Health technology assessment of medical devices
Second edition
WHO Medical device technical series

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Preface

Sustainability and the efficient use of scarce resources are two of the greatest challenges facing health systems around the world but is especially acute for low- and middle-income countries (LMICs) that are working towards achieving universal health coverage. An evidence-based approach to define the right balance and support prioritisation of new and innovative health technologies and interventions is critical to the successful progression towards universal health coverage. Health technology assessment (HTA) is a well-recognised and methodologically robust evidence-based priority-setting tool used to provide information on the safety, efficacy, quality, appropriateness, and cost-effectiveness of health technologies, and in so doing, supporting coverage decision-making, optimising the efficient use of limited healthcare resources to meet the needs of the population. As such, in 2014, the World Health Assembly adopted Resolution WHA67.23: Health Intervention and Technology Assessment for Universal Health Coverage, providing a mandate to support countries in the development of health intervention and technology assessment mechanisms (1).

The World Health Organization (WHO) actively supports Member States, especially LMICs, to promote evidence-based health policy by strengthening capacity to enable the pursuit of HTA as a priority in the drive to implement and achieve universal health coverage. The WHO is developing a series of reference documents that encompass all aspects of health technologies included in Resolution WHA67.23 (medicines, vaccines, medical devices and equipment, procedures and preventive interventions); however, this guideline will focus on developing HTA of medical devices in LMICs.

Methodology

This book is an update of the 2011 publication ‘Health technology assessment of medical devices’, which was developed as part of the WHO Medical device technical series. Since the 2011 publication and the approval of HTA resolution WHA67.23 in 2014 there has been updated methodologies for the assessment of different types of medical devices, to address benefit packages for universal health coverage. The proposal to update the 2011 edition was discussed and approved by the WHO’s Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) members, with the initial table of
contents proposed by a STAG MEDEV HTA subgroup, and WHO secretariat. The table of contents was subsequently discussed, edited and approved by the STAG MEDEV (2). A list of collaborators and reviewers were identified in conjunction with WHO regional advisors as well as STAG MEDEV members to ensure input from different regions and professionals who have no conflict of interest. The first version of the document was drafted by a technical writer according to the table of contents circulated to identified collaborators. This first draft will be reviewed by the STAG MEDEV working group on HTA and the WHO. In addition, a list of non-governmental organisations (NGOs) with official relations to the WHO, as well as WHO Collaborating Centers will be invited to comment on the document in an open consultation process. The technical writer, WHO Secretariat and the STAG MEDEV working group for HTA will address all comments in the second draft. The updated document will then be reviewed by WHO STAG MEDEV before submission to the WHO executive clearance.
Acknowledgements

Acknowledgement section to be drafted...

Declaration of interests

Conflict of interest statements....
### Acronyms and abbreviations

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<th>Acronym/Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AI</td>
<td>Artificial Intelligence</td>
<td></td>
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<tr>
<td>CED</td>
<td>Coverage with evidence development</td>
<td></td>
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<tr>
<td>HS</td>
<td>Horizon scanning</td>
<td></td>
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<td>HTA</td>
<td>Health technology assessment</td>
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<td>HB-HTA</td>
<td>Hospital-based HTA</td>
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<td>HTAi</td>
<td>Health Technology Assessment international</td>
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<tr>
<td>ICER</td>
<td>Incremental cost-effectiveness analysis</td>
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<td>IMDRF</td>
<td>International Medical Device Regulators Forum</td>
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<td>LMIC</td>
<td>Low to middle-income countries</td>
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<tr>
<td>MCDA</td>
<td>Multi-criteria decision analysis</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<tr>
<td>QALY</td>
<td>Quality-adjusted life year</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>RWD</td>
<td>Real-world data</td>
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<td>RWE</td>
<td>Real world evidence</td>
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<td>STAG MEDEV</td>
<td>Strategic and Technical Advisory Group on Medical Devices (WHO)</td>
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<td>UHC</td>
<td>Universal health coverage/care</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Definitions

For consistent use of health technology assessment (HTA) terminology, users of this document should refer to the HTA glossary, which aims to promote a common vocabulary for users and producers of technology assessments. As of 2024, the HTA Glossary is available in English, French, German, Spanish and Russian (3).

*Health technology assessment:* HTA is 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 in order to promote an equitable, efficient, and high-quality health system (4).

*Health technology:* is an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organise healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (3).

*Medical device:* is any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for medical purposes (5).

*Artificial intelligence (AI):* the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages (6).

*Rapid Review:* a form of knowledge synthesis that accelerates the process of conducting a traditional systematic review through streamlining or omitting a variety of methods to produce evidence for stakeholders in a resource-efficient manner (3).

*Real world data (RWD):* Data collected during the routine delivery of health care. Note 1: Sources may include observational data, administrative data, research data, patient-generated data or professional-generated data. These data may be collected in administrative datasets, case notes, surveys, product and disease registries, social media, electronic health records, claims and billing datasets, or mobile health applications (3).

*Real world evidence (RWE):* Evidence derived from the analysis of real-world data. Note 1: Real world data are primarily analysed through observational study designs. This real-world evidence is
characterised by the actual use of the technology in practice and by findings that are generalisable to the target population for the technology (3).
Executive summary
1 Introduction

The role of health technology assessment (HTA) is to provide evidence-based advice to health policy decision-makers to enable equitable, efficient access to high-quality healthcare (7). HTA is defined as a multidisciplinary process that synthesises the best available evidence describing the dimensions of a health technology in a systematic and transparent manner in comparison to existing alternatives.

Common dimensions of value assessed include the efficacy, clinical effectiveness, safety and economic implications (cost-effectiveness and financial impact), but ethical, legal, social and cultural issues, as well as organisational and environmental aspects relating to the health technology in question, should also be appraised and considered (4).

Driven largely by concerns about increasing healthcare costs, early HTA mainly focused on pharmaceuticals rather than non-drug technologies to inform both regulatory and payer coverage decision-making on their introduction to the health system (8). Medical devices are essential tools for the prevention, diagnosis and treatment of illness and disease and patient rehabilitation. However, there are important differences between drug therapies and medical devices, including product lifecycle, clinical evaluation, user issues, costs and economic evaluation, and intellectual property (9).

HTA methodologies for the assessment of pharmaceuticals are more developed, robust, widely used and well-understood compared to HTA for non-drug technologies, including medical devices (10).

As such, this document, commissioned by the WHO, aims to provide policy advice to advance the use of HTA for medical devices and to strengthen evidence-based decision-making in health care, especially in low-to-middle-income countries.

2 Health technology assessment, the WHO perspective

In 2007, the World Health Assembly adopted Resolution WHA60.29, where the WHO and Member States were urged to collaborate with other organisations to develop methodological tools and technical guidelines to support the prioritisation, selection and use of health technologies, particularly medical devices (11). Subsequent resolutions relevant to progressing the use of HTA include WHA67.20, WHA67.23 and WHA76.5, which urged Member States to strengthen regulatory capacity and to consider the establishment of health technology assessment systems to support decision-making for access to safe, efficacious and affordable medical products in the context of universal health coverage (UHC) (1, 12, 13). As such, the 2014 Resolution 67.23: Health Intervention and Technology Assessment for
Universal Health Coverage provides a mandate supporting Member States to develop these health intervention and technology assessment mechanisms (1, 14), which aligns with the 2021 and 2023 resolutions of the General Assembly of the United Nations to scale up and accelerate efforts towards the achievement of universal health coverage for all by 2030 (15, 16).

2.1 HTA in the Global Atlas of Medical Devices 2022

The 2007 resolution WHA60.29 on Health Technologies urged Member States to “formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices” (11). In response to WHA60.29, the WHO has conducted a survey of Member States every 3-years to identify key areas that require support for the development or improvement of health technology programs, with a particular focus on medical devices. The 2022 Global Atlas of Medical Devices provides global, regional and country data on the availability of medical device policies, regulation of medical devices, incorporation, national lists of priority medical devices, inventories, use of medical device nomenclature system, and biomedical engineering resources (17). Importantly, the survey also collects information on health technology assessment and health technology management capacity, which in 2017 indicated that 61% of Member States did not have a formalised HTA unit (18). The 2022 Global Atlas focused on determining the status of medical devices and how access to priority devices can support the Sustainable Development Goals (SDGs) as countries move towards achieving UHC.

It should also be noted that in 2019, the Executive Board of the WHO acknowledged the need for an international system for the classification, coding, and nomenclature of medical devices (EB145/3), the lack of which has hampered the development of an evidence-based database to provide guidance on appropriate medical devices (19).
3  Links between health technology regulation, assessment and management of medical devices

HTA is the link that bridges the three distinct but complementary functions of health technology decision-making (Figure 1):

i. regulatory approval of technologies for market access;
ii. policy around coverage, reimbursement or benefit packages; and
iii. management of the day-to-day use of approved technologies, including decommissioning or disinvestment (20, 21).

The WHO’s 2007 resolution WHA60.29 urged Member States to “formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering.” (11).

