germany, citizens suggest topics, while in Austria, healthcare payers exclusively propose topics, and the AIHTA processes them with funding from healthcare payers (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**). Systematic approaches are often used for prioritisation (including, for example, predefined criteria). The prioritisation criteria often include the following aspects: health impact (e.g., frequency of problem/health technology use), economic impact (e.g., societal costs), and expected influence of an evaluation (e.g., reduced variability in practice or inappropriate use of health technology) [24].
- The scope of the health technology helps the prioritisation process by identifying previous assessments (to avoid redundancies), providing an initial overview of the health technology (including characteristics, expectations, development stage, prevalence, etc.), identifying disease (frequency), or patient groups, and helping develop the research question.
- The prioritisation process often begins with a "horizon scan", which systematically screens emerging medical technologies expected to attract the interest of healthcare payers (e.g., very high-priced innovations).
- A current international example of horizon scanning in the pharmaceutical sector is the International Horizon Scanning Initiative (IHSI) [25]. The IHSI maintains a shared database in which information on emerging pharmaceutical innovations from several national horizon scanning systems is collated and continuously updated. The aim is to provide HTA institutions, public payers, and other decision-makers with an early, structured overview of relevant new active substances and indications to support evidence-based planning and decision-making processes. Cooperation within the IHSI is based on shared fundamental principles, including transparency,

independence from commercial interests, methodological traceability, and the voluntary exchange of information among public sector stakeholders.

4.2 Steps in creating HTA

Creating an HTA report involves several steps (Figure 4-1), although the specific process varies depending on the HTA body's position within a healthcare system. However, to ensure methodological standards, key principles apply to all HTA projects.

After prioritising which health technology to evaluate, the scoping process begins. During this step, researchers transform the policy question into a more precise, scientifically addressable research question. Topic providers and sometimes other stakeholders (like patients) are involved in this process. Their involvement comes through a non-systematic preliminary search and an initial scope of the health technology (if researchers have not completed that during the prioritisation process).

In the next step, the report plan is created (before conducting the actual assessment). This plan serves as a project protocol that predefines specific question(s), planned methods, and the timeframe. Typically, the report plan can be reviewed and commented on by various stakeholders, depending on the context (e.g., clients, patient representatives, citizens, affected companies).

After publishing the report plan, the actual assessment begins, using various scientific methods to answer the research question (see Chapter 4.4), regardless of the methodology. A preliminary final report is created and undergoes internal and external quality assurance review. The latter review process may be a peer review by an external expert or may include comments from other stakeholder groups (e.g., industry, patients). Some HTA bodies publish both the comments and their responses, detailing how they incorporated the feedback.

After completing the quality assurance process, the team publishes the report. The publication of HTA reports, regardless of their findings, is a fundamental principle of HTA. However, implementation varies across contexts. In some countries with limited transparency or less formalised HTA regulations, clients sometimes withhold unfavourable results or delay publication (e.g., to facilitate sensitive negotiations). For example, in Austria, evidence analysis reports on individual medical services (MEL) in inpatient facilities are published after decisions about their inclusion in the catalogue of procedures have been finalised (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

Figure 4-1 Steps involved in the HTA

4.3 Domains of HTA

The components or assessment domains of an HTA are:

Clinical domains	Non-clinical domains
■ Health problem and current use of technology ■ Description and technical characteristics of health technology ■ Clinical effectiveness ■ Safety	■ Costs and economic evaluation ■ Ethical analysis ■ Organisational aspects ■ Social aspects ■ Legal aspects ■ Environmental aspects

The included domains, scope, and focus of an HTA report can vary significantly and depend on specific decision-making needs, available resources, legal requirements and other factors.

- Here are a few examples of assessments focusing on different domains:
- Ethical implications (https://eprints.aihta.at/1281/)
- Clinical effectiveness and safety (https://eprints.aihta.at/1254/)
- Costs and economic evaluation (https://eprints.aihta.at/760/)

An HTA report addressing all domains is called a comprehensive or full HTA, while rapid assessments typically focus only on the clinical domains. The EUnetHTA core model standardises these domains to improve transferability between countries and contexts, reduce redundancy, and structure domains with numbered questions. The European HTA network EUnetHTA developed the HTA core model [26], which continues to serve as the methodological basis for assessments to this day, even though the EU project ended in 2023. The work is now being continued under the EU HTA Regulation, with EUnetHTA having laid the groundwork for the methodology. This approach enables customisation by systematically addressing relevant questions, excluding those that are not pertinent, and adapting questions to specific technologies. Table 4-1 presents four example questions from clinical domains. The following section describes the key contents of each domain.

Table 4-1: Example of standardised research questions for HTA domains

Health problem and current use	
Element ID	Research question
A0001	For which health conditions, and for what purposes is the technology used?
A0002	What is the disease or health condition in the scope of this assessment?
Clinical effectiveness	
Element ID	Research question
D0001	What is the expected beneficial effect of the technology on mortality?
D0003	What is the effect of the technology on the mortality due to causes other than the target disease?

Health problem and current use of technology

This domain covers the health problem, associated risk factors, disease progression, disease effects, long-term consequences for both those affected and society, current diagnostic and treatment options, and disease prevalence.

Description and technical characteristics of health technology

This domain provides a structured description of the health technology under assessment. It includes features of the health technology itself, potential treatment alternatives, precise approval conditions (timing, indication, etc.), development and implementation stages, care context and usage methods, necessary

prerequisites (infrastructure, personnel, etc.), and information about current public funding status of the intervention.

Clinical effectiveness

This domain addresses the health technology's effects on mortality, morbidity, and quality of those affected, as well as its impact on disease progression and activities of daily living.

Safety

This domain compares the health technology's safety profile to alternatives, evaluates whether risks are dose-dependent or setting-dependent, identifies patient groups particularly vulnerable to harm and determines which documentation forms are relevant for adequate safety monitoring.

Costs and economic evaluation

This domain focuses on the resources (type and quantity) required by the health technology compared to alternatives, as well as impacts on other resources (e.g., potential savings), and cost-effectiveness. Cost-effectiveness evaluates the difference in costs and effects between alternatives through an incremental cost-effectiveness ratio (see Chapter 4.4.2). Additionally, this domain addresses uncertainties in cost-effectiveness results and evaluates the validity of calculation methods used.

Ethical analysis

The domain of ethical aspects covers issues relating to various dimensions:

- **Benefit-harm ratio** (e.g., expected advantages and disadvantages for patients, relatives, organisations, or society)
- **Autonomy** (e.g., impact on vulnerable groups, effects of health technology on patient autonomy, information requirements for enabling informed decision-making)
- **Respect and dignity** (e.g., potential impairment of moral, religious, or cultural integrity by health technology)
- **Justice** (e.g., resource distribution implications of health technology)
- **Legal regulations** (e.g., effects on fundamental human rights)
- **Ethical consequences of the assessment** (e.g., implications of selected outcome or assessment parameters)

Organisational aspects

The domain of organisational aspects analyses the impact of a new health technology on structures and processes within the healthcare system. In particular, the following issues are considered:

- **Implementation** (e.g., whether organisational processes need to be adapted and whether additional coordination and communication are needed)
- **Structural aspects** (e.g., how can patients' access to relevant services be ensured)
- **Process-related impacts** (e.g., how the use of new health technology changes the need for other medical technologies or services)
- **Management aspects** (e.g., organisational challenges and potential opportunities)
- **Cultural aspects** (e.g., acceptance of health technology among the professional groups involved)

Social aspects

This domain focuses on the perspective of patients (e.g., how do patients view the health technology? How do patients describe the disease?), social groups (e.g., do certain patient groups with the disease lack access to treatment?), and communication (e.g., how are treatment alternatives communicated to patients?).

Legal aspects

This domain evaluates patient autonomy from a legal perspective (e.g., what legal requirements are necessary to inform patients effectively?). It also addresses privacy considerations (e.g., disclosure of results to family members) and principles of equitable healthcare access (e.g., ensuring health technology

availability for all affected patients). It also examines ethical aspects, for example, whether implantation might present ethical challenges not contemplated in existing legislation. Additional considerations include authorisation and safety (e.g., registration), ownership and liability (e.g., intellectual property), and market regulation (e.g., price regulations, health technology usage regulations).

Environmental aspects

Since HTA already assesses the effects of healthcare interventions across various domains, it seems logical that providing independent information on the environmental impacts of healthcare interventions should also be part of HTA's task, and that the environmental impacts of health technologies should be presented as a further component of decision-making support. One example highlighting the environmental impact of health technologies is robot-assisted surgery, which generates 43% higher greenhouse gas emissions and up to 24% more waste than traditional laparoscopy. HTA institutions in various countries are already beginning to actively address the issue independently, but there is still no consensus on suitable methods [27].

Additional possible contents of HTA

Beyond the previously mentioned domains, HTAs can also focus on methodological approaches, such as those used in primary research. This method-focused HTA analyses research methods described in the existing literature to inform and strengthen future evaluation designs. Such assessments systematically extract methodological information (including assessment tools, questionnaires, benefit parameters, and whether instruments have been validated or standardised) from relevant studies. The following example provided a systematic overview of international evaluation methods (endpoints and assessment tools) used in paediatric and youth rehabilitation centres (https://eprints.aihta.at/1222/). It supported the planning and standardisation of evaluation approaches for Austrian paediatric rehabilitation services.

4.4 Scientific methods in HTA

The research question under examination, along with its corresponding domain, determines the methodological approach. Table 4-2 provides an overview of these methods.

Table 4-2: Overview of HTA methods

Domain	Commonly used HTA methods
Health problem and current standard of care	■ Non-systematic literature reviews ■ Routine data analyses
Description of the health technology evaluated	■ Non-systematic literature reviews ■ (Primary data collection, e.g. qualitative interviews)
Clinical effectiveness	■ Systematic literature reviews ■ Meta-analyses ■ Indirect comparisons ■ (Routine data analyses)
Safety	■ Systematic literature reviews ■ Meta-analyses ■ Routine data analyses
Costs and economic evaluation	■ Health economic evaluations ■ Budget impact analyses
Ethical, organisational, social, legal, and environmental aspects	■ Primary data collection, e.g., qualitative interviews ■ Non-systematic literature reviews ■ Routine data analyses

The following sections detail the systematic literature review and health economic evaluation (HEE) methods, followed by a brief overview of other relevant approaches.

4.4.1 Systematic Review

The systematic review attempts to collate all empirical evidence relating to a health technology's benefits and safety profile. It is a narrative (qualitative) systematic synthesis of evidence about a health technology compared to existing alternatives. It is the most frequently used methodology in HTA. The course "Methodology of HTA Reports" covers that in-depth; therefore, only an overview is provided here.

Before starting the search, it is important to formulate a well-structured question by using the PICO process. PICO stands for population (Who is it about?), intervention (Which intervention or approach does the assessment involve?), comparison (What do you want to compare?) and outcome (What is the desired outcome?). An example is shown in Table 4-3

Table 4-3: Example for PICO

P	**Population**	Patients with chronic wounds (e.g., diabetic ulcers, venous ulcers, pressure ulcers)
I	**Intervention**	Antimicrobial agents
C	**Control**	Placebo or standard therapy
O	**Outcome**	Wound repair (complete recovery, remaining wound surface, wound healing scores)

Source: [28]

Researchers conduct a systematic search using the well-constructed PICO question, as defined in the report plan. The selection process for relevant references is transparent. It includes several stages: identifying relevant literature based on the abstracts, obtaining full-texts from potentially relevant citations, assessing eligibility of the full-texts with predefined inclusion and exclusion criteria, and including studies in the evidence synthesis. Using a second reviewer throughout the selection process can increase the number of relevant literature identified for use. After examining studies for potential biases, data included in the systematic review is extracted by two independent reviewers with the help of a data extraction template. The results of the included studies are presented and summarised transparently with frameworks such as GRADE [29]. GRADE (grading of recommendations, assessment, development, and evaluations) is a tool for systematic evidence synthesis of benefits and safety features of a health technology. Researchers present the evidence for all predefined outcome parameters in the results of a systematic review, clearly describing their quality and reliability so that readers can easily recognise these aspects.

Different types of sources and study designs can be used as evidence bases in a systematic review depending on the research question. These are often randomised controlled trials (RCTs) or other clinical studies where individual interventions were tested on study participants (see Chapter 6.2.1). Most methodology manuals refer to this type of systematic review (see Chapter 4.5).

