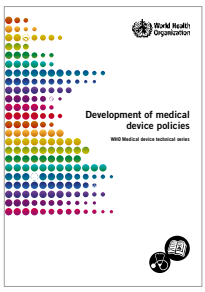
World Health Organization

Health technology assessment of medical devices

Second edition

WHO medical device technical series



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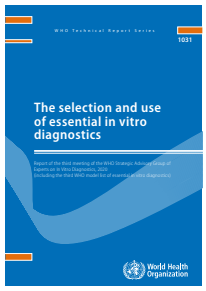

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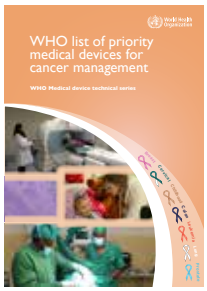

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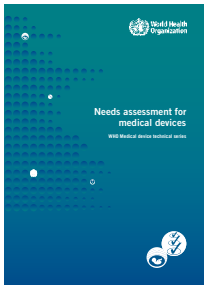

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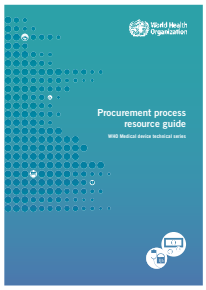

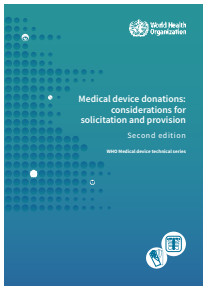

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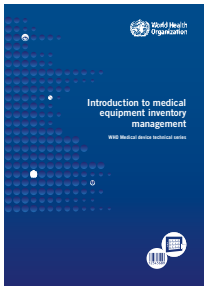

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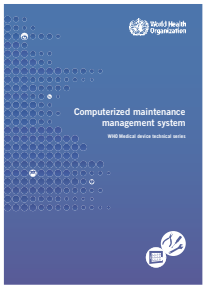

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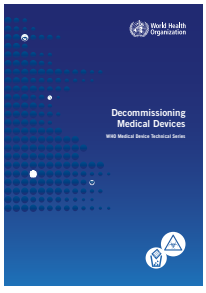

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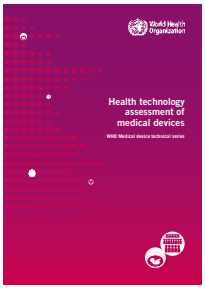

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* To be updated in 2024

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Contents

Preface

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

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 UHC. The WHO is currently 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.

This document is intended to provide guidance to policy-makers, particularly those in LMICs that are currently developing HTA capacity. The document is *not* intended to provide a methodology or framework for the assessment of specific medical devices or to be prescriptive regarding those practitioners who should be involved in HTA. This document does, however, describe general concepts of HTA and points to best-practice resources to enable LMICs to make consistent, transparent and informed decision-making on the adoption and use of medical devices to ensure clinical needs are met whilst delivering value to patients, healthcare providers, and the broader health system.

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The draft was reviewed by members of the WHO Strategic and Technical Advisory Group on Medical Devices (STAG-MEDEV) particularly the HTA subgroup: Susan Horton, Canada; Mouna Jameleddine, Tunisia; Brendon Kearney, Australia; Dimitra Lingri, Greece; Placide Muhayimana, Rwanda; and Ana Perez, Uruguay.

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Other WHO staff that provided input to the document: Adriana Velazquez from Medical Devices team in the Health Products Policy and Standards department, Altea Sitruk and Andrew Mirelman, from Health Financing department and Emilie van Deventer and Ferid Shannoun from Radiation and Health Unit in HQ From regional offices: Edith Annan, Sheick Oumar Coulibaly, Theonille Mukabagorora, Aissatou Sougou, Martha Tusabe, AFRO; Alexandre Lemgruber and Alfonso Rosales, PAHO; Mohamed Wehbi, EMRO; Rasmus Gjesing, Stanislav Kniazkov, Tarang Sharma and Tifenn Humbert, EURO; Mohammad Ameel, SEARO and Jinho Shin, WPRO. Noting that the document was being reviewed in the monthly meetings of the STAG MEDEV where the regional advisors, listed above, also participate.

The draft was also reviewed by: Awafung Emmanuel Adie, Kampala International University, Uganda; Silvina Benchetrit, Institute of Clinical Effectiveness, Argentina; Murilo Conto, IFMBE, Healthcare Technology Assessment Division, Brazil; Ahmad Nader Fasseeh, Syreon University, Egypt; Inaki Gutierrez Ibarluzea, Basque Office for Health Technology Assessment, Spain; Catherina Manuelle Lee, De La Salle University Manila, Philipines; Marco Marchetti, Universitá Cattolica del Sacro Cuore, Italy; Antonio Migliore, HTAi, Italy; Debjani Mueller, University of Pretoria, South Africa; Daniel Ollendorf, Institute for Clinical and Economic Review (ICER), United States of America (USA) (2024); Maximilian Otte, Euroscan, Germany; Nicolas Pallikarakis, IFMBE Healthcare Technology Assessment Division, Greece; Steven D Pearson, ICER, USA; Elena Petelos, Maastricht University, Netherlands; Andres Pichon, Institute for Clinical Effectiveness and Health Policy, Argentina; Julie Polisena, J P Consulting, Canada; Rabia Sucu, HTAi, Türkiye; Saudamini Vishwanath Dabak, HITAP, Thailand; Sophie Werko, Swedish Agency for Health Technology Assessment and Assessment of Social Service, Sweden; and Oortwijn Wija, HTAi and Radboud University Medical Center, Netherlands It was received by the Medical Devices Working Group of the Health Technology Assessment Network of the Americas (RedETSA): Victoria Hurtado Meneses, Ministry of Health of Chile, Chile; Verónica Gallegos Rivero, National Centre for Health Technology Excellence, México; Verónica Alfie, Institute for Clinical Effectiveness and Health Policy, Argentina; Silvina Benchetrit, Ministry of Health of the Government of the City of Buenos Aires, Argentine Public Network for Health Technology Assessment, Argentina; Marisa da Silva Santos, National Institute of Cardiology, Brazil; Wendy Beatriz Villalta Quintanilla, Superintendence of Sanitary Regulation (SRS) of El Salvador, El Salvador; Mario Ernesto Vega Valenzuela, SRS of El Salvador, El Salvador; José Adán Sandoval, Salvadoran Social Security Institute, El Salvador; Malen Hollman, Pan American Health Organization, WDC.

Declaration of interests

The WHO secretariat collected, managed and reviewed the declarations of interests (DOIs) submitted and signed by the STAG MEDEV members, and all experts, reviewers, and consultants commissioned by WHO prior to commencing their work, and found no STAG MEDEV members, experts, reviewers, and consultants to have a potential conflict of interest.

Abbreviations

AI	artificial intelligence
DHT	digital health technology
EMDN	European medical devices nomenclature
GMDN	global medical devices nomenclature
HS	horizon scanning
HTA	health technology assessment
HB-HTA	hospital-based HTA
HTAi	Health Technology Assessment international
INAHTA	International Network of Agencies for Health Technology Assessment
ICER	incremental cost-effectiveness ratio
IFMBE	International Federation for Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
LMICs	low and middle-income countries
MCDA	multi-criteria decision analysis
NICE	National Institute for Health and Care Excellence
PAHO	Panamerican Health Organization
QALY	quality-adjusted life year
RCT	randomized controlled trial
RWD	real-world data
RWE	real world evidence
STAG MEDEV	Strategic and Technical Advisory Group on Medical Devices (WHO)
SDG	Sustainable Development Goal
UHC	universal health coverage
WHO	World Health Organization

Glossary

For consistent use of HTA terminology, users of this document can refer to the HTA glossary, which aims to promote a common vocabulary for HTA practitioners. As of 2024, the HTA Glossary is available in English, French, German, Spanish and Russian *(2).* Other references are provided here for terms that are not included in the HTA glossary.

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 *(3)*.

Combination product: Is defined by many jurisdictions as a product comprising two or more different types of medical products (that is, a combination of a medicine, device and/or biological product with one another) such that the distinctive nature of the drug component and device component is integrated in a singular product *(4)*.

Early HTA: An assessment conducted shortly after the certification and initial market introduction of new health technologies, during the early phase of their implementation in healthcare settings. This phase is crucial as it can provide RWE on the performance, safety, and value of the technology before it is widely adopted *(5).*

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 *(6)*.

Health technology: is an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system *(2).*

Horizon scanning: The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to affect health, health services and/or society *(2).*

In vitro diagnostic device (IVD): 'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. NOTE 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status *(7).*

Medical device: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or physiological process;
- supporting or sustaining life;
- control of conception;
- cleaning, disinfection or sterilization of medical devices;

- providing information by means of in vitro examination of specimens derived from the human body;
- and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. NOTE 1: Products which may be considered to be medical devices in some jurisdictions but not in others include:
  - » disinfection substances,
  - » aids for persons with disabilities,
  - » devices incorporating animal and/or human tissues,
  - » devices for in-vitro fertilization or assisted reproduction technologies *(7).*

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 *(2).*

Real-world data (RWD): Data collected during the routine delivery of healthcare. 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 *(2).*

Real-world evidence (RWE): Evidence derived from the analysis of real-world data. Note 1: Real world data are primarily analyzed through observational study designs. This real-world evidence is characterized by the actual use of the technology in practice and by findings that are generalizable to the target population for the technology *(2).*

Executive summary

HTA is a multidisciplinary process used to evaluate the clinical, economic, ethical implications and social impact of new health technologies. This document describes the critical role of HTA in supporting decision-making by informing policy-makers about the adoption and/or reimbursement of medical technologies by healthcare systems. As such, the WHO and other global health organizations provide support for regional and national initiatives to advance the use of HTA in developing and emerging countries. Developing HTA capacity in LMICs enables evidence-based decision-making and, in so doing, ensures that healthcare resources are spent efficiently and effectively and that investment in new technologies adds value to the health system by improving patient outcomes while ensuring equitable access. Importantly, by evaluating financial impact, HTA helps to avoid unnecessary spending on ineffective or costly interventions. Health systems are strengthened when HTA is integrated into all aspects of decision- and policy-making; however, HTA requires good governance to provide a policy approach that assures all stakeholders of transparency and accountability.

HTA links the three distinct but complementary functions of health technology decision-making, the first being regulatory approval of health technologies for market access, followed by HTA for the adoption of technologies into health systems, and lastly, health technology management across the lifetime of a technology. Health systems are strengthened when these functions remain differentiated but mutually supportive. As such, HTA can be applied at different time points in the lifecycle of a health technology: during pre-market regulatory approval, early assessment when a technology is beginning to diffuse into the health system (horizon scanning), once the technology is established in healthcare practice (HTA with or without an economic and financial impact analysis), procurement, and finally through to reassessment and potential disinvestment if superseded by new technologies.

Many of the basic principles of HTA can be applied to all health technologies; however, the aim of this document is to provide guidance to policy-makers, especially those in LMICs on the use of HTA for medical devices. Medical devices differ from other health technologies; therefore, HTA for medical devices must be different. Conducting HTA for medical devices (see section 7.1) is associated with many unique challenges compared to HTA for pharmaceuticals. The most critical of these challenges is that the very nature of medical devices often means that it is not feasible to generate good quality, robust evidence in clinical studies due to factors such as a lack of appropriate comparators, randomization and blinding HTA of implantable devices needs to consider the dependence on a surgical procedure, with due consideration given to the learning curve plateau and training required for device use, which may affect outcomes.

This document is intended to provide guidance to policy-makers in LMICs that are currently developing an HTA capacity, and provides best-practice resources to ensure consistent, transparent and informed decision-making for the adoption and use of medical devices. Several sections of this document discuss the potential use of different HTA methodologies for medical devices and the advantages they may have for LMICs. Many LMICs currently do not have the capability, capacity or financial means to conduct complex systematic reviews for all health technologies. Methodologies that allow timely and context-sensitive evaluations such as rapid HTA, multi-criteria decision analysis, adaptive HTA, and the use of RWE may be particularly useful for the assessment of medical devices in these countries (see sections 7.3, 7.5, 7.7 and 8.2).

Collaboration and stakeholder engagement remain at the core of HTA activities, encouraging the strengthening of national institutions by supporting regional and international networking. This document therefore refers to several international agencies that have readily available resources to support the global advancement of HTA (section 9) Health Technology Assessment international (HTAi) and the International Network of Agencies in Health Technology Assessment (INAHTA) have a demonstrated global commitment to advancing and collaborating on HTA, especially with LMICs and the WHO.

By promoting the use of HTA, the WHO endorses an evidence-based approach to decision-making to improve health systems and population health.

1. Introduction

The role of HTA is to provide evidence-based advice to health policy decision-makers, particularly in LMICs, to enable equitable, efficient access to high-quality healthcare *(8).* In LMICs, where resources are often limited, HTA plays a crucial role in ensuring health interventions are both cost-effective and aligned with the unique health needs of the population. HTA is a multidisciplinary process that synthesizes the best available evidence describing the dimensions of a health technology in a systematic and transparent manner in comparison to existing alternatives (see above definition). 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 political, organizational and environmental aspects relating to the health technology in question, should also be appraised and considered *(6).*

Driven largely by concerns about increasing healthcare costs, the primary focus of HTA for many years was the cost-effectiveness of pharmaceuticals rather than non-pharmaceutical technologies to inform payer coverage decision-making on their introduction to the health system *(9).* Medical devices are essential tools for the prevention, diagnosis and treatment of illness and disease and patient rehabilitation. However, there are important differences between pharmaceutical therapies and medical devices, including product lifecycle, clinical evaluation, user issues, costs and economic evaluation, and intellectual property (see section 7.1)*(10).* HTA methodologies for the assessment of pharmaceuticals are more developed, robust, widely used and well-understood compared to HTA for non- pharmaceutical technologies, including

medical devices *(11).* When introducing a medical device into the healthcare system, it is therefore imperative an appropriate HTA methodology is used that accounts for the inherent differences between medical devices compared to new pharmaceuticals.

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.

1.1 Methodology

Methodology

This document is an updated version of the 2011 WHO publication *Health Technology Assessment of Medical Devices*, part of the WHO Medical Device Technical Series. The current edition was developed using a multi-step approach combining a structured literature review, grey literature analysis, synthesis of national experiences, and expert consultation through the WHO Strategic and Technical Advisory Group on Medical Devices (STAG-MEDEV).

a) Methodological objectives

This document is a narrative review describing the current landscape of medical devices, providing a synthesis of the characteristics and challenges of HTA of medical devices. As such it is not intended to provide a methodology or framework for the assessment of specific medical devices or to be prescriptive regarding those practitioners who should be involved in HTA. This narrative review of the general concepts of HTA for medical devices was conducted by searching the literature in PubMed published since 2000. Relevant papers were reviewed for inclusion, and their citations 'snowballed' to identify other relevant references in addition to searching the grey literature. The main objective was to identify and synthesize current best practices, policies, and methodological recommendations related to the health technology assessment (HTA) of medical devices, with a specific focus on the needs and realities of low- and middle-income countries (LMICs). The aim was to support evidence-informed and context-appropriate adoption of medical technologies aligned with universal health coverage (UHC) priorities.

b) Literature search framework

A targeted literature review was conducted from April to July 2023. The scope of the search was framed by key questions related to:

- The implementation of HTA mechanisms for medical devices in LMICs
- Methodological adaptations for assessing non-pharmaceutical technologies
- Data challenges and governance structures in resource-limited settings
- Use of HTA in priority setting, procurement, and regulation

The following databases and sources were used:

- Scientific and indexed sources: PubMed, Embase, Global Index Medicus
- HTA-specific sources: HTA Database (INAHTA), NICE Evidence Search, GRADEpro
- Institutional and normative frameworks: WHO guidelines and tools, OECD reports, PAHO publications, EU Network for HTA (EUnetHTA), RedETSA outputs

Search terms included: *"health technology assessment"*, *"medical devices"*, *"low-income countries"*, *"HTA methods"*, *"real-world data"*, *"rapid HTA"*, *"priority setting"*, and were adapted for each database's syntax.

c) Inclusion criteria and evidence appraisal

Documents were selected based on:

- Publication date: 2010 to 2023
- Geographic relevance: Focus on LMICs, or applicable to LMIC health systems
- Methodological rigor: Peer-reviewed systematic reviews, official guidelines, evaluated institutional experiences, case studies, and WHO normative documents

All sources were independently screened by two reviewers. A data extraction matrix was used to collect key information on: objectives, methods, HTA institutional models, priority-setting mechanisms, barriers and enablers, and implementation outcomes. The evidence was synthesized narratively, and grouped according to thematic areas aligned with the structure of the report.

d) Glossary definitions

Definitions included in the glossary were primarily drawn from internationally recognized sources such as the INAHTA Glossary, WHO, HTA Glossary, NICE, IMDRF and GRADE.

e) Validation process

The first draft of this report was prepared by a technical writer in collaboration with WHO and reviewed by the STAG-MEDEV HTA subgroup. A public consultation process followed, conducted between April and July 2024. A total of 27 organizations from multiple WHO regions—including several African, European and Latin-American institutions— and multiple experts, who submitted feedback. The writing team and STAG-MEDEV subgroup reviewed 486 individual comments, which were discussed, prioritized, and integrated through several iterative rounds.

The final version of the document underwent technical editing, WHO internal clearance, and layout review prior to publication.

2. Global health technology assessment

2.1 World Health Assembly mandates

In 2007, the World Health Assembly adopted Resolution WHA60 29, urging the WHO and Member States to collaborate with other organizations to develop methodological tools and technical guidelines for the prioritization, selection and use of health technologies, particularly medical devices *(12).* For LMICs, these guidelines provide a framework for the systematic evaluation of health technologies, ensuring that they are not only effective but also affordable and suitable for the local context. Subsequent resolutions relevant to progressing the use of HTA include WHA67.20 *(13)*, WHA67.23 *(1)* and WHA76.5 *(14)*, which urged Member States to strengthen regulatory capacity and to consider the establishment of HTA systems to support decision-making for access to safe, efficacious and affordable medical products in the context of UHC. As such, the 2014 Resolution WHA 67 23: *Health intervention and technology assessment for universal health coverage (1)* provides a mandate supporting Member States to develop health intervention and technology assessment mechanisms *(15)* that is aligned with the 2021 and 2023 resolutions of the General Assembly of the United Nations to scale up and accelerate efforts towards the achievement of UHC for all by 2030 *(16, 17).* The continuous support of the WHO assists LMICs in building capacity and integrating HTA into their health systems, in so doing, promoting sustainable health policies and developing UHC.

2.2 HTA in the Global Atlas of Medical Devices 2022

The 2007 resolution WHA60.29 *(12)* on Health Technologies urges 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 response, WHO surveyed Member States in 2010, 2017 *(18)* and 2022 *(19)* to identify areas that require support for the development or improvement of health technology programs, with a focus on medical devices. These findings are published in the 3 editions of the Global Atlas of Medical Devices and provide 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 systems, and biomedical engineering resources. The global surveys also collect information on HTA and health technology management capacity. The 2017 survey indicated that 61% of Member States had no formalized HTA for medical devices unit *(18)*. The 2022 Global Atlas included determination of the status of medical devices and how access to priority devices can support achievement of the Sustainable Development Goals (SDGs) as countries move towards achieving UHC (see section 4.1).

In 2019, the Executive Board of the WHO acknowledged the need for an international system for the classification, coding and nomenclature of medical devices *(20)*, the lack of which had hampered the development of an evidence-based database to provide guidance on appropriate medical devices. Since 2019, regulators and ministries of health have made efforts to harmonize the nomenclature of medical devices. In 2022, the World Health Assembly in decision WHA75.25, resolved in agreement with the European medical devices nomenclature (EMDN) and the global (GMDN), to integrate information related to medical devices, including name, code and definition, into the web-based Medical Devices Information System (MEDEVIS) *(21)* database to serve as a reference for stakeholders and Member States *(22)*. Ideally, these nomenclature systems should be used in the health technology assessment reports of the different types of medical devices to classify and identify them for reference.