The types of evidence considered for each of these steps differ (Figure 2 and Table 1). Evidence used for regulatory approval and reimbursement decisions of pharmaceuticals is usually similar. However, the evidence requirements for the regulation of medical devices, where the level of associated risk and safety of the device needs to be demonstrated, often differs markedly from that required for coverage decisions, where evidence demonstrating comparative effectiveness to a standard of care is required (21).
Recommendations to adopt technologies made at the national level may be difficult for management to implement at the local level, where there may be a need for training, organisational change (of facilities and/or staffing) or budgetary constraints. Although health technology management should be carried out on all levels of the health system, the development of a dedicated holistic health technology management system at the health organisation level (e.g. hospital) should be encouraged to oversee the acquisition, deployment, day-to-day support and finally, decommissioning requirements of medical devices (22). However, initiatives such as hospital-based HTA (see section 6.3), shifting the HTA focus from the national to the local level, may result in a fragmented national approach to UHC (21).

Table 1  Comparison of health technology regulation, assessment and management

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Health technology regulation</th>
<th>Health technology assessment</th>
<th>Health technology management</th>
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<tr>
<td><strong>Perspective</strong></td>
<td>Safety and efficacy</td>
<td>Efficacy, effectiveness, and appropriateness</td>
<td>Needs analysis, alternative technologies</td>
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<td>Market entry</td>
<td>Population-level</td>
<td>Local-level health facilities</td>
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<td><strong>Requirement</strong></td>
<td>Mandatory</td>
<td>National recommendation on complex technologies</td>
<td>Local implementation of recommended technologies</td>
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<tr>
<td><strong>Role</strong></td>
<td>Prevent harm</td>
<td>Maximise clinical and cost-effectiveness, value-based decision-making</td>
<td>Management across the lifecycle of the device, from adoption to decommissioning</td>
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3.1 HTA for regulatory approval

Regulatory bodies are primarily concerned with the safety of a product, with no requirement to evaluate evidence of how well the intervention compares with existing clinical practice or whether it represents value for money. Regulators classify medical devices based on the potential level of hazard and risk to
patients, with risk defined depending on the duration of use, level of invasiveness, whether the device is implantable or non-implantable, or is active or contains an active substance (23, 24). Different countries have different risk classification systems, but in general, devices such as thermometers would be categorised as low risk, with medium risk applying to devices such as hearing aids and infusion pumps, whilst devices such as implanted stimulators would be high risk.

A total product life cycle regulatory framework for medical devices should include product design, manufacture, and pre-and post-market data collection. However, personalised (e.g. remote monitoring devices), point-of-care or digital (including artificial intelligence and machine learning) medical devices present challenges to existing regulatory frameworks (25). As such, the core objective of the International Medical Device Regulators Forum (IMDRF) is to develop a common international classification standard to harmonise global regulatory requirements and to encourage information sharing, capacity building, and strengthening of regulatory processes (26).

For market access, regulators require all medical devices to be evaluated, ranging from the simple, such as medical gloves, bandages, and syringes, to more complex devices, such as hip prostheses and cardiac implants to imaging and radiation therapy systems. Regulatory approval is a requirement for an HTA, however, unlike pharmaceuticals, not all medical devices will be required to undergo an HTA. Decision-making for regulatory approval and HTA of medical devices share some elements of evidence but clinical data obtained as part of the regulatory process will not be sufficient for HTA due to the reasons outlined in Section 3.1 (21, 27). Although independent processes, regulatory approval and HTA of health technologies are linked (Figure 3). Evaluation of efficacy and safety is usually sufficient for regulatory approval; that is, is the device safe, and does it do what it says it should do? HTA must consider the effectiveness of the device along with questions of value for money, equity, acceptability to patients and healthcare providers, organisational impact and ethical issues (20). Given the lower evidence requirements for market approval for patient health and safety, standardised post-marketing data collection should be encouraged to not only detect device-related incidents or adverse events but to assess real-world effectiveness and any implementation issues (e.g. training or infrastructure requirements) of devices (21). However, the costs associated with setting up and maintaining post-market registries are prohibitive even for high-income countries.
Figure 3 Stages and values of HTA and their relationship to the regulatory process (20)

See the WHO’s Global model regulatory framework for medical devices including in vitro diagnostic medical devices that describes the essential characteristics a country/region/local medical device regulatory system (28). Also see the IMDRF’s four regional harmonisation initiatives: Asia-Pacific, Pan American, African and global (26).

3.2 HTA to support procurement

The procurement process for all health technologies begins with identifying need, followed by evaluation of options, planning, financing and finally, contracting. Although separate from the procurement process, HTA informs the first step by evaluating needs aligned with health system priorities based on consideration of burden of disease, as well as the impact on health outcomes (29). Coverage and procurement decision-making for pharmaceuticals tend to be value-based, informed by cost-effectiveness analyses performed as part of an HTA assessment, which then forms the basis for price negotiations (14). In comparison, cost-effectiveness and value frameworks are more difficult to apply to medical devices, where frequent device iterations and user learning curves make it difficult to generalise health outcomes and, therefore, value to the health system (30). Medical device procurement needs to consider the upfront cost of the device, as well as patient and clinician preferences, infrastructure, technical and implementation considerations, running costs, including...
maintenance and consumables, as well as warranties (30, 31). To meet health priorities and the needs of health organisations, medical device procurement needs to consider these factors and not necessarily accept the lowest tendered price (18). Some countries have lists of necessary medical devices that can be purchased as they align with national health priorities, and many countries are moving towards centralised procurement for the cost advantages of economies of scale; however, this may not suit countries with diverse health needs (29).

Procurement tends to be conducted at the local rather than national level, managing the budgetary, reimbursement, and cost constraints of the healthcare organisation in question. Procurement requires good governance and should be a transparent process. Effective procurement practice should consider HTA recommendations and, if possible, develop links with hospital HTA practitioners to ensure efficient and equitable access to healthcare technologies (30).

For a summary of resources for achieving good procurement practice, the WHO Procurement process resource guide (32).

### 3.3 Role of biomedical engineers

As stated above, Resolution WHA60.29 urged collaboration between HTA and biomedical engineering personnel (11). The WHO also recommends that biomedical engineers be employed in HTA agencies to provide advice on the selection, prioritisation and management of medical devices (20, 33).

The expertise of biomedical engineers is the link between medical device research, design and management in hospitals and healthcare organisations, with a skill base that crosses disciplines including physics, math, engineering, biology and medicine. Recognising these multi-disciplinary attributes and natural synergies, the International Federation of Medical and Biological Engineering (IFMBE) endorsed HTA as a core biomedical engineering learning in 2011. To further this goal, the IFMBE has developed HTA training courses designed specifically for biomedical engineers, incorporating an HTA e-learning platform and guidelines for the assessment of medical devices, especially early, pre-market HTA. As medical devices are dependent on the environment in which they are used, it follows that medical device HTA depends on the environment where a medical device is intended to work, affecting the generalisability of HTA reports produced in other (often high-income) countries (33). Involving biomedical engineers in the HTA process when acquiring new medical equipment can provide insight into the technical characteristics, comparison with similar technologies, usability, performance, safety and organisational impact of devices throughout their lifecycle, as well as informing economic analyses.
with the provision of maintenance, installation, and operational costs (9). As such, one of the IFMBE’s priorities is fostering HTA-related capacity building in LMICs (33).

See the Health Technology Assessment Division, featuring the freely available HTA eLearning platform, of the IFMBE for more information (34). Also, see the WHO publication ‘Human Resources for Medical Devices, the Role of Biomedical Engineers’ for definitions of biomedical engineering and its sub-specialties as well as describing the different roles a biomedical engineer can play in managing the life cycle of a medical device from introduction to decommissioning (20).

3.4 HTA data from the WHO survey of 2020/21

In parallel to the Global Atlas survey, the WHO also conducts a global survey of Member States to assess the status of HTA conducted by government or national institutes, usually under the auspices of the Ministry of Health. The surveys, conducted in 2015 and 2020/21 are intended to measure:

- How HTA is utilised in public sector decision-making (i.e. planning and budgeting, reimbursement, determining benefit packages or clinical practice guidelines);
- Scope of HTA (i.e. which technologies and what criteria are assessed) and availability of HTA guidelines;
- Institutional capacity to support HTA and requirements to strengthen capacity to improve the use of HTA in health care policy; and
- Governance of the HTA process (35, 36).

These surveys are a way to measure the global progress in the investment in the systematic use of HTA in the formal health decision-making process. HTA was found to primarily inform governments about planning and budgeting, clinical practice guidelines and the design of health benefit packages. Importantly, the Global Atlas also surveyed the barriers to using and producing HTA, identifying areas to be addressed by future WHO resolutions to assist countries in establishing mechanisms to institutionalise HTA. In the 2020/21 survey, a lack of awareness of the importance of HTA and a lack of budget and dedicated human resources were the top-ranked barriers to using and producing HTA, respectively (35).

3.5 HTA selection process for WHO priority list of medical devices

In addition to the Global Atlas and the surveys, the WHO also publish and continuously updates lists of priority medical devices that are designed to improve access to suitable medical devices, increase safety,
support quality of care and strengthen health care systems. The lists are designed to provide evidence-based guidance to assist decision-making to guide policy, facilitating the development or updating of national priority device lists and promoting their availability to support UHC. The Priority Medical Device Project identifies key medical devices that, when adapted to the local context, address the management of healthcare priorities such as disease elimination, high-burden diseases (e.g. cancer) and those that target specific populations, including the elderly, pregnant women, and newborns. The full list of WHO publications on priority medical devices can be accessed here, including essential in vitro diagnostics, medical devices for the COVID-19 response and those for the management of cardiovascular disease and diabetes.