For broader research questions or published systematic reviews on related topics within the same area, existing systematic reviews can be incorporated into new systematic reviews, which are referred to as an overview of reviews. Guidelines are also often included in systematic reviews. Systematic reviews based on guidelines, also known as guideline synopses, are described below.

Guidelines are systematically developed decision-making tools for healthcare providers and patients that outline the appropriate course of action for specific health problems. Unlike other sources (e.g., clinical studies), guidelines provide recommendations: they not only take into account the available evidence on, for example, the efficacy and safety, but also incorporate a clinical assessment of the significance and applicability of study results, a balance of benefits and harms of alternative approaches, practice experiences, and patient preferences [30, 31].

The Association of Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF) distinguishes between different levels of guidelines based on their methodological concept. The highest level, S3, represents guidelines with evidence- and consensus-based recommendations. Evidence-based recommendations are derived from systematic literature searching, selection, appraisal, and synthesis on clinically relevant issues. The level of evidence (LoE) is also determined in this process. Subsequently, as part of the consensus-building process, the synthesised evidence is evaluated by a representative group of experts from a clinical perspective. Recommendations are discussed and agreed upon based on this, and a grade of recommendation (GoR) is specified. [32]. Internationally, different classification systems for LoE and GoR are used, including the GRADE Working Group methodology [33].

Guideline synopses summarise guideline recommendations (systematically searched and of high quality). To identify relevant guidelines, useful databases include the Guidelines International Network (GIN), the AWMF database, and the websites of various organisations that create guidelines (e.g., the National Institute for Health and Care Excellence, NICE; the United States Preventive Services Task Force, USPSTF). To assess the methodological rigour and transparency of guideline development, the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument or the refined AGREE II instrument is often used [34]. For example, in Germany, guideline synopses are used to develop and update treatment programmes for people with chronic diseases (disease management programmes) [30]. Guideline synopses can also provide a summarised overview of recommendations for broad subject areas (e.g., screenings for children and adolescents) [35].

4.4.2 Health economic evaluation

Definition

A comparative analysis of the costs and consequences of treatment options is called economic evaluation, which is covered in the domain of “costs and economic evaluation”. The significance and frequency of economic evaluations vary greatly in healthcare. For example, the Netherlands, Sweden and the United Kingdom conduct economic evaluations often, whereas Germany and Austria do not (Austria almost exclusively uses it for the drug reimbursement process at the moment) [36].

It compares the costs and benefits of alternative interventions to examine the best use of limited resources (goal: maximising population health and welfare) [37, 38]. However, economic evaluations in health care do not determine the size of the healthcare budget or replace health policy discussions related to resource allocation. Economic evaluations differ from budget impact analyses (BIAs) that assess the expected changes in health expenditure of the budget holder due to the implementation of health technologies.

Economic evaluation methods

There are different approaches used for healthcare economics. Some evaluation types only examine the costs of an intervention or a disease independently. In contrast, other types examine both the costs and consequences of an intervention (partial economic evaluations versus full economic evaluations). While economic evaluations are based on similar principles, they differ in fundamental methodology and interpretation. A key difference across different types of full economic evaluation is how the outcome is expressed (see Figure 4-2). The measured outcome can be monetary or non-monetary (non-monetary is used almost exclusively).

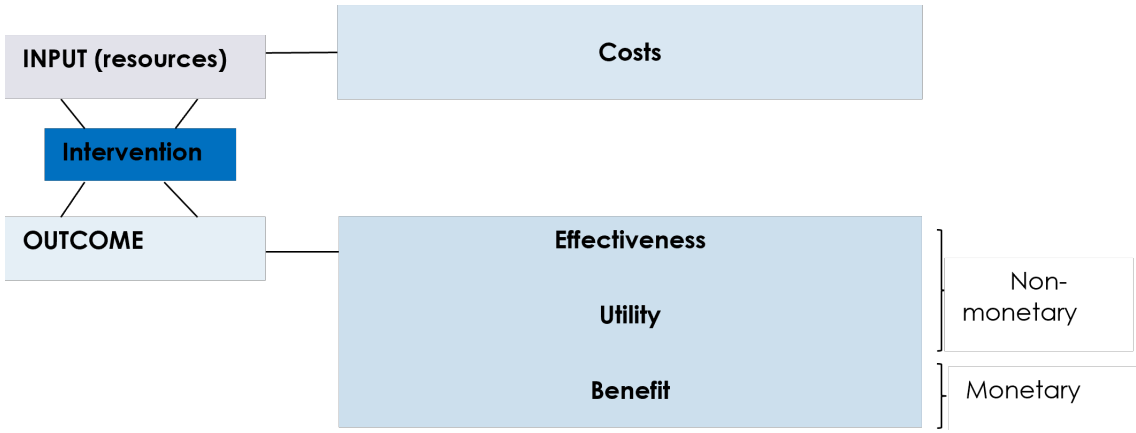


Figure 4-2: Presentation of HEE

Source: adapted from Schöffski and von der Schulenburg [38]

Economic evaluations are divided into cost-effectiveness analyses (CEA), cost-utility analyses (CUA), cost-benefit analyses (CBA) and cost-consequence analyses (CCA). HTA most commonly uses CEA and CUA for economic evaluations.

Cost-effectiveness analysis

A type of economic evaluation that calculates outcomes of compared health technologies in natural units (e.g., the intervention's impact on clinical measures, life years gained). These measurable outcomes are compared to costs.

Drawbacks of CEA include:

- Improved clinical outcomes may be irrelevant to patients (e.g., lowering high blood pressure is considered a success, patients are more concerned with improvements in quality of life or mortality outcomes)
- CEA cannot compare different health benefits because it measures outcomes in different units (outcome parameters) (e.g., comparing breast cancer treatments with secondary preventions of coronary heart disease is impossible)
- It cannot inform broader resource allocation across different sectors or diseases.

Cost-utility analysis

This type of economic evaluation assesses the utility of health outcomes primarily using the measure of quality-adjusted life years (QUALYs). It can facilitate comparisons across different health interventions by using a standard unit of effect (ranked by costs per QUALY, as shown in the LEAGUE table).

QUALYs combine health effects in terms of quality (quality of life) and quantity (lifetime) into a single measure, reducing the complexity of decision-making and allowing comparisons of cost-effectiveness across health interventions (e.g., comparing kidney transplants and appendectomies). QALYs combine the dimensions of "quality of life" and "gained lifetime" that an intervention brings into a one-dimensional generic metric, which reduces the complexity of the decision-making situation and makes different interventions comparable in terms of cost-effectiveness (e.g., comparing kidney transplants with appendectomies). However, much information is lost in this analysis.

Drawbacks of CUA include:

- Methodological limitations in QALY calculations
- The ranking of interventions is limited by study timeframes/contexts/assessment tools
- Problematic for some diseases (e.g., mental illness)

Table 4-4: Types of health economic evaluations

Type of economic evaluation	Quantification of target variables
CMA	Analysts measure costs in monetary units, assuming an equivalent outcome.
CEA	Analysts measure costs in monetary units and effectiveness in similar outcome variables (e.g., life extension in years).
CUA	Analysts measure costs in monetary units and effectiveness in utility measures (combined outcome measures, e.g., QUALY).
CBA	Analysts measure costs in monetary units and effectiveness in monetary units.
CCA	Analysts measure costs in monetary units and effectiveness with outcome parameters (presented side by side).

Incremental cost-effectiveness or cost-utility ratio

New health technologies can have a better or worse health effect than the alternative (e.g., standard intervention) and costs can be higher or lower (see **Fehler! Verweisquelle konnte nicht gefunden werden.**). The ratio of change in costs to change in effects of the intervention, which is referred to as the incremental cost-effectiveness ratio (ICER) or incremental cost-utility ratio, is expressed as a result of an HEE. Most cost-effectiveness analyses deliver results in the first quadrant in **Fehler! Verweisquelle konnte nicht gefunden werden.**, in which the new intervention generates more health but is more expensive.

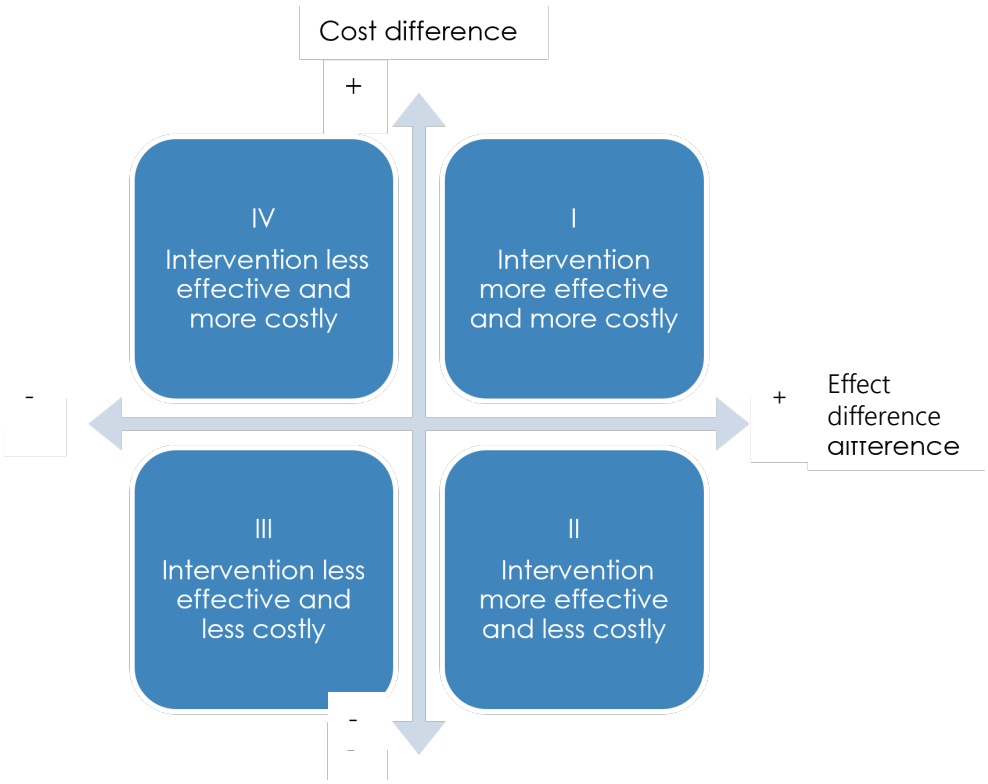


Figure 4-3: Cost-effectiveness plane

Source: [37]

Suppose a technology proves both more effective and more expensive than the compared alternative. In that case, evaluators use a threshold (e.g., incremental cost-utility ratio in € per QALY) for the final assessment of results. It is also a reference point for healthcare decision-making by indicating whether funding a new health technology outweighs overall health gains compared to health lost elsewhere (opportunity costs, i.e. displaced health benefits). For example, suppose the threshold is €50,000 per QALY, and the CUA result is €80,000 per QALY. In that case, it exceeds the threshold: Funding this health technology

with available resources would result in an overall loss of health because more health is lost elsewhere than gained with the new technology. Depending on the design of the healthcare system and the threshold concept, different thresholds can be defined [39]. Factors such as a country's economic performance and healthcare productivity play a role here. So far, no ICER threshold has been defined or discussed in Austria. Only a few countries, such as the UK, define explicit thresholds for cost-effectiveness. However, implicit thresholds are frequently applied [39].

4.4.3 Other relevant methods

Meta-analysis

A meta-analysis is a statistical summary of effect measures from multiple studies. It is also used to assess the effectiveness and safety of an intervention (clinical domains in Chapter 4.3). With this methodological approach, effect sizes (the magnitude of treatment effects) from all relevant studies and their variability are examined through statistical analysis, and statements are made about the precision of the combined overall estimate. There are potential biases, e.g., publication bias (the non-publication of unfavourable study results from individual studies). The heterogeneity of individual studies is particularly relevant, as it can lead to misleading results and, therefore, needs to be examined more carefully in separate analyses [28].

Indirect comparisons

Many clinical studies compare the new health technology with a placebo and direct comparisons with treatment alternatives (head-to-head comparisons) are often lacking. Indirect comparisons estimate the relative effects of two interventions that were not directly compared [40]. To achieve this, studies examining the interventions of interest and a common comparator are needed. Indirect comparisons also require specific types of meta-analyses (so-called network meta-analyses). However, the risk of bias for this type of comparison is generally higher than for meta-analyses of direct comparisons [28].

The Cochrane Collaboration notes that indirect comparisons within randomised controlled trials share similar risks of bias (keyword: confounding variables) with comparisons in observational studies. For results to be valid, groups within randomised controlled trials must be similar in all important factors except for the intervention received [40].