2.3 HTA data from the WHO survey of 2020/21

The 3 editions of the Global Atlas of Medical Devices were are complemented by the 2015 Global Survey on Health Technology Assessment by National Authorities *(23)* that reported on the use and scope of HTA for all health products and interventions conducted by governmental or national institutes, usually under the auspices of the ministry of health. It also surveyed institutional capacity and human resources as well as requirements for strengthening HTA capacity. The follow-up 2020/2021 survey provided detailed information on country profiles for all HTA processes, not only medical devices *(24)*. These surveys were intended to measure:

- how HTA is used in public sector decision-making (i.e. planning and budgeting, reimbursement, determining benefit packages or clinical practice guidelines);
- the scope of HTA (i.e. the technologies and criteria used) and the availability of HTA guidelines;
- institutional capacity to support HTA and requirements to strengthen capacity to improve the use of HTA in healthcare policy; and
- governance of HTA.

These surveys are a way to measure the global progress in the investment in the systematic use of HTA in formal health decision-making. HTA was found to primarily inform governments about planning and budgeting, clinical practice guidelines and the design of health benefit packages. The barriers to using and producing HTA were also surveyed, to identify areas to be addressed by future WHO resolutions to assist countries in establishing mechanisms to institutionalize HTA. In the 2020/2021 survey, a lack of awareness of the importance of HTA and a lack of budget and dedicated human resources were the main barriers conducting HTA *(25)*.

2.4 HTA process for selection of WHO Priority List of Medical Devices and for Essential in vitro diagnostic tests.

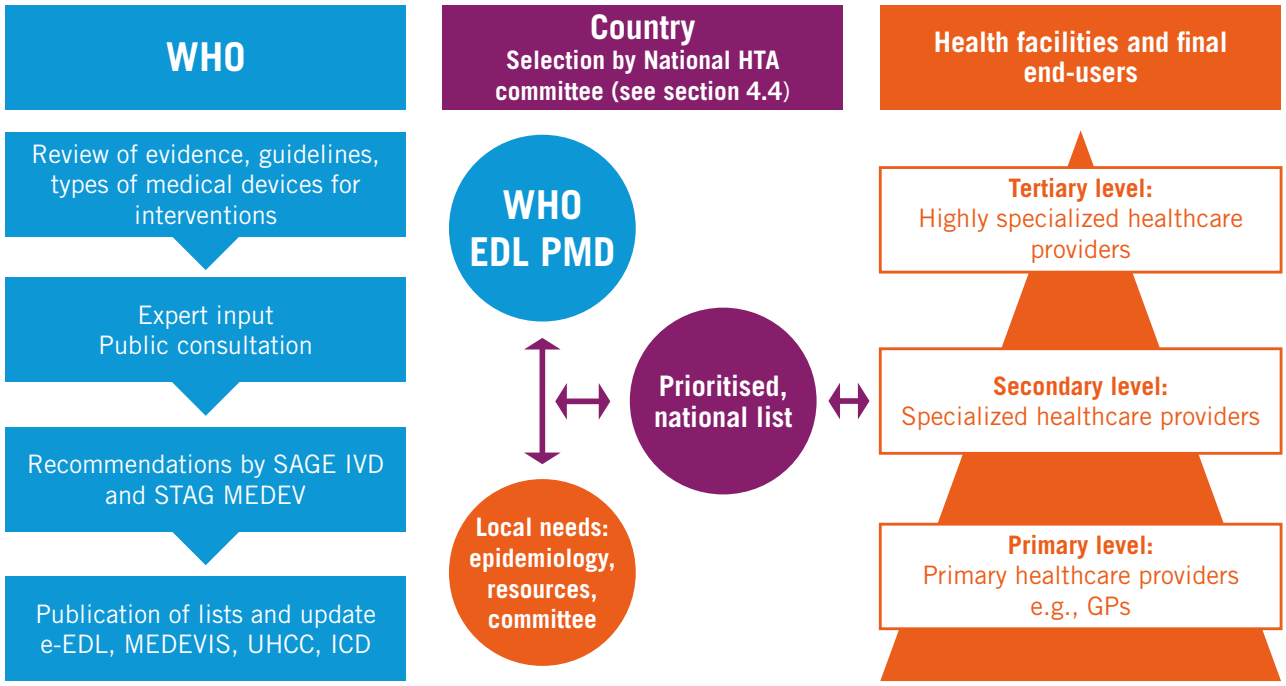
Based on the WHO Essential Medicines model list, WHO publishes and continuously updates priority lists to improve access to suitable medical devices, to support quality of care, address health care needs and strengthen healthcare systems. The lists provide evidence-based guidance to assist policy-makers to facilitate the development or update of national priority device lists and promote their availability to support UHC. WHO uses an HTA based process to define the medical devices and in vitro diagnostics. The Priority Medical Device aims to identify 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 affect specific populations, including the elderly, pregnant women, and newborns.

The WHO model lists includes: 5 editions of Essential in vitro diagnostics tests (EDL) and 4 editions of Priority Medical devices, *(26)* for the response to the coronavirus disease 2019 (COVID-19) pandemic *(27)* and those for the management of cancer *(28)* and cardiovascular disease and diabetes *(29)* and those priority medical devices required to manage reproductive, maternal, newborn an child care *(30)* among others, and WHO is continuously expanding the lists. The electronic database of all WHO priority medical devices is available in the WHO Medical Devices Information System (MeDevIS) to be available as a reference of assessed technologies for uptake by countries. The methodology and evidence used to develop the lists are available in the publications, for reference.

The EDL is a health policy document, based on scientific evidence, consisting of a list of categories of IVD tests and recommendations for using those tests in relation to the assay format, test purpose, specimen type and health care setting. EDL 4 *(31)* lists IVD tests that are recommended by WHO for use in countries to improve access to IVD testing. The list is not intended to be prescriptive with respect to the specific tests nor the level of the health care system at which IVDs can or should be used. Rather, the list aims to serve as a reference to guide development of or to update a national EDL (NEDL) at the country level within the framework of universal health coverage. In all cases, countries are expected to decide for themselves which IVD tests to select and where to use them depending on their local context, needs and priorities. The revised evidence includes diagnostic accuracy, clinical utility, economic impact, ethics, equity and human rights considerations. The Strategic Advisory Group of Experts on IVD recommend WHO the list for approval, after dedicated meeting to review each addition or modification to the WHO model list. *(31)*

The WHO Priority Medical Devices List and Essential in vitro diagnostics can be used as a reference by Member States to develop or update their national medical devices lists for reimbursement, public procurement or to define towards the implementation of essential or priority interventions towards universal health coverage. The process by which WHO adds new devices or in vitro diagnostics is shown in the first column of Fig.1. Then, at country level, it is proposed that a national HTA committee or decision-making body decides which of the technologies to prioritize based on factors including clinical need, burden of disease and available infrastructure and resources.

Fig.1 *Updating of WHO Priority Medical Devices and uptake by countries, towards developing their national lists*



e-EDL, electronic version of WHO Model List of Essential In Vitro Diagnostics; PMD, Priority Medical Devices; MEDEVIS, Priority Medical Devices Information System; SAGE IVD, Strategic Advisory Group of Experts on In Vitro Diagnostics; STAG MEDEV, Strategic Advisory Group of Experts on Medical Devices; UHCC, universal health coverage compendium.

See the WHO Medical devices information system MedevIS which includes terms, codes, definitions, types of medical device, primary use, health care unit, service delivery platform, health care level, technical specifications, training materials *(21)*.

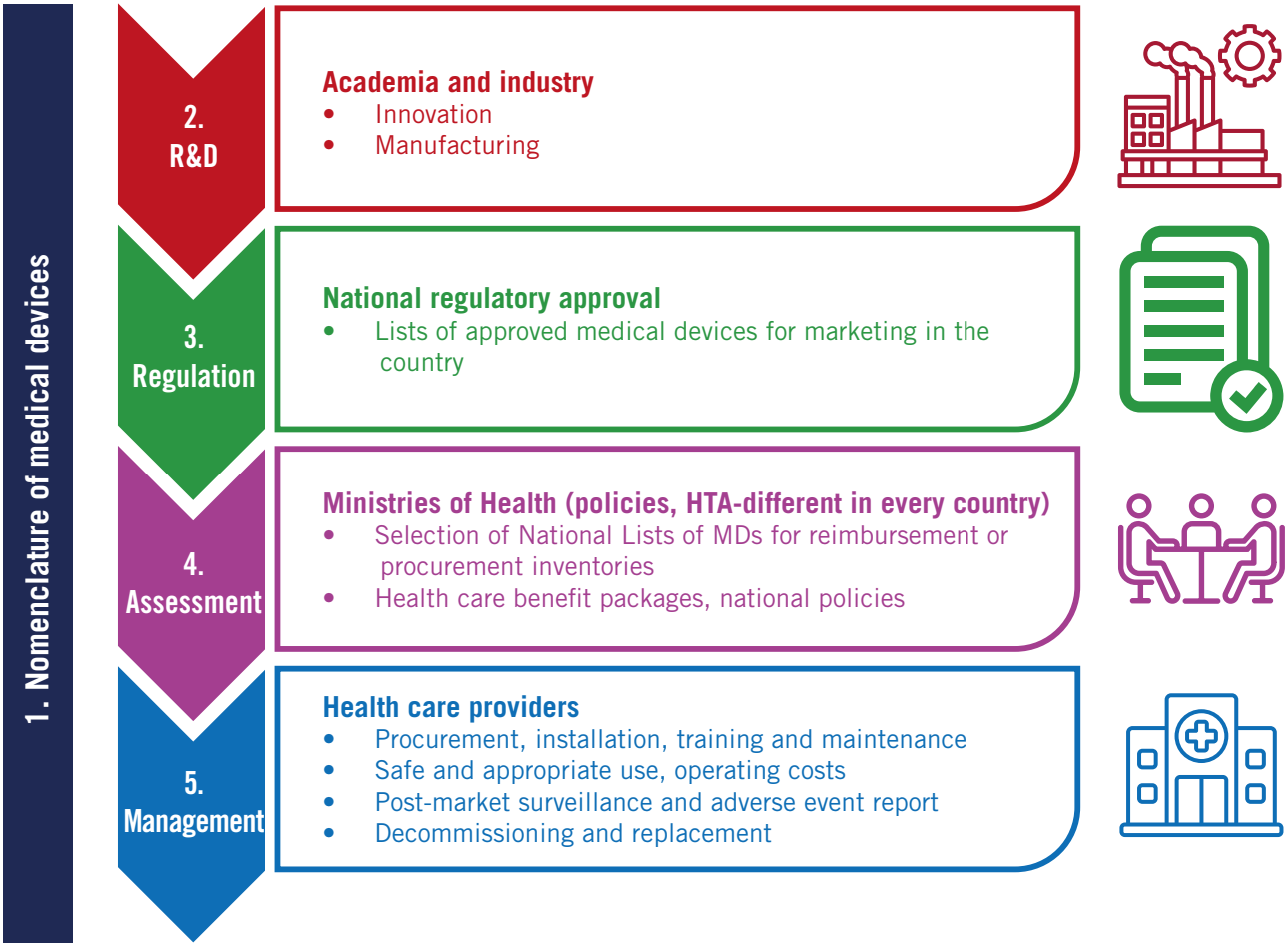
See also electronic essential in vitro diagnostic list that includes the IVD purpose, assay format, review of evidence and recommendations by the Advisory Committee *(32)*.

2.5 Regulation, assessment and management of medical devices

Once a new medical technology is developed and named, HTA is the link that bridges the three distinct but complementary functions of health technology decision- making for medical devices towards its use (Fig 2):

1. Nomenclatuer of medical devices;
2. research, development and manufacturing;
3. regulatory approval of technologies for market access;
4. policy for coverage, reimbursement or benefit packages (HTA); and
5. management of the use of approved technologies, including procurement to decommissioning or disinvestment *(33, 34).*

Fig.2 *The role of HTA in health technology decision-making in the value chain.*



R&D = research and development

In LMICs, HTA can ensure that regulatory practices are informed by robust evidence, support policy decisions on coverage that are based on cost-effectiveness, and aid in the management of medical devices by providing data on their real-world performance and their impact on health outcomes.

The types of evidence considered for each of these functions differ (Table 1). Regulatory approval of medical devices requires evidence that can assess the level of associated risk and safety. However, evidence for coverage decision-making often differs markedly, usually requiring evidence that demonstrates effectiveness compared to the current standard of care *(33).*

Recommendations to adopt technologies made at the national level may be difficult to implement at the local level, where there may be budgetary constraints or additional training, organizational changes (facilities and/or staffing) may be needed. Conducting health technology management in conjunction with HTA at all levels of the health system may assist implementation and ensure optimal use of scarce healthcare resources. The development of a dedicated holistic health technology management system at the health organization level (e. g. hospital) should be encouraged to oversee the acquisition, deployment, day-to-day use and support and finally, the decommissioning of medical devices *(35).* However, any initiative such as hospital-based HTA (see section 4.3), may shift the HTA focus from the national to the local level, resulting in a fragmented national approach to UHC *(33).*

Table 1 *Comparison of health technology regulation, assessment and management*

Characteristics	Health technology regulation	Health technology assessment	Health technology management
Perspective	Market access: considerations include quality, safety, performance and efficacy	Population-level: considerations include efficacy, relative effectiveness, safety, patient-relevant outcomes, appropriateness (including ethics, social and legal issues) and accessibility	Local-level health facilities: considerations include needs analysis, procurement, affordability, training and alternative technologies towards quality of care
Requirement	Mandatory	National recommendation on complex technologies	Local implementation of recommended technologies
Role	Prevent harm	Maximize clinical and cost-effectiveness, value-based decision-making	Management across the lifecycle of the device, from adoption to decommissioning to enhance appropriate and safe use

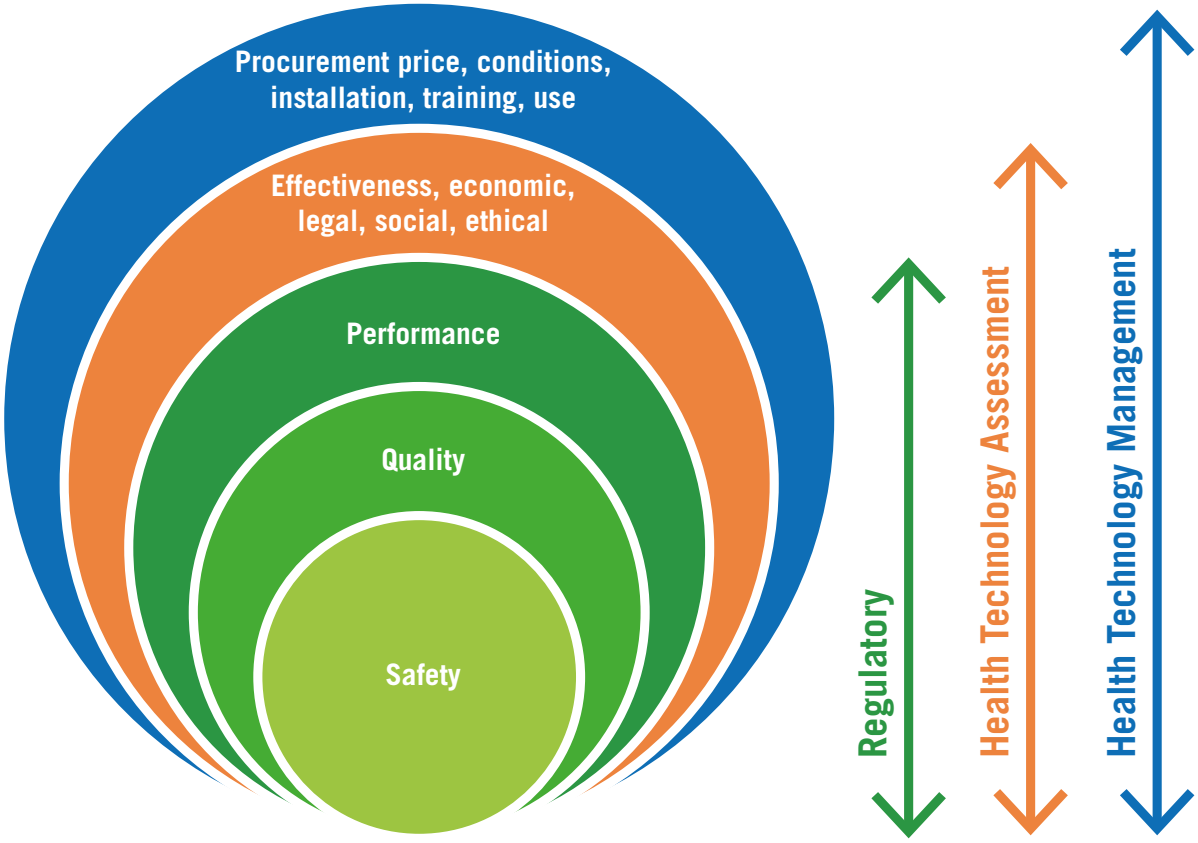
2.6 Commonalities between HTA and regulatory process

Regulatory bodies are primarily concerned with the quality, safety and performance of a product, with no requirement to evaluate evidence of whether the effect of the intervention is comparable to existing clinical practice or whether it represents value for money. Regulators classify medical devices according to factors such as the potential level of hazard and risk to patients, with risk being defined in relation to the duration of use, degree of invasiveness, whether the device is implantable or non-implantable, or whether it is active or contains an active substance *(36, 37).* Different countries have different risk classification systems, but in general, simple devices such as thermometers are categorized as low risk, while devices such as hearing aids and infusion pumps for intravenous medications are classified as medium risk, and devices such as implanted stimulators as high risk.

A regulatory framework for the entire life cycle of a medical device should include product design, manufacture, and pre-and post-market data collection. Personalized (e. g. remote monitoring devices), point-of-care or digital (including artificial intelligence and machine learning) medical devices present a challenge to existing regulatory frameworks *(38).* The core objective of organizations such as the WHO and International Medical Device Regulators Forum (IMDRF) is to develop a common international classification standard to harmonize global regulatory requirements and to encourage information-sharing, capacity-building, and strengthening of regulatory processes *(39).*

For market access, regulators require that all medical devices be evaluated, from simple products 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 most pharmaceuticals (which are unlikely to undergo HTA when used off-label), low-risk medical devices are not required to undergo an HTA. Decision-making for regulatory approval and HTA of medical devices share some elements of evidence; however, clinical data obtained as part of the regulatory process will not be sufficient for HTA due to the reasons outlined in section 7.1 *(33, 40)*. Although regulatory approval and HTA of health technologies are independent processes, they are linked and share common aspects for submission for review (Fig 3).

Fig.3 *Stages and values of HTA (34) in relation to regulatory process and health technology management*



Evaluation of efficacy and safety is usually sufficient for regulatory approval; that is, determining whether the device is safe and whether it does what it should do. HTA must consider the effectiveness of the device as well as questions of value for money, equity, acceptability to patients and healthcare providers, organizational impact and ethical issues *(34)*. Given the lower evidence requirements for market approval for patient health and safety, standardized post-marketing data collection should be encouraged, not only to detect device-related incidents or adverse events but also to assess the real-world effectiveness and any implementation issues (e. g. training or infrastructure requirements) of devices *(33)*. The costs associated with setting up and maintaining post-market registries are; however, prohibitive even for high-income countries.

See 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 *(41)*. Also see the IMDRF's four regional harmonization initiatives: Asia-Pacific, Pan-American, African and global *(39)*.

2.7 HTA for procurement

Procurement of all health technologies begins with identifying a need *(42)*, followed by evaluation of good quality options, planning, financing and, finally, contracting. Although separate from procurement, HTA evaluates needs that are aligned with health system priorities based on consideration of the burden of disease and the impact on health outcomes *(43)*. Coverage and procurement decision-making of pharmaceuticals tends to be value- based, informed by cost-effectiveness analyses performed as part of an HTA assessment, which then forms the basis for price negotiations *(15)*. However, cost-effectiveness and value frameworks are not always appropriate for and are more difficult to apply to medical devices, where frequent device iterations and user learning curves make it difficult to generalize health outcomes and, therefore, value to the health system *(44)*.

Medical device procurement should include consideration of the quality and safety of the device first, then upfront cost of the device, patient and clinician preferences, infrastructure requirements, technical and implementation considerations, operating costs, as well as any operational efficiencies (such as bed days saved, reduction in operating room time, use of hospital and staff resources, including maintenance, consumables and warranties) *(44, 45)*. A cost-benefit or budget-impact analysis may be more appropriate when investment in a new medical device delivers health system benefits such as reducing length of stay. To meet health priorities and those of health organizations, medical device procurement should include consideration of these factors and not simply accept the lowest tendered price *(18)*. Procurement practices vary among countries. Some countries have lists of necessary medical devices that align with national health priorities, while other countries are moving towards centralized procurement to take advantage of economies of scale. The latter may not; however, be suitable for countries with diverse health needs *(43)*.