The process used by the WHO to add new devices or in vitro diagnostic is described in Figure XXX. The National HTA Committee or decision-making body of individual countries would decide which of these technologies to prioritise based on a number of factors including clinical need, burden of disease and available infrastructure and resources.

6 bis The Priority medical devices list (MDL) and Essential in vitro diagnostics (EDL) can be used as a reference to Member States to develop or update medical devices national lists.

https://www.who.int/publications/i/item/9789240030923

Selection of essential in vitro diagnostics at country level: using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics,
Discuss to have a national committee to decide based on their needs.

Methods in HTA for Medical Devices

Medical devices are different to other health technologies; therefore, it follows that the assessment of medical devices needs to be different. The definition of a medical device is broad and may vary depending on whether the device is evaluated by a regulatory body or assessed prior to introduction into a health system. HTA can be applied at different points in the lifecycle of a medical device: during the pre-market regulatory approval process, early assessment when a device is beginning to diffuse into the health system and has been identified by horizon scanning, full HTA with or without an economic and financial impact analysis once the device has become established in health care practice,
procurement, and finally through to reassessment and potential disinvestment when superseded by new devices (Figure 4).

Figure 4  The life cycle approach: the movement of a medical device through the health system

For the assessment of any health technology, including medical devices, Drummond et al. (2008) proposed fifteen key principles that should be used to guide HTA for resource allocation, with the aim of improving the interface between those conducting HTA and health policymakers. The principles describe the structure of HTA programs, the methods of HTA, processes for the conduct of HTA and the use of HTA in decision-making (Table 2) (21).
### Key principles for the conduct of HTA for resource allocation decisions (21, 37)

<table>
<thead>
<tr>
<th>Principle 1</th>
<th>The goal and scope of the HTA should be explicit and relevant to its use.</th>
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<tr>
<td>Principle 2</td>
<td>HTA should be an unbiased and transparent exercise.</td>
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<td>Principle 3</td>
<td>HTA should include all relevant technologies.</td>
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<td>Principle 4</td>
<td>A clear system for setting priorities for HTA should exist.</td>
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<td>Principle 5</td>
<td>HTA should incorporate appropriate methods for assessing costs and benefits.</td>
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<td>Principle 6</td>
<td>HTAs should consider a wide range of evidence and outcomes.</td>
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<td>Principle 7</td>
<td>A full societal perspective should be considered when undertaking HTAs.</td>
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<td>Principle 8</td>
<td>HTAs should explicitly characterise uncertainty surrounding estimates.</td>
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<tr>
<td>Principle 9</td>
<td>HTAs should consider and address issues of generalisability and transferability.</td>
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<tr>
<td>Principle 10</td>
<td>Those conducting HTAs should actively engage all key stakeholder groups (e.g. professional bodies, patient organisations, manufacturers).</td>
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<tr>
<td>Principle 11</td>
<td>Those undertaking HTAs should actively seek all available data.</td>
</tr>
<tr>
<td>Principle 12</td>
<td>The implementation of HTA findings needs to be monitored.</td>
</tr>
<tr>
<td>Principle 13</td>
<td>HTA should be timely.</td>
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<tr>
<td>Principle 14</td>
<td>HTA findings need to be communicated appropriately to different decision-makers.</td>
</tr>
<tr>
<td>Principle 15</td>
<td>The link between HTA findings and decision-making processes needs to be transparent and clearly defined.</td>
</tr>
</tbody>
</table>

See the *HTA Toolbox for Emerging Settings* for guidance, resources and tools at each stage of the HTA process (38).

**4.1 Full HTA – devices are different**

There are many similarities in conducting HTA for all health technologies; however, there are many reasons why devices, and therefore HTA for devices, are fundamentally different to medicines and require special consideration:

- medical devices can have multiple therapeutic, instrumental, or diagnostic uses (39, 40);
• medical devices are characterised by short product lifecycles (1-3 years), with incremental innovations rapidly superseding older generation devices, resulting in HTA of medical devices quickly becoming outdated;
• the intellectual property associated with medical devices is less well protected than patents on new drugs (7);
• clinical studies for new devices tend to be fit-for-purpose to meet regulatory approval, building on existing evidence (40);
• the quality and level of evidence generated in clinical studies for new devices may be less robust due factors such as a lack of appropriate comparators, randomisation and blinding (39, 41);
• the current standard of care (comparator) for a medical device may vary from jurisdiction to jurisdiction, and may not be a single technology, but rather a mixture of existing technologies (21);
• medical devices often depend on a surgical procedure, so HTA must consider device-user interactions including the learning curve plateau and training for using the device, as well as the surgical procedure (7, 41);
• some medical devices are hybrid technologies, combining a device with a drug, requiring HTA of both components;
• some medical devices require additional infrastructure or form part of a complex clinical pathway; and lastly,
• many of these factors make it difficult to quantify the direct impact of medical devices on patient outcomes, adding to the complexity of conducting economic analyses (7).

Several agencies have published step-by-step guidelines for conducting assessments of non-drug health technologies including therapeutic and diagnostic medical devices:

• the National Institute for Health and Care Excellence (NICE) (42);
• the Australian Medical Services Advisory Committee (MSAC) (43); and
• Singapore’s Agency for Care Effectiveness (ACE) (44).

Also see *HTA 101: Introduction to Health Technology Assessment* for guidance on all aspects of conducting a full HTA to inform funding decisions (45).
4.2 Horizon scanning

Horizon scanning (HS) is a risk management tool that can be used to reduce uncertainty and future-proof health systems by facilitating the appropriate adoption of new health technologies. HS proactively identifies technologies early in the life cycle, usually prior to regulatory or market approval, that may impact the health system. HS can also identify new uses for existing technologies, as well as reassessment/disinvestment targets. By responding to demand signalling, HS can also actively identify the needs and key priorities/challenges of a health service by scanning and mapping groups of technologies in a clinical care pathway rather than just single technologies. To identify sources of early evidence, it is recommended that good stakeholder relationships be developed (46).

By delivering intelligence on potentially disruptive or high-cost health technologies, HS assists policymakers in procurement and health system planning (47, 48).

See the EuroScan toolkit for guidance on how to develop an HS capability (49). Sharing HS intelligence and resources, including identified technologies and assessments, through collaborative networks such as the International Horizon Scanning Initiative for medical devices (46) or International HealthTechScan (50) would be especially beneficial for developing countries by decreasing duplication, reducing costs and increasing efficiency.

4.3 Rapid HTA

Rapid HTA focuses on technologies that address a specific health issue, providing less comprehensive evidence than a systematic HTA but enabling policymakers to make informed decisions around health care in a short time frame. Rapid HTA can be used to great effect during emergencies, such as the COVID-19 pandemic, when timely advice and urgent decision-making is required in short timeframes (sometimes 5-10 days). Rapid HTA requires modification of standard systematic review methods. As such, there is a trade-off between speed and rigour, with rapid HTA associated with greater uncertainty (51-54). The assessment of medical devices may be well suited for rapid HTA, where there are often incremental iterations, with device versions rapidly replaced by newer generation devices with a very short life cycle.

Resources on rapid HTA methodologies include Cochrane Rapid Reviews Methods Group (55), and papers by King et al (2022) (51) and Smela et al (2023) (53), in addition to guidance developed by the WHO (52).
4.4 Living HTA

Unlike traditional HTA, living HTA is a responsive and dynamic process that embraces the life cycle approach to assessment (56), incorporating new safety or effectiveness evidence, and comparators or cost information as it becomes available, and in so doing, addressing uncertainties in the decision-making process (57). Living HTA can be useful when assessing medical devices where refinements in a class of technology can result in a cumulative beneficial impact and incremental iterations results in rapid replacement by newer generation devices with very short life cycles (57). By embracing the lifecycle approach, living HTA is an efficient resource allocation methodology that is especially useful for the assessment of medical devices, supporting both investment and disinvestment decision-making (58).

However, as living HTA is resource intensive, requiring all aspects of the HTA to be updated (literature searches, evidence synthesis and economic modelling), it may not be suitable for LMICs with limited resources (57, 59).

See Heron et al. (2023) and Thokala et al. (2023) for guidance on how to conduct living HTA (57, 59).

4.5 Multiple-criteria decision analysis (MCDA)

The weighting of traditional HTA criteria may not always capture the value or full range of benefits of new health technologies (60, 61). MCDA can overcome these limitations by using explicit criteria that address localised needs and priorities. Scores or weightings associated with these criteria are ranked or rated, with multiple factors combined into a single value that, through a deliberative, collaborative process, can be used to reach consensus and support healthcare decision-making for priority-setting (62). Criteria may include traditional outcomes in addition to those describing the patient experience (e.g. level of invasiveness, tolerability), as well as ease of implementation (e.g. training or resources required, or portability) and health system affordability (63, 64). MCDA can inform stakeholder preferences that are relevant to the local context, expediting early access to beneficial technologies. A full HTA may follow with the development of additional evidence (65).