Routine data analysis (real-world data, RWD / real-world evidence, RWE)

Real-world Data (RWD) refers to data on patients' health status or healthcare routinely collected outside clinical trials. It is sourced from electronic health records, claims data, registries and wearables [41]. Routine data analyses help to understand different HTA domains, for example, by describing the health problem and organisational aspects related to current practices. However, routine data (e.g., administrative data) is secondary data (collected initially for different purposes) and has limitations. For example, data may be available at different aggregation levels (e.g., at the level of billing cases or service contacts rather than at the individual patient level) than those required to address the research question, or specific parameters of interest may be unavailable (e.g., billing data in Austrian outpatient facilities does not usually contain information about diagnoses), nor is access to this data always guaranteed.

However, the advantage of such data is that it reflects the healthcare situation in real-world settings (real-world evidence, RWE) and can also provide information on the effectiveness of health technologies in real-world settings. Additionally, routine data (such as administrative billing information) is readily available (and does not involve time-consuming collection); however, data preparation can be considerably time-intensive, particularly when integrating information from multiple routine data sources [28]. For the quality-assured analysis of routine data, the validity and appropriateness of different datasets are assessed for research questions. Also, the planned methodological approaches for evaluation are defined in the study protocol. However, routine data carries the risk of bias, particularly in assessing a health technology's effectiveness or safety [28]. This potential bias can be minimised using various statistical methods. Unlike some countries (e.g., Scandinavia) where routine data utilisation has been established for many years, Austria and Germany have only recently increased their initiatives and research efforts to leverage these data resources [42]. Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are increasingly incorporating real-world data into their procedures [41, 43].

Primary data collection and analysis

Some HTA domains or specific questions require primary data collection and analysis (e.g., surveying patient preferences and exploring ethical considerations), primarily using empirical methods of social science research. Frequently employ survey methods, which are conducted in writing or orally, and may utilise either qualitative or quantitative research approaches. For example, qualitative research methods are used to address patient-related or organisational questions and quantitative research methods are used to understand epidemiological issues. Both data collection and subsequent evaluation must be considered during method selection (varying time efforts of different methods). A balance between effort and information needs is required [28].

Budget impact analysis

Budget impact analysis (BIA) estimates the financial consequences of adopting a new health technology, reimbursing a new health technology, or changing the use of an existing technology [44]. Although BIA is based on similar data used in health economic evaluation (see Chapter 4.4.2), its focus is different: taking the payer's perspective, using typically short-term horizons, and considering only costs without relating it to health benefits. Typically, sensitivity analyses are conducted to assess the impact of uncertainty in various financial scenarios [28].

4.5 Methodological quidelines

Numerous methodological manuals provide detailed step-by-step instructions for various HTA domains; however, the implementation should not be viewed as a purely mechanical process. Each technology presents unique features that require individualised methodological decisions. Deviations from standard methods are sometimes necessary, particularly for emerging technologies such as e-health or m-health applications that evolve rapidly and may not be adequately evaluated using conventional approaches.

Nevertheless, methodological manuals contribute to a robust, transparent, and systematic approach, ensuring scientific quality and adherence to standards when appropriately applied. These considerations are critical in HTA contexts, as assessments are often meticulously scrutinised for errors or weaknesses (especially when results question a health technology's benefits and potentially impact manufacturer markets). Authors must, therefore, justify their methodological decisions according to internationally recognised HTA standards.

In Austria, the methodological manual for HTA [28] and the methodological guidelines, published under the EU HTA Regulation and the Joint Clinical Assessment (JCA) at the EU level [45], serve as the key methodological foundations for conducting HTAs (that meet standardised and scientific quality criteria).

Many countries have developed country-specific guidelines for standardised HEE, either as recommendations or mandatory requirements (e.g., for reimbursements of pharmaceuticals). AIHTA has recently published an overview of HEE and international best practices for Austria [46]. These guidelines show substantial agreement on recommended methodological principles, differing primarily in the following:

Recommended perspective of evaluation (e.g., societal versus healthcare perspective)

Preferred outcome measures (e.g., QALYs versus natural units)

Approaches for managing uncertainty

For Austria, the Institute for Pharmacoeconomic Research (IPF) led a consensus process with national experts to develop guidelines. These recommendations do not specify methodological requirements (e.g., the use of specific outcome parameters). The Austrian HTA methodological manual includes recommendations for economic evaluations, but these remain non-binding [28] and allow considerable methodological flexibility. AIHTA is currently developing a framework for an updated Austrian guideline on the conduct of health economic evaluations.

5 Internationalisation and networking

This chapter describes networking in HTA. The objectives of this chapter are to:

- Identify key HTA networks and their objectives
- Explain the historical development of networking in HTA

5.1 International networks

The International Society of Technology Assessment in Health Care (ISTAHC) was formed in 1985 to encourage internationalisation and networking in HTA. It was founded in 2003 as Health Technology Assessment International (HTAi). It is a multidisciplinary expert association and provides a forum for international discussion, including the annual HTAi conference.

In 1993, the International Network of Agencies for HTA (INAHTA) (https://www.inahta.org/) was founded, consisting of 52 HTA agencies in 33 countries to cooperate and share information about HTA. The international HTA database is particularly useful, as it provides free access to bibliographic information on ongoing and published health technology assessments worldwide and serves as a single point of access to information from various organisations that would otherwise be difficult to find.

Another important network is ISPOR (https://www.ispor.org/). Founded in 1995, it now has several thousand members from more than 100 countries. As a non-profit organisation focused on educational and scientific purposes, ISPOR primarily addresses health economics and outcomes research. The Society has developed numerous methodological Good Practice Guidelines (GPGs) for areas such as decision-analytic modelling and budget impact analysis. ISPOR also offers regular training programmes.

5.2 European networks

At the European level, HTA has been promoted as a research-based decision-support tool since the mid-1990s. The EU has supported several projects, beginning with the EUR-ASSESS project (1994-1997), which brought together all major European HTA agencies to address methodological questions and develop recommendations systematically. This was followed by the European Collaboration in HTA (ECHTA) and the European Collaboration for Health Technology Assessment – Assessment of Health Interventions (ECAHI) projects, which further refined methodological standards. Since 2006, the former EU directorate SANCO has funded EUnetHTA through a series of joint actions. The most recent initiative, Joint Action 3, includes 80 organisations from 30 countries.

Furthermore, in 2004, the EU defined HTA as a political priority. Later, in 2011, It formalised HTA through Article 15 of the Cross Border Directive (CBD) as a quality assurance measure for patient mobility across borders within the EU [47].

A tool created as part of the EUnetHTA was the planned and ongoing projects (POP) database, which provided all members with information on current HTA projects in various HTA agencies. The database aims to promote collaboration between HTA agencies and avoid duplication of work (several countries conducting HTA on the same technology). Since Joint Action 1, the rate of identical or very similar HTA projects consistently remained at ten per cent [48]. The database has been replaced by the INAHTA database, which contains only finalised HTA reports (https://database.inahta.org/).

Another very significant development from EUnetHTA is the HTA Core Model®, which standardises the content of HTAs in nine domains (see Chapter 4.3). Various methodological guidelines have also been created (see Chapter 4.5). The model aims to improve the applicability across regional and national HTAs

and reduce duplication of work. To increase the standardisation of report structures, several templates have been created [48].

Austria played a leading role in collaborative HTA development within the framework of EUnetHTA. In 2013, the former Ludwig Boltzmann Institute for HTA (LBI-HTA) initiated the first collaboratively conducted pilot report on "other technologies" (medical devices and medical procedures) [49]. During Joint Action 3 (2016-2021), numerous joint assessments for pharmaceutical products and "other technologies" have already been created. The main challenges in joint assessments included language barriers (e.g., within specific national contexts), the timely identification and completion of topics (due to different timelines and deadlines across EU Member States), and variations in report structures and quality specifications. HTA agencies that utilised EUnetHTA reports instead of their own reported significant resource savings [48].

In 2018, a proposal for EU regulation was drafted (Proposal for a Regulation of the European Parliament and of the Council on Health Technology Assessment and amending Directive 2011/24/EU) that, among other provisions, would ensure the use of joint outputs in Member States. Additionally, the proposal aimed to converge developed tools, procedures, and methodologies at the EU level. It encountered significant resistance from numerous member countries. However, following various negotiations, the Regulation (EU) 2021/2282 on health technology assessment (HTAR) came into force on 11 January 2022. The HTA Regulation stipulates that joint HTAs – or "Joint Clinical Assessments" (JCAs) – are to be carried out stepwise for all authorised medicinal products and certain medical devices in specific risk classes. Individual Member States are obliged to take these assessments into account in their decision-making [50].

Several other European networks have been founded, including:

- The Beneluxa Initiative (https://beneluxa.org/) established in 2015 is an initiative involving pharmaceutical policy in Belgium, the Netherlands, Luxembourg, Austria (since 2016), and Ireland (since 2018), aiming to ensure affordable access to effective therapies and innovative medicines.
- The Central and Eastern European Society of Technology Assessment in Health Care (CEESTAHC): The CEESTHAC (https://ceestahc.org/eng/) aims to promote the development and standardisation of HTA methods, develop a common language, and advance HTA and evidence-based medicine (EBM) in Central and Eastern Europe (primarily focusing on training in HTA and EBM methods) [51].
- Health Evidence Network (HEN): HEN [https://www.who.int/europe/groups/health-evidence-network-(hen)] is an information service by the WHO Regional Office for Europe (WHO/Europe) for public health decision-makers. It cooperates with other European agencies, including the EC, and commissions research on specific issues in public health [52].

6 HTA in Austria

This chapter describes how HTA is integrated into the Austrian healthcare system. The objectives of this chapter are to:

- Understand the Austrian healthcare system structure
- Know the regulatory and control processes
- Recognise how HTA is integrated into control processes
- Describe the processes and methods used in HTA in Austria
- List agencies that conduct HTA in Austria

6.1 Structure and financing of the Austrian healthcare system

Austria is a federal republic composed of nine states, each partitioned into numerous municipalities (except for Vienna) [53]. Responsibilities for healthcare governance are distributed among the federal and state governments, municipalities and the social health insurance (SHI) as self-governing bodies. A combination of sources finances the Austrian healthcare system: 75% from public sources (45% social insurance, 30% from taxes) and 25% from private sources [54]. The financing of health services relies on three principles: solidarity, affordability, and universality. These principles ensure equitable access to healthcare services, irrespective of individual income [55]. In 2024, healthcare expenditures, including long-term care, amounted to €57,8 billion (11.7% of the gross domestic product [GDP]) [56, 57]. The GDP share of healthcare expenditure in Austria exceeds the EU average.

The federal government is responsible for legislation. Regarding hospitals, the federal government is limited to establishing overarching principles. The states are responsible for enacting, implementing and enforcing laws [53]. The federal government primarily handles general health policy (long-term strategies, health targets, public health service planning, prevention, etc.). The nine states are responsible for financing and detailed planning of regional hospital groups. A federal-level structural commission oversees the creation of a major equipment plan (e.g., radiation therapy facilities, cardiac catheterisation laboratories), supply planning in acute and short-term care, and maintenance of the catalogue of procedures within the procedure-oriented hospital financing introduced in 1997 (Leistungsorientierte Krankenanstaltenfinanzierung, LKF, an adapted diagnosis-related group, DRG, case-based reimbursement system). Social insurance is responsible for contracting services and tariffs with outpatient providers (e.g., physicians, therapists) and financing medications in the outpatient sector [54].

The “Zielsteuerung-Gesundheit” healthcare reform has been in place since 2017; it is an agreement between the federal government and the states of Austria, under Article 15a of the Federal Constitutional Law (B-VG), that governs the organisation, management, and financing of the Austrian healthcare system. With the 2024 update, it was carried over into a new target-based management period (2024–2028) with adjusted targets and spending caps. It serves to make healthcare provision more efficient, control costs and improve cooperation between healthcare sectors, with a federal target management commission setting the strategic framework that the states’ commissions implement at the regional level [58].

Fehler! Verweisquelle konnte nicht gefunden werden. shows an overview of financing for hospitals and outpatient facilities. Preventive medicine and rehabilitation services are not presented because they are not financed using the DRG system.