Procurement tends to be conducted at the local rather than national level, to manage the budgetary, reimbursement, and cost constraints of specific healthcare organizations. Procurement requires good governance, should be transparent and value-based and should meet health system priorities and patient needs. Effective procurement should consider HTA recommendations and, if possible, develop links with hospital HTA practitioners, to ensure efficient and equitable access to healthcare technologies *(44)*. The HTA assessments should consider budget impact and other financial priorities locally or nationally. The information of the HTA assessments should be reviewed by the biomedical or clinical engineers in hospital facilities and to expand to clinical outpatient settings and community health services to ensure the medical devices address the local community needs and related budget impact.

Noting that the new procurement practices should evaluate first the quality and safety of the product then the budget impact and the sustainability perspectives.

For a summary of resources for achieving good procurement practice, WHO *Procurement process resource guide (46).*

2.8 Role of biomedical engineers

Resolution WHA60.29 recommends collaboration between HTA and biomedical engineering personnel *(12).* WHO also recommends that biomedical engineers be employed in HTA agencies to provide advice on the selection, prioritization and management of medical devices *(34, 47).*

The interdisciplinary expertise of biomedical engineers is essential for the research, design and management of medical devices in hospitals and healthcare organizations, with a skill base that includes physics, mathematics, engineering, biology and medicine. Recognizing these multi-disciplinary attributes and natural synergies, in 2011 the International Federation of Medical and Biological Engineering (IFMBE) endorsed HTA as a core learning for biomedical engineering. The IFMBE has developed HTA training courses designed specifically for biomedical engineers, including an e-learning platform and guidelines for HTA of medical devices throughout their lifecycle. Methodologies are also available for pre-market evaluation to identify expected value. As medical devices depend on the environment in which they are used, HTA of medical devices depends on the environment in which the device is intended to work, limiting the generalizability of HTA reports produced in other (often high-income) countries *(47)*. Involvement of biomedical engineers in HTA when new medical equipment is acquired can provide information on its technical characteristics, comparison with similar technologies, usability, performance, safety and organizational impact of the device throughout its lifecycle, as well as informing economic analyses with the provision of maintenance, installation, and operational costs *(10)*. One of the priorities of the IFMBE is to therefore foster HTA-related capacity-building in LMICs *(47)*.

> See 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 *(34)*.
>
> Also see the Health Technology Assessment Division, featuring the freely available HTA eLearning platform, of the IFMBE for more information *(48)*.

3.
HTA and health policy

3.1 Decision-making and governance

WHO defines health system governance as *"the processes, structures and institutions that are in place to oversee and manage a country's healthcare system" (49).* Governance comprises management of the relationship among healthcare stakeholders, including government agencies, healthcare providers, patients and their families, community and civil society organizations, and the private sector. Many LMICs are faced with increasingly complex healthcare landscapes characterized by limited financial resources, inadequate health infrastructure, and a shortage of skilled personnel (see section 5 for a discussion of these challenges). External factors such as climate change, demographic changes (including ageing, migration and increasing urbanization), the increase in the prevalence of chronic and non-communicable diseases and the threat of infectious disease outbreaks are of the greatest importance in these countries. Political and medical change, including new technologies, are also relevant. It is therefore critical to ensure effective health system governance for structured decision-making and policy implementation, and the efficient and equitable allocation of healthcare resources for all members of society, regardless of socioeconomic status, ethnicity, culture, gender or other factors. The quality of governance affects the ability of a 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 *(50)*.

The five important attributes of health system governance are:

i. accountability, whereby a relationship exists between actors (e.g. an agency) and a forum (e.g. a legislature). The actor can be mandated and 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, whereby the health system informs the public and other stakeholders of decisions made and how and why they were made;

iii. participation of affected parties that have access to decision-making and power to ensure a meaningful role in the work of the institution, this may take the form of advisory committees, stakeholder forums or consultations;

iv. integrity, whereby representation, decision-making and enforcement are clearly specified, and all members can understand and predict the way in which an institution takes and applies decisions. Individuals should have a clearly allocated role and responsibility; and

v. policy capacity, whereby the ability to develop policy is aligned with resources in pursuit of goals *(50).*

Good health system governance requires a strategic policy framework is in place with effective oversight, coalition-building, appropriate regulations and incentives, attention to system design, and accountability *(49)*. These factors ensure that good health system governance will result in better health outcomes.

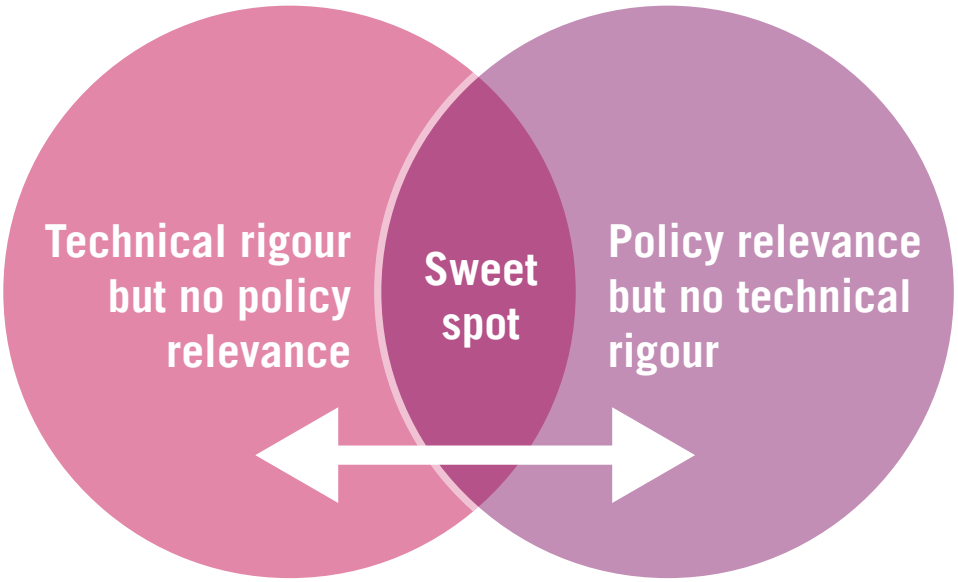
Consistent and transparent decision-making not only requires a policy framework in which decision-making is no longer opinion but evidence-based policy but also requires the political will to accept the information provided by HTA. Having regulations in place and normalizing their use will empower policy-makers to use evidence in decision-making. Capacity-building at both the individual and organizational levels (see section 5.1) provides health policy-makers with the technical ability to interpret and use evidence effectively and to distinguish between research of high or low methodological quality. Provision of targeted training in basic HTA skills 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 *(51)*. This is especially true in LMICs, where HTA could be the basis for shaping health policies and related legal frameworks.

Each country should develop its own policy framework according to its health system structure and the relationships between research institutions, funding bodies and the government *(52)*. The framework may need to be adjusted as the uptake of evidence-based decision-making increases over time.

3.2 HTA for evidence-informed and context-based decision-making

HTA is an essential component of any health system seeking to develop an accountable, evidence-based, and policy-driven approach to health decision-making. By building HTA capacity and capability, health systems will introduce technical rigor into the decision-making process. The technical rigor of HTA must be matched to its relevance to policy (Fig.4), with the 'sweet spot' being where the evidence is both technically rigorous (i. e. evidence and data are reliable and trustworthy) and contextualized, making it relevant to policy-makers and health system priorities. Moving to the left or right, away from the centre, occurs when more dialogue between policy-makers and health researchers or evidence generators is needed *(53)*.

Fig.4 *The relationship between technical rigor and policy relevance*

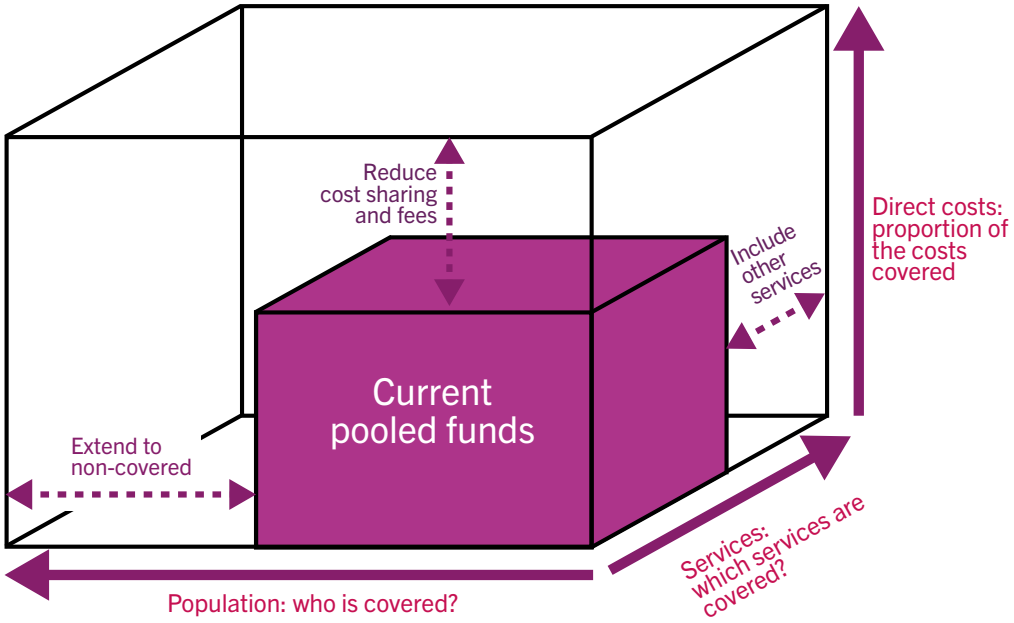


4.
HTA in health systems

4.1 The role of HTA in UHC

In 2015, the United Nations General Assembly 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 (54)"*. 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 users to financial hardship *(55)*. The objectives of UHC are the same in all settings: to ensure equity of access to quality health services that will improve health and well-being irrespective of a person's economic circumstances *(56, 57)*. UHC is commonly described using three dimensions: service coverage, financial protection, and population coverage, presented in the form of a cube (Fig. 5). Depth of coverage indicates the extent of services covered by pooled funds (i e what treatments should be included for reimbursement), the breadth refers to the percentage of the population who can access these services, and the height relates to direct costs associated with coverage (i e what will it cost patients to access to these services). The three dimensions represent policy trade-offs, where progress in one dimension (e.g. increased services) may negatively impact the other two dimensions *(58)*.

Fig.5 *The three dimensions to consider when moving towards UHC (18)*

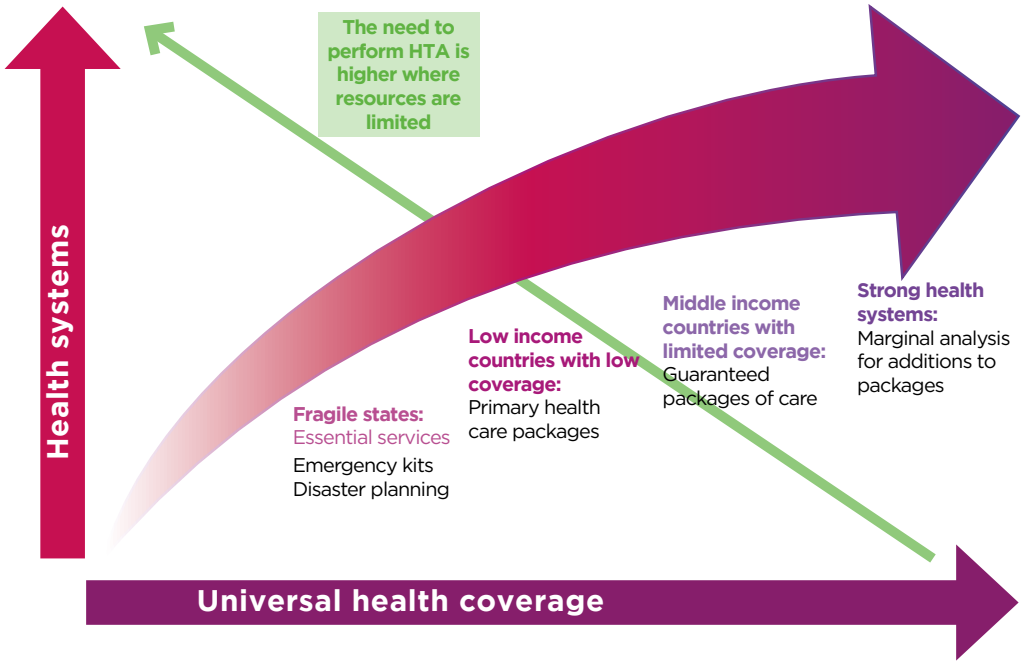


All health systems, particularly those in LMICs, are struggling to achieve UHC in a resource-constrained environment exacerbated by the COVID-19 pandemic. Healthcare policy, practice and decision-making need to maximize the potential positive effects of health technologies while optimizing the value from the cost of providing the technologies. Achievement of UHC requires the identification of health interventions that should be included in benefit packages for reimbursement. Competing demands for limited resources require a standardized priority-setting process to ensure the provision of the most clinically- and cost-effective interventions for a given population. In comparison to high-income countries, LMICs usually have the resources to only deliver a smaller set of services. Taking into consideration the cost of implementation, HTA is one of the key tools available for policy-makers as health systems work towards the goal of UHC in an explicit, systematic and transparent approach manner *(57, 59)* prioritizing technologies such as those described by WHO's list of essential in vitro diagnostics or priority medical devices *(19, 28, 31)*. Using HTA to determine the content of benefit packages should take into account the specific context in which the technology will be used when integrated into the health system setting, including the health system structure, local costs, budgets, and demographic, epidemiological and societal factors, including existing inequalities and patient preferences, all of which influence the value for money of specific interventions *(57, 60)*.

In countries with well-established UHC HTA is a well-recognized priority-setting tool for public reimbursement and coverage decision-making. In countries where resources are limited, there is an even greater need to conduct HTA (Fig. 6). Integration of HTA into the health systems of LMICs involves building technical capacity, developing regulatory frameworks and ensuring stakeholder engagement HTA in LMICs also requires data, as estimating the potential costs and health effects of interventions and technologies is challenging in the face of limited access to accurate demographic and epidemiological data *(57)*.

A more extensive role of HTA is an important policy goal that LMICs should work towards developing. The long-term negative consequences of disregarding evidence-based healthcare priority-setting in the development of UHC benefit packages may result in inefficient and inequitable healthcare systems, opposite to the goals of UHC *(61)*. Despite such challenges, several countries have made significant advances in using HTA to support their health policy decisions, demonstrating the potential for HTA to enhance health systems.

Fig.6 *Levels of HTA application as the development of UHC progresses (18)*



4.2 HTA for priority-setting

As summarized by the WHO, countries that have adopted systematic priority-setting follow all, or most of, the following eight principles: that essential benefit design should:

1. be impartial, aim for universality;
2. be democratic and inclusive with public involvement, including disadvantaged populations;
3. base priorities on national values and clearly defined criteria;
4. use data and evidence, including revisions as new evidence is developed;
5. respect the differences among data, dialogue, and decision;
6. ensure robust financing mechanisms;
7. include effective service delivery mechanisms to promote quality care;
8. be open and transparent at all steps of the process and clearly communicate decisions including trade-offs *(62)*.

In environments with limited healthcare resources, policy-makers must use a transparent, fair, and independent priority-setting process for the allocation of scarce funds to maximize health outcomes and improve access to health services for all, not just a few. The use of a validated and explicit process, such as HTA, to guide priority-setting can meet these goals, whereas an informal process may result in inefficient resource allocation and entrench inequalities by the provision of poor-quality healthcare, delaying the transition to UHC. The explicit criteria used in the HTA framework will depend on the definition of essential health services that align with the priorities of the health system. These criteria may include the burden of disease, clinical effectiveness, budget and economic impact, with cost-effectiveness used as a quantitative measure. The latter may be inappropriate to assess the value of medical devices and is often misinterpreted as a cost-containment measure, whereas other simpler methods of economic evaluation, such as a cost-benefit analysis, may be

more appropriate High-income countries can incrementally add new technologies to the health system as they emerge LMICs; however, start from a lower baseline of established services and have 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 *(63, 64).*

See WHO's Principles of health benefit packages *(62)* 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 *(65)*.

4.3 Institutionalized HTA

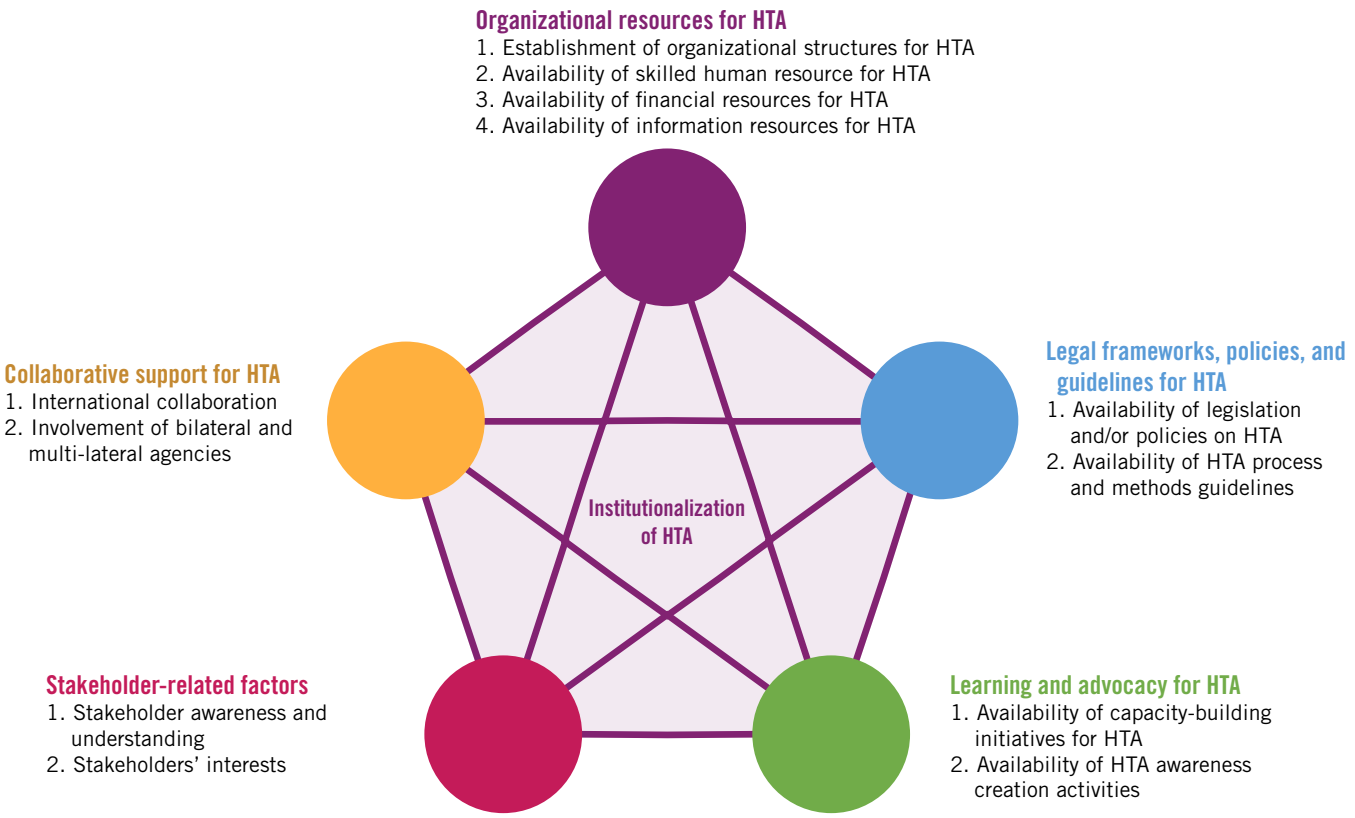
As more LMICs move towards providing UHC, evidence-informed priority-setting to ensure an equitable, efficient, and sustainable health system becomes essential. As recognized by resolutions by WHO and United Nations member states, HTA is one of the most important priority-setting tools, and an HTA capability should be fostered and encouraged. HTA usually informs health system policy at the national (macro) level, information for system-wide regulatory and reimbursement decision-making for new health technologies. High-income countries with well-developed HTA capacity have developed institutional and organizational structures and processes, linking HTA agencies with regional or national government, ensuring the efficient use of national resources (66-68). Institutionalization of HTA is pivotal to supporting UHC by improving the allocation of finite resources and maximizing health outcomes Institutionalized HTA informs health policy on:

- development and revision of health technologies for reimbursement;
- development of contextualized clinical practice guidelines;
- use of market-authorized health technologies; and
- regulations on pricing and reimbursement of health technologies *(67)*

Some of the challenges to establishing institutionalized HTA include those that are country-specific, such as a fragmented health system; a lack of capacity - scarcity of human resources; a lack of stakeholder involvement; a lack of data and data management infrastructure; a lack of political will; difficulties translating HTA into policy; and insufficient financial resources *(68, 69)*. A framework for successful institutionalization of HTA should first ensure that there is a mandate to establish HTA, then establish a legal framework before putting institutional arrangements in place *(66)*. Once these are in place, local capacity-building can commence and the procedural aspects of assessment and appraisal can be addressed *(15)*. A schematic framework by Mbau et al (Fig 7) describes these elements and how they relate to other factors including the importance of stakeholders *(67)*.

