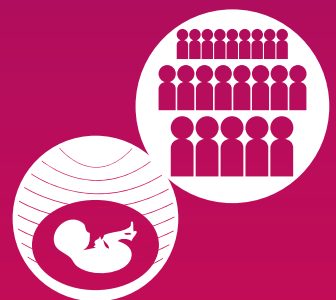