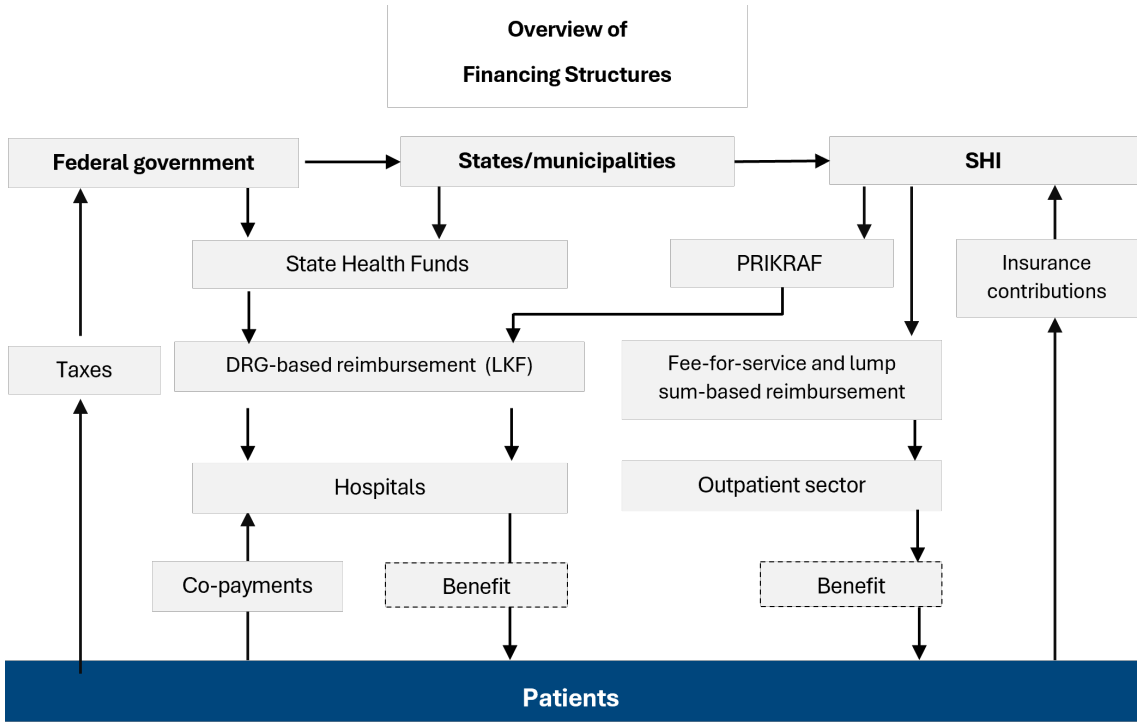


Figure 6-1: Financing of inpatient and outpatient services

Abbreviations: LKF=Austrian DRG system (Leistungsorientierte Krankenanstaltenfinanzierung), PRIKRAF=private hospitals financing fund (Privater Krankenanstaltenfinanzierungsfonds)

Own simplified illustration, for more details see Bachner et al. 2019 [54]

State health funds (Landesgesundheitsfonds) fund services in hospitals (Fondskrankenanstalten) based on a procedure-related fee-per-case system. The Private Hospitals Financing Fund (Privatkrankenanstalten-Finanzierungsfond, PRIKRAF) funds services in private for-profit hospitals (under contract with SHI). SHI funds outpatient services with a combination of fee-for-service and contract capitations. SHI also covers medications prescribed by outpatient physicians and listed in the Austrian Code of Reimbursement (Erstattungskodex, EKO). Patients must pay a prescription fee (€7,55 in 2026) unless they are granted a prescription fee exemption [55]. The financing and organisational structure of the Austrian healthcare system favours hospital-centred care, resulting in Austria having one of the highest densities of acute care hospital beds and hospital admission rates in Europe.

6.2 Marketing authorisation

The process of obtaining marketing authorisation in Austria varies according to the type of health technology, with the most formalised and structured procedures for pharmaceuticals. Medical devices, however, are subject to other regulations and depend on the risk class. Meanwhile, services provided by healthcare professionals, such as physicians and physical therapists, do not require any formal approval process.

6.2.1 Pharmaceuticals

In 1995, a significant EU regulation on marketing authorisation of pharmaceuticals came into effect, establishing the centralised approval procedure through EMA as the predominant pathway for

pharmaceutical approvals in the EU. This procedure is mandatory for a range of medications, including novel therapies, monoclonal antibodies, and human medicines with new active ingredients for treating AIDS, diabetes, cancer, neurodegenerative diseases, autoimmune diseases, other immunodeficiencies, and viral diseases. Orphan drugs developed to treat rare diseases are also subject to this mandatory procedure. For numerous other medications, access to this centralised procedure remains optional. While national procedures, which were the sole means of authorising medications in the EU before 1995, have significantly lost their importance, many currently marketed medications received their authorisation through these national pathways. In Austria, the Austrian Agency for Health and Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES) serves as the national authorisation authority, which operates under the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG).

Obtaining marketing authorisation for pharmaceuticals requires demonstrating safety, effectiveness, and pharmaceutical quality through research (preclinical and clinical research). Preclinical research involves animals, and clinical research evaluates human application in four phases:

- Phase 1 studies assess the safety and tolerability of the treatment. Pharmacokinetic measurements are also conducted, usually involving healthy volunteers.
- Phase 2 studies aim to establish the preliminary effectiveness and tolerability of the treatment while determining the optimal dosage through dose-finding studies in small subject groups.
- Phase 3 studies provide definitive evidence of effectiveness and are ideally conducted as randomised controlled trials.
- Phase 4 studies take place after marketing authorisation and primarily enhance safety assessment by identifying rare side effects that may have been missed or not appeared in earlier limited trials with fewer participants and shorter follow-up periods. Sometimes, they also serve marketing purposes (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

Marketing authorisation primarily focuses on safety, requiring only minimal evidence of effectiveness compared to a placebo. The approval process does not require demonstrating that the new product offers greater patient-relevant benefits than existing treatment options already funded by the public health system. As a result, in the past, only slightly modified active ingredients were frequently approved, whilst genuine product innovations were less common. Only in recent years have novel procedures (e.g., advanced therapy medicinal products) been developed and approved more regularly.

For orphan drugs, special regulations allow accelerated authorisation pathways (faster approval, less stringent data requirements, and longer patent protection). While these provisions are intended to incentivise pharmaceutical development for rare diseases, they have led to studies with methodological limitations and less reliable evidence. Common issues include the absence of control groups, reliance on surrogate endpoints instead of patient-relevant outcomes, small sample sizes, and inadequate follow-up periods [59].

Consequently, marketing authorisation does not guarantee that the medication provides meaningful patient-relevant benefits, particularly in comparison to existing treatment alternatives. Therefore, obtaining marketing authorisation does not automatically ensure reimbursement by public healthcare systems (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

6.2.2 Medical devices

Medical devices encompass instruments, apparatus, substances, software and more used for the detection, treatment, and prevention of diseases, injuries, or disabilities, as well as for the examination, replacement, or modification of anatomical structures or physiological processes. The purpose of medical devices is typically not achieved by pharmacological, immunological or metabolic means (unlike pharmaceuticals) [60].

Medical devices are classified into four risk groups based on the risk during use (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Table 6-1 Classification of medical devices

Class	Definition
I	Devices with low risk, non-invasiveness, and temporary use (<60 minutes) (e.g., walking aids, support stockings)
IIa	Devices with medium risk, moderate invasiveness, and short-term use (< 30 days) or uninterrupted/repeated use of the same device (non-active products with medium risk, invasive and non-invasive products for short-term use (e.g. disposable syringes, hearing aids)
IIb	Devices with increased risk, systemic effect, and long-term use (> 30 days) (e.g., ventilators, defibrillators)
III	Devices with high risk, direct application to the heart, circulatory or nervous system, implantable and/or highly invasive (e.g., cardiac catheters, stents, artificial joints)

Medical devices bear the CE marking (granted by notified bodies), which indicates their conformity with EU regulations. Until recently, medical devices entered the European market approximately five to seven years before receiving US authorisation, operating under a regulatory framework with limited safety testing and no efficacy testing. Recently, a gap between the requirements for high-risk medical device market authorisation in Europe and those for market entry (reimbursement decisions based on HTAs) has been widely discussed. Ultimately, it was safety scandals relating to medical devices (e.g., PIP breast implants, metal wear/corrosion from hip implants) that led to the adaption of new European regulations: Regulation (EU) 2017/745 on medical devices (Medical Device Regulation, MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (In Vitro Diagnostic Regulation, IVDR), which were adopted by the European Parliament in May 2017.

The mandatory implementation of the medical device regulation, initially set for May 2020, was delayed to May 2021 due to the COVID-19 pandemic. The IVDR has been in force since May 2022, with gradual transition periods for certain product categories. The MDR specifies that new higher-risk medical devices (classes 2b and 3, including active and electrically supported implantable and selected non-active implantable medical devices, such as heart valves, non-resorbable vascular prostheses, stents, hip/knee replacements, vertebral body replacement systems, intervertebral disc prostheses, and breast implants) must undergo clinical testing (clinical studies on safety and efficacy) rather than just performance evaluation (proof-of-concept and technical performance) as was previously required for authorisation. Only after the new regulation is fully implemented will it be possible to assess whether the gap in clinical data requirements has been reduced [61-63].

Borderline products, where it is unclear whether they fall under pharmaceuticals or medical devices, are subject to special regulations, which include contrast agents, combination products combining blood products with medical devices, and advanced therapy medicinal products (ATMPs), such as gene therapies or cell therapies (all ATMPs are authorised centrally via the EMA) [60].

6.2.3 Services provided by healthcare professionals

For services provided by healthcare professionals, there is no approval process. The implementation is primarily governed by various professional laws (e.g., the Psychotherapy Act) or results from discussions within professional groups. Standards of care are increasingly reflected in speciality-specific guidelines. Additionally, various treatments are regulated by other requirements, such as hygiene, occupational safety, and data protection [60].

6.3 Integration of HTA in the Austrian healthcare system

HTA has been employed in Austria for over 25 years as a scientific policy advisory tool. As early as 2002, decision-makers recognised the significance of HTA through specific case examples where health technology assessments led to quality improvements and cost containment. Since then, HTA has become an increasingly important tool in resource planning, investment decisions, and reimbursement decisions.

Despite its growing role, there is still no legal requirement for mandatory evidence analysis before such decisions across the various decision-making processes [64].

6.3.1 Integration into law

Until 2024, unlike in other countries, there was no legal regulation in Austria requiring systematic evaluation of medical services for their actual clinical added value using HTA methodological standards prior to their inclusion in routine care. A legal act governing pharmaceutical provision in the outpatient sector requires pharmacological, medical-therapeutic, and economic evaluations before a drug can be added to the EKO. However, it is not explicitly defined as HTA and therefore, no methodological HTA standards are specified. Furthermore, the assessments conducted are not publicly accessible, which contradicts a fundamental principle of HTA. The economic evaluation outlined in the legal act for pharmaceutical assessment primarily serves as a price comparison. Only a few cases require a more comprehensive economic evaluation, as intended in the HTA context (i.e., comparative CEA, see Chapter 4.4.2) [36, 65].

In accordance with the healthcare reform adopted in 2023, an appraisal board was established to evaluate selected high-cost and specialised medicinal products in the hospital area or at the interface between inpatient and outpatient areas. The appraisal board has been operational since September 2024 and the conduct of HTAs is explicitly stipulated in the associated law (the Hospitals and Health Resorts Act, KAKuG) [66]. The HTAs serve as the evidence base for the appraisal board when drawing up standardised recommendations for use across Austria, as well as forming the basis for national price negotiations (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

The use of HTA is generally addressed within the Framework of the Target-Based Governance of the Healthcare System (Zielsteuerung-Gesundheit) agreement: "According to Article 12, Paragraph 1, Clause 4 of this agreement, the use of HTA, EBM, and evidence-based public health (EBPH) will be further promoted. These methods contribute to evidence-based, transparent, and patient-benefit-oriented decisions in healthcare, particularly in therapeutic, diagnostic, organisational, and public health interventions [67].

The Federal Target-Based Governance Agreement 2024–2028 [68], through strategic objective 2 and operational objectives 8 and 13, further outlines the following measures:

- Development and implementation of care models and cross-sector funding schemes involving shared financial responsibility: conducting a review of existing shared funding arrangements and establishing a framework agreement for standardised nationwide funding, in close consultation with the appraisal board (for specialised medicinal products at the interface)
- Ensuring quality across the entire healthcare sector, including national implementation of the EU HTA Regulation and systematic synthesis of evidence (incl. methodological quality assessments).