See 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 *(15)*.

Fig.7 *A conceptual framework of factors influencing institutionalization of HTA (67)*



Hospital-based HTA

Hospital-based HTA (HB-HTA) provides localized decision-making tailored to the specific individual healthcare organization, taking into account existing technologies, budgetary and organizational limitations, the expertise of healthcare professionals, strategic priorities and characteristics of the patient population *(70-72)*. As its structure addresses the specific needs of the hospital, the resources available, and the level of stakeholder involvement, it should be noted that many LMICs have insufficient resources and capacity to support HB-HTA. Unlike HTA conducted at the national level for reimbursement decision-making, HB-HTA tends to be clinician- led to inform the acquisition of new technologies and should therefore be informed by relevant experts. HB-HTA usually has a shortened assessment time, considers budget impact rather than cost-effectiveness and compares current technologies to the proposed new technology, rather than the gold standard *(72)*. HB-HTA recommendations may not be transferable to other settings due to consideration of local conditions, values and priorities in the assessment *(70)*.

See the AdHopHTA handbook and toolkit for hospital-based HTA, as well as HTAi's Interest Group on Hospital-Based HTA *(73-75)*.

4.4 Membership and role of a national HTA committee

In forming an HTA expert advisory committee, countries should decide whether the committee will operate under the auspices of the government or as an independent advisory body. Many countries have independent bodies, such as the French National Authority for Health (Haute Autorité de Santé, or HAS) or the Medical Services Advisory Committee (MSAC) in Australia, that make non-binding recommendations to decision-makers in the Ministry or Department of Health *(76, 77)*. The number of committees must also be decided, which may depend on the resources available. Although some countries have separate HTA committees, aside from regulatory agencies, to consider different types of technologies (pharmaceuticals or other non-pharmaceutical technologies), it is advisable that all HTA committees should report to one decision-making body that is responsible for the formulation of health benefit packages designed to achieve UHC. For example, the National Institute for Health and Care Excellence in the United Kingdom has nine separate committees: quality standards, public health, medical technologies, interventional procedures, diagnostics and indicator advisory committees; antimicrobials and highly specialized technologies evaluation committees; and the technology appraisal committee *(78)*; however, they all sit under the one decision-making body. Depending on the mandate and national legal framework, committees should be independent bodies with non-statutory or statutory authority capable of making non-binding or binding recommendations, respectively.

Some of the roles and responsibilities of a national committee (not necessarily an HTA committee) are described in Table 2. The committee should have defined terms of reference that describe its purpose and function and should meet regularly to ensure relevancy and to maintain skills. The size and range of expertise in an HTA advisory committee 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, the tenure of committee members should be time-limited, with staggered appointments to ensure continuity, and the committee should be supported by a secretariat Membership should include clinical experts from a range of specialties, and experienced experts with knowledge of a particular topic or specialty who can be co-opted to consider specific applications. Other committee members may be social care practitioners, allied health professionals, technical experts such as biomedical engineers, and legal or regulatory experts, HTA academics, especially those with expertise in HTA methodologies, epidemiology and health economics, are important to include in any decision-making body. Consumers should also be represented to ensure the appropriate inclusion of the patient perspective and consideration of patient-relevant outcomes.

See MaHTAS – Health Technology Assessment Section, Ministry of Health Malaysia, was established in August 1995 under the Medical Programme, Ministry of Health (MOH) in keeping with the Ministry's policy of ensuring that safe, effective and cost-effective technology is being used in the MOH facilities *(79)*.

See CONITEC – National Committee for Technology Incorporation, Brazil, established in 2011, which provides for the therapeutic care and the incorporation of health technologies within the Brazilian Public Health System *(80)*.

See Tunisia's INEAS – An Early Model for National HTA Governance in Francophone Africa.

Table 2 *Roles and responsibilities of a national high-level committee, adapted from (81)*

	Roles and responsibilities of a national high-level committee
1	The Ministry of Health, with responsibility for overseeing the development and implementation of essential health technology lists (e. g. medical devices), should secure political commitment and support from other relevant ministries.
2	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.
3	Oversee the work of any sub-committees.
4	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.
5	Ensure that the priority list of medical devices is aligned with the goals of national health plans and caters to the clinical needs of priority health interventions.
6	Forge partnerships with national and international agencies for technical support in the development and implementation of the priority list.
7	Ensure that the priority list is approved, embedded as policy and disseminated widely for implementation.
8	Provide guidance to the implementation committee on the availability of resources for implementation and regulatory structures for the procurement of products and services.
9	Provide adequate resources (funds, equipment, infrastructure, human resources) for the rollout of clinical services and their future expansion.
10	Oversee the work of the implementation committee for the provision of technologies listed.
11	Hold extraordinary sessions for outbreaks and health emergencies with the Ministry of Health.
12	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.
13	Ensure that the priority list is continually updated with relevant technologies, as and when the resources, policies and regulatory framework of the country permit.

5. HTA challenges in developing countries

To reduce health inequalities by increasing access to essential health care and services, many LMICs are moving towards UHC. For many, however, financing and delivering UHC are major challenges. Many non- governmental organizations play a vital role in funding healthcare programs globally Healthcare needs in many LMICs are changing, with some countries still experiencing a significant level of communicable diseases while others have a growing burden of chronic diseases such as cardiovascular and respiratory diseases LMICs must design UHC benefit packages that are appropriate to the burden of disease, represent good value for money and are also socially and politically acceptable. HTA is an appropriate tool to prioritize interventions by consideration of the social, ethical, legal and policy implications of a new health technology *(82)*. The importance of HTA to support UHC in resource-constrained LMICs is well recognized, although there are challenges and barriers to embedding HTA in practice, especially in linking evidence with policy and practice. Affordability, implementation issues, a lack of awareness, access, patient characteristics, lack of health literacy, equity, value for money and a lack of political will, leadership and legislation are some of the barriers that need to be overcome. 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 *(83).* Collaboration with more mature HTA agencies may be beneficial to ensure that processes and policies are not only scientifically robust but account for the realities of each individual healthcare system.

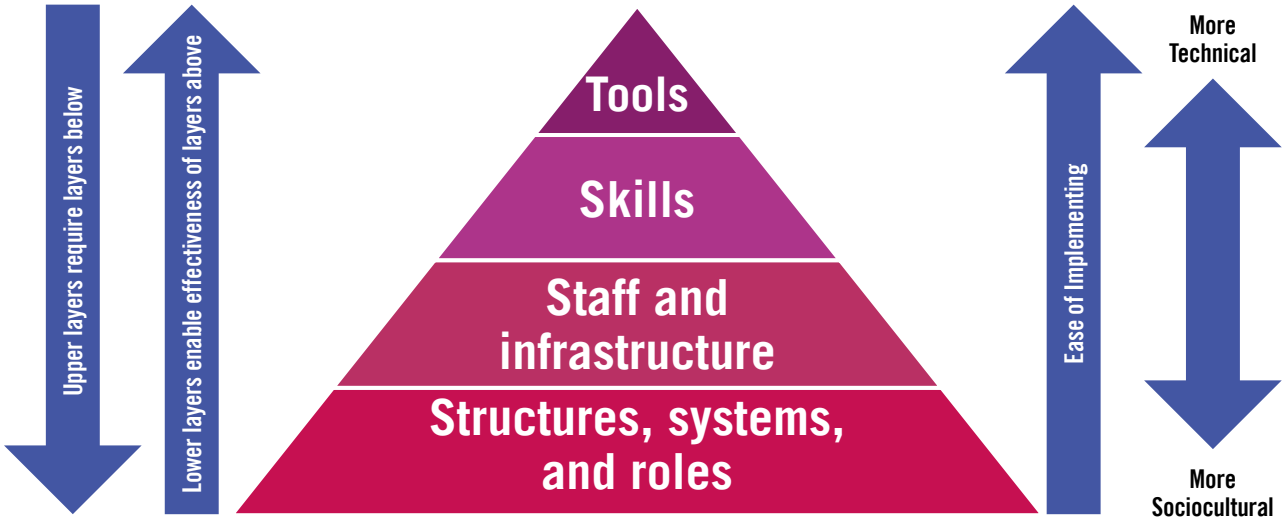
5.1 Capacity building

Priority-setting with HTA ensures the efficient use of limited healthcare resources. As the demand for HTA increases, the gap between supply and demand of HTA capacity also increases *(84)*. Strengthening priority-setting by building HTA capacity at the individual, organizational and environmental levels of the health system is therefore critical for the design of benefits in the drive to achieve UHC *(85)*.

These three levels are interconnected and rely on each other, and networking and collaboration between levels are essential for increasing capacity and transferring HTA knowledge and skills to others. Although organizational and environmental levels are critical for HTA to be embedded into health systems, improving an individual's HTA skills, experience, and knowledge by providing access to information, 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 *(59, 84)*.

Potter and Brough developed a hierarchy of capacity requirements relating to the different levels within the health system and the interactions between them. The four broad areas of capacity need are tools, skills, staff and infrastructure, and structures, systems and roles (Fig 8), where those at the lower level of the pyramid are required to enable the layers above, and the upper layers require the layers below *(86)*.

Fig.8 *Potter and Brough capacity pyramid (86, 87)*



At the organizational level, capacity-building is context-dependent and requires strengthened internal structures, policies and procedures developed through strategies, plans, processes and procedures both within and between organizations *(88, 89)*. Universities may act as centres of capacity-building and HTA knowledge repositories, as local technical HTA expertise is often concentrated amongst researchers and academics. Embedding HTA agencies within universities or hospitals and developing direct relationships between agencies and government health policy-makers could help educate policy-makers and build capacity *(90)*.

At the environmental or system level, the aim of capacity-building is to improve policy frameworks to enable organizations, institutions and agencies at all levels to enhance HTA capacity by addressing economic, political, environmental, legal and social factors in a coherent manner *(88, 89)*. Political, governance and policy structures are required to institutionalize and integrate HTA into health systems and support the decision-making process. Where HTA capacity is lacking, hospital-based biomedical engineers may assist the decision-making process for new medical devices by providing information on the technical characteristics, comparisons with similar technologies, usability, performance, safety and the organizational impact of devices throughout their lifecycle *(10, 34)*. Networking within and among countries is another important element of capacity-building and should be developed, facilitating opportunities to share HTA experiences, resources, and methodological learnings *(91)*.

See Li et al (2017) for an evidence-informed capacity-building framework for setting health priorities in low- and middle-income countries *(91)*. Also, see HTAi's 2022 Asia Policy Forum background paper for a catalogue of (mostly online) HTA-specific capacity-building initiatives *(92)*.

5.2 Data

HTA can lay the foundation for good healthcare decision-making by assessing the evidence on associations between interventions and health outcomes. HTA must be based on the best available evidence based on the best available, preferably local, data. Context-appropriate data are required to enable all stakeholders (policy-makers, clinicians and patients) to make informed healthcare decisions. Data can be used to 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. Furthermore, the data requirements of a country may change over time. Generating, capturing, storing, and analyzing data requires a well-functioning health information system, which may be a limiting factor in many countries, including LMICs, due to costs and a lack of basic technology infrastructure and political will *(93)*. LMICs would benefit from locally generated, high-quality evidence rather than relying on data from clinical trials conducted in non-representative populations from higher-income countries that do not reflect the biological variations (e.g. genetics or body weight) of the country or differences in local clinical practice. WHO Resolution 67. 23 encourages member states to strengthen routine collection of health system data as a necessary step towards achieving UHC *(1)*; however, when local data are not available, policy-makers should agree on the conditions for accepting data from other countries *(94)*.

Several data sources can support health technology assessment (HTA), including national DHIS2 platforms, Health Facility and Workforce Assessments (HHFA) *(95)*, as well as health observatories such as the WHO Global Health Observatory *(96)*, regional platforms like the WHO-AFRO Regional Health Observatory, and the West Africa Health Observatory (WAHO), which provide aggregated data on service availability, human resources, and health outcomes *(97)*.

See the IHME database *(98)*, as well as WHO's Global Health Observatory *(96)* for freely available sources of global data.

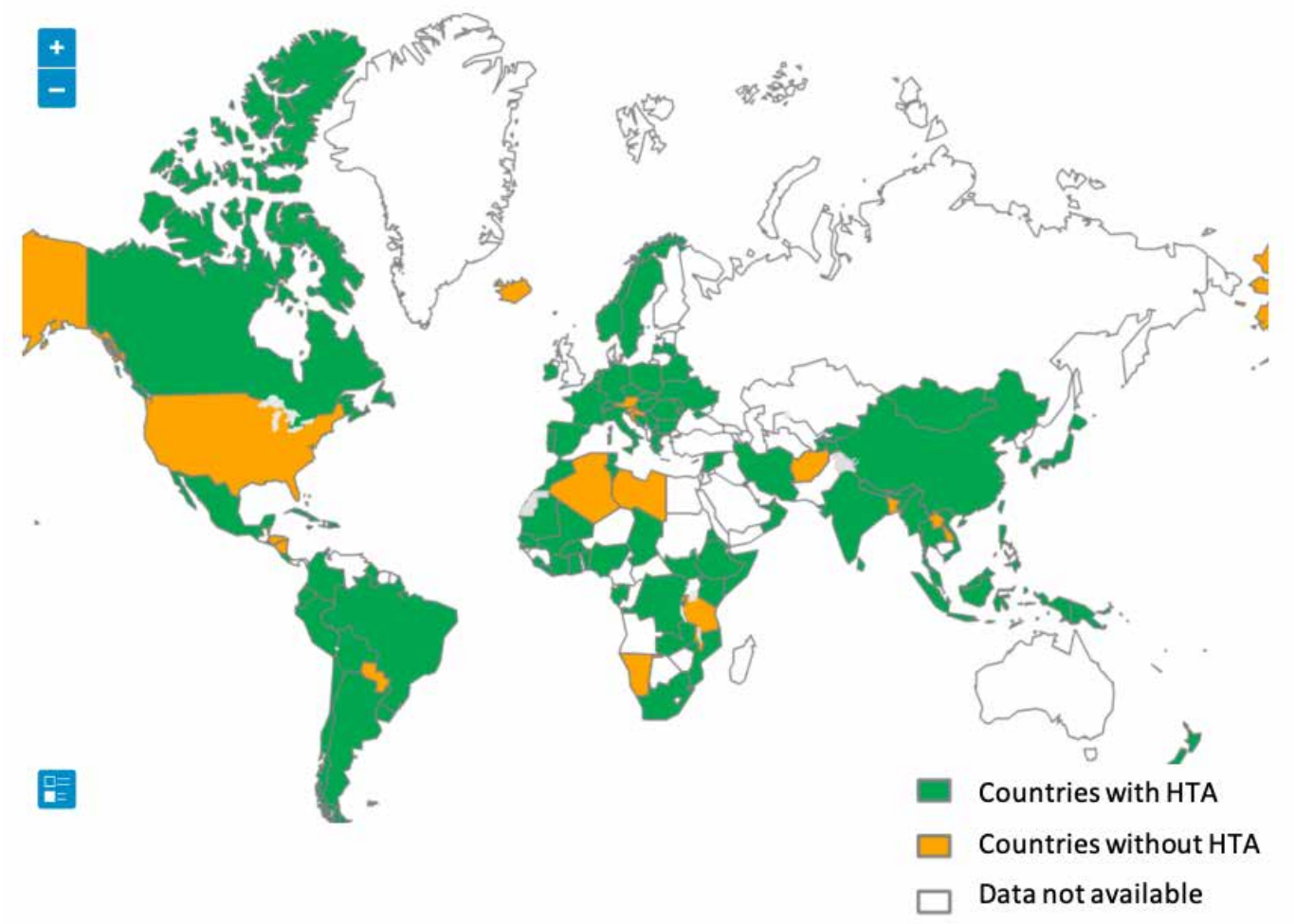
5.3 Case report

WHO helps to improve health outcomes in LMICs by addressing public health challenges, developing health systems, and promoting global health equity. By providing evidence-based guidelines, policies, and protocols, technical support, training, and capacity-building initiatives, WHO assists many LMICs in strengthening their health systems, which is crucial for achieving UHC. As part of this support and guidance, WHO promotes the use of HTA as a key tool for decision-making in healthcare, to achieve effective, equitable, and efficient health systems. The importance of these factors is described in the following case report from the Middle East and North Africa region.

HTA is increasingly recognized as a crucial tool for informed decision-making in healthcare in the Middle East and North Africa (MENA). While HTA implementation is still nascent, the recognition of its value in guiding resource allocation and policy development is increasing. The region's diverse healthcare systems, economic conditions, and policy agendas have led to varying degrees of HTA maturity and adoption (Fig 9). Some countries, such as Egypt and Tunisia, have taken significant steps in establishing a formal HTA body with the creation of the Egyptian Authority for Unified Procurement (UPA) and the National Authority for Assessment and Accreditation in Healthcare (INEAS), respectively. Other countries are developing road maps and strategic plans to strengthen future HTA capacity. Several challenges persist, however, that hinder effective HTA implementation, including lack of capacity, limited availability of local data, and a lack of dedicated infrastructure and adequate governance. In addition, the level of political awareness and buy-in varies across countries. To address these challenges and to ensure the sustainable growth of HTA, investment in capacity-building and collaboration must be made. Strengthening local data infrastructure by establishing patient registries and payer databases is crucial for tailoring HTA to the unique needs and contexts of the MENA region *(99)*.

WHO has been instrumental in supporting HTA development, organizing conferences and providing technical assistance to countries in the MENA region. This support has been complemented by the work of regional networks and scientific societies.

Fig.9 *Global survey of HTA status (24)*



Ghana – Use of HTA for Essential Medicines and Benefit Package Design.

Practice Profile: Ghana's HTA Journey – Linking Evidence to UHC Policy.

6. Stakeholder engagement

Stakeholders are often categorized as the 7Ps:

- patients;
- the public and carers;
- providers or health professionals;
- purchasers;
- payers; policy-makers;
- product makers (industry); and
- principal investigators (academia) *(100)*.

The involvement of multiple stakeholders legitimizes decision-making and may also increase stakeholders' acceptance of HTA decisions *(101)*. Guidance from WHO states that one of the key principles to be considered in the design of benefit packages is public involvement, especially from disadvantaged populations, in priority-setting for UHC *(62)*. In LMICs, stakeholder engagement is crucial for the success of HTA, as involving local communities, healthcare workers, and patient advocacy groups ensures that HTA is inclusive and reflects the needs and preferences of the population. Effective stakeholder engagement legitimizes HTA decisions and improves the implementation and acceptance of health technologies. The inclusion of diverse stakeholders, including local communities and health workers in HTA ensures health policies and interventions meet the

needs and preferences of the population. Stakeholder involvement may depend on the technology being assessed or the stage of the HTA, for example, during topic nomination or prioritization, during the assessment itself, during appraisal of the assessment, or when the results of the assessment are disseminated *(74)*. HTA decision-making bodies must develop materials that are understandable for a variety of stakeholders and that an executive summary written in plain language is made available at the end of the assessment.