See Howard et al. (2019) for guidance on how to develop an MCDA framework for non-drug health technology funding decision-making (62).
5 HTA and health policy

5.1 Decision-making and governance

The WHO defines health system governance as ‘the processes, structures and institutions that are in place to oversee and manage a country’s healthcare system’. Governance manages the relationships between different healthcare stakeholders, including government agencies, healthcare providers, patients and their families, the community and civil society organizations, as well as the private sector (66). Many LMICs are faced with increasingly complex healthcare landscapes, with external factors such as climate change, demographic changes including ageing, migration and increasing urbanisation, the increase in chronic and non-communicable diseases and the threat of infectious disease outbreaks, political change and medical change (new technologies), all exerting pressure on scarce funding resources. In response to these factors, it is critical to have effective health system governance to provide structured decision-making and policy implementation, ensuring the efficient and equitable allocation of healthcare resources for all members of society, regardless of their socioeconomic status, ethnicity, culture, gender or other factors. The quality of governance affects the ability of the health system to be sustainable, universal and of high quality. With good governance comes accountability, whilst bad governance may result in inequity, inefficiencies and, at worst, corruption (67).

Health system governance has five key attributes:

i. Accountability, where a relationship exists between actors (e.g. an agency) and a forum (e.g. a legislature). The actor can be mandated and can be sanctioned, and must inform others of, and explain decisions. Accountability mechanisms may take the form of contracts, regulations, codes of conduct or standards;

ii. Transparency, where the health system informs the public and other stakeholders of decisions that have been made and the process and grounds those decisions were made on;

iii. Participation of affected interests, where affected parties have access to decision-making and power so that they acquire a meaningful stake in the work of the institution. This may take the form of advisory committees, stakeholder forums or consultations;

iv. Integrity, meaning that the processes of representation, decision-making and enforcement are clearly specified, with all members being able to understand and
predict the processes by which an institution takes and applies decisions. Individuals
should have a clear allocation of roles and responsibilities; and

v. Policy capacity, where the ability to develop policy is aligned with resources in pursuit of
goals (67).

Good health system governance requires a strategic policy framework to be in place combined with
effective oversight, coalition-building, provision of appropriate regulations and incentives, attention to
system design, and accountability (66). With all these factors in place, good health system governance
will ultimately lead to better health outcomes.

Consistent and transparent decision-making not only requires a policy framework that shifts decision-
making away from being opinion-based towards evidence-based policy but also the political will to
accept the information provided by HTA. Having regulations in place and normalising their use will
empower policy-makers to use evidence in decision-making. Capacity building at both the individual and
organizational levels (see Figure 5 and section 7.1) is therefore important to give health policymakers
the technical ability to interpret and use evidence effectively and distinguish research of high or low
methodological quality. Providing targeted basic HTA skills training to all decision-makers in health
systems will equip them to better identify policy-relevant evidence, enabling appropriate transfer and
uptake of research into policy and practice in a timely fashion (68).

Each country should develop its own policy framework depending on the health system structure and
the relationships between research institutions, funding bodies and government (69). The framework
may need adjustment as the uptake of evidence-based decision-making increases over time.
5.2 HTA for evidence-informed context-based decision-making

HTA is an essential component of any health system seeking to develop an accountable, policy-driven approach to health decision-making. By building HTA capacity and developing an HTA capability, health systems will introduce technical rigour into their decision-making process. The technical rigour of the HTA process must be matched to policy relevance (Figure 6), with the 'sweet spot' being where the evidence is both technically rigorous (i.e. evidence and data are reliable and trustworthy) and contextualised to make it relevant to policy-makers and health system priorities. Moving to the left or right, away from the centre, is when increased dialogue between policymakers and health researchers or evidence generators is needed (71).
6.1 The role of HTA in Universal Health Coverage

In 2015, the United Nations adopted 17 Sustainable Development Goals (SDGs) to be achieved by 2030. SDG 3.8 was to “achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all (72).” The WHO defines UHC as a means for all people and communities to access effective promotive, preventive, curative, rehabilitative and palliative health services that they need while ensuring that the use of these services does not expose the user to financial hardship (73). The objectives of UHC are the same regardless of setting: provide equity of access to quality health services that will improve health and well-being irrespective of a person’s economic circumstances (74, 75). UHC is commonly described using three dimensions: service coverage, financial protection, and population coverage, presented in the form of a cube (Figure 7), with the depth of coverage referring to the extent of services covered by pooled funds, the breadth to the percentage of the population covered, and the direct costs to the financial risk associated with current coverage (76).
All health systems, particularly LMICs, are struggling with the challenge of how to achieve UHC in a resource-constrained environment exacerbated by COVID-19. Healthcare policy, practice and decision-making needs to maximise the potential positive impact of health technologies while optimising the value from the cost of providing the technologies. The critical question in trying to achieve UHC is identifying those health interventions that should be included in the benefit package. Competing demands for limited resources requires a standardised priority-setting process, to ensure provision of the most clinically and cost-effective interventions for a given population. Compared to high-income countries, LMICs have resources to only deliver a smaller set of services, therefore an explicit, systematic and transparent approach to priority setting is required. HTA is one of the key tools available for policymakers to achieve this goal as health systems work towards UHC (75, 77). Using HTA to determine benefit packages needs to take into account the specific context in which the technology will be used when integrated into the health system setting, considering the health system structure, local costs, budgets, and demographic and epidemiological factors (i.e. countries that are at high versus low or moderate risk of certain diseases e.g. transmission of malaria), as well as societal factors, including existing inequalities and patient preferences — all of which influence the value for money of specific interventions (75, 78).
In countries with well-established UHC, such as Australia and the United Kingdom, HTA is a well-recognised priority-setting tool used to support public reimbursement and coverage decision-making. In countries where resources are limited, there is an even greater need to conduct HTA (Figure 8). However, the need for HTA is concomitant to the need for data, as estimating the potential costs and health effects of benefit packages is challenging when faced with limited access to accurate demographic and epidemiological data in LMICs (75). A more extensive role of HTA is an important policy tool that all countries should develop as the long-term negative consequences of disregarding evidence-based healthcare priority-setting in the development of UHC benefits packages may result in inefficient and inequitable healthcare systems, which are opposite outcomes to the goals of UHC (79).

Figure 8 The levels of application of an HTA process as UHC is developed (18)

See Chapter 3 of the World Bank’s Disease Control Priorities: Improving Health and Reducing Poverty for details of a model benefits package referred to as essential UHC, which identifies a subset of interventions of the highest priority and considered appropriate to the health needs and constraints of LMIC (75).

6.2 Institutionalised HTA

As more LMICs move towards providing UHC, there is a critical need for evidence-informed priority setting to ensure an equitable, efficient, and sustainable health system. As recognised by resolutions from the WHO and the UN, HTA is one of the most important priority-setting tools, and a HTA capability should be fostered and encouraged. HTA tends to inform health system policy at the national (macro)
level, providing support to inform system-wide regulatory and reimbursement decision-making for new health technologies. High-income countries with a well-developed HTA capacity have developed institutional and organisational structures and processes, linking HTA agencies to regional or national government, ensuring efficient use of national resources (80-82). The institutionalisation of HTA is pivotal to supporting UHC by improving the allocation of finite resources and maximising health outcomes. Institutionalised HTA informs health policy on:

- The development and revision of health benefits packages for health technologies;
- The development of contextualised clinical practice guidelines;
- Regulatory/market authorisation of health technologies; and
- Pricing and reimbursement regulations for health technologies (81).

There are many challenges to establishing institutionalised HTA, some of which may be country-specific, including: a fragmented health system; a lack of capacity - scarcity of human resources; a lack of stakeholder involvement or buy in; a lack of data and data management infrastructure; a lack of political will; difficulties translating HTA into policy; and insufficient financial resources (82, 83). A framework for the successful institutionalisation of HTA would first ensure that there is a mandate to establish HTA, then establish a legal framework before putting in place institutional arrangements (80). Once these are in place, local capacity building can commence then the procedural aspects of assessment and appraisal can be addressed (14). Mbau et al.’s (2023) schematic framework (Figure 9) describes these elements and how they relate to other factors including the importance of stakeholders (81).

See the WHO’s ‘Institutionalizing health technology assessment mechanisms: a how to guide’ for guidance on the mechanisms required to establish an HTA capability in countries that have made the decision to implement HTA (14).
Figure 9  A conceptual framework on factors influencing institutionalisation of HTA (81)

Hospital-based HTA (HB-HTA)

Many new health technologies, especially surgical procedures and medical devices, often enter the health system through hospitals, replacing or adding to existing technologies. Decision-making at the institutional or hospital (meso) level requires contextualised information and consideration of the primary end-users – hospital managers and clinicians, as well as the impact on patient care. Hospital-based HTA (HB-HTA) provides localised decision-making that understands the individual healthcare organisation – existing technologies, budgetary and organisational limitations, the expertise of healthcare professionals, strategic priorities and, importantly, the characteristics of the patient population (84-86). Compared to HTA, HB-HTA tends to be clinician rather than policy-maker-initiated to inform acquisition rather than reimbursement decision-making. HB-HTA usually has a shortened assessment time, considers budget impact rather than cost-effectiveness and compares current versus proposed rather than the gold standard technology (86). In addition, biomedical engineers can play a fundamental role in the medical device decision-making process in hospitals (Section 4.3) (20). The structure of HB-HTA is dependent on the specific needs of the hospital, the resources available and the level of stakeholder involvement. Note that HB-HTA recommendations may not be transferable due to consideration of the local conditions, values and priorities in the assessment (84).
See the AdHopHTA handbook and toolkit for hospital-based HTA, as well as HTAi’s Interest Group on Hospital-Based HTA (87-89).