HTA principles are also indirectly reflected in the following laws:

- General Social Insurance Act (Allgemeines Sozialversicherungsgesetz, AVSG): Overall, treatment must be adequate and appropriate but must not exceed what is necessary.
- Federal Hospitals Act (Bundeskrankenanstaltengesetz, B-KAG) on quality assurance: A high-quality, effective, and efficient healthcare must be ensured,
- Health Quality Act (Gesundheitsqualitätsgesetz, GQG): To improve quality in Austrian healthcare, considering the principles of patient orientation and transparency, contributing to medium- to long-term improvements in effectiveness and efficiency, ultimately enhancing healthcare provisions for the population and ensuring long-term affordability.

6.3.2 Integration into governance processes

Although HTA is not legally required in most governance processes for reimbursement and pricing, it has been incorporated into all central processes (albeit not with a systematic approach in all areas). **Fehler! Verweisquelle konnte nicht gefunden werden.** provides an overview of relevant healthcare service areas, illustrating the processes through which the benefits catalogues (e.g., pharmaceuticals in the outpatient

sector, medical devices in the hospital sector, also referred to as individual medical service, medizinische Einzelleistung, MELs) are created and maintained, thus defining service reimbursement eligibility.

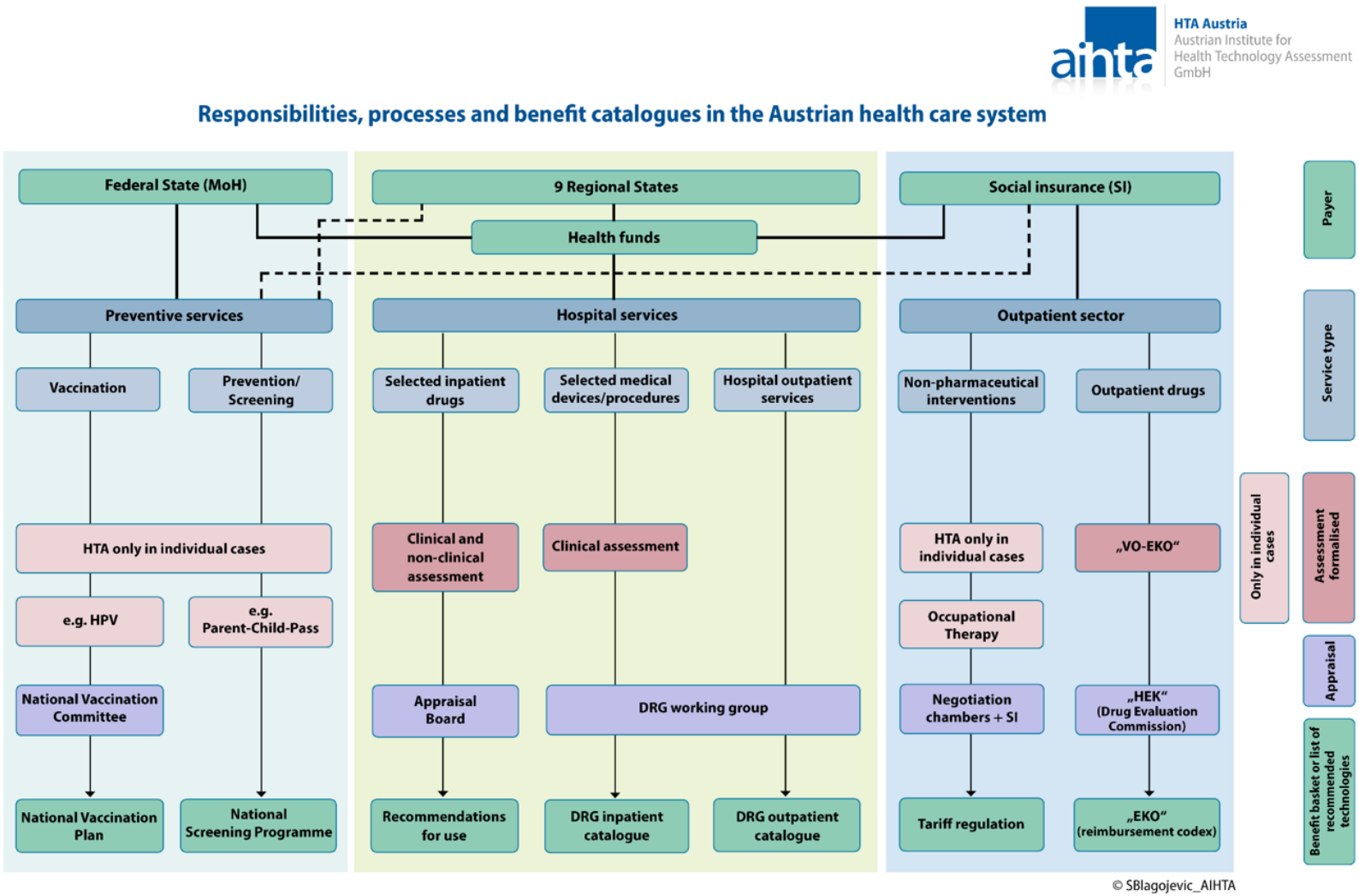
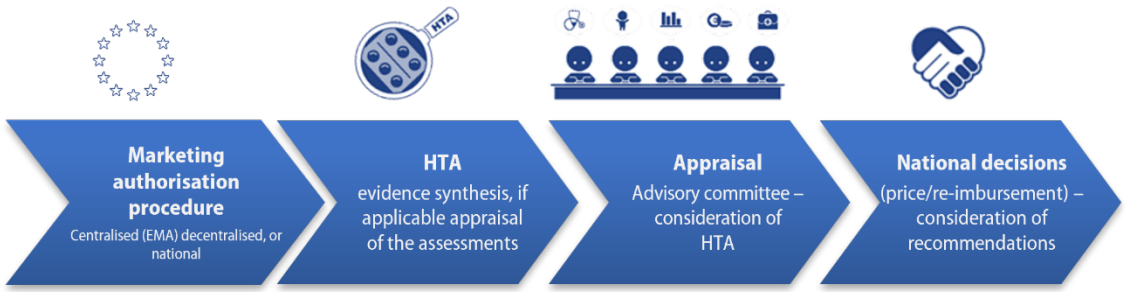


Figure 6-2: Governance process and catalogues of services in the Austrian healthcare system

EKO: reimbursement code (Erstattungskodex); HEK: drug evaluation commission (Heilmittel-Evaluierungskommission); LKF: services catalogue (Leistungsorientierte Krankenanstaltenfinanzierung); MEL: individual medical services (medizinische Einzelleistung); VAEF: management of proposals for amendments and additions to the benefits catalogue (Verwaltung von Änderungs- und Ergänzungsvorschlägen für den Leistungskatalog); VO-EKO: Ordinance on the Reimbursement Code (Verordnung Erstattungskodex); own adapted illustration.

Formalised assessment processes (e.g., benefit assessments) before decisions on inclusion in the benefits catalogue or recommendations for use exist in three instances: for pharmaceuticals in the outpatient sector, MELs in the hospital sector, and for selected high-cost and specialised medicinal products in the hospital sector or at the interface between the hospital and outpatient sectors (appraisal board).

In the overall reimbursement process, the distinction between "assessment" and "appraisal" is crucial (see **Fehler! Verweisquelle konnte nicht gefunden werden.**). Assessment refers to the systematic and objective review of evidence regarding safety, efficacy, and other factors. In contrast, appraisal involves the critical evaluation and discussion of these results in the context of health policy. In addition to the available evidence, appraisal incorporates additional health policy criteria such as health objectives, equity considerations, and affordability. These significantly influence the final decision on public funding or recommendation of a service in the framework of national bodies such as the appraisal board, which issues the relevant recommendations. The decision always represents a value judgement about the appropriateness of needs and benefits, as well as questions of distributive justice (determining how resources are allocated across different diseases, treatments, patient groups, etc.). The following figure illustrates this framework using pharmaceuticals as an example.



EMA: European Medicines Agency, HTA: health technology assessment; source: [65]

Figure 6-3: Assessment, appraisal, and decision-making process: Example of pharmaceuticals

Pharmaceuticals in outpatient facilities

As previously described (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**), medicinal products submitted for inclusion in the EKO by authorised distribution companies undergo pharmacological, medical-therapeutic, and economic evaluation (primarily through price comparison) under the Act. The evaluation results, including a price proposal and defined use, are presented to the Pharmaceutical Evaluation Board (Heilmittelevaluierungskommission, HEK), which consists of representatives from social insurance, chambers of commerce, labour, pharmacy and medicine, patient advocates, a representative of the states, and independent scientific representatives from relevant disciplines. This board recommends whether to include the requested medicinal product in the EKO. The Federation of Social Insurances (DVSV), as the payer for medicinal products, makes the final decision. Appeals against this decision can be filed with the Federal Administrative Court. Standardised HTA methods are relevant for the medical-therapeutic assessment (if applied by the authority) and for the economic evaluation. In some cases (e.g., when the submitted pharmaceutical demonstrates a significant additional therapeutic benefit compared to existing alternatives, as classified by the manufacturer), the manufacturer must submit an economic evaluation (typically a CEA), which is incorporated into the overall assessment. However, the significance of the economic evaluation results (i.e., cost-effectiveness) for the decision to include the medicinal product in the EKO remains unclear [36].

Individual medical services in inpatient facilities

The second area featuring a standardised HTA within the formalised process is maintaining the catalogue for procedure-oriented hospital financing (LKF catalogue). Key components of this catalogue are the MELs (primarily medical devices or procedures), which are annually adapted to reflect the latest technological

developments. **Fehler! Verweisquelle konnte nicht gefunden werden.Fehler! Verweisquelle konnte nicht gefunden werden.** shows the overall catalogue maintenance process and HTA's role within it.

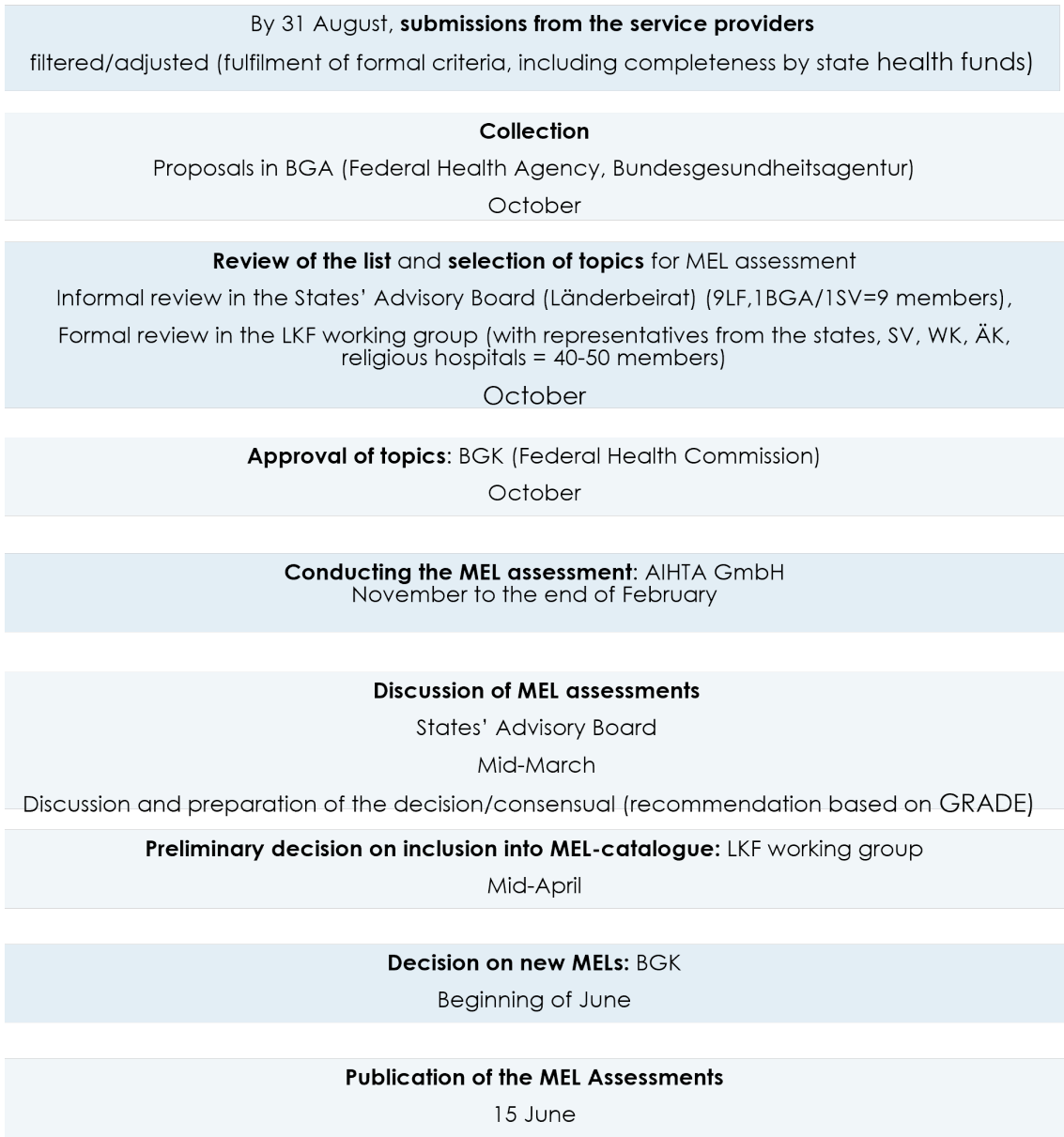


Figure 6-4: Process of evidence analyses for the catalogue of medical individual services (MEL)