There are several ways to engage stakeholders in the HTA process. Many HTA decision-making bodies include a general consumer representative who may not have personal knowledge of the technology being considered or the condition or disease it is designed to address, but who can promote the interests of consumers and ensure accountability and recognition of consumer concerns *(102)*. It is especially important that the views of marginalized patient groups be represented, particularly those with rare diseases where there is limited clinical knowledge and uncertainty around clinical care pathways, the natural history of the disease and long-term clinical outcomes *(101)*. Involving patients early in the HTA process may help to broaden the scope of evaluation *(103)*. Other HTA bodies conduct targeted consultations with stakeholders who may be directly affected or impacted by the introduction of a new technology, including specific patient organizations or caregivers, clinicians or healthcare professional organizations that may use the technology, or the technology to be displaced by the new technology *(76)*. Some countries consult payers (e.g. insurance companies), industry partners or the academic community *(101)*.

Industry associations and health technology developers, such as the medical device industry, are key stakeholders in HTA, although their involvement varies widely. In some jurisdictions, industry submits technologies for evaluation by funders for coverage reimbursement. Industry has had to become more proficient in HTA as applicants must provide the funder with a body of clinical evidence (with or without an economic evaluation) to support submissions. In some LMICs, local suppliers lack the relevant experience and financial capacity to meet these rigorous demands. Therefore, capacity-building for industry should also be considered. In some countries, applicants pay a fee to the government, which is used to fund the assessment by an independent HTA agency. The standard of submissions is considered to improve when a fee is charged, reducing the number of inadequate or poor submissions. Industry often works with HTA agencies, providing unpublished data, and with patient groups. Potential issues with industry stakeholder engagement include some stakeholders having a conflict of interest, leading to bias in the evaluation or requirements for some information to remain commercial-in-confidence *(104)*.

Conflicts of interest and other biases of stakeholders participating in HTA should be transparent and noted.

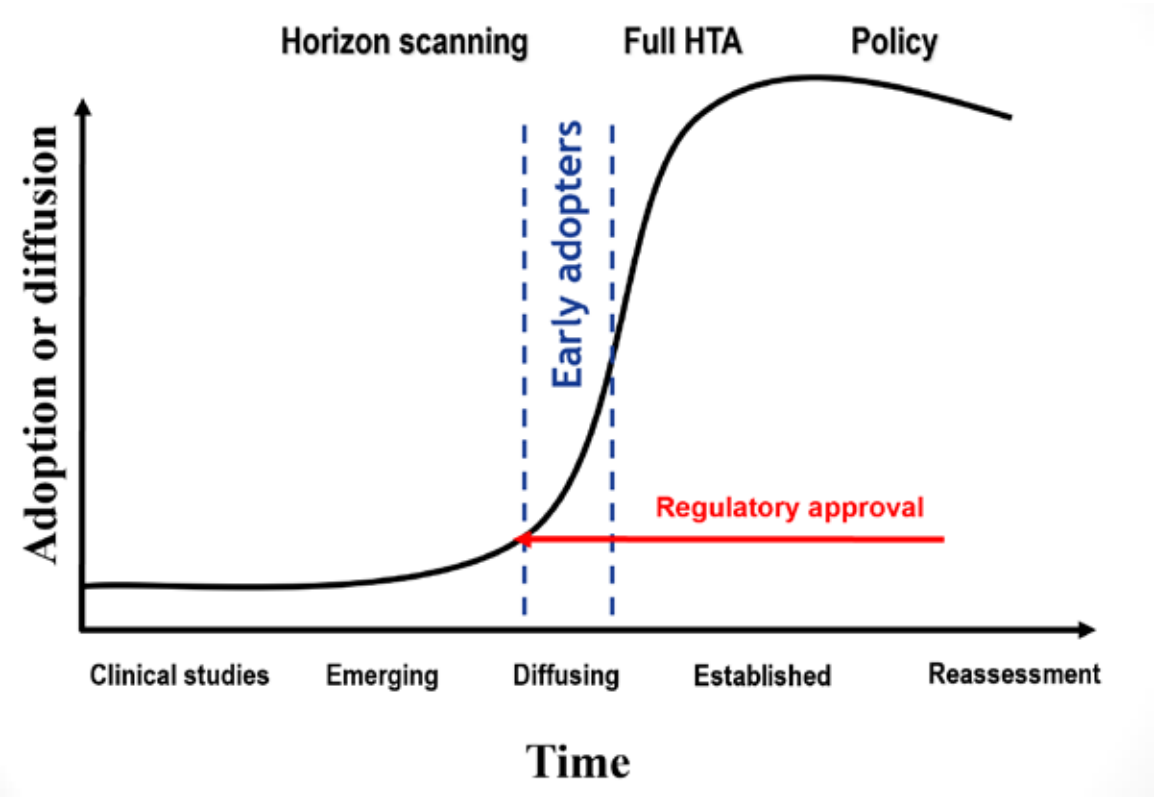
See HTAi's interest groups for patient and citizen involvement in HTA and early career network for resources on patient and social engagement in HTA *(74)*. Also, see WHO's 2021 handbook on social participation for UHC *(105)*.

7.
HTA methods for medical devices

Medical devices are different to other health technologies; therefore, it follows that the assessment of medical devices needs to be different. In LMICs, methodologies that allow for timely and context-sensitive evaluations, such as rapid HTA, adaptive HTA, and the use of RWE, may be particularly useful (see sections 7.3, 7.7 and 8.2). The definition of a medical device can be broad, ranging from items such as a tongue depressor, which may be regarded as a medical device by a regulatory body, to more complex medical devices, such as an implantable heart pump that must undergo regulatory approval in addition to an HTA, prior to introduction into a health system.

HTA can be applied at different points in the lifecycle of a medical device: during pre-market regulatory approval, during early assessment when a device, identified by horizon scanning, is beginning to diffuse into a health system, full HTA, with or without an economic and financial impact analysis, once the device has become established in health care practice, for procurement, and finally through to reassessment and potential disinvestment when superseded by a new device (Fig 10). Regardless of the point in the lifecycle of the medical device that HTA is being conducted, it is important that relevant experts and legislation are consulted.

Fig.10 *The life cycle approach: movement of a medical device through the health system*



Drummond et al (2008) proposed fifteen key principles for the assessment of any health technology, including medical devices, that should be used to guide HTA for resource allocation, with the aim of improving the interface between those conducting HTA and health policy-makers. These principles describe the structure of an HTA programme, HTA methods and the conduct and use of HTA in decision-making (Table 3) *(33)*.

See TRS Selection of Essential in vitro diagnostics for WHO model lists that includes review of evidence, references, clinical guidelines to add, edit or delist in vitro diagnostic tests *(31)*. See selection of WHO list of priority medical devices for management of cardiovascular diseases and diabetes *(29)*.

Table 3 *Key principles for the conduct of HTA for resource allocation decisions (33, 106)*

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

See the HTA Toolbox for Emerging Settings for guidance, resources and tools at each stage of the HTA process *(107)*.

7.1 Full HTA – medical devices are different

There are many similarities in conducting HTA for all health technologies. The following reasons summarize why devices, and therefore HTA for medical devices, are fundamentally different to pharmaceuticals and require special consideration:

- medical devices can have multiple therapeutic, instrumental, or diagnostic uses *(108, 109)*;
- the intellectual property associated with medical devices is less well protected than patents on new pharmaceuticals *(8)*;
- 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 *(33)*;
- 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 *(8, 110)*;
- some medical devices are combination products, combining a device with a pharmaceutical, requiring HTA of both components;
- the quality and level of evidence generated in clinical studies for new devices may be less robust due to factors such as a lack of appropriate comparators, randomization and blinding *(108, 110)*, which may not be feasible due to the nature of the technology;
- some medical devices require additional infrastructure or form part of a complex clinical pathway;
- 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 *(8)* ;
- many medical devices are characterized by short product lifecycles (1-3 years), with incremental innovations rapidly superseding older-generation devices. Some of these iterations may not result in significant changes in efficacy, effectiveness, safety or cost, and therefore further HTA may not be required; however, some may result in HTA becoming outdated;
- clinical investigations of new devices aim to meet regulatory approval requirements, building on existing evidence *(109)*; and lastly,
- when considering the introduction of medical technologies that emit ionizing radiation, radiation protection aspects and regulatory bodies should consider the 'Bonn Call for Action', and decision-makers should consult with radiation protection aspects and radiation protection authorities and medical physicists among others, during the HTA process.

Several agencies have published step-by-step guidelines for conducting assessments of non-pharmaceutical health technologies including therapeutic and diagnostic medical devices: the National Institute for Health and Care Excellence (NICE) *(111)*; the Australian Medical Services Advisory Committee (MSAC) *(112)*; and Singapore's Agency for Care Effectiveness (ACE) *(113)*.

7.2 Horizon scanning

Horizon scanning (HS) is a risk management tool used to reduce uncertainty and future-proof health systems by identifying new health technologies early and allowing health systems to prepare for the effective adoption of innovation. Proactively identifying technologies early in the life cycle, sometimes prior to regulatory or market approval, HS provides intelligence on potentially disruptive or high-cost health technologies, which assists policy-makers in procurement and health system planning *(114, 115)*. HS can also identify new uses for existing technologies, as well as reassessment/disinvestment targets. By responding to demand signaling, HS can also actively identify the needs and 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 relationships with stakeholders be developed *(116)*.

See WHO's Global Health Foresight function for resources to assist Member States in developing horizon-scanning capabilities and to accelerate the gains from emerging technologies that are likely to lead to health, social, and economic benefits. WHO Global Health Foresight not only publishes global horizon scans of innovative technologies that could solve global health challenges, but it also offers training and guidance for the integration of Foresight approaches into practice *(117)*. Also, see the EuroScan toolkit for guidance on how to develop an HS capability *(118)*. Sharing HS intelligence and resources, including identified technologies and assessments, through collaborative networks such as the International Horizon Scanning Initiative for medical devices *(116)* or International HealthTechScan (i-HTS) *(119)* would be especially beneficial for developing countries by decreasing duplication, reducing costs and increasing efficiency.

7.3 Rapid HTA

Rapid HTA is used to address specific health issues by providing a less comprehensive overview of the evidence compared to a systematic HTA but still enabling policy-makers to make an informed decision in a short time frame. Rapid HTA can be used to great effect during emergencies, such as during the COVID-19 pandemic, when timely advice and urgent decision-making were required in a short timeframe (sometimes within 5-10 days). Rapid HTA uses a modified standard systematic review methodology, including considering fewer domains and searching fewer databases. There is; however, a trade-off between speed and rigor, with the results of rapid HTA associated with greater uncertainty *(120-123)*. Rapid HTA may be suitable for the assessment of some medical devices, especially those with short life cycles that frequently undergo incremental iterations, with old device versions rapidly replaced by newer generation devices. Rapid HTA may also be suitable for LMICs with healthcare systems that have limited capacity and resources to conduct a full HTA.

Resources on rapid HTA methodologies include Cochrane Rapid Reviews Methods Group *(124)*, and papers by King et al (2022) *(120)* and Smela et al (2023) *(122)*, in addition to guidance developed by WHO *(109)* and Spanish language guidance developed by the Spanish Ministry of Health *(125)*.

7.4 Living HTA

Unlike traditional HTA, living HTA is a responsive and dynamic process that supports the life cycle approach to assessment *(126).* Living HTA incorporates new safety or effectiveness evidence, and comparators or information on costs as it becomes available, and in so doing, addresses uncertainties in the decision-making process *(127)*. Living HTA can be useful for assessing medical devices where refinements in a class of technology result in a cumulative beneficial impact and incremental iterations result in rapid replacement by newer generation devices with very short life cycles *(128)*. By using 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 *(128)*. Living HTA, however, may not be suitable for LMICs with limited resources as it is resource-intensive, requiring all aspects of the HTA to be updated, including literature searches, evidence synthesis and economic modelling *(127, 129)*.

See Heron et al (2023) and Thokala et al (2023) for guidance on how to conduct living HTA *(127, 129).*

7.5 Multiple-criteria decision analysis

Traditional HTA criteria may not always capture the value or full range of benefits of new health technologies *(130, 131).* Multiple-criteria decision analysis (MCDA) can overcome these limitations by applying *explicit* criteria that address localized 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 *(132).* Criteria may include traditional health outcomes in addition to those that describe the patient experience, such as the degree of invasiveness or tolerability, ease of implementation (e. g. training or resources required, or portability) and health system affordability *(28, 133)*. Criteria specific to medical devices could include technical characteristics, supply reliability, capacity for implementation and even innovation, as well as criteria such as clinical benefit, safety, burden of disease and clinical need. MCDA informs stakeholder preferences relevant to the local context and may expedite early access to beneficial technologies. It should be noted; however, that there are significant challenges associated with this approach, especially around uncertainties in the weighting and scoring of the criteria used and the potential for a lack of consensus among participants. A full HTA should follow with the development of additional evidence *(122)*.

See Howard et al (2019) for guidance on how to develop an MCDA framework for non-pharmaceutical health technology funding decision-making *(132)*.

See the section methodology MCDA for selection of Priority medical devices for cancer *(28)*.

Defining priority medical devices for cancer management: a WHO initiative, The Lancet oncology, *(133)*.

7.6 Strategies for developing HTA

Many LMICs lack national HTA guidelines to guide the development and implementation of HTA, and 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. National health economic guidelines are crucial for standardizing HTA processes; however, LMICs can adopt information from WHO model lists of essential in vitro diagnostics or Priority medical devices as a reference, and international HTA frameworks, and adapt them to the local context. To achieve this, a situational analysis to understand the local health system and economic environment should be conducted. The needs analysis enables stakeholders, including government, academia, industry, and civil society, to establish a multi-disciplinary committee to oversee the development and implementation of HTA guidelines. These guidelines should be piloted in select regions or institutions to ensure that they are appropriate and to allow for further refinement.

7.7 Adaptive HTA

Adaptive HTA uses HTA from other settings and adapts it to the local setting and context by incorporating local data such as patient characteristics and ethnicity, burden of disease, healthcare costs, health system structure and local clinical expertise. Adaptive HTA practices in LMICs may be facilitated by establishing partnerships or links with international HTA agencies or networks. Adaptive HTA may be useful in the short term, especially for well-studied technologies, to provide the basis for local capacity-building and more sustainable HTA structures dedicated to local priorities *(134, 135)*. Adaptive HTA may not be as useful for medical devices as newer generation devices with short life cycles are rapidly replaced, resulting in HTA that may be outdated before adaptation occurs. Differences between high-income countries and LMICs in costs, resources and other domains make HTA conclusions difficult to generalize or transfer, but with minimal local capacity, conclusions can be modified to fit the local context *(134)*. HTA agencies developing their capacity should seek to adapt relevant evidence from countries in their own regions with similar health systems.

See the 2011 EUnetHTA HTA Adaption Toolkit for guidance on how to adapt HTA *(136)*, and also papers by Nemzoff et al describing adaptive HTA in LMICs *(135, 137)*. Medical device HTAs can be accessed from reference countries such as the United Kingdom's NICE *(138)*, Australia's MSAC *(139)* and Canada's CADTH *(140)* or the database hosted by INAHTA *(2)*.

8. Special HTA topics

The development and potential introduction of new, transformative health technologies present challenges to both regulators and policy-makers, including the cost of, or access to, a technology. A major challenge is the continual need for HTA methodologies to be reviewed and refined to assess the safety, effectiveness and, if possible, the cost-effectiveness of new classes of health technologies. The following section describes topical issues that may be of great benefit to LMICs, and whilst not strictly medical devices, they do; however, require special consideration.

8.1 HTA and innovation

WHO's Health Innovation Group defines innovation as 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 " (141).* How innovation is defined, valued and captured in HTA and the healthcare priority-setting process is inconsistent, and HTA is often viewed as a barrier or gatekeeper, rather than a facilitator, of patient access to innovative technologies. Assessing the extent of innovation of medical devices may be difficult due to the potential for incremental iterations of devices and differences in the quality and level of the available evidence *(142)*.

Criteria defining what constitutes innovation should be developed, which can then 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 *(110, 143).* The criteria may be patient-orientated, such as unmet clinical need, added therapeutic value, severity of disease or public health benefit, or technology-specific, including implementation considerations such as infrastructure, financial and organizational factors. Whether the new technology is disruptive in the health system (i.e. if the technology is new or provides an incremental improvement in health outcomes) should also be a criteria considered *(143, 144).*

See the NICE's criteria for defining innovation in the decision-making process *(143, 145),* and also Ciani et al (2016) *(110)* who describe the dimensions of innovation relating specifically to non-pharmaceutical health technologies such as medical devices.

8.2 Real-world data and real-world evidence

When assessments of health technologies are associated with a degree of uncertainty or evidence is lacking, regulators and health policy-makers may use real-world evidence (RWE) and real-world data (RWD) to inform decision-making, in order to ensure timely patient access. RWD generated from routine healthcare can be collected from various sources apart from clinical trial settings, including electronic health records, administrative data, product or disease registries, claims or billing data, or patient-generated data including patient-reported outcomes and data from digital health technologies such as wearables and mobile devices. RWE is derived from the analysis of RWD, providing clinical evidence and insights around the usage and benefits or risks of a health technology in a real-world setting throughout the life cycle of the technology, beyond the strict inclusion and exclusion criteria of clinical trials. This is particularly important for racial or ethnic groups who are often under-represented in clinical trials. Data for RWE studies can be collected prospectively or retrospectively. Although RWE could bridge gaps in data availability in LMICs, the resources to collect it (i. e. electronic health records) and the information technology infrastructure required to analyze the large volumes of RWD may be lacking in some of these countries *(146, 147)*. The increasing use of mobile health technologies, as seen in Africa, could, however, facilitate the collection of RWD and improve health service delivery.

RWE may be particularly useful in the HTA of medical devices for all the reasons that make the assessment of devices more difficult than that of pharmaceuticals: lower quality clinical evidence due to a lack of randomization, lack of blinding and comparators, and frequent iterations or predicate devices *(148, 149)*. Methodological challenges must be overcome before RWE can be utilized effectively in HTA and healthcare decision-making *(147)*.

See the FDA's Examples of Real-World Evidence (RWE) used in Medical Device Regulatory Decisions *(150)*, the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR) guide on RWE *(151)*, the NICE real-world evidence framework *(152)* and the REALISE project's RWD decision-making guidance *(154).* In addition, see HTAi's Interest Group on RWE and AI *(74)*.

8.3 Digital health technologies

WHO global strategy and framework on digital health issued in 2021 *(154)* is based on the following precepts:

> "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."

Digital health technologies (DHTs) include a range of health system, health professional and patient tools that can be used in low-, middle- and high-income settings. DHTs considered to be medical devices include digital diagnostics used to detect and characterize disease or measure disease status, response, progression or recurrence, and digital therapeutics used to treat or alleviate disease by delivering a medical intervention with a therapeutic effect *(155)*. Access to digital health services requires investment in infrastructure (i.e. Internet access, data protection, cybersecurity), workforce capacity, governance and regulation to support the changes necessary to digitize health systems and deliver services *(154)*. 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 solutions to more people, especially those in rural and remote areas *(156)*. 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 *(157, 158)*. It should be noted that many LMICs may have limited access to the Internet; however, many of these countries have readily available mobile data (3G, 4G and 5G).

There is currently no agreement on a standard definition of what constitutes a DHT or on a framework for their assessment. For many of the same reasons that make medical devices difficult to assess in comparison to pharmaceuticals (frequent iterations and short lifecycles of DHTs, a lack of RCTs and relevant comparators), traditional HTA frameworks are inadequate for the evaluation of DHTs, which may be a barrier to their integration into clinical practice. Health and wellness apps are a rapidly growing market and few are subject to medical device regulation. For those that are not regulated, the European Commission has issued guidance for manufacturers to label health apps to help consumers, patients, carers, healthcare professionals, authorities, and health insurers make informed decisions on their adoption and use in a care pathway. Although not an assessment framework, the Label2Enable initiative requires app manufacturers to provide evidence to support the healthcare claims of the app, giving users assurance of its quality and reliability *(159)*.

See the United Kingdom of Great Britain and Northern Ireland's NICE framework for the evaluation of DHTs intended for medical, health or wellness, or health system efficiency purposes *(160)*. Also, see Germany's framework for the provision and reimbursement of digital health applications (DiGA) *(161, 162)*.