6.3 HTA and innovation

The WHO’s Health Innovation Group’s definition of innovation is the development of “new or improved health policies, systems, products and technologies, and services and delivery methods that improve people’s health, with a special focus on the needs of vulnerable populations.” (90) How innovation is defined, valued and captured in HTA and the healthcare priority-setting process is inconsistent, with HTA often viewed as a barrier or gatekeeper, rather than a facilitator, of patient access to innovative technologies. Assessing the level of innovation for medical devices is difficult due to differences in the quality and level of available evidence (91).

Innovation criteria need to be developed that can be applied during the priority-setting process to assist decision-makers, without which the full value of a new medical device is likely to be underestimated (41, 92). Criteria can be patient-orientated criteria (e.g. unmet clinical need, added therapeutic value, severity of disease and public health benefit), as well as technology-specific criteria (implementation considerations such as financial and organisational factors), and whether the new technology is disruptive (i.e. a new technology or an incremental improvement) (92, 93).

See the NICE’s criteria for defining innovation in the decision-making process (92, 94), as well the dimensions of innovation relating specifically to non-drug health technologies such as medical devices described by Ciani et al (2016) (41).

7 HTA challenges in developing countries

To reduce health inequalities by increasing access to essential health care and services, many LMICs have prioritised moving towards UHC. For many LMICs, financing and delivering UHC is a major challenge, with some still experiencing significant levels of communicable disease, whilst in others, chronic diseases such as cardiovascular and respiratory disease, are a growing burden. The challenge in LMICs is to define a UHC benefit package that is appropriate to the burden of disease and represents good value for money while being socially and politically acceptable. HTA is an appropriate tool to assist in the prioritisation of interventions whilst considering a health technology’s social, ethical and legal implications (95). The need for HTA to support UHC in resource-constrained LMICs is well recognised. There are, however, many challenges and barriers to embedding HTA in practice, especially linking
evidence with policy and practice. Affordability, implementation issues, access, patient characteristics, equity, value for money and a lack of political will, leadership and legislation are some of the barriers that need to be overcome. However, for most LMICs, limited technical expertise and a lack of HTA-related capacity building are major challenges along with access to good quality and accurate local data (96).

7.1 Capacity building

By supporting priority-setting, HTA ensures the efficient use of limited healthcare resources. However, as the demand for HTA grows, the gap between supply and demand of HTA capacity also grows (97). Strengthening priority-setting by building HTA capacity at the individual, organisational and environmental levels is therefore critical for the formulation of benefit packages in the drive to achieve universal health coverage (98).

Individual, organisational, and environmental levels of capacity building are interconnected and reliant on each other, and networking and collaboration between levels are key to growing capacity and transferring HTA knowledge and skills to others. Organisational and environmental levels are critical for HTA to be embedded into health systems; however, improving an individual’s HTA skills, experience, and knowledge by providing access to information, knowledge, education, training and hands-on experience is essential for a successful HTA program. Institutional arrangements are critical in providing training opportunities at the individual level and ensuring that a credible and transparent assessment process can be established to translate evidence into policy in a relevant, local context (77, 97).

Potter and Brough developed a hierarchy of capacity needs that relate to the different levels within the system and the interactions between them. The four broad areas of capacity need are tools, skills, staff and infrastructure, and structures, systems and roles (Figure 10), where those at the lower level are needed to enable the layers above, and the upper layers require the layers below (99).
At the organisational level, capacity building is context-dependent and needs strengthened internal structures, policies and procedures achieved through strategies, plans, processes and procedures both within and between organisations (101, 102). Universities can act as centres of capacity building and HTA knowledge brokers as local technical HTA expertise is often concentrated amongst researchers and academics. Embedding HTA agencies within universities of hospitals and developing direct relationships between agencies and government health policymakers could help educate policymakers and build capacity (103).

At the environmental or system level, capacity building aims to improve policy frameworks to enable organisations, institutions and agencies at all levels to enhance HTA capacity by addressing economic, political, environmental, legal and social factors in a coherent manner (101, 102). Political, governance and policy structures are required to enable the institutionalization and integration of HTA into health systems to support the decision-making process. In settings where HTA capacity is lacking, fostering relationships with hospital-based biomedical engineers may assist the decision-making process for new medical devices by providing insights on the technical characteristics, comparison with similar technologies, usability, performance, safety and organizational impact of devices throughout their lifecycle (9, 20). In addition, networking within and between countries is an important element of capacity-building and should be developed, facilitating opportunities to share HTA experiences, resources, and methodological learnings (104).
See Li et al. (2017) for an evidence-informed capacity-building framework for setting health priorities in low- and middle-income countries (104). Also see HTAi’s 2022 Asia Policy Forum background paper for a catalogue of (mostly on-line) HTA-specific capacity building initiatives (105).

7.2 Data

HTA can lay the foundation for good healthcare decision-making by assessing the evidence linking interventions with health outcomes. The key to HTA is to use the best available data. Context-appropriate data is needed to support this process, enabling all stakeholders (policy-makers, clinicians and patients) to make informed healthcare decisions. Data can identify patterns of morbidity and mortality, describe the burden of disease, compare the effectiveness of therapies and procedures, determine the cost of care, and evaluate the delivery of care on patient outcomes.

Access to the right type of data and data linkage remains a worldwide issue, and a country’s data needs change over time. Generating, capturing, storing, and analysing data needs well-functioning health information systems, which may be a limiting factor in many LMICs due to costs and a lack of basic technology infrastructure and political will (106). LMICs need reliable, locally generated, high-quality evidence rather than relying on data from clinical trials being conducted in the USA or Europe in non-representative populations that do not reflect the biological variations (genetic makeup, body weight, etc) as well as differences in local clinical practice. WHO’s Resolution 67.23 encourages member states to strengthen the routine collection of health system data as a necessary step towards achieving UHC (1); however, when local data is unavailable, policymakers need to agree on the conditions for accepting data from other countries (107).

See the IHME database (108), as well as the WHO’s Global Health Observatory (109) for freely available sources of global data.

8 Strategies for developing HTA

8.1 Adaptive HTA

Many LMICs are constrained by limited capacity, time, and financial resources to establish a fully funded, dedicated HTA agency to support priority setting in the drive to achieve UHC. Adaptive HTA can leverage HTA from other settings and adapt it to the local setting and context by incorporating local data (e.g. patient characteristics and ethnicity, burden of disease, healthcare costs, health system structure.
and local clinical expertise). Adaptive HTA can be used to good effect in the short term, especially for well-studied technologies, providing the basis for local capacity building, leading to more sustainable HTA structures dedicated to local priorities (110, 111). Adaptive HTA may not be as useful for medical devices, where device versions are rapidly replaced by newer generation devices with a very short life cycle, meaning that HTA may be outdated before adaptation. Differences between high-income countries and LMICs in costs, resources and other domains make HTA conclusions difficult to generalise or transfer; but, with minimal local capacity, these can be modified to fit the local context (110).

Developing HTA agencies should seek to adapt more relevant evidence from countries within their own regions with similar health systems.

See the EUnetHTA HTA Adaption Toolkit for guidance on how to adapt HTA (112). Medical device HTAs can be accessed from reference countries such as the United Kingdom’s NICE (113), Australia’s MSAC (114) and Canada’s CADTH (115) or the database hosted by INAHTA (116).

8.2 Priority setting for HTA

In environments of limited healthcare resources, policymakers need a transparent, fair, and independent priority-setting process as a means of allocating scarce funds to maximise the health outcomes and improve access to health services for all, not just a few. Using a validated and explicit process, such as HTA, to guide priority setting can achieve these goals, whereas an informal process may lead to inefficient resource allocation, and entrench inequalities with the provision of poor-quality healthcare, hindering the transition to UHC. The HTA framework, and the type and number of explicit priority-setting criteria within these frameworks will depend on the definition of essential health services that fit with a health system’s priorities. Often these criteria include burden of disease, clinical effectiveness, and budget and economic impact, using cost-effectiveness as a quantitative measure. The latter is often interpreted as cost-containment and is often inappropriate to assess the value of medical devices. High-income countries can incrementally add new technologies to the health system as they emerge. However, LMICs starting from a lower baseline of established services, need to make difficult choices about what health services to provide, for whom and at what price using an evidence-based methodology appropriate to their setting that has the support of all stakeholders (117, 118).

As summarised by the WHO, countries that have adopted systematic priority setting follow all or most of the following eight principles:

1. Essential benefit package design should be impartial, aiming for universality.
2. Essential benefit package design should be democratic and inclusive with public involvement, also from disadvantaged populations.

3. Essential benefit package design should be based on national values and clearly defined criteria.

4. Essential benefit package design should be data driven and evidence-based, including revisions in light of new evidence.

5. Essential benefit package design should respect the difference between data, dialogue, and decision.

6. Essential benefit package design should be linked to robust financing mechanisms.

7. Essential benefit package design should include effective service delivery mechanisms that can promote quality care.

8. Essential benefit package design should be open and transparent in all steps of the process and decisions including trade-offs should be clearly communicated (119).