Abbreviations: ÄK: Austrian Medical Chamber (Ärztekammer), BGK: Federal Health Commission (Bundesgesundheitskommission), GRADE: Grading of Recommendations Assessment, Development and Evaluation, LF: state health funds (Länderfond), LKF-AK: performance-based funding of hospitals workgroup (leistungsorientierte Krankenhausfinanzierung-Arbeitskreis; MEL: fee-for-service (medizinische Einzelleistung); SV: social insurance (Sozialversicherung), WK: Austrian Federal Economic Chamber (Wirtschaftskammer); own illustration

After reviewing services submitted by the state health funds, the LKF working group in the federal ministry selects topics for HTA s. For selected topics, the Austrian HTA Institute (AIHTA GmbH, see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) conducts evidence analyses annually, concluding with recommendations regarding possible inclusion in the LKF catalogue. The Federal Health Commission makes final decisions on inclusion (or the conditions for inclusion), and AIHTA GmbH publishes

these assessments. Since 2026, the HTA Regulation has also provided for JCAs for selected high-risk medical devices with the potential to have a significant impact on patients, public health and healthcare systems.

Pharmaceuticals in inpatient facilities and at the interface between the inpatient and outpatient sectors

A distinctive feature of the Austrian system is that medications administered in inpatient settings do not fall under the social insurance area of responsibility and are, therefore, subject to separate regulations. Even within the hospital sector, these medications are typically managed through distinct processes, which is why they have not been included in the AIHTA's annual evidence analyses for the MEL catalogue yet.

To support consistent, transparent and evidence-based decision-making across Austria, a nationwide assessment process has been established for selected high-cost and specialised medicines. This process is carried out by the appraisal board and is regulated by the Hospitals and Health Resorts Act KAKuG (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) [66]. Since autumn 2024, selected medicines have been systematically assessed.

The aim of the appraisal board is to support hospital providers and decision-making bodies in the evaluation and use of new medicines to ensure quality-assured care, the efficient use of resources and, as far as possible, consistent application across Austria.

The assessment process comprises several steps. First, potentially relevant medicines are identified, for example, through horizon scanning activities or submissions from stakeholders such as social security providers or states. Once a medicinal product has been selected by the appraisal board, a comprehensive HTA report is produced in the form of a full HTA, covering all relevant HTA domains (see Chapter 4.3).

For inpatient medicines, the AIHTA assists the appraisal board secretariat – established within the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (BMASGPK) – in preparing these HTAs. The umbrella organisation of Austrian social insurance providers (the Federation of Social Insurances, DVSV) is designated to prepare HTAs for medicines at the intramural-extramural interface.

The HTA reports summarise the best available evidence on the additional medical and therapeutic benefits compared with relevant alternative treatments, considering aspects of cost-effectiveness, as well as social, ethical, organisational, and legal issues relating to the implementation of new medicines. On this basis, the AIHTA prepares an appraisal proposal that consolidates the HTA assessment results and evaluates them in the context of the Austrian healthcare system.

This appraisal proposal is discussed by the appraisal board, with the involvement of medical experts and other stakeholders, and is amended where necessary; it forms the basis for the decision-making process. In addition to the added clinical benefit, particular consideration is given to cost-effectiveness and feasibility, as well as possible criteria for use and accompanying measures.

Based on this process, the appraisal board formulates recommendations for use and on the criteria for its use or accompanying measures. The appraisal board consists of experts from various disciplines, including representatives from the Federal Ministry, the states and the social security bodies, independent scientists, and a representative of the patients' advocacy group in an advisory capacity. Individual patient-specific treatment decisions remain the responsibility of the treating doctors.

Link with the EU HTA Regulation

As already outlined in Chapter 5.2, EU-wide Joint Clinical Assessments (JCAs) have been carried out in accordance with the HTA Regulation since January 2025. These must be considered in national processes and are drawn up jointly by two Member States (the assessor and the co-assessor).

In addition, Member States are called upon to participate in defining the scope of the assessment (PICO question), so that the joint assessment provides the necessary answers for all Member States. In Austria, the AIHTA is responsible for coordinating the PICO surveys for medicinal products for hospital use. Clinical experts and professional societies are involved in this process. Furthermore, consultation takes place

with representatives of the states. Feedback from these consultations is incorporated into the finalisation of the national PICO proposal. The consolidated Austrian PICO proposal is then submitted to the European JCA process. On this basis, further coordination of the assessment scope takes place at the European level among the Member States, leading to the establishment of the assessment framework for the JCAs. This ensures the relevance and applicability of the joint clinical assessment results across all EU Member States. For medicines used in the outpatient sector, the Federation of Social Insurances (DVSV) is responsible for providing the national inputs to the PICO surveys.

The JCAs are prepared in parallel with the authorisation process. They must be published no later than 30 days after authorisation and can then be considered in the national pricing and reimbursement processes. JCAs relating to medicinal products for hospital use are contextualised for Austria by the AIHTA and are either used in greater depth by the appraisal board or made available directly to the states' health funds or hospital providers. The use of JCAs for medicines in the outpatient sector is the responsibility of the DVSV. The precise details of these processes are currently still being finalised.

Outpatient hospital services

Although outpatient hospital services have been part of the LKF catalogue since 2019, they have not yet been subjected to systematic evidence analyses. However, in some cases, such services have been the subject of an assessment, e.g. outpatient surgical services (https://eprints.aihta.at/1225/).

Medical and therapeutic services in outpatient facilities

Benefits and cost catalogues for medical and therapeutic services in the outpatient sector result from negotiations between lobbies of professional groups (e.g., medical chambers) and social insurance. As Bachner et al. [54] describe the negotiation system has evolved historically, with social insurance primarily focusing on the fair distribution of total funds. Consequently, negotiation outcomes reflect overall cost-covering shares within the physician group average (rather than the actual costs of providing individual services).

Although HTA is not formally integrated into these negotiation processes, topics addressed by AIHTA demonstrate that systematically prepared evidence on service benefits, sometimes including costs or organisational implications, has gained increasing importance for decision-makers (such as supporting negotiations). Examples include assessments requested by social insurance for services provided by various non-medical professional groups under contract with social insurance providers, such as occupational therapy (e.g. https://eprints.aihta.at/1016/), psychotherapy (e.g. https://eprints.aihta.at/1157/), physical therapy (e.g. https://eprints.aihta.at/951/) or music therapy (e.g. https://eprints.aihta.at/1280). An example of a medical service is the evaluation of the HPV test as a decision-making basis for obstetrical-gynaecological services (https://eprints.aihta.at/1223/). Similarly, rehabilitative services funded by social insurance providers are also increasingly, albeit not systematically, subject to assessment (e.g. https://eprints.aihta.at/1222/), which guides funding allocation.

Preventive services

Preventive services are also subject to separate funding and control responsibilities, with vaccination funding differing from other preventive programmes (e.g., screening programmes). Examples of evidence analyses conducted before decisions were made also exist for preventive services, such as an HEE of HPV vaccination (https://eprints.aihta.at/760/) or extensive evidence analyses for the redesigning of the mother-child-pass (now parent-child-pass), a screening programme for pregnant women and infants (https://eprints.aihta.at/1112/). However, there is currently no systematic implementation of assessments or a formalised process for integrating HTAs into decision-making processes [36, 65].

6.4 Prioritisation of HTA topics and HTA content in Austria

It is not possible to subject all new developments to a comprehensive evaluation. Therefore, it is necessary to pre-select health technologies for assessment in Austria, except for medicinal products in the outpatient sector, where all pharmaceuticals submitted for reimbursement must undergo the legally required evaluation process.

Formal, cross-sector prioritisation processes do not exist in Austria. Nevertheless, a structured prioritisation process is in place for selected products (particularly high-cost and specialised medicinal products) within the appraisal board framework. The term "specialised" refers, amongst other things, to medicinal products authorised for the treatment of rare diseases requiring complex diagnosis and determination of indications, an initial prescription from a specialist department or a designated centre within the hospital setting, or which require specific administration or handling according to the summary of product characteristics.

Apart from this formal process, other prioritisation processes are taking place in Austria. For example, in the service area of individual medical services in the hospital sector, prioritisation is carried out by the responsible working group for hospital funding (see **Fehler! Verweisquelle konnte nicht gefunden werden.**), primarily applying formal criteria, where only fully completed proposals are considered. Similarly, only services that are not already included in fixed rates are considered [55].

For the other service areas, the prioritisation process for topics discussed at the AIHTA GmbH is described as an example. The institute's shareholders, who also represent the key payers of the Austrian healthcare system, form an operational board. Following internal prioritisation within their respective institutions (e.g., within the social insurance institutions), they submit annual topic proposals for the preparation of an HTA. AIHTA takes an inventory and prepares a proposal for the selection of topics, considering the available budgetary constraints, personnel resources, and the following criteria:

- High costs
- Uncertainty regarding effectiveness
- Control potential
- Significant political pressure (national, regional)
- Published studies available
- There is no recent, high-quality HTA from another institution

These criteria serve as guidelines for determining whether conducting an HTA is justified. However, they depend on the case. For example, tremendous pressure is exerted on the public payers regarding the funding of a service. In that case, it may also be necessary to highlight missing evidence or evidence of low quality.

If recent European HTA reports are already available, a separate Austrian assessment is usually not conducted. The compiled shortlist is discussed by board members at the board meeting, and they recommend a final list of topics. The formal decision is then made during the annual general assembly.

Austrian HTAs predominantly focus on the safety and clinical effectiveness domains. As already mentioned, the HTAs carried out by the appraisal board are an exception. These also systematically take into account economic, ethical, organisational and social aspects. This is particularly important, as the implementation of the usually highly complex technologies evaluated there requires, amongst other things, an understanding of the organisational prerequisites. Another new feature is that development costs, particularly public investment in research and development, are now systematically investigated and incorporated into the assessment, and patient surveys are conducted and considered in the HTA.

Like Austria, many other countries do not usually conduct full HTAs. However, they often include economic implications (in addition to the safety and clinical effectiveness domain) [36, 65]. A distinguishing characteristic of Austria's approach is its extensive utilisation of health services research methods compared to other countries. This methodological approach stems from research questions that not only consider

assessing the health technology but also provide appropriate care. Increasingly, administrative data (and not just data from published clinical studies) is being employed as an evidence source. One example of this is the "Health Services Research in Oncology" project, which utilised administrative data (billing data) to compare clinical study evidence with care delivery patterns in clinical practice (e.g., https://eprints.aihta.at/1227/). Another example is a data analysis on percutaneous aortic valve replacement in Austria (https://eprints.aihta.at/1141/).

6.5 National HTA strategy

In 2010, the Austrian Public Health Institute (Gesundheit Österreich GmbH, GÖG) published a national strategy for HTA in Austria, establishing a framework for transparent and quality-assured evaluation processes of HTA. The strategy outlined key components, including topic identification and prioritisation, reporting standards, review methodologies, results publication, and practical implication guidance. The HTA working group, comprising various HTA providers and coordinated by the GÖG, developed supplementary specifications, such as process and methodology handbooks, to guide organisations conducting HTAs [69].