8.4 Artificial intelligence

In 2021, WHO issued guidance on the use of artificial intelligence (AI) in health *(163)*. Although AI promises to improve the delivery of healthcare and medicine worldwide, there are ethical challenges and risks associated with its use, and the guidance summarizes six consensus principles to ensure that AI benefits all countries:

- protecting human autonomy;
- promoting human well-being and safety and the public interest;
- ensuring transparency, explainability and intelligibility;
- fostering responsibility and accountability;
- ensuring inclusiveness and equity; and
- promoting AI that is responsive and sustainable *(163).*

AI is an umbrella term used to describe various technologies, including machine learning, natural language processing, robotics and neural networks. These technologies have been described as learning systems that are capable of mimicking human intelligence. Data is collected, and algorithms "learn" from experience in real-time to recognize patterns, solve problems, and make decisions *(164)*. AI can be used to deliver healthcare (e.g. telehealth chatbots), perform administrative tasks in the health system (e.g. coding and electronic health records) and conduct aspects of HTA (e.g. study selection, data extraction and cost-effectiveness modelling *(165)*). AI can also be used to collect and analyze RWD. AI may be useful in LMICs with limited human capacity to conduct aspects of HTA such as data extraction. Although AI could revolutionize healthcare, there is much uncertainty and concern about its technical limitations, its governance and regulation, and issues such as ethics, data privacy and security *(166)*.

In the United Kingdom, the National Institute for Health and Care Research Innovation Observatory (NIHRIO) uses AI tools and methods to conduct HS and technology guidance on behalf of NICE *(167).* Also, see Reddy et al (2021) for a framework to monitor and evaluate AI-based applications in healthcare *(168).* This publication stems from the international collaboration, Translational Evaluation of Healthcare AI (TEHAI) which has several freely accessible resources *(169).* In addition, HTAi has an Interest Group on RWE and AI *(74)*.

8.5 Additive manufacturing (3D-printing)

Three-dimensional (3D) printing is a "disruptive technology" with the potential to provide low-cost customized medical devices for various health applications, including surgical and dental implants; prostheses *(170-172)* ; surgical instruments; medical supplies such as personal protective equipment; educational, training and surgical planning models *(173-175)* and laboratory equipment, including microscopes *(176)*. With recent advances in materials, speed, resolution, accuracy, reliability, and repeatability, 3D printing has the potential to transform healthcare and clinical practice *(173)*, and, in so doing, reduce the burden of disability and death in resource-limited healthcare settings. In addition, enabling the "in-house" manufacture of medical products in LMICs may avoid the high cost of purchasing commercial products and address many of the issues in logistics and the manufacturing supply chain, which were exacerbated by COVID-19.

Although 3D-printed medical products are generally regulated within medical device frameworks, HTA evaluation of these products has proved problematic as there is no HTA framework available. The customized nature of 3D printing is not conducive to high-quality clinical studies, and therefore to traditional HTA evaluation of clinical efficacy and cost-effectiveness *(173)*. Evaluation of 3D-printed products, especially their safety, including the biocompatibility of materials used in the manufacturing process, can be conducted for individual products *(175)*.

See the United States FDA guidance for recommendations on the testing and characterization of 3D-printed devices *(177)*.

8.6 Emergency preparedness

Emergencies due to natural disasters, technological or societal hazards can significantly affect people and health systems at all levels of society. According to WHO *(178)*, the elements of preparedness for these emergencies should include:

- operational readiness: the ability to respond to emergencies in a timely, effective and efficient manner by establishing, strengthening and maintaining health infrastructure; and
- health system resilience: including investment in the health workforce, maintenance of health facilities to ensure reliable supplies of medicines and equipment, disease surveillance systems and laboratory services.

Emergency preparedness frameworks should address local and national outbreaks of infectious diseases that have the potential to cross borders, such as the SARS-CoV-2 viral outbreak. The COVID-19 pandemic, however, highlighted deficiencies and inequities in global health system preparedness. Pandemics are defined as large-scale outbreaks of infectious disease that can greatly increase morbidity and mortality over a wide geographical area and cause significant economic, social and political disruption, disproportionately affecting LMICs. The risk of pandemics has increased due to the growth in global travel and integration, urbanization, changes in land use and greater exploitation of the natural environment HTA can be used to inform policy preparing for and mitigating against the impact of pandemics *(179)*.

During the COVID-19 emergency, policy-makers were under pressure from the public and healthcare workers to provide rapid solutions and provisionally approve public health measures and health technologies based on limited safety and efficacy evidence and limited assessment of clinical or cost-effectiveness *(180)*. At the height of the pandemic, normal transparent HTA processes were sidelined by emergency use authorizations by regulators, and value for money was bypassed by direct price negotiation and procurement, which significantly impacted health budgets *(181)*. The challenges and opportunities presented by COVID-19 called for new methods of healthcare delivery (virtual care and artificial intelligence) and shifted the priority from technology-driven demand to public health *(182)*. In response to these complex demands, existing HTA methodologies were adapted, with greater use of RWE, rapid or ultra-rapid reviews (speed versus rigor) and rolling or living HTA updates. By adapting, HTA provided timely advice to policy-makers, laying the foundation for value-based healthcare assessment and prioritizing high-value over low-value care *(183)*. HTA was also used to combat misinformation on mainstream and social media throughout the pandemic. The COVID-19 pandemic increased international HTA collaboration, especially in data sharing and the development of guidelines, and was critical in connecting science, innovation, technology, and health policy. It also, however, highlighted the lack of HTA capacity, especially in LMICs.

See the collaborative project by the British Medical Journal, BMJ Rapid Recommendations *(184)*, that updated and disseminated freely available COVID guidelines, the EUnetHTA repository for rapid reviews on COVID-19 diagnostics *(185)* and therapeutics *(186)* and COVID-END, the COVID-19 Evidence Network to support decision-making that summarized public health and social responses, clinical management, health-system organization and economic evidence from low-, middle- and high-income countries *(187)*. Also see Chapter 17 of the *World Bank's Disease Control Priorities: Improving Health and Reducing Poverty on Pandemics: Risks, Impacts, and Mitigation (179)*.

9. International collaboration in HTA

After the declaration of a worldwide COVID-19 pandemic in March 2020, the World Health Assembly passed a resolution in May 2020, requesting Member States to:

> "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" *(188).*

The resolution also emphasized the importance of solidarity, resource redistribution, and collective action *(189)*. The reasons for collaboration in health are clear. Firstly, collective health risks are difficult to manage independently; secondly, sharing of knowledge and experience accelerates understanding and facilitates progress; and lastly, agreement on standards will establish good practices and strengthen a shared understanding and mutual trust. There has been an international move to ensure that agencies share work programmes to improve efficiencies and outputs in an economically constrained environment. Facilitating collaboration and networking among countries is an important element of HTA capacity-building, providing opportunities to share HTA experiences, knowledge, resources, and methodological learnings *(91)*. The sharing of work programmes and expertise among agencies and countries to support a common HTA approach and methodology would be beneficial to many LMICs while maintaining their independence for local decision-making and implementation. An example of this is the European Union Health Technology Assessment Regulation (EU-HTAR), which requires common assessments among member states but allows local decision-making on implementation. Regional collaboration should be encouraged, as should private-sector partnerships, with appropriate safeguards against any conflicts of interest *(190)*.

LMICs could leverage some of the HTA agencies and bodies whose remit is to encourage and provide opportunities for collaboration, facilitate the global exchange of information and ensure the development of HTA best practice. Some of these are described below.

9.1 Health Technology Assessment international (HTAi)

Heath Technology Assessment international (HTAi) provides an open platform for global collaboration to improve health outcomes worldwide. HTAi represents over 80 organizations and thousands of individuals from 65 countries It is the scientific and professional global society for leaders in HTA, academic and industry researchers, patients, caregivers, patient organizations, HTA agencies, decision-makers, providers, and health professionals It is a non-state actor in official relations with the WHO.

The mission of HTAi is to promote the development, communication, understanding, and use of HTA around the world. It has four areas of focus *(191):*

1. Grow the presence of HTAi globally through membership, with an emphasis on LMICs to expand the global presence of HTA.
2. Expand HTA by sharing knowledge and disseminating information through partnerships. Explore new and existing partnerships and collaborate with other international, evidence-based health organizations on priority topics and projects, including education (such as webinars and workshops), competency development and outreach to emerging HTA markets.
3. Advance scientific knowledge and support capacity development HTAi develops environmental, organizational, 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 centres and academia, and forming partnerships with governmental and nongovernmental HTA bodies to develop the necessary resources. HTAi advocates for political support in the development of HTA agencies and organizations in countries in which HTA is nascent and works with established HTA communities to increase their capacity to use HTA methodologies as technologies and regulatory requirements change.
4. Ensure continued financial stability and good governance.

HTAi serves as a hub for various collaborations, including:

- the annual international meeting, a major opportunity 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), which provide opportunities for open discussion among leading HTA practitioners and industry in areas of shared strategic interest *(192)*;
- interest groups *(74)*, which provide an opportunity for HTAi members to network, exchange information, and collaborate on projects of mutual interest throughout the year. Interest groups include: 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; 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 HTA agencies. The network connects HTA agencies to each other to share knowledge and exchange information. It also serves as a forum for the identification and promotion of other interests of HTA agencies. INAHTA members play an important role in health systems by providing evidence to support decision-making about new health technologies, including their reimbursement, implementation, optimization, and/or disinvestment. INAHTA member agencies support health system decision-making in 31 countries, connecting agencies to cooperate, collaborate, and share and disseminate evidence-based information, advice, recommendations, and tools *(193)*.

INAHTA's goal is to develop opportunities for learning and exchange among members in areas of identified need by offering:

- training and opportunities for knowledge exchange in high-priority areas including the impact of HTA and its evaluation, approaches to assessing highly innovative technologies, methodological best practices and challenges in conducting rapid assessments; and
- webinars for developing agencies to pose questions and discuss issues with leaders from established agencies.

The main communication forum of INAHTA is the Internet Online activities include:

- the INAHTA Listserv, an email list connecting member agencies, allowing members to exchange information on current and planned HTA projects;
- the International HTA database, which provides a single point of access for INAHTA members and non-members to ongoing and published HTAs undertaken by HTA organizations *(2)*; and
- INAHTA checklists to foster a consistent and transparent approach to HTA.

9.3 Global network of WHO Collaborating Centres

WHO collaborating centres are part of an international collaborative network of institutions, such as units in ministries of health, research institutes, universities and academies, which are designated by the WHO Director-General to conduct activities to support WHO programmes and provide strategic support for WHO's mandated work and program objectives. They also develop and strengthen institutional capacity in countries and regions. By 2024, there were over 800 WHO collaborating centres in over 80 Member States, working with WHO in diverse areas such as nursing, occupational health, communicable diseases, nutrition, mental health, chronic diseases and health technologies *(194)*.

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

- Departamento de Evaluación de Tecnologías Sanitarias (ETS) y Economía de la Salud, Instituto de Efectividad Clinica y Sanitaria (IECS), Argentina *(195)*;
- Fudan University Shanghai – WHO Collaborating Centre for Health Technology Assessment and Management in China;
- Division of Healthcare Technology & Innovations - WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy in India;

- National Center for Health Technology Excellence (CENETEC), Ministry of Health – WHO Collaborating Centre in Health Technology in Mexico;
- Norwegian Centre for Telemedicine (NST), University Hospital of North Norway – WHO Collaborating Centre for Telemedicine in Norway.

9.4 international HealthTechScan (i-HTS)

EuroScan was established in the 1990s as a network of agencies to create a European system for early identification of emerging health technologies. The horizon scanning network, i-HTS was established in 2016, to assume the secretariat functions and membership of EuroScan, which remains the legal entity. Renaming the network to i-HTS more accurately reflects the growing global membership. The aim of the network is to share information, methodologies and tools for the early identification of new and innovative health technologies *(119)*.

9.5 European Union Health Technology Assessment Regulation 2021/2282 (EU-HTAR)

The European Network for Health Technology Assessment (EUnetHTA), financed by the European Commission, was founded in 2006 to harmonize HTA methodologies, coordinate and increase collaboration and reduce duplication of effort in Europe. Its 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 policy-making *(196, 197)*. In 2018, the European Union adopted Regulation 2021/2282, which effectively replaced the voluntary EUnetHTA collaboration of national authorities with the EU HTAR The EU HTAR, which requires mandatory uptake of joint assessments, was legislated in January 2022 and came into effect in January 2025, when the totality of its implementing acts were published *(198)*. The EU HTAR has established a coordination group, composed of representatives of the Member States, which jointly developed methodological and procedural guidance for the work of subgroups tasked with conducting technical HTA work in four key areas:

- Joint Clinical Assessments (JCA) of medicines and high-risk medical devices and in vitro medical devices (IVDs);
- Joint Scientific Consultations (JSC), where health technology developers (i e pharmaceutical industry and device manufacturers) can seek advice from HTA agencies and regulators;
- horizon scanning for the identification of emerging health technologies at an early stage to assist the health systems of Member States to prepare for them; and
- development of methodological and procedural guidance and continuing voluntary cooperation in other aspects of HTA *(197, 199).*

In particular, the implementing acts, their accompanying guidance and templates for JSC and JCA and for medical devices and IVDs will guide the HTA process for these products in all the 27 European Union countries as well as Iceland, Liechtenstein and Norway countries from 2025. Many countries applying for EU accession are also aligning their HTA systems, structures, methods and processes to the EU HTAR, so this is driving strong methodological development in this field in the countries of the WHO European Region.

Many of the tools developed by EUnetHTA remain freely available on their website *(200)* and all the HTA guidance documents are available on the EU HTAR site.

9.6 RedETSA and initiatives in the Americas

Larger Latin American countries such as Argentina, Brazil and Colombia have the capacity to generate evidence and HTA reports; however, many countries in the region rely on evidence from other countries to produce HTA reports and guide healthcare decision-making. The transferability of these data to Latin American populations; however, may be limited. In addition, rather than evaluating technologies one by one, Latin American countries may need to take a more holistic approach to HTA by evaluating health programmes for chronic diseases in a bid to reduce mortality and morbidity on a population level, in so doing, reducing overall healthcare costs *(82)*. Building HTA capacity in the region is required to meet these needs.

The Red de Evaluación de Tecnologías en Salud de las Américas (RedETSA) network was launched in 2011 to promote and strengthen HTA and support decision-making in the Americas region by adopting common methodologies and capacity-building measures *(34, 201)*. The Pan American Health Organization (PAHO) have been actively promoting HTA in the region since the early 1980s and in 2012, passed Resolution CSP28 R9, which encourages Member States to establish decision-making processes that include HTA and to become active members of RedETSA *(202, 203).* As of 2024, the RedETSA network has 21 member countries represented by 42 institutions, comprising health ministries and institutions, HTA agencies, regulatory authorities, WHO Collaborating Centers, PAHO and other education and research institutions in the region *(201)*.

RedETSA provides its members with freely accessible resources and access to an online assessment database (BRISA). It also hosts four working groups: adaptation of HTA reports, equity, the use of RWE, and medical devices, It also conducted a systematic review on HTA methodologies for medical devices that is in the process of being published. Significant progress has been made in the use of HTA in RedETSA member countries compared to non-member countries, demonstrating the value of this collaborative network *(202)*. Individual RedETSA members, such as the Brazilian Network for Health Technology Assessment, also provide HTA resources, guidance and working groups. RedETSA is an active participant in the HTAi Latin American Policy Forum, which was established in 2016 to bring together policy-makers who make coverage and reimbursement decisions, HTA agencies and biomedical companies. Forum participants discuss a chosen topic selected by participants in an environment of trust and openness *(192, 204-206).*

See RedETSA for a repository of HTA resources and webinars *(201)*.

9.7 HTAsiaLink

The HTAsiaLink Network was established in 2011 as a collaborative research network for countries in Asia to share their experiences, lessons and resources in HTA, share technical and methodological knowledge, and build mutual trust, respect, and open communication. In a region in which there are many LMICs, the network strongly advocates for strengthening HTA capacity in countries where HTA is not fully recognized for policy-making and priority-setting. The mission of HTAsiaLink is to:

- strengthen individual and institutional capacity in HTA research and integration of HTA evidence into policy decisions for the public good;
- avoid duplication, especially in reviewing the safety and clinical efficacy of vaccines and medicines for HTA, facilitate learning, reduce wasteful resource use, and enhance efficiency at the organizational level through collaborative activities among the network; and
- fulfil the need for transferring and sharing HTA-related lessons among countries and organizations in Asia and beyond *(207)*.

Key activities of HTAsiaLink include events for sharing information, such as public forums, study visits among member countries, and an annual conference that provides a forum for young researchers to present their work in a safe environment. HTAsiaLink also encourages members to conduct policy-relevant joint research projects, such as the two ongoing projects, 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 *(207)* and Developing a New Region-Specific Preference-Based Measure in East and Southeast Asia *(208)*.

References

1. Resolution WHA67.23: Health intervention and technology assessment in support of universal health coverage (online). Geneva, Switzerland: World Health Organization; 2014. https://iris.who.int/bitstream/handle/10665/162870/A67_R23-en.pdf?sequence=1&isAllowed=y.
2. Welcome to the international HTA database (online). International Network of Agencies for Health Technology Assessment; 2024. https://database.inahta.org/.
3. Dictionary (online). Oxford, United Kingdom: Oxford University Press; 2024. https://languages.oup.com/google-dictionary-en/.
4. WHO. WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017.
5. Glossary for Health Technology Lifecycle by EuroScan (online). i-HTS; 2024. https://glossary.i-hts.org/index.php?title=Early_HTA.
6. O'Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: A milestone in international collaboration. Int J Technol Assess Health Care. 2020;36(3):187-90. doi:10.1017/s0266462320000215.
7. IMDRF. Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. International Medical Device Regulators Forum; 2024.
8. Ming J, He Y, Yang Y, Hu M, Zhao X, Liu J, et al. Health technology assessment of medical devices: current landscape, challenges, and a way forward. Cost Eff Resour Alloc. 2022;20(1):54. doi:10.1186/s12962-022-00389-6.
9. Banta D. The development of health technology assessment. Health Policy. 2003;63(2):121-32. doi:https://doi.org/10.1016/S0168-8510(02)00059-3.
10. Polisena J, Castaldo R, Ciani O, Federici C, Borsci S, Ritrovato M, et al. HEALTH TECHNOLOGY ASSESSMENT METHODS GUIDELINES FOR MEDICAL DEVICES: HOW CAN WE ADDRESS THE GAPS? THE INTERNATIONAL FEDERATION OF MEDICAL AND BIOLOGICAL ENGINEERING PERSPECTIVE. Int J Technol Assess Health Care. 2018;34(3):276-89. doi:10.1017/s0266462318000314.
11. Ciani O, Wilcher B, Blankart CR, Hatz M, Rupel VP, Erker RS, et al. Health technology assessment of medical devices: a survey of non-European union agencies. Int J Technol Assess Health Care. 2015;31(3):154-65. doi:10.1017/s0266462315000185.
12. Resolution WHA60.29: Health technologies (online). Geneva, Switzerland: World Health Organization; 2007. https://iris.who.int/bitstream/handle/10665/22609/A60_R29-en.pdf?sequence=1&isAllowed=y.
13. Resolution WHA67.20: Regulatory system strengthening for medical products (online). Geneva, Switzerland: World Health Organization; 2014. https://iris.who.int/bitstream/handle/10665/162864/A67_R20-en.pdf?sequence=1&isAllowed=y.
14. Resolution WHA76.5: Strengthening diagnostics capacity (online). Geneva, Switzerland: World Health Organization; 2023. https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R5-en.pdf.
15. Bertram M, Dhaene G, Tan-Torres Edejer T. Institutionalizing health technology assessment mechanisms: a how to guide. Geneva: World Health Organization; 2021.
16. Resolution 75/315: Scope, modalities, format and organization of the high-level meeting on universal health coverage (online). Geneva: United Nations; 2021. https://documents.un.org/doc/undoc/gen/n21/227/55/pdf/n2122755.pdf.
17. Resolution 78/4: Political declaration of the high-level meeting on universal health coverage (online). Geneva: United Nations; 2023. https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/07/FINAL-draft-UHC-Political-Declaration.pdf.
18. WHO. Global atlas of medical devices 2017. Geneva: World Health Organization; 2017.
19. WHO. Global atlas of medical devices 2022. Geneva: World Health Organization; 2022.
20. EB145/3: Standardization of medical devices nomenclature (online). Geneva, Switzerland: World Health Organization; 2019. https://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf?ua=1.