See the WHO’s Principles of health benefit packages (119) and the Center For Global Development’s book (available online) for guidance on policy issues relating to priority-setting and the development of health benefit packages (120).

8.3 Defining members and roles for a national HTA committee

What does the ideal HTA expert advisory committee look like? Firstly, countries should decide whether their HTA committee should operate under the auspices of government or as an independent advisory body. Many European countries have independent bodies, such as the French National Authority for Health (Haute Autorité de Santé, or HAS), which make non-binding recommendations to decision-makers in the Ministry of Health (121). Secondly, the number of committees must be decided – is there is a need to have separate committees, aside from regulatory agencies, that would consider different technologies? For example, a committee for the approval of drugs and one for medical services (interventions, diagnostics, etc.) where expertise in these areas is a prerequisite for membership. The Australian health system uses this two-committee approach in addition to a prostheses committee (122), whereas the UK’s NICE has nine separate committees: quality standards, public health, medical technologies, interventional procedures, diagnostics and indicator advisory committees; antimicrobials and highly specialised technologies evaluation committees; and the technology appraisal committee (123). Depending on the mandate and legal framework of the country, these committees should be independent bodies that may be non-statutory or have a statutory authority (i.e. the committee can
make non-binding or binding recommendations, respectively). Some of the roles and responsibilities of a national committee are described in Table 3.

The committee should have a defined term of reference that describes its purpose and function and meet regularly to ensure relevancy and maintain skills. The size of, and range of expertise within HTA advisory committees should be determined by the primary stakeholder or end-user, such as the Department of Health, and should have an appointed Chair and Deputy Chair. Ideally, committee members should have a time-limited tenure, with staggered appointments to ensure continuity, with the committee supported by a secretariat function. Membership should include a range of clinical experts from different specialities, or experienced experts with knowledge of a particular topic or specialty can be co-opted to consider a specific application. Other committee members may be social care practitioners or allied health professionals, or technical experts such as biomedical engineers, or legal and regulatory experts. HTA academics, especially those with expertise in HTA methodologies and health economics, are important inclusions in any decision-making body. Consumer representation is also important to ensure the appropriate inclusion of the patient perspective and consideration of patient-relevant outcomes.

Table 3  Roles and responsibilities of a national high-level committee, adapted from (124)

<table>
<thead>
<tr>
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<th>The Ministry of Health, as the leader of the process, should secure political commitment for the development of a list of essential health technologies (e.g. medical devices), including garnering support from other relevant ministries. It is responsible for overseeing the development and implementation of the list.</th>
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<tbody>
<tr>
<td>1</td>
<td>National technical committees for the development and implementation of the list should be appointed, with adequate representation of all relevant stakeholders. Regional or state subcommittees could also be appointed for implementation.</td>
</tr>
<tr>
<td>2</td>
<td>Oversee the work of any sub-committees. Assess the available resources and existing policies and regulatory frameworks. Assess the need for additional resources and, if required, modifications to policies and regulatory frameworks to ensure the provision of clinical services.</td>
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<tr>
<td>3</td>
<td>Ensure that the priority list is aligned with the goals of national health plans and caters to the clinical needs of priority health interventions.</td>
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<tr>
<td>4</td>
<td>Forge partnerships with national and international agencies for technical support in the development and implementation of the priority list.</td>
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<tr>
<td></td>
<td>Ensure that the priority list is approved, embedded as policy and disseminated widely for implementation.</td>
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<tr>
<td>8</td>
<td>Provide guidance to the implementation committee on the availability of resources for implementation and regulatory structures for the procurement of products and services.</td>
</tr>
<tr>
<td>9</td>
<td>Provide adequate resources (funds, equipment, infrastructure, human resources) for the rollout of clinical services and their future expansion.</td>
</tr>
<tr>
<td>10</td>
<td>Oversee the work of the implementation committee for the provision of technologies listed.</td>
</tr>
<tr>
<td>11</td>
<td>Hold extraordinary sessions for outbreaks and health emergencies with the Ministry of Health.</td>
</tr>
<tr>
<td>12</td>
<td>Provide an enabling environment for research and development, manufacture, market access and validation of medical devices to increase access to high-quality, affordable technologies in the country.</td>
</tr>
<tr>
<td>13</td>
<td>Ensure that the priority list is continually updated with relevant technologies, as and when the resources, policies and regulatory framework of the country permit.</td>
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### International collaboration in HTA *(note: global and regional input is welcome)*

In the wake of the declaration of a worldwide pandemic in March 2020, the WHO passed a resolution in May of the same year, requesting Member States “*work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response*” (125), emphasising the need for solidarity, resource redistribution, and collective action (126). The reasons for collaboration in health remain clear. Firstly, collective health risks are difficult to manage independently; secondly, sharing knowledge and experience accelerates learning and facilitates progress; and lastly, agreeing on standards will establish good practices and underpin shared understanding and mutual trust. Similarly, facilitating collaboration and networking between countries is an important element of HTA capacity-building, developing opportunities to share HTA experiences, knowledge, resources, and methodological learnings (104). Regional collaboration should be encouraged, as well as private sector partnerships (127). There are many HTA agencies and bodies whose remit is to encourage and provide opportunities for collaboration to facilitate the global exchange of information and development of HTA best practice.
9.1 Health Technology Assessment international (HTAi)

Health Technology Assessment international (HTAi) provides an open platform for global collaboration that leverages collective intelligence to improve health outcomes worldwide. Representing over 80 organisational members and thousands of individuals from 65 countries, HTAi is the scientific and professional global society for HTA thought leaders, academic and industry researchers, patients, caregivers, patient organisations, HTA agencies, decision-makers, providers, and health professionals.

HTAi’s mission is to promote the development, communication, understanding, and use of HTA around the world. To accomplish this mission, HTAi has four areas of focus:

1. Expand and grow the presence of HTAi globally through our membership, with an emphasis on LMICs to help expand the global presence of HTA;

2. Expand HTA through knowledge sharing and information dissemination through partnerships. Explore new and existing partnerships and collaborate with other international, evidence-informed health organisations on priority topics and projects, including educational offerings (such as webinars and workshops), competency development, and outreach to emerging HTA markets;

3. Advance scientific knowledge and support capacity development. HTAi will continue to develop environmental, organisational, and individual HTA capacity around the world, building an efficient learning environment within HTAi. HTAi supports learning by identifying the needs of HTA producers and users within the HTAi community, collaborating with teaching centers and academia, as well as partnering with governmental and nongovernmental HTA bodies to develop necessary resources. HTAi advocates for political support in the development of HTA agencies and organisations within countries where HTA is nascent, and works with established HTA communities to upskill capacity to support the production and use of HTA as methodologies, technologies, and regulatory requirements advance.

4. Ensure continued financial stability and good governance (128).

HTAi serves as a hub for a range of collaborative work, including:

- The annual international meeting, which serves as a major gathering point for global networking, information sharing, and dissemination of the latest advances in policy, methods, and other areas of HTA research;
HTAi Policy Forums (Global, Asia and Latin America) that provide opportunities for open
dialogue between leading HTA practitioners and industry in areas of shared strategic interest
(129);

- Interest groups (IGs) that provide a forum for HTAi members to network, exchange information,
and collaborate on projects of mutual interest throughout the year, including Disinvestment and
Early Awareness, Early Career Network, Ethical Issues, Hospital-based HTA, HTA in Developing
Countries, Information Retrieval, Patient and Citizen Involvement, Public Health, Rare Diseases,
Real World Evidence and Artificial Intelligence and Medical Devices; and

- publication of HTAi’s official academic journal, the International Journal of Technology
Assessment in Health Care.

9.2 International Network of Agencies in Health Technology Assessment (INAHTA)

The International Network of Agencies in Health Technology Assessment (INAHTA) is a non-profit global
network of publicly-funded health technology assessment (HTA) agencies. The network connects HTA
agencies to each other to support knowledge sharing and the exchange of information and also serves
as a forum for the identification and promotion of other interests of HTA agencies. INAHTA members
serve an important role in health systems by providing evidence to support decision-making about
health technologies, including their reimbursement, implementation, optimisation, and/or divestment.
Collectively, INAHTA member agencies support health system decision-making in 31 countries,
connecting agencies together to cooperate, collaborate, and share information about the production
and dissemination of evidence-based information, advice, recommendations, and tools. INAHTA serves
this purpose (130).

INAHTA’s key communication forum is the Internet, and online activities include:

- offering training and knowledge exchange opportunities in high-priority areas including HTA
impact and its evaluation, approaches to assessing highly innovative technologies,
methodological best practices and challenges in conducting rapid assessments; and
- offering webinars for developing agencies to ask questions and discuss issues with leadership
from established agencies.
• the INAHTA Listserv, an email list that connects all member agencies, providing a forum for all members to ask questions of each other regarding current and planned HTA projects;
• the International HTA Database that provides a free single point of access to INAHTA members and non-members to ongoing and published HTA undertaken by HTA organisations internationally (116); and
• INAHTA Checklists are an aid to fostering a consistent and transparent approach to HTA.

9.3 WHO Collaborating Centers and their global network

WHO collaborating centres form part of an international collaborative network of institutions such as units in ministries of health, research institutes, universities or academies, which are designated by the WHO Director-General to carry out activities in support of WHO’s programmes and provide strategic support to implement WHO's mandated work and programme objectives, as well as developing and strengthening institutional capacity in countries and regions. As of 2024, there are over 800 WHO collaborating centres in over 80 Member States working with WHO on diverse areas such as nursing, occupational health, communicable diseases, nutrition, mental health, chronic diseases and health technologies (131).