A 2015 evaluation of the strategy revealed mixed results. While HTA awareness had increased, this was primarily attributed to initiatives from providers (especially the LBI-HTA) rather than the strategy itself. The evaluation identified several significant shortcomings, including ineffective and non-binding federal organisational frameworks, low prioritisation of HTA among key stakeholders, a lack of transparency in reimbursement decisions, an absence of structural responsibility for assessments, and inadequate coordination in topic selection.

Based on this evaluation and the recommendations of the 2016 study on efficiency in the Austrian social security and healthcare sector, the federal target management commission established a project group to prepare recommendations for action. The aim was to develop targeted, implementable recommendations for systematically establishing HTA within the Austrian healthcare system. The first version of the HTA recommendations was published in 2020. This was updated in 2024 (in connection with the EU Regulation on health technology assessment, which came into force on 11 January 2022). The updated version was approved for publication in March 2024.

The twelve recommendations for action include, for example, defining areas for the use of HTA, HTA in the context of health-related performance management, defining processes, and criteria for topic identification (identification, pre-selection, prioritisation and selection), the preparation of HTA reports, the evaluation of the processed information and the derivation of recommendations, decision-making and consistent implementation within the healthcare system, and the communication and dissemination of results [70]. The extent to which these recommendations have been followed can be assessed only partially. The decision to establish AIHTA GmbH (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) was already made prior to the establishment of the specialist group; recommendation 10 had therefore already been fulfilled by the time the recommendations were published.

6.6 HTA provider

The "Austrian Institute for Health Technology Assessment GmbH", based in Vienna, has the longest HTA tradition in Austria. It was founded in 2020 as the successor institution to the Ludwig Boltzmann Institute for HTA (LBI-HTA), which in turn emerged from a research unit of the Institute for Technology Assessment at the Austrian Academy of Sciences in 2006. While LBI-HTA was initially financed at 60%, later reduced to 40% from public research funds and otherwise from the budgets of the payers of the Austrian healthcare system, AIHTA GmbH is now financed exclusively by the public healthcare system (with a

small additional share from third-party funds). The shareholders of the GmbH are the BMASGPK, the DVSV and the nine state health funds or governments. The ownership and financing structure of AIHTA GmbH reflects the financing structure of the Austrian healthcare system.

With currently around 30 full-time equivalents, AIHTA GmbH carries out assessments on complex interventions (rehabilitation, prevention/screening, etc.) on the one hand, and on the other hand, it prepares assessments on individual medical technologies and procedures (high-tech interventions in hospitals) for which an application for benefit reimbursement has been submitted (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**). As a result of the work for the appraisal board, HTAs on medicinal products (in the hospital sector) have also played a significant role since the end of 2024. However, questions closely related to healthcare research and health economics (e.g., minimum volume standards for day surgery procedures) are also being addressed. The stronger integration of health services research in the Austrian HTA Institute compared to others is due to the fact that there is no academic focus on health services research in Austria, where such projects could be pursued as an alternative. In addition, deliberate public relations work aimed at contributing to the objectification of the discourse and sometimes the creation of a critical counter-public to dominant opinion leaders, as well as HTA methodological research and HTA teaching in various university courses, are part of the AIHTA profile. AIHTA can also allocate a small percentage of the budget to self-defined topics, including those that receive less attention (e.g., because there is no industrial product) and methodological topics. An example of the former is the benefit assessment of healthcare for vulnerable groups (e.g., homeless people) (https://eprints.aihta.at/1195/). An example of the latter is the development of a framework for evaluating digital health applications (m-health) (https://eprints.aihta.at/1279/).

Thanks to its history, scope of responsibilities and legal structure, AIHTA today acts as the national HTA institute, which is demonstrated by the performance capacity (number of full-time equivalents and high HTA productivity), scientific credibility (peer-reviewed publications and use of HTAs in court cases), as well as public visibility (media reports, work in advisory and decision-making bodies) and close international networking (e.g., in EU projects), which is underpinned.

The AIHTA also plays an important role in the framework of the HTAR (EU) 2021/2282. The institute is represented in both the HTA coordination group and three of the four sub-groups and carries out joint European assessments (JCAs) with other HTA institutes.

In addition to the AIHTA, several other (academic) institutes - all specialised in methodological or content-related fields - work in the field of HTA and EBM and cooperate in the Austrian HTA network.

- The Department of Evidence-based Medicine and Clinical Epidemiology at the University for Continuing Education Krems (formerly the Danube University Krems, DUK) was founded in 2007 and has been the Austrian branch of the Cochrane Collaboration since 2010. The institute focuses on EBM, prevention and screening, as well as the evaluation of health promotion programmes. It serves as a regional EBM consultancy for physicians (for the state of Lower Austria).
- The Department of Public Health and Health Technology Assessment at the UMIT / Private University for Health Sciences, Medical Informatics and Technology was founded in 2005. Its methodological focus is on modelling and decision analysis. In addition to regional accompanying research projects, international commissions are also a focal point.
- The Institute of General Practice and Evidence-based Health Services Research (IAMEV) at the Medical University of Graz was founded in 2015. However, an EBM Research Unit has already existed at the Institute of Medical Informatics, Statistics and Documentation (IMI) since 2009. The institute has a methodological focus on EBM and focuses on health services research in general practice and regional consultation (Styria).
- At the Medical University of Vienna (MUW), the Departments of Health Economics and General and Family Medicine at the Centre for Public Health are particularly concerned with HTA/EBM issues.

In addition to academic institutions, GÖG occasionally carries out HTAs - primarily in the form of international third-party-funded contracts - or prepares evidence analyses to advise the BMASGPK.

The Federation of Social Insurances (DVSV, formerly the Main Association of Social Insurance Institutions) evaluates pharmaceuticals before they are included in the EKO. The extent to which standardised HTA methods are used is not publicly published (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**). The DVSV is also involved in conducting joint European assessments of medicinal products relevant to the outpatient sector and is designated to conduct HTAs within the appraisal board framework for so-called interface products. The former "Evidence and cost-effectiveness" department, which previously prepared HTAs for social insurance institutions, was dissolved as part of the 2019 restructuring.

7 HTA in the life cycle of health technologies

This chapter describes at which points in the life cycle of therapies HTA can be used. The objectives of this chapter are to:

- Assess when an HTA is appropriate for a particular health technology.
- To better understand the diffusion of health technologies in routine care.

HTA can be used at different stages of a health technology's development. Based on the concept of the "life cycle of a technology", different stages can be distinguished:

- **Future technologies** that are in the design or early development stage
- **Experimental technologies** that are in the preclinical development and testing phase
- **Technologies undergoing clinical trials** (clinical studies)
- **Established technologies** that are defined as the standard of care and are usually widely used
- **Obsolete technologies** that are replaced by newer technologies have proven to be ineffective

In the case of pharmaceuticals, these phases are by regulatory measures. For example, that before a drug can move from the trial stage to the established therapy stage, it must be approved by the authorities, which in turn requires proof of efficacy, safety and quality (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**). A drug can be withdrawn based on pharmacovigilance data if there are safety concerns, for example. For other health technologies, these regulatory measures are only partially in place (e.g., for medical devices) or not at all (e.g., for screening programs and disease management programs). Nevertheless, even less regulated health technologies go through these stages of development.

One of the challenges for HTA is to determine at which stage of the technology's life cycle an assessment should be conducted. At a very early stage, there is usually still little reliable data available, meaning that decisions must be made under great uncertainty. However, if we wait too long, health technologies have often already "diffused into the system", and it is much more difficult to remove them from standard care (e.g. from a benefits catalogue) if there is insufficient evidence of efficacy. One example of this is the so-called vasoprotectants, medicines for the treatment of chronic venous insufficiency and haemorrhoids. These have been widely prescribed in Austria for decades and are still listed in the EKO even after the publication of a comprehensive HTA (https://eprints.aihta.at/1047/), which found a lack of proof of efficacy. Reasons for this include the fact that removal from the benefits catalogue is challenging to implement in the face of resistance from the company entitled to distribute the product and would ultimately lead to many patients paying for the medication privately because prescribing habits do not directly align with the evidence. Another example is nusinersen, a high-priced drug for the treatment of spinal muscular atrophy, which was already administered and publicly paid for due to pressure from the pharmaceutical industry and the affected patients or their relatives before an HTA. The restrictions recommended in the report for specific patient groups (those for whom there is proven evidence of efficacy) are retrospectively de facto impossible to implement, as patients who do not fall within the defined indications are already being treated. From the perspective of users and/or service providers, often backed by media coverage, there are concerns that patients may lose access to the care they are already familiar with. Additionally, there is a debate about whether the treatment of new patients is unequal compared to those who were previously receiving care. The lack of evidence of effectiveness is often of secondary importance.

Given the countless new products that enter the medical market every day, it is illusory to evaluate all new technologies at a very early stage. Horizon scanning programmes have been established to filter and assess new technologies that are particularly relevant for decision-makers early on (see Chapter 0).

In addition to early assessment, assessments are often carried out (for medicines and, in some cases, medical devices) around the time of approval (as soon as meaningful clinical data is available). However, even after health technologies are already part of standard care, an assessment can provide relevant findings,

e.g. on effectiveness in everyday practice (are the effects from the clinical studies confirmed?) or on (longer-term) side effects. In the pharmaceutical sector, so-called Phase 4 studies (observational studies) are often conducted for this purpose; however, these are sometimes used by the pharmaceutical industry purely as a marketing measure. Systematic follow-up, on the other hand, is not a common practice in the pharmaceutical sector or other health technologies. This is crucial where healthcare research is needed: for instance, to develop suitable instruments (e.g., registries) that produce meaningful data.

Knowing when to conduct an HTA is crucial for decision-makers. The timing can significantly impact the effectiveness of their choices and ultimately shape the future of healthcare innovations. However, the timing is also crucial for the manufacturers. A negative assessment at an early stage can have negative economic consequences for the companies concerned. It may also prevent access to health technologies whose benefits only become apparent at a later stage (e.g., after practical application experience). Diffusion management, therefore, is a balancing act between uncontrolled diffusion and premature residual restriction.

The extent to which a health technology diffuses into the healthcare system during its life cycle depends on several factors. In principle, diffusion is influenced by inclusion in various benefit catalogues and the related public reimbursement (see Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**). In the case of health technologies that have officially regulated approval processes (such as drugs and medical products), there are often misunderstandings (or demands from industry, patients or service providers). Many assume that receiving approval automatically guarantees reimbursement. In other words, just because a health technology is deemed effective in principle (compared to a placebo), it does not necessarily mean that it will be publicly funded. Since public funds are on the one hand and limited funds on the other, other criteria must be applied when deciding on reimbursement. The main criteria are effectiveness compared to existing therapies, but also affordability and efficiency (i.e., cost-effectiveness), as well as needs (e.g., if there has been no therapy for a disease to date) or general health objectives (e.g., if the intervention leads to significant health improvements for particularly vulnerable population groups who are disadvantaged in terms of health). However, these criteria are often not, or only partially, explicitly stated in healthcare systems. In Austria, for example, the effectiveness compared to alternatives and price criteria are explicitly defined in a statutory regulation for the inclusion of a drug in the EKO; other criteria are also implicitly considered for reimbursement decisions. One instrument for controlling diffusion is the so-called “Managed Entry Agreements” between manufacturers and public payers, which are used to link the payment of health technology to defined success criteria (conditional reimbursement) or the generation of reliable evidence (coverage with evidence development). However, these agreements often entail a significant amount of administrative effort, so they should be used with care [71]. They also have the disadvantage of being confidential, meaning that the actual prices paid for medicines negotiated in this way are usually not publicly known.

The widespread adoption of a health technology, once it has been added to a service catalogue, depends on how well it is accepted by both service providers and recipients, as well as the intensity of its marketing efforts. The level of health technology diffusion can be assessed by analysing its usage. Increasingly, administrative data (such as billing data from health insurance companies) is being utilised for this analysis, which may also be included as part of an HTA. However, access to the data and its informative value is often limited, as it was primarily documented for other purposes (see Chapter 4.4.3).

8 Stakeholder involvement in the HTA process

This chapter describes the basics of stakeholder involvement in the HTA process. The objectives of this chapter are to:

- Explain the advantages and disadvantages of stakeholder involvement
- Know different ways of integrating

The HTA process often involves various stakeholders, including healthcare system participants such as payers, service providers, industry representatives, and patients, as well as scientific institutions. This involvement is primarily aimed at increasing the acceptance of the HTA process and the reports that result from it [60]. Stakeholder participation can occur to varying degrees and at different stages of the HTA process. For instance, stakeholders can contribute to the development of the methodology used for creating HTA reports. This inclusion can enhance the acceptance of the reports conducted by this method; however, stakeholder involvement must not compromise the fundamental methodological standards of HTA. Stakeholder involvement can occur at various stages of preparing a HTA report, such as when identifying topics, when defining the report plan, or as part of a commenting procedure after publication of the first report version. Stakeholders can also be consulted for targeted information research (e.g. patient representatives can be included to identify patient-relevant outcomes). Involvement can take various forms, such as written comment procedures, oral hearings, focus groups, or objection procedures [60].