21. MEDEVIS (online). Geneva, Switzerland: World Health Organization; 2025. https://medevis.who-healthtechnologies.org/.

22. Resolution WHA75.25: Standardization of medical devices nomenclature (online). Geneva, Switzerland: World Health Organization; 2022. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(25)-en.pdf.

23. WHO. 2015 Global Survey on Health Technology Assessment by National Authorities. Geneva: World Health Organization; 2015.

24. Health Technology Assessment Survey 2020/2021 (online). Geneva, Switzerland: World Health Organization; 2021. https://www.who.int/data/stories/health-technology-assessment-a-visual-summary.

25. Health Technology Assessment and Health Benefit Package Survey 2020/2021 (online). Geneva, Switzerland: World Health Organization; 2021. https://www.who.int/teams/health-financing-and-economics/economic-analysis/health-technology-assessment-and-benefit-package-design/survey-homepage.

26. Prioritizing medical devices (online). Geneva, Switzerland: World Health Organization; 2024. https://www.who.int/activities/prioritizing-medical-devices.

27. WHO. Priority medical devices list for the COVID-19 response and associated technical specifications: interim guidance. Geneva: World Health Organization; 2020.

28. WHO. WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017.

29. WHO. WHO list of priority medical devices for management of cardiovascular diseases and diabetes. Geneva: World Health Organization; 2021.

30. WHO. Interagency list of medical devices for essential interventions for reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2016.

31. WHO. The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022 (‍ including the fourth WHO model list of essential in vitro diagnostics)‍ . Geneva: World Health Organization; 2023.

32. WHO Model List of Essential In Vitro Diagnostics (online). Geneva, Switzerland: World Health Organization; 2025. https://edl.who-healthtechnologies.org/.

33. Drummond M. Health Technology Assessment and Its Interface with Regulation, Policy and Management. In: del Llano-Señarís JE, Campillo-Artero C, editors. Health Technology Assessment and Health Policy Today: A Multifaceted View of their Unstable Crossroads. Cham: Springer International Publishing; 2015. p. 3-14.

34. WHO. Human resources for medical devices, the role of biomedical engineers. Geneva: World Health Organization; 2017.

35. McCarthy JP, Scott R, Blackett P, Amoore J, Hegarty FJ. Health Technology Management. Clinical Engineering: Elsevier Ltd; 2014. p. 43-57.

36. Aronson JK, Heneghan C, Ferner RE. Medical Devices: Definition, Classification, and Regulatory Implications. Drug Saf. 2020;43(2):83-93. doi:10.1007/s40264-019-00878-3.

37. French-Mowat E, Burnett J. How are medical devices regulated in the European Union? J R Soc Med. 2012;105 Suppl 1(Suppl 1):S22-8. doi:10.1258/jrsm.2012.120036.

38. Chen YJ, Chiou CM, Huang YW, Tu PW, Lee YC, Chien CH. A Comparative Study of Medical Device Regulations:: US, Europe, Canada, and Taiwan. Ther Innov Regul Sci. 2018;52(1):62-9. doi:10.1177/2168479017716712.

39. IMDRF. IMDRF Strategic Plan 2021 - 2025. International Medical Device Regulators Forum; 2020.

40. Hogervorst MA, Møllebæk M, Vreman RA, Lu TA, Wang J, De Bruin ML, et al. Perspectives on how to build bridges between regulation, health technology assessment and clinical guideline development: a qualitative focus group study with European experts. BMJ Open. 2023;13(8):e072309. doi:10.1136/bmjopen-2023-072309.

41. WHO. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices, Annex 3. Geneva: World Health Organization; 2023.

42. WHO. Needs assessment for medical devices. Geneva: World Health Organization; 2011.

43. Rahmani K, Karimi S, Raeisi AR, Rezayatmand R. Comparative Study of Medical Equipment Procurement in Selected Countries. Med J Islam Repub Iran. 2022;36:40. doi:10.47176/mjiri.36.40.

44. Cangelosi M, Chahar A, Eggington S. Evolving Use of Health Technology Assessment in Medical Device Procurement-Global Systematic Review: An ISPOR Special Interest Group Report. Value Health. 2023;26(11):1581-9. doi:10.1016/j.jval.2023.06.005.

45. Tarricone R, Torbica A, Ferré F, Drummond M. Generating appropriate clinical data for value assessment of medical devices: what role does regulation play? Expert Rev Pharmacoecon Outcomes Res. 2014;14(5):707-18. doi:10.1586/14737167.2014.950233.

46. WHO. Procurement process resource guide. Geneva: World Health Organization; 2011.

47. Pecchia L, Pallikarakis N, Magjarevic R, Iadanza E. Health Technology Assessment and Biomedical Engineering: Global trends, gaps and opportunities. Med Eng Phys. 2019;72:19-26. doi:10.1016/j.medengphy.2019.08.008.

48. Health Technology Assessment Division (online). International Federation of Medical and Biological Engineering; 2023. https://ifmbe.org/organisation-structure/divisions/htad/.

49. Health system governance (online). Geneva: World Health Organization; 2024. https://www.who.int/health-topics/health-systems-governance#tab=tab_1.

50. WHO. Strengthening Health System Governance: Better policies, stronger performance. European Observatory on Health Systems and Policies; 2016.

51. Uneke CJ, Ezeoha AE, Uro-Chukwu HC. Promoting evidence-informed policymaking through capacity enhancement in implementation research for health researchers and policymakers in Nigeria: A cross-sectional study. J Educ Health Promot. 2018;7:28. doi:10.4103/jehp.jehp_103_17.

52. Green A, Bennett S. Sound choices: enhancing capacity for evidence-informed health policy. Geneva; 2007.

53. Segone M. Country-led monitoring and evaluation systems: Better evidence, better policies, better development results. New York: United Nations International Children's Emergency Fund; 2009.

54. SDG 3: Ensure healthy lives and promote well-being for all at all ages (online). Geneva: United Nations' Department of Economic and Social Affairs; 2024. https://sdgs.un.org/goals/goal3#targets_and_indicators.

55. Universal health coverage (online). Geneva, Switzerland: World Health Organization; 2024. https://www.who.int/health-topics/universal-health-coverage#tab=tab_1.

56. Savedoff WD, de Ferranti D, Smith AL, Fan V. Political and economic aspects of the transition to universal health coverage. Lancet. 2012;380(9845):924-32. doi:10.1016/s0140-6736(12)61083-6.

57. Watkins D, Jamison DT, Mills A, Atun R, Danforth K, Glassman A, et al. Universal Health Coverage and Essential Packages of Care. In: Jamison DT, Gelband H, Horton S, Jha P, Laxminarayan R, Mock CNN, R., editors. Disease Control Priorities: Improving Health and Reducing Poverty. 9. Third ed. Washington, DC: World Bank; 2018.

58. Mataria A, El-Saharty S, Mazumdar S, Abubakar A, Hajjeh R, Siddiqi S. Universal Health Coverage and Health System Strengthening. In: Siddiqi S, Mataria A, Rouleau K, Iqbal M, editors. Making Health Systems Work in Low and Middle Income Countries: Textbook for Public Health Practitioners. Cambridge: Cambridge University Press; 2022. p. 34-50.

59. Uzochukwu BSC, Okeke C, O'Brien N, Ruiz F, Sombie I, Hollingworth S. Health technology assessment and priority setting for universal health coverage: a qualitative study of stakeholders' capacity, needs, policy areas of demand and perspectives in Nigeria. Global Health. 2020;16(1):58. doi:10.1186/s12992-020-00583-2.

60. Iqbal M, Sameen H, Abu-Zaineh M, Mataria A, Siddiqi S. Decision-Making Tools for Informed Decisions by Health Policymakers and Managers. In: Siddiqi S, Mataria A, Rouleau KD, Iqbal M, editors. Making Health Systems Work in Low and Middle Income Countries: Textbook for Public Health Practitioners. Cambridge: Cambridge University Press; 2022. p. 186-207.

61. Chootipongchaivat S, Tritasavit N, Luz A, Teerawattananon Y, Tantivess S. Factors conducive to the development of health technology assessment in Asia: Impacts and policy options. Geneva, Switzerland: World Health Organization; 2015.

62. WHO Technical Advisory Group on Health Benefit Packages. Principles of health benefit packages. Geneva: World Health Organization 2021.

63. Chalkidou K, Glassman A, Marten R, Vega J, Teerawattananon Y, Tritasavit N, et al. Priority-setting for achieving universal health coverage. Bull World Health Organ. 2016;94(6):462-7. doi:10.2471/blt.15.155721.

64. Glassman A, Giedion U, Sakuma Y, Smith PC. Defining a Health Benefits Package: What Are the Necessary Processes? Health Syst Reform. 2016;2(1):39-50. doi:10.1080/23288604.2016.1124171.

65. CFGD. What's in, what's out : designing benefits for universal health coverage. Washington DC, USA: Center For Global Development; 2017.

66. Kim T, Sharma M, Teerawattananon Y, Oh C, Ong L, Hangoma P, et al. Addressing Challenges in Health Technology Assessment Institutionalization for Furtherance of Universal Health Coverage Through South-South Knowledge Exchange: Lessons From Bhutan, Kenya, Thailand, and Zambia. Value Health Reg Issues. 2021;24:187-92. doi:10.1016/j.vhri.2020.12.011.

67. Mbau R, Vassall A, Gilson L, Barasa E. Factors influencing institutionalization of health technology assessment in Kenya. BMC Health Serv Res. 2023;23(1):681. doi:10.1186/s12913-023-09673-4.

68. Suharlim C, Kumar R, Salim J, Mehra M, Gilmartin C, Amaris Caruso A, et al. Exploring facilitators and barriers to introducing health technology assessment: a systematic review. Int J Technol Assess Health Care. 2021;38(1):e5. doi:10.1017/s0266462321000623.

69. O'Rourke B, Werkö SS, Merlin T, Huang LY, Schuller T. The 'Top 10' Challenges for Health Technology Assessment: INAHTA Viewpoint. Int J Technol Assess Health Care. 2020;36(1):1-4. doi:10.1017/s0266462319000825.

70. Gagnon MP. Hospital-based health technology assessment: developments to date. Pharmacoeconomics. 2014;32(9):819-24. doi:10.1007/s40273-014-0185-3.

71. Sampietro-Colom L, Lach K, Pasternack I, Wasserfallen JB, Cicchetti A, Marchetti M, et al. GUIDING PRINCIPLES FOR GOOD PRACTICES IN HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT UNITS. Int J Technol Assess Health Care. 2015;31(6):457-65. doi:10.1017/s0266462315000732.

72. Sampietro-Colom L, Martin J. Hospital-Based Health Technology Assessment: The Next Frontier. In: Sampietro-Colom L, Martin J, editors. Hospital-Based Health Technology Assessment The Next Frontier for Health Technology Assessment: Springer; 2016. p. 3-11.

73. Welcome to the toolkit for hospital-based Health Technology Assessment (HB-HTA) (online). The AdHopHTA Project; 2015. https://www.adhophta.eu/toolkit/.

74. HTAi Interest Groups (online). Alberta, Canada: Health Technology Assessment international; 2022. https://htai.org/interest-groups/.

75. Sampietro-Colom L, Lach K, Cicchetti A, Kidholm K, Pasternack I, Fure B, et al. The AdHopHTA handbook: a handbook of hospital-based Health Technology Assessment (HB-HTA). The AdHopHTA Project; 2015.

76. Health technology assessments (online). Canberra, Australia: Australian Government, Department of Health and Aged Care; 2022. https://www.health.gov.au/topics/health-technologies-and-digital-health/health-technology-assessments.

77. Rochaix L, Xerri B. National Authority for Health: France. Issue Brief (Commonw Fund). 2009;58:1-9.

78. Meetings in public - Advisory Committee (online). National Institute for Health and Care Excellence 2024.

79. MaHTAS – Health Technology Assessment Section, Ministry of Health Malaysia (online). International Network of Agencies for Health Technology Assessment; 2025. https://www.inahta.org/members/mahtas/.

80. CONITEC – National Committee for Technology Incorporation (online). International Network of Agencies for Health Technology Assessment; 2025. https://www.inahta.org/members/conitec/.

81. WHO. 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. Geneva: World Health Organization 2021.

82. Simões Corrêa Galendi J, Caramori CA, Lemmen C, Müller D, Stock S. Expectations for the Development of Health Technology Assessment in Brazil. Int J Environ Res Public Health. 2021;18(22). doi:10.3390/ijerph182211912.

83. Babigumira JB, Jenny AM, Bartlein R, Stergachis A, Garrison LP. Health technology assessment in low- and middle-income countries: a landscape assessment. Journal of Pharmaceutical Health Services Research. 2016;7(1):37-42. doi:10.1111/jphs.12120.

84. Sharma M, Teerawattananon Y, Dabak SV, Isaranuwatchai W, Pearce F, Pilasant S, et al. A landscape analysis of health technology assessment capacity in the Association of South-East Asian Nations region. Health Res Policy Syst. 2021;19(1):19. doi:10.1186/s12961-020-00647-0.

85. Liu G, Wu EQ, Ahn J, Kamae I, Xie J, Yang H. The Development of Health Technology Assessment in Asia: Current Status and Future Trends. Value Health Reg Issues. 2020;21:39-44. doi:10.1016/j.vhri.2019.08.472.

86. Potter C, Brough R. Systemic capacity building: a hierarchy of needs. Health Policy and Planning. 2004;19(5):336-45. doi:10.1093/heapol/czh038.

87. Weber MB, Baumann AA, Rakhra A, Akwanalo C, Gladys Amaning Adjei K, Andesia J, et al. Global implementation research capacity building to address cardiovascular disease: An assessment of efforts in eight countries. PLOS Glob Public Health. 2023;3(9):e0002237. doi:10.1371/journal.pgph.0002237.

88. United Nations. Capacity development. United Nations Development Group; 2018.

89. Zamfir I. Understanding capacity-building/capacity development. A core concept of development policy. European Parliament; 2017.

90. Pichler F, Oortwijn W, Ruether A, Trowman R. Defining capacity building in the context of HTA: a proposal by the HTAi Scientific Development and Capacity Building Committee. Int J Technol Assess Health Care. 2019;35(5):362-6. doi:10.1017/s0266462319000631.

91. Li R, Ruiz F, Culyer AJ, Chalkidou K, Hofman KJ. Evidence-informed capacity building for setting health priorities in low- and middle-income countries: A framework and recommendations for further research. F1000Res. 2017;6:231. doi:10.12688/f1000research.10966.1.

92. HTA capacity building in Asia: towards one goal. nt J Technol Assess Health Care. 2023 Aug 15;39(1):e56. doi: 10.1017/S0266462323000405.

93. Mundy L, Trowman R, Kearney B. OVERCOMING THE BARRIERS TO ACHIEVING UNIVERSAL HEALTH CARE IN THE ASIAN REGION. Int J Technol Assess Health Care. 2018;34(4):352-9. doi:10.1017/s0266462318000417.

94. Lou J, Kc S, Toh KY, Dabak S, Adler A, Ahn J, et al. Real-world data for health technology assessment for reimbursement decisions in Asia: current landscape and a way forward. Int J Technol Assess Health Care. 2020;36(5):474-80. doi:10.1017/s0266462320000628.

95. Harmonized Health Facility Assessment (HHFA) (online). Geneva, Switzerland: World Health Organization; 2025. https://www.who.int/data/data-collection-tools/harmonized-health-facility-assessment/introduction.

96. The Global Health Observatory (online). Geneva, Switzerland: World Health Organization; 2024. https://www.who.int/data/gho.

97. The integrated African Health Observatory (online). Geneva, Switzerland: World Health Organization; 2025. https://aho.afro.who.int/.

98. Data sources (online). Seattle, USA: Institute for Health Metrics and Evaluation, University of Washington; 2024. https://www.healthdata.org/data-tools-practices/data-sources.

99. Fasseeh A, Karam R, Jameleddine M, George M, Kristensen FB, Al-Rabayah AA, et al. Implementation of Health Technology Assessment in the Middle East and North Africa: Comparison Between the Current and Preferred Status. Front Pharmacol. 2020;11:15. doi:10.3389/fphar.2020.00015.

100. Baltussen R, Jansen M, Oortwijn W. Evidence-Informed Deliberative Processes for Legitimate Health Benefit Package Design - Part I: Conceptual Framework. Int J Health Policy Manag. 2022;11(10):2319-26. doi:10.34172/ijhpm.2021.158.

101. CADTH. Narrative Review of Multi-Stakeholder Engagement in Health Technology Assessment. Canada: Canada's Drug Agency; 2022.

102. Guidelines for Consumer Representatives (online). Consumers Health Forum of Australia; 2022. https://www.chf.org.au.

103. Wale JL, Thomas S, Hamerlijnck D, Hollander R. Patients and public are important stakeholders in health technology assessment but the level of involvement is low - a call to action. Res Involv Engagem. 2021;7(1):1. doi:10.1186/s40900-020-00248-9.

104. Pichon-Riviere A, Soto N, Augustovski F, Garcia-Marti S, Sampietro-Colom L. Involvement of relevant stakeholders in health technology assessment development. Health Technology Assessment international; 2017.

105. WHO. Voice, agency, empowerment - handbook on social participation for universal health coverage. Geneva: World Health Organization; 2021.

106. Drummond MF, Schwartz JS, Jönsson B, Luce BR, Neumann PJ, Siebert U, et al. Key principles for the improved conduct of health technology assessments for resource allocation decisions. Int J Technol Assess Health Care. 2008;24(3):244-58; discussion 362-8. doi:10.1017/s0266462308080343.

107. Advance HTA. Health Technology Assessment Toolbox for Emerging Settings. Best Practices and Recommendations. Granada: ADVANCE-HTA; 2015.

108. Drummond M, Griffin A, Tarricone R. Economic evaluation for devices and drugs--same or different? Value Health. 2009;12(4):402-4. doi:10.1111/j.1524-4733.2008.00476_1.x.

109. Taylor RS, Iglesias CP. Assessing the clinical and cost-effectiveness of medical devices and drugs: are they that different? Value Health. 2009;12(4):404-6. doi:10.1111/j.1524-4733.2008.00476_2.x.

110. Ciani O, Armeni P, Boscolo PR, Cavazza M, Jommi C, Tarricone R. De innovatione: The concept of innovation for medical technologies and its implications for healthcare policy-making. Health Policy and Technology. 2016;5(1):47-64. doi:https://doi.org/10.1016/j.hlpt.2015.10.005.

111. NICE health technology evaluations: the manual (online). Manchester, United Kingdom: National Institute for Health and Care Excellence; 2023. https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation.

112. Guidelines for preparing assessments for the MSAC (online). Canberra, Australia: Australian Government; 2021. https://www.msac.gov.au/sites/default/files/2024-10/guidelines-for-preparing-assessments-for-msac.pdf.

113. Medical Technologies Evaluation Methods and Process Guide (online). Republic of Singapore: Ministry of Health; 2022. https://www.ace-hta.gov.sg/docs/default-source/process-methods/ace-med-tech-evaluation-methods-and-process-guide-(mar-2022).pdf.

114. Mundy L. Platelet-rich plasma: a case study for the identification of disinvestment opportunities using horizon scanning. Aust Health Rev. 2017;41(1):33-7. doi:10.1071/ah15075.

115. Packer C, Gutierrez-Ibarluzea I, Simpson S. The evolution of early awareness and alert methods and systems. Int J Technol Assess Health Care. 2012;28(3):199-200. doi:10.1017/s0266462312000426.

116. Ormstad SS, Wild C, Erdös J, Moulton K. Mapping horizon scanning systems for medical devices: similarities, differences, and lessons learned. Int J Technol Assess Health Care. 2023;39(1):e69. doi:10.1017/s0266462323002684.

117. WHO Foresight: Monitoring emerging technologies and building futures-thinking (online). Geneva: World Health Organization; 2023. https://www.who.int/activities/who-foresight---monitoring-emerging-technologies-and-building-futures-thinking.

118. EuroScan International Network. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham; 2014.

119. Innovative health technologies - be part of the network (online). EuroScan international network; 2024. https://ihts.org/.

120. King VJ, Stevens A, Nussbaumer-Streit B, Kamel C, Garritty C. Paper 2: Performing rapid reviews. Syst Rev. 2022;11(1):151. doi:10.1186/s13643-022-02011-5.