WHO collaborating centres with full membership to the network whose work is either directly or indirectly linked to HTA include:

• National Center for Health Technology Excellence (CENETEC), Ministry of Health – WHO Collaborating Centre in Health Technology in Mexico.
• Fudan University Shanghai – WHO Collaborating Centre for Health Technology Assessment and Management in China.
• Fundação Oswaldo Cruz Instituto Oswaldo Cruz (FIOCRUZ) – WHO Collaborating Centre for Education of Health Technicians in Brazil.
• Institute of Population Health – WHO Collaborating Centre for Knowledge Translation and Health Technology Assessment in Health Equity in Canada.
• Norwegian Centre for Telemedicine (NST), University Hospital of North Norway – WHO Collaborating Centre for Telemedicine in Norway.
• CES University – WHO Collaborating Centre for Health Technology in Colombia.
• Division of Healthcare Technology & Innovations - WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy in India.
9.4 international HealthTechScan

The horizon scanning network, i-HTS was established in 2016, to take over the Secretariat functions and membership of EuroScan. Renaming the network to i-HTS more accurately reflects the growing global HS membership rather than a Euro-centric viewpoint. The aim of the network is to share information, methodologies and tools around the early identification of new and innovative health technologies.

9.5 EU Member State Coordination Group on HTA (CGHTA) (to be updated, input is welcome)

The European Network for Health Technology Assessment (EUnetHTA), supported by the European Commission, was founded in 2006 to harmonise HTA methodologies, coordinate and increase collaboration and reduce duplication of effort across Europe. EUnetHTA’s aim was to establish a collaborative network of public national HTA agencies, research institutes and health ministries to strengthen the link between HTA and healthcare policymaking (132, 133). EUnetHTA was essentially a voluntary network and has since been replaced by the EU-funded Coordination Group of HTA (CGHTA) after the implementation of Regulation (EU) 2021/2282, which came into force in January 2022 and will apply as of January 2025, when the totality of its implementing acts will be published. The CGHTA, whilst building on the methods, processes, and tools developed by EUnetHTA, has created the following subgroups to perform technical HTA work:

- Joint Clinical Assessments (JCA) for medicines and high-risk medical devices and in vitro medical devices;
- Joint Scientific Consultations (JSC), whereby health technology developers (i.e., pharmaceutical industry and device manufacturers) can seek advice from HTA agencies;
- identification of emerging health technologies, with a view to identifying promising technologies at an early stage,
- development of methodological and procedural guidance; and
- continuing voluntary cooperation in other aspects of HTA (132, 134).

Many of the tools developed by EUnetHTA are still freely available on the website (135).

9.6 RedETSA and Initiatives in the Americas (to be updated, input is welcome)

Latin American countries rely heavily on evidence from other countries to produce HTA reports and guide healthcare decision-making; however, the transferability of this data to Latin American
populations may be limited. In addition, rather than evaluating technologies one by one, Latin American countries need to take a more holistic approach to HTA by evaluating health programs for chronic diseases in a bid to reduce mortality and morbidity on a population scale, in so doing, reducing overall healthcare costs (95). To meet these needs, it is important to build HTA capacity in the region. The Health Technology Assessment Network of the Americas (RedETSA) network was launched in 2011 with the aim of promoting and strengthening the HTA evaluation process and supporting decision-making in the Americas region by adopting common methodologies and capacity-building measures (20, 136). In 2012, the Pan American Health Organization (PAHO) passed Resolution CSP28.R9, encouraging Member States to establish decision-making processes to incorporate health technologies based on HTA and to become active members of RedETSA (137, 138). As of 2024, the RedETSA network has 21 member countries represented by 42 institutions, comprising health ministries and institutions, health technology assessment agencies, regulatory authorities, WHO Collaborating Centers, the Pan American Health Organization (PAHO) and other education and research institutions in the Americas region (136). Significant progress has been made in HTA implementation in RedETSA member countries compared to non-member countries, demonstrating the value of this collaborative network (138).

RedETSA, along with PAHO, are active members of HTAi’s Latin American Policy Forum, which was established in 2016 to provide a forum that brings together policymakers who make coverage and reimbursement decisions, HTA agencies and biomedical companies. Forum participants are free to discuss a chosen topic, prioritised and selected by participants, without fear or favour, in an environment of trust and openness (129, 139-141).

See RedETSA for a repository of HTA resources and webinars (136).

9.7 HTAsiaLink

HTAsiaLink Network was established in 2011 as a collaborative research network to facilitate countries across the Asia region to share their HTA experiences, learnings and resources, provide opportunities to share technical and methodological know-how, build mutual trust, respect, and open communication. In a region where many countries are LMICs, the network places great importance on being strong advocates for strengthening HTA capacity in countries where HTA is not fully recognised as a tool for policy-making and priority-setting. As such, HTAsiaLink’s mission is to address the following issues:

- strengthening individual and institutional capacity in HTA research and integration of HTA evidence into policy decisions for the public good;
• avoiding duplication especially in reviewing the safety and clinical efficacy of vaccines and medicines for HTA, facilitating learning, reducing wasteful resource use, and enhancing efficiency at the organisational level through collaborative activities among the network; and
• fulfilling the need for transferring and sharing HTA-related lessons across countries and organisations in Asia and beyond (142).

Key activities of HTAsiaLink include joint events for information sharing, such as public forums, study visits among country members, as well as an annual conference that provides a forum for young researchers to present without fear or favour. As well as providing a network to share data and best practices, HTAsiaLink also encourages members to conduct policy-relevant joint research projects, such as the ongoing project, the Guide for Economic Analysis and Research (GEAR) database, a web-based resource designed to aid in research and analysis of economic evaluations in LMICs (142) and Developing a New Region-Specific Preference-Based Measure in East and Southeast Asia (143).

9.8 Initiatives in other regions

• Sub-Saharan region (to be drafted, input is welcome)
• Eastern Mediterranean region (to be drafted, input is welcome)
• Southeast Asia (to be drafted, input is welcome)

10 Special HTA topics

10.1 Real-world data (RWD) and real-world evidence (RWE)

When health technologies are associated with a degree of uncertainty or evidence is lacking, regulators and health policymakers can use RWE and RWD to support HTA and inform decision-making, ensuring timely patient access. RWD generated from routine healthcare delivery can be collected from a variety of sources outside of traditional clinical trial settings including electronic health records, administrative data, product or disease registries, claims or billing data, or patient-generated data (patient-reported outcomes), as well as digital health technologies such as wearables and mobile devices. RWE is the evaluation of RWD, providing clinical evidence and insights around the usage, and benefits or risks of a health technology in a real-world setting during all stages of a technology’s life cycle, beyond the strict inclusion and exclusion criteria of clinical trials. This is especially important for racial or ethnic groups often under-represented in clinical trials. Data for RWE studies can be collected prospectively or retrospectively. The resources to collect (i.e. electronic health records) and the information technology...
infrastructure needed to analyse large volumes of RWD may currently be lacking in some LMICs (144, 145).

RWE may be particularly useful to HTA of medical devices for all the reasons that make assessment of devices more difficult compared to drugs: lower quality clinical evidence due to a lack of randomisation, lack of blinding and comparators, as well as frequent iterations or predicate devices (146, 147); however, methodological challenges need to be overcome before RWE can be utilised effectively in HTA and healthcare decision-making (144).

See the FDA’s Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions (148), ISPOR’s guide on RWE (149), the NICE real-world evidence framework (150) and the REALISE project’s RWD decision-making guidance (151). In addition, see HTAi’s Interest Group on RWE and AI (89).

10.2 Digital health technologies (DHTs)

The WHO’s global strategy and framework on digital health released in 2021 states:

“Digital transformation of health care can be disruptive; however, technologies such as the Internet of things, virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, tools enabling data exchange and storage and tools enabling remote data capture and the exchange of data and sharing of relevant information across the health ecosystem creating a continuum of care have proven potential to enhance health outcomes by improving medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care and person-centred care as well as creating more evidence-based knowledge, skills and competence for professionals to support health care.”(152)

Digital health technologies (DHTs) encompass a range of health system, health professional and patient tools (Figure 11) that can be used in low, middle, and high-income settings (153). However, access to digital health services for all requires investment in infrastructure (i.e. internet access, data protection, cybersecurity), workforce capacity, governance and regulation to support the changes needed to digitise health systems and deliver services (152). In low-resource settings with a limited healthcare workforce, DHTs can support UHC by overcoming geographical and practical barriers to healthcare, making healthcare more accessible and equitable by delivering health solutions to more people, especially in rural and remote areas (154). By improving access, digital health can reduce inefficiencies in the health system by lowering costs, and improving the financial sustainability and quality of healthcare delivery.
It should be noted that in many LMICs there may be limited access to Wi-Fi/internet; however, many of these countries do have readily available mobile data (3G/4G/5G).

Figure 11 Health system and patient-facing categories of digital health technologies (153)

Traditional HTA frameworks are inadequate for the evaluation of DHTs and may act as a barrier to their integration into clinical practice. See the UK’s NICE framework for the evaluation of DHTs intended for medical, health or wellness, or health system efficiency purposes (157). Also see Germany’s framework for the provision and reimbursement of digital health applications (DiGA) (158, 159).