Stakeholder involvement must always be structured, transparent, and understandable; otherwise, the objectivity of an HTA is compromised. For instance, individual interest groups influence how results are presented. To address this, it is essential to publish all stakeholder contributions and clearly explain how they have been integrated into the report, in addition to the final report itself. However, this thorough involvement can be time-consuming and may delay the completion of assessments [24].

While the focus of stakeholder involvement in the past was primarily on cost bearers, such as industry and administration, the involvement of patients and/or healthcare professionals is now becoming increasingly important (patient and public involvement). However, the HTA community has been addressing this topic for over 20 years. Advocates of such processes see it as an important input for the assessment of patient-relevant endpoints. According to surveys conducted, the proportion of HTA institutions that involve patients has risen steadily, although the extent and form of involvement vary considerably. Patients are also involved in the context of the EU HTA Regulation and the preparation of joint clinical assessments. There is still limited evidence regarding the benefits and advantages of participation, and methodological challenges exist in its implementation. In Austria, patients or citizens are only sporadically involved in HTA processes [72]. One exception is the appraisal board process, in which patients are involved in a structured manner through questionnaires from the start of an HTA process.

9 Dissemination and effects of HTA results

- This chapter outlines the activities that follow the preparation of an HTA report. The objectives of this chapter are to:
- Understand the measures and target groups for the dissemination of HTA results
- Learn about the approaches and specific examples for measuring the impact of HTA
- Explain strategies to increase the influence of HTA

9.1 Dissemination

In the context of HTA, dissemination refers to the intentional and targeted (active) communication of HTA results to primary audiences, such as clients and target groups. Additionally, it can involve sharing information with a broader public, such as professional societies, without specific targeting [73, s. 356]. Some HTA organisations have developed focused strategies for sharing their results. Overall, the literature suggests that it is important to communicate with primary audiences through multiple information channels, and adequate resources should be allocated for this purpose.

The strategies are designed to impact the knowledge of the target group and, in some instances, to encourage behaviour changes that align with evidence-based practices. Thus, effectively disseminating the results is essential for achieving the overall impact of an HTA.

Gerhardus et al. [73] have summarised some measures for the targeted dissemination of HTA results (Box 1).

Box 1: measures for dissemination

Target groups:

- Health administration and governance
- Healthcare professionals
- Expert associations and academic networks
- Research networks
- Citizens and patient organisations
- Medical industry representatives
- Media outlets

Goals:

- Stimulate interest and initiate discussions
- Ensure that target groups are familiar with HTA reports and their key messages

Measures:

- Join press conferences for selected HTA reports; consider involving a press or marketing agency for assistance and crafting memorable messages.
- Create a distribution list of specialised journalists from newspapers, radio, television, online media, and engage multipliers and opinion leaders.
- Targeted dissemination of the summaries and patient-friendly versions of the reports, along with communication to relevant patient organisations.
- Prepare slide presentations for download that highlight the most important results of the HTA reports and present them at scientific congresses.

Furthermore, the internet offers additional possibilities, including social media, podcasts and really simple syndication (RSS) feeds. However, concerns have been raised regarding the high level of competition for attention, suggesting that a solely online strategy may not be sufficient [73].

9.2 Effects of HTA: impact measurement

9.2.1 What are the possible effects of HTA?

The impact of the HTA is often assessed based on whether the recommendations in the report align with the decision made afterwards. In contrast, if a decision deviates from the report's recommendations, it can be seen as having no effect. However, the perspective should be scrutinised for several reasons. First, numerous factors influence decision-making, and objective evidence is just one criterion among various others, including social, economic and cultural factors. Second, the interests and influence of the stakeholders involved significantly affect decisions. The rational and linear model adopted in decision-making, referred to by Weiss [74] as a problem-solving model, has often been shown to lack empirical support [75]. Therefore, HTA should be regarded less as a technical process and more as a discursive one. As a result, the impact of HTA is also multi-dimensional, and can spark what has been described as a "kaleidoscope of effects [73, s. 359]". Gerhardus et al. [76] have proposed a hierarchical stage model comprising six stages that relate to the direct effect of HTA results: (1) perception, (2) acceptance, (3) policy processes, (4) political decision, (5) practice, and (6) outcome. Additionally, the authors describe indirect effects in the form of concepts and theoretical perspectives that inform decisions and decision-making processes, referring to this phenomenon as "enlightenment".

9.2.2 Status of impact measurement in HTA organisations

HTA aims to support informed decision-making and promote evidence-based choices, ultimately enhancing the healthcare system. While the application of HTA findings is a key aspect of its legitimacy, there is rarely a systematic evaluation to determine whether this goal is being achieved. An INAHTA study [77, 78] revealed that only one-third of the surveyed HTA institutions worldwide confirmed having a formal strategy for evaluating their activities. However, many do so selectively. The type of decisions supported by the HTA agencies plays a role here. Most frequently, HTA supports reimbursement decisions for benefit catalogues but also plays a role in the development of clinical guidelines and decisions within the framework of HTAs, particularly in purchasing before making significant investments or in implementing comprehensive healthcare programmes. The indicators to measure the HTA impact are correspondingly diverse. The spectrum of impact measurement ranges from analysing a report at a basic level (e.g., examining the format and download volume) to assessing indicators at an organisational level (e.g., changes in awareness of the organisation). It also includes evaluating the actual influence on health policy decisions, which could involve demonstrating that the results of a report are considered in decision-making processes. Additionally, it covers indicators that reflect changes, such as the implementation of new purchasing strategies or adjustments in clinical practice, as well as effects that extend beyond the health system, including media coverage and parliamentary debates.

The methods used for this analysis are similarly diverse. They may involve analysing administrative data to study changes in prescribing practices, conducting qualitative interviews or questionnaires with relevant stakeholders, performing media or document analyses, and observing meetings of decision-making bodies.

Currently, there are no standardised methodologies for measuring impact, so the evaluation approach must be tailored to the specific context in which the HTA agency operates. An openness to different methods is helpful in the concretisation of an impact measurement. However, impact measurement can only

be successful if it is a priority at the management level of the individual HTA institutions and resources are consciously reserved for it. Avoiding impact measurement due to fear of adverse outcomes, as highlighted in the INAHTA report, is the wrong approach. It is challenging for HTA to seek evidence of the benefits of medical services while neglecting evaluation.

9.2.3 Example of an impact measurement in Austria

This example describes an empirical impact study [79], which aimed to evaluate the HTA activities of the LBI-HTA (now AIHTA GmbH) and the previous activities of the Institute for Technology Assessment (ITA) at the Austrian Academy of Sciences.

The basis for the analytical framework was the hierarchical stage model of Gerhardus et al. [76, 80]. However, the impact categories were not understood hierarchically but rather as equally possible forms of impact and extended by one category (Table 9-1).

The categories examined thus include "perception", "acceptance", "use of HTA in the policy process", "justification of decisions with HTA", "implementation of research results in practice", "outcomes" in the sense of economic effects and "enlightenment" in the sense of more "HTA culture" in the scientific, media and decision-making context. Several empirical methods were employed: partially standardised interviews with 15 representatives of the various target groups, a content analysis of 92 publications, a questionnaire survey among LBI-HTA employees, a routine data analysis on changes in the volume and price of the evaluated medical services, and a print media analysis.

Table 9-1: Framework for empirical impact analysis

Target groups/levels				
Impact categories	Microlevel	Mesolevel	Makrolevel	Methods
Perception Acceptance Policy process Political decision Practice Outcomes Enlightenment	Scientists, patients, journalists, clinicians, citizens	Hospitals, insurances, expert associations, professional associations, patient organisations	Political/governmental institutions and decision-making councils, media, industry	Document analysis, Questionnaire, Interview, Routine data analysis, Media analysis

Adapted from Gerhardus et al. [76, 80]

The analysis came to the following conclusion:

Perception: Significantly higher download frequencies and increasing media coverage were observed. Between 2006 and 2009, the average reference frequency of reports increased from 1.7 to approximately 23 per month. In the same period, the number of identified media reports increased from 6 to 50. However, the image attributed to the institute in the press articles differs from its self-image. For example, the institute is often described as a cost-cutting organisation. The vehicle, in line with the institute's mission statement, views the goal as the sensible use of resources in the healthcare system rather than cost reduction. The level of awareness is relatively high among individual hospital associations, social insurance institutions and the Ministry of Health, but low at the state level and among individual doctors and journalists, where only selective awareness can be identified. Reports with a high level of media interest are most frequently obtained. At the same time, those based on complex methodological principles and without a direct reference to political decision-making are relatively rare.

Acceptance: The research results are perceived by the administration in the Ministry of Health and social insurance companies as helpful for preparing negotiations and in hospital administration for measures to change the use of technology (e.g., creating guidelines and personnel structure planning). For individual doctors, the work is supportive in administrative and research activities but less so in individual patient contact.

Policy process/decision: In some cases, particularly for benefit catalogue expectations and individual vaccination decisions, HTA results were utilised as a basis for the decision.

Clinical practice and reimbursement practice: Changes in clinical practice were observed for products that had been identified as being overused in hospitals. The shift was anticipated due to more restrictive criteria for including new services in the benefit catalogue. For instance, a university hospital showed an above-average consumption of immunoglobulins following organ transplants. The results of the HTA identified specific indications where patients benefit from the use of immunoglobulins. As a result of indication-specific use, the number of immunoglobulins administered decreased by 20,000 units over the study period from 2002 to 2009, compared to the average consumption beforehand. Additionally, new reimbursement models, such as conditional reimbursement, are increasingly integrated with HTA in social insurance and hospital funding.

Outcomes: The most noticeable economic effects are seen in the hospital sector. Based on interviews and routine data analysis, the reduction in expenditure linked to the publication of HTA reports is estimated to be several hundred million euros. The standardisation of evidence-based analyses in maintaining service catalogues within the hospital sector has the potential to reallocate resources toward more effective and safe services.

Enlightenment: In individual decision-making processes, such as maintaining the hospital service catalogue, the results of HTA are increasingly considered and presented in a standardised format. These changes are often associated with initiatives aimed at enhancing transparency, such as the requirement of conflict-of-interest statements. The dissemination of research findings within the research community and the healthcare system, including through teaching, has increased significantly during the reviewed period, leading to numerous follow-up projects both nationally and internationally. However, there is limited evidence of a growing "HTA culture" in the media, and balanced communication regarding risks and benefits is lacking.

Overall, the study demonstrated an impact across all examined categories, although the degree of impact varied depending on the user group. The most substantial evidence of impact was seen in increased awareness and economic effects. For the primary target groups, the most significant impact was observed in hospital management and financing, followed by social insurance providers and federal political institutions. The impact is not solely contingent on the acceptance of HTA by medical staff; it is also influenced and accelerated by administrative frameworks, financial incentives and media pressure.

Additionally, the study indicated that the impact of HTA research could be enhanced in all categories. A lack of implementation of HTA results in medical practice is frequently attributed to external factors, such as decision-makers' reluctance to adopt them and opposing influences like the medical association. The strongest drivers of impact were identified as research that is timely and relevant to decision-making, increased integration of HTA in decision-making processes, and resource flexibility to enable rapid response to health policy issues.

9.3 Governance of HTA report impact

The Austrian example, along with other studies, illustrates that the influence of HTA depends on various factors. For HTA to have the most significant impact, the reports must be relevant and of high quality. Additionally, specific system requirements need to be established, such as the standardised incorporation of HTA into decision-making processes [73]. At the system level, essential elements include a culture of evaluation, the integration of HTA reports into routine decision-making processes, and awareness of HTA among relevant institutions. Another critical requirement is that the HTA organisation must be neutral and independent, possess an excellent scientific reputation, and have adequate resources to conduct high-quality work.

Gerhardus et al. [73] suggested that, ideally, measurable "impact objectives" should be defined before the preparation of an HTA report. This way, the report can be focused on these objectives from the beginning. Both clients and HTA authors should engage in this planning process. Finally, the effects of HTA reports should be evaluated retrospectively based on criteria established prospectively.

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