121. Langlois EV, Straus SE, Antony J, King VJ, Tricco AC. Using rapid reviews to strengthen health policy and systems and progress towards universal health coverage. BMJ Glob Health. 2019;4(1):e001178. doi:10.1136/bmjgh-2018-001178.

122. Smela B, Toumi M, Świerk K, Francois C, Biernikiewicz M, Clay E, et al. Rapid literature review: definition and methodology. J Mark Access Health Policy. 2023;11(1):2241234. doi:10.1080/20016689.2023.2241234.

123. Wagner G, Nussbaumer-Streit B, Greimel J, Ciapponi A, Gartlehner G. Trading certainty for speed - how much uncertainty are decisionmakers and guideline developers willing to accept when using rapid reviews: an international survey. BMC Med Res Methodol. 2017;17(1):121. doi:10.1186/s12874-017-0406-5.

124. Garritty C, Hamel C, Trivella M, Gartlehner G, Nussbaumer-Streit B, Devane D, et al. Updated recommendations for the Cochrane rapid review methods guidance for rapid reviews of effectiveness. Bmj. 2024;384:e076335. doi:10.1136/bmj-2023-076335.

125. Puñal-Riobóo J, Baños Álvarez E, Varela Lema L, Castillo Muñoz MA, Atienza Merino G, Ubago Pérez R, et al. Guideline for the Elaboration and Adaptation of Rapid Health Technology Assessment Reports. Madrid, Spain: Ministry of Health; 2016.

126. Kirwin E, Round J, Bond K, McCabe C. A Conceptual Framework for Life-Cycle Health Technology Assessment. Value Health. 2022;25(7):1116-23. doi:10.1016/j.jval.2021.11.1373.

127. Thokala P, Srivastava T, Smith R, Ren S, Whittington MD, Elvidge J, et al. Living Health Technology Assessment: Issues, Challenges and Opportunities. Pharmacoeconomics. 2023;41(3):227-37. doi:10.1007/s40273-022-01229-4.

128. Sarri G, Forsythe A, Elvidge J, Dawoud D. Living health technology assessments: how close to living reality? BMJ Evid Based Med. 2023;28(6):369-71. doi:10.1136/bmjebm-2022-112152.

129. Heron L, Buitrago-Garcia D, Ipekci AM, Baumann R, Imeri H, Salanti G, et al. How to update a living systematic review and keep it alive during a pandemic: a practical guide. Syst Rev. 2023;12(1):156. doi:10.1186/s13643-023-02325-y.

130. Gongora-Salazar P, Rocks S, Fahr P, Rivero-Arias O, Tsiachristas A. The Use of Multicriteria Decision Analysis to Support Decision Making in Healthcare: An Updated Systematic Literature Review. Value Health. 2023;26(5):780-90. doi:10.1016/j.jval.2022.11.007.

131. Wahlster P, Goetghebeur M, Kriza C, Niederländer C, Kolominsky-Rabas P. Balancing costs and benefits at different stages of medical innovation: a systematic review of Multi-criteria decision analysis (MCDA). BMC Health Serv Res. 2015;15:262. doi:10.1186/s12913-015-0930-0.

132. Howard S, Scott IA, Ju H, McQueen L, Scuffham PA. Multicriteria decision analysis (MCDA) for health technology assessment: the Queensland Health experience. Aust Health Rev. 2019;43(5):591-9. doi:10.1071/ah18042.

133. Velazquez Berumen A, Jimenez Moyao G, Rodriguez NM, Ilbawi AM, Migliore A, Shulman LN. Defining priority medical devices for cancer management: a WHO initiative. Lancet Oncol. 2018;19(12):e709-e19. doi:10.1016/s1470-2045(18)30658-2.

134. Heupink LF, Peacocke EF, Sæterdal I, Chola L, Frønsdal K. Considerations for transferability of health technology assessments: a scoping review of tools, methods, and practices. Int J Technol Assess Health Care. 2022;38(1):e78. doi:10.1017/s026646232200321x.

135. Nemzoff C, Ruiz F, Chalkidou K, Mehndiratta A, Guinness L, Cluzeau F, et al. Adaptive health technology assessment to facilitate priority setting in low- and middle-income countries. BMJ Glob Health. 2021;6(4). doi:10.1136/bmjgh-2020-004549.

136. EUnetHTA. E U n e t H T A HTA Adaption Toolkit European Network for Health Technology Assessment; 2011.

137. Nemzoff C, Shah HA, Heupink LF, Regan L, Ghosh S, Pincombe M, et al. Adaptive Health Technology Assessment: A Scoping Review of Methods. Value Health. 2023;26(10):1549-57. doi:10.1016/j.jval.2023.05.017.

138. Guidance, NICE advice and quality standards (online). National Institute for Health and Care Excellence; 2024. https://www.nice.org.uk/guidance/published?ngt=Medical%20technologies%20guidance&ndt=Guidance.

139. Medical Services Advisory Committee Application Page (online). Canberra, Australia: Australian Government Department of Health and Aged Care; 2024. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/application-page.

140. Canadian Agency for Drugs and Technologies in Health (online). Ottawa, Canada: Canadian Agency for Drugs and Technologies in Health; 2024. https://www.cadth.ca/.

141. Syeed MS, Poudel N, Ngorsuraches S, Veettil SK, Chaiyakunapruk N. Characterizing attributes of innovation of technologies for healthcare: a systematic review. J Med Econ. 2022;25(1):1158-66. doi:10.1080/13696998.2022.2140591.

142. de Solà-Morales O, Cunningham D, Flume M, Overton PM, Shalet N, Capri S. DEFINING INNOVATION WITH RESPECT TO NEW MEDICINES: A SYSTEMATIC REVIEW FROM A PAYER PERSPECTIVE. Int J Technol Assess Health Care. 2018;34(3):224-40. doi:10.1017/s0266462318000259.

143. Rejon-Parrilla JC, Espin J, Epstein D. How innovation can be defined, evaluated and rewarded in health technology assessment. Health Econ Rev. 2022;12(1):1. doi:10.1186/s13561-021-00342-y.

144. Syeed MS, Poudel N, Ngorsuraches S, Diaz J, Chaiyakunapruk N. Measurement and valuation of the attributes of innovation of healthcare technologies: a systematic review. J Med Econ. 2022;25(1):1176-84. doi:10.1080/13696998.2022.2143170.

145. Charlton V, Rid A. Innovation as a value in healthcare priority-setting: the UK experience. Social Justice Research. 2019;32(2):208-38. doi:10.1007/s11211-019-00333-9.

146. Dang A. Real-World Evidence: A Primer. Pharmaceut Med. 2023;37(1):25-36. doi:doi:10.1007/s40290-022-00456-6.

147. Zisis K, Pavi E, Geitona M, Athanasakis K. Real-world data: a comprehensive literature review on the barriers, challenges, and opportunities associated with their inclusion in the health technology assessment process. J Pharm Pharm Sci. 2024;27:12302. doi:10.3389/jpps.2024.12302.

148. Pongiglione B, Torbica A. How real can we get in generating real world evidence? Exploring the opportunities of routinely collected administrative data for evaluation of medical devices. Health Econ. 2022;31 Suppl 1(Suppl 1):25-43. doi:10.1002/hec.4562.

149. Pongiglione B, Torbica A, Blommestein H, de Groot S, Ciani O, Walker S, et al. Do existing real-world data sources generate suitable evidence for the HTA of medical devices in Europe? Mapping and critical appraisal. Int J Technol Assess Health Care. 2021;37(1):e62. doi:10.1017/s0266462321000301.

150. FDA. Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions. Maryland, USA: US Food and Drug Administration; 2019.

151. Real-World Evidence (online). New Jersey, USA: The Professional Society for Health Economics and Outcomes Research (ISPOR); 2024. https://www.ispor.org/strategic-initiatives/real-world-evidence.

152. NICE. NICE real-world evidence framework. Manchester, United Kingdom: National Institute for Health and Care Excellence; 2022.

153. Kc S, Lin LW, Bayani DBS, Zemlyanska Y, Adler A, Ahn J, et al. What, Where, and How to Collect Real-World Data and Generate Real-World Evidence to Support Drug Reimbursement Decision-Making in Asia: A reflection Into the Past and A Way Forward. Int J Health Policy Manag. 2023;12:6858. doi:10.34172/ijhpm.2023.6858.

154. WHO. Global strategy on digital health 2020-2025. Geneva: World Health Organization; 2021.

155. Digital Health Technology Ecosystem Categorization (online). 2023. https://dtxalliance.org/wp-content/uploads/2023/06/DTA_FS_DHT-Ecosystem-Categorization.pdf.

156. van de Vijver S, Tensen P, Asiki G, Requena-Méndez A, Heidenrijk M, Stronks K, et al. Digital health for all: How digital health could reduce inequality and increase universal health coverage. Digit Health. 2023;9:20552076231185434. doi:10.1177/20552076231185434.

157. Digital Health (online). Treasure Island, Florida, USA: StatPearls Publishing; 2023. https://www.ncbi.nlm.nih.gov/books/NBK470260/.

158. Sharma A, Harrington RA, McClellan MB, Turakhia MP, Eapen ZJ, Steinhubl S, et al. Using Digital Health Technology to Better Generate Evidence and Deliver Evidence-Based Care. J Am Coll Cardiol. 2018;71(23):2680-90. doi:10.1016/j.jacc.2018.03.523.

159. About CEN-ISO/TS 82304-2 (online). 2021. https://label2enable.eu/about-cen-iso-ts-82304-2.

160. NICE. Evidence standards framework for digital health technologies. Manchester, United Kingdom: National Institute for Health and Care Excellence; 2023.

161. Gensorowsky D, Witte J, Batram M, Greiner W. Market access and value-based pricing of digital health applications in Germany. Cost Eff Resour Alloc. 2022;20(1):25. doi:10.1186/s12962-022-00359-y.

162. Mantovani A, Leopaldi C, Nighswander CM, Di Bidino R. Access and reimbursement pathways for digital health solutions and in vitro diagnostic devices: Current scenario and challenges. Front Med Technol. 2023;5:1101476. doi:10.3389/fmedt.2023.1101476.

163. WHO. Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: World Health Organization; 2021.

164. Davenport T, Kalakota R. The potential for artificial intelligence in healthcare. Future Healthc J. 2019;6(2):94-8. doi:10.7861/futurehosp.6-2-94.

165. Kaltenthaler E, Cooper K, Pandor A, Martyn-St James M, Chatters R, Wong R. The use of rapid review methods in health technology assessments: 3 case studies. BMC Med Res Methodol. 2016;16(1):108. doi:10.1186/s12874-016-0216-1.

166. Rajpurkar P, Chen E, Banerjee O, Topol EJ. AI in health and medicine. Nat Med. 2022;28(1):31-8. doi:10.1038/s41591-021-01614-0.

167. NIHR Innovation Observatory (online). The University of Newcastle upon Tyne: National Institute for Health and Care Research Innovation Observatory (NIHRIO) 2024. https://www.io.nihr.ac.uk/about/.

168. Reddy S, Rogers W, Makinen VP, Coiera E, Brown P, Wenzel M, et al. Evaluation framework to guide implementation of AI systems into healthcare settings. BMJ Health Care Inform. 2021;28(1). doi:10.1136/bmjhci-2021-100444.

169. Translational Evaluation of Healthcare AI (TEHAI) – A guide for implementing AI in healthcare (online). North Ryde, NSW: Australian Alliance for AI in Healthcare; 2021. https://aihealthalliance.org/2021/10/28/translational-evaluation-of-healthcare-ai-tehai/.

170. Awuah WA, Tenkorang PO, Adebusoye FT, Ng JC, Wellington J, Abdul-Rahman T, et al. 3D printing in surgery: revolutionizing trauma and fracture care in low and middle-income countries. Postgrad Med J. 2023;100(1179):1-3. doi:10.1093/postmj/qgad100.

171. Hussaini A, Kyberd P, Mulindwa B, Ssekitoleko R, Keeble W, Kenney L, et al. 3D Printing in LMICs: Functional Design for Upper Limb Prosthetics in Uganda. Prosthesis. 2023;5(1):130-47. doi:https://doi.org/10.3390/prosthesis5010011.

172. van der Stelt M, Grobusch MP, Koroma AR, Papenburg M, Kebbie I, Slump CH, et al. Pioneering low-cost 3D-printed transtibial prosthetics to serve a rural population in Sierra Leone - an observational cohort study. EClinicalMedicine. 2021;35:100874. doi:10.1016/j.eclinm.2021.100874.

173. Diment LE, Thompson MS, Bergmann JHM. Clinical efficacy and effectiveness of 3D printing: a systematic review. BMJ Open. 2017;7(12):e016891. doi:10.1136/bmjopen-2017-016891.

174. Ibrahim AM, Jose RR, Rabie AN, Gerstle TL, Lee BT, Lin SJ. Three-dimensional Printing in Developing Countries. Plast Reconstr Surg Glob Open. 2015;3(7):e443. doi:10.1097/gox.0000000000000298.

175. Kumar Gupta D, Ali MH, Ali A, Jain P, Anwer MK, Iqbal Z, et al. 3D printing technology in healthcare: applications, regulatory understanding, IP repository and clinical trial status. J Drug Target. 2022;30(2):131-50. doi:10.1080/1061186x.2021.1935973.

176. Collins JT, Knapper J, Stirling J, Mduda J, Mkindi C, Mayagaya V, et al. Robotic microscopy for everyone: the OpenFlexure microscope. Biomed Opt Express. 2020;11(5):2447-60. doi:10.1364/boe.385729.

177. FDA. Technical Considerations for Additive Manufactured Medical Devices. Maryland, USA: US Food and Drug Administration; 2017.

178. WHO. A strategic framework for emergency preparedness. Geneva: World Health Organization; 2017.

179. Madhav N, Oppenheim B, Gallivan M, Mulembakani P, Rubin E, Wolfe N. Pandemics: Risks, Impacts, and Mitigation. In: Jamison DT, Gelband H, Horton S, Jha P, Laxminarayan R, Mock CNN, R., editors. Disease Control Priorities: Improving Health and Reducing Poverty. 9. Third ed. Washington, DC: World Bank; 2018.

180. Elvidge J, Dawoud D. Assessing Technologies for COVID-19: What are the Challenges for Health Technology Assessment Agencies? Findings From a Survey and Roundtable Workshop. Pharmacoeconomics. 2021:1-9. doi:10.1007/s40273-021-01097-4.

181. COVID-19: Challenges and Opportunities for the Global Health Technology Assessment Community (online). The Professional Society for Health Economics and Outcomes Research (ISPOR); 2021. https://www.ispor.org/publications/journals/value-outcomes-spotlight/vos-archives/issue/view/expanding-the-value-conversation/covid-19-challenges-and-opportunities-for-the-global-health-technology-assessment-community.

182. HTA's Evolving Role through the COVID Pandemic and Beyond – Virtual ISPOR 52nd HTA Roundtable – Latin America (online). ISPOR - the Professional Society for Health Economics and Outcomes Research; 2021. https://press.ispor.org/LatinAmerica/2021/02/htas-evolving-role-through-the-covid-pandemic-and-beyond-virtual-ispor-52nd-hta-roundtable-latin-america/

183. Bhatia RS, Shojania KG, Levinson W. Cost of contact: redesigning healthcare in the age of COVID. BMJ Qual Saf. 2021;30(3):236-9. doi:10.1136/bmjqs-2020-011624.

184. Improving patient care through trustworthy guidelines, evidence summaries, policy and decision aids (online). Making Grade the Irresistible Choice (MAGIC); 2024. https://magicevidence.org/solutions/bmj-rapidrecs/.

185. COVID-19 Diagnostics (online). European Network for Health Technology Assessment; 2021.

186. COVID-19 Treatments (online). European Network for Health Technology Assessment; 2021.

187. COVID-END - COVID-19 Evidence Network to support Decision-making (online). Hamilton, Ontario2021. https://www.mcmasterforum.org/networks/covid-end.

188. A73/CONF./1 Rev.1: COVID-19 response (online). Geneva, Switzerland: World Health Organization; 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf.

189. Bump JB, Friberg P, Harper DR. International collaboration and covid-19: what are we doing and where are we going? Bmj. 2021;372:n180. doi:10.1136/bmj.n180.

190. Falkowski A, Ciminata G, Manca F, Bouttell J, Jaiswal N, Farhana Binti Kamaruzaman H, et al. How Least Developed to Lower-Middle Income Countries Use Health Technology Assessment: A Scoping Review. Pathog Glob Health. 2023;117(2):104-19. doi:10.1080/20477724.2022.2106108.

191. HTAi. 2020-2025 Strategic Plan. Alberta, Canada: Health Technology Assessment international; 2022.

192. Latin America Policy Forum (online). Health Technology Assessment international; 2024. https://htai.org/policy-forums/.

193. Welcome to INAHTA (online). International Network of Agencies for Health Technology Assessment; 2024. https://www.inahta.org/.

194. Collaborating centres (online). Geneva, Switzerland: World Health Organization; 2024. https://www.who.int/about/collaboration/collaborating-centres.

195. Institute for Clinical and Sanitary Effectiveness (online). Beunos Aires: Institute for Clinical and Sanitary Effectiveness; 2024. https://iecs.org.ar/.

196. Erdös J, Ettinger S, Mayer-Ferbas J, de Villiers C, Wild C. European Collaboration in Health Technology Assessment (HTA): goals, methods and outcomes with specific focus on medical devices. Wien Med Wochenschr. 2019;169(11-12):284-92. doi:10.1007/s10354-019-0684-0.

197. Ruether A, Imaz-Iglesia I, Bélorgey C, Lo Scalzo A, Garrett Z, Guardian M. European collaboration on health technology assessment: looking backward and forward. Int J Technol Assess Health Care. 2022;38(1):e34. doi:10.1017/s026646232200006x.

198. Drummond M, Tarricone R, Torbica A. European union regulation of health technology assessment: what is required for it to succeed? Eur J Health Econ. 2022;23(6):913-5. doi:10.1007/s10198-022-01458-6.

199. Member State Coordination Group on HTA (HTACG) (online). Brussels: European Commission; 2024. https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment/member-state-coordination-group-hta-htacg_en.

200. Tools (online). European Network for Health Technology Assessment; 2021.

201. Red de Evaluación de Tecnologías Sanitarias de las Américas (online). 2023. https://redetsa.bvsalud.org/.

202. Lessa F, Caccavo F, Curtis S, Ouimet-Rathé S, Lemgruber A. Strengthening and implementing health technology assessment and the decision-making process in the Region of the Americas. Rev Panam Salud

Publica. 2017;41:e165. doi:10.26633/rpsp.2017.165.

203. Resolution CSP28.R9: Health Technology Assessment and Incorporation into Health Systems (online). Washington, USA: The Pan American Health Organization; 2012. https://iris.paho.org/handle/10665.2/3684?locale-attribute=en.

204. Pichon-Riviere A, Augustovski F, García Martí S, Alfie V, Sampietro-Colom L. The link between health technology assessment and decision making for the allocation of health resources in Latin America. Int J Technol Assess Health Care. 2020;36(2):173-8. doi:10.1017/s0266462320000033.

205. Pichon-Riviere A, Garcia-Marti S, Oortwijn W, Augustovski F, Sampietro-Colom L. Defining the Value of Health Technologies in Latin America: Developments in Value Frameworks to Inform the Allocation of Healthcare Resources. Int J Technol Assess Health Care. 2019;35(1):64-8. doi:10.1017/s0266462319000072.

206. Pichon-Riviere A, Soto NC, Augustovski FA, García Martí S, Sampietro-Colom L. HEALTH TECHNOLOGY ASSESSMENT FOR DECISION MAKING IN LATIN AMERICA: GOOD PRACTICE PRINCIPLES. Int J Technol Assess Health Care. 2018;34(3):241-7. doi:10.1017/s0266462318000326.

207. Teerawattananon Y, Luz K, Yothasmutra C, Pwu RF, Ahn J, Shafie AA, et al. HISTORICAL DEVELOPMENT OF THE HTAsiaLINK NETWORK AND ITS KEY DETERMINANTS OF SUCCESS. Int J Technol Assess Health Care. 2018;34(3):260-6. doi:10.1017/s0266462318000223.

208. Projects (online). 2024. https://htasialink.com/.

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