10.3 Artificial intelligence (AI)

Artificial intelligence is an umbrella term used to describe a collection of technologies including machine learning, natural language processing, robotics, and neural networks. AI is described as learning systems that are capable of mimicking human intelligence, where data is collected, and algorithms ‘learn’ from experience in real-time, recognising patterns, solving problems, and making decisions (160). AI can be a tool used to deliver healthcare (e.g. telehealth chatbots), perform administrative tasks in the health system (e.g. coding and electronic health records), conduct aspects of HTA (e.g. study selection, data extraction and cost-effectiveness modelling (161)), as well as being harnessed for the collection and analysis of real-world data (RWD). Although AI has the potential to revolutionise healthcare, it is associated with high levels of uncertainty and concern around its technical limitations, governance and regulation, ethics, data privacy and security (162).
See Reddy et al (2021) for a framework to monitor and evaluate AI-based applications in health care (163). This publication stems from the international collaboration, Translational Evaluation of Healthcare AI (TEHAI) that has several freely accessible resources (164). Also see the UK’s National Institute for Health and Care Research Innovation Observatory (NIHRIO) that uses AI tools and methods to conduct HS and technology guidance on behalf of NICE (165), as well as HTAi’s Interest Group on RWE and AI (89).

10.4 Additive manufacturing (3D-printing)

Three-dimensional (3D) printing is a disruptive technology with the potential to provide low cost, affordable customised medical devices across a diverse range of health applications including surgical and dental implants, prostheses (166-168), drugs and drug delivery (e.g. polypills), surgical instruments, medical supplies such as personal protective equipment, as well as educational, training and surgical planning models (169-171) and laboratory equipment including microscopes (172). With recent advances in the types of materials, speed, resolution, accuracy, reliability and repeatability 3D-printing has the potential to transform healthcare and clinical practice (170), and in so doing, reducing the burden of disability and death in resource-limited health care settings. In addition, by enabling the “in-house” manufacture of medical products in LMICs avoids the high cost of purchasing commercial products and addresses many of the logistics and manufacturing supply chain issues exacerbated by COVID-19.

Although 3D-printed medical products are generally regulated under medical device frameworks, HTA evaluation of these products has proved problematic, with a framework currently lacking. The customised nature of 3D printing is not conducive to high-quality clinical studies, and therefore the traditional HTA evaluation of clinical efficacy and cost-effectiveness (170). Evaluation, especially of safety, including the biocompatibility of materials used in the manufacturing process, can be conducted on an individual basis (169).

See the United States FDA guidance for recommendations on the testing and characterisation of 3D-printed devices (173).

10.5 Pandemic

Pandemics are defined as large-scale outbreaks of infectious disease that can greatly increase morbidity and mortality over a wide geographic area and cause significant economic, social, and political disruption, with a disproportionate impact on LMICs. The risk of a pandemic has increased due to an
increase in global travel and integration, urbanisation, changes in land use, and greater exploitation of
the natural environment. HTA can inform policy that aims to prepare for and mitigate against the impact
of pandemics (174).

The COVID-19 pandemic highlighted deficiencies and inequities in global health system preparedness.
During this emergency, policymakers were placed under pressure from the public and healthcare
workers to provide rapid solutions and make provisional approvals of public health measures and health
technologies based on limited safety and efficacy results, with little assessment of clinical or cost-
effectiveness (175). At the height of the pandemic, normal transparent HTA processes were sidelined by
emergency use authorisations from regulators, and value for money was bypassed in favour of direct
price negotiation and procurement, impacting significantly on health budgets (176). The challenges and
opportunities presented by COVID-19 included finding new methods of healthcare delivery (virtual care
and artificial intelligence) and shifting the focus from technology-driven demand to prioritising public
health (177). In response to these complex demands, existing HTA methodologies were adapted,
including using RWE, conducting rapid or ultra-rapid reviews (speed versus rigour) and rolling or living
HTA updates. In so doing, HTA provided timely advice to policymakers that laid the foundation for value-
based healthcare assessment, prioritising high-value over low-value care (178). HTA also played an
important role in combating misinformation from mainstream and social media throughout the
pandemic. COVID-19 increased international HTA collaboration, especially data sharing and COVID
guidelines, and was critical in connecting science, innovation, technology, and health policy; however, it
also highlighted the lack of HTA capacity, especially in LMICs.

See the collaborative project by British Medical Journal, BMJ Rapid Recommendations (179), that
updated and disseminated freely available COVID guidelines, the EUnetHTA repository for rapid reviews
on COVID-19 diagnostics (180) and therapeutics (181) and COVID-END, the COVID-19 Evidence Network
to support Decision-making that summarised public health and social responses, clinical management,
health-system organisation and economic evidence from low-, middle- and high-income countries (182).
Also see Chapter 17 of the World Bank’s Disease Control Priorities: Improving Health and Reducing
Poverty on Pandemics: Risks, Impacts, and Mitigation (174).

11 Stakeholders

Stakeholders are often categorised as the 7Ps: patients, the public and carers; providers or health
professionals; purchasers; payers; policymakers; product makers (industry) and Principal investigators.
Involving multiple stakeholders contributes to the legitimacy of decision-making and may also increase stakeholders’ acceptance of HTA decision-making. Guidance from the WHO states that one of the key principles when designing benefit packages is the inclusion of public involvement, especially from disadvantaged populations, in the priority setting for UHC.

Stakeholder involvement may vary between countries depending on the technology being assessed or by stage of the HTA process, for example during topic nomination or prioritisation, during the HTA assessment or appraisal of the assessment, or when the results of assessment are disseminated. It is important that HTA decision-making bodies develop materials that are understandable for a variety of stakeholders and that at the end of the assessment, an executive summary written in plain language is made available.

There are several ways to engage stakeholders in the HTA process. Many HTA decision-making bodies will include a general consumer representative who may not have personal knowledge of the technology being considered or the condition or disease it addresses but can promote the interests of consumers and ensure accountability and recognition of consumer concerns. It is especially important to represent the views of marginalised patient groups, particularly those with rare diseases where there is limited clinical knowledge and a great deal of uncertainty around clinical care pathways, the natural history of the disease and long-term clinical outcomes. In addition, involving patients early in the HTA process may help to broaden the scope of evaluation. Other HTA bodies, such as Australian funders, conduct targeted consultations of stakeholders that may be directly affected or impacted by the introduction of a new technology, including specific patient organisations or caregivers, clinicians or healthcare professional organisations that may use the technology, or the technology displaced by the new technology. Some countries may consult payers (e.g. insurance companies), industry partners or the academic community.

Industry associations and health technology developers, such as the medical device industry, are key stakeholders in the HTA process, although their involvement varies globally. Some countries have representatives from industry associations sitting on their HTA committees. In many jurisdictions, industry submits technologies for evaluation by funders for inclusion in the benefits package. Industry has needed to become HTA proficient as applicants must provide the funder with a body of clinical evidence (± an economic evaluation) to support their submission. In some jurisdictions, such as Australia, the applicant pays a fee to the government, which is then used to fund the assessment by an independent HTA agency. It is thought that the standard of submissions is improved when a fee is
charged, preventing inadequate or poor submissions. Industry also often works with HTA agencies by providing unpublished data, as well as working with patient groups. There are issues with industry stakeholder engagement, with some stakeholders having a conflict of interest, leading to bias in the evaluation, and some technologies having commercial-in-confidence requirements (187).

See HTAi’s interest group for patient and citizen involvement in HTA (89).
References


34. IFMBE. Health Technology Assessment Division [Internet]. International Federation of Medical and Biological Engineering; 2023 [Accessed 3rd May 2024]. [Available from: https://ifmbe.org/organisation-structure/divisions/htad/]

35. WHO. Health Technology Assessment Division [Internet]. International Federation of Medical and Biological Engineering; 2023 [Accessed 3rd May 2024]. [Available from: https://ifmbe.org/organisation-structure/divisions/htad/]


50. International HealthTechScan. Innovative health technologies - be part of the network [Internet]. EuroScan international network; 2024 [Accessed 23rd March 2024]. [Available from: https://ihts.org/].


87. AdHopHTA. Welcome to the toolkit for hospital-based Health Technology Assessment (HB-HTA) [Internet]. The AdHopHTA Project; 2015. [Available from: https://www.adhophta.eu/toolkit/].


89. HTAi. HTAi Interest Groups [Internet]. Alberta, Canada: Health Technology Assessment international; 2022. [Available from: https://htai.org/interest-groups/].


112. EUnetHTA. E UnetHTA HTA Adaption Toolkit European Network for Health Technology Assessment; 2011.


165. NIHRIO. NIHR Innovation Observatory [Internet]. The University of Newcastle upon Tyne: National Institute for Health and Care Research Innovation Observatory (NIHRIO) 2024 [Accessed 6th April 2024]. [Available from: https://www.io.nihr.ac.uk/about/].


177. ISPOR. HTA’s Evolving Role through the COVID Pandemic and Beyond – Virtual ISPOR 52nd HTA Roundtable – Latin America [Internet]. ISPOR - the Professional Society for Health Economics and Outcomes Research; 2021 [Accessed 30th September 2021]. [Available from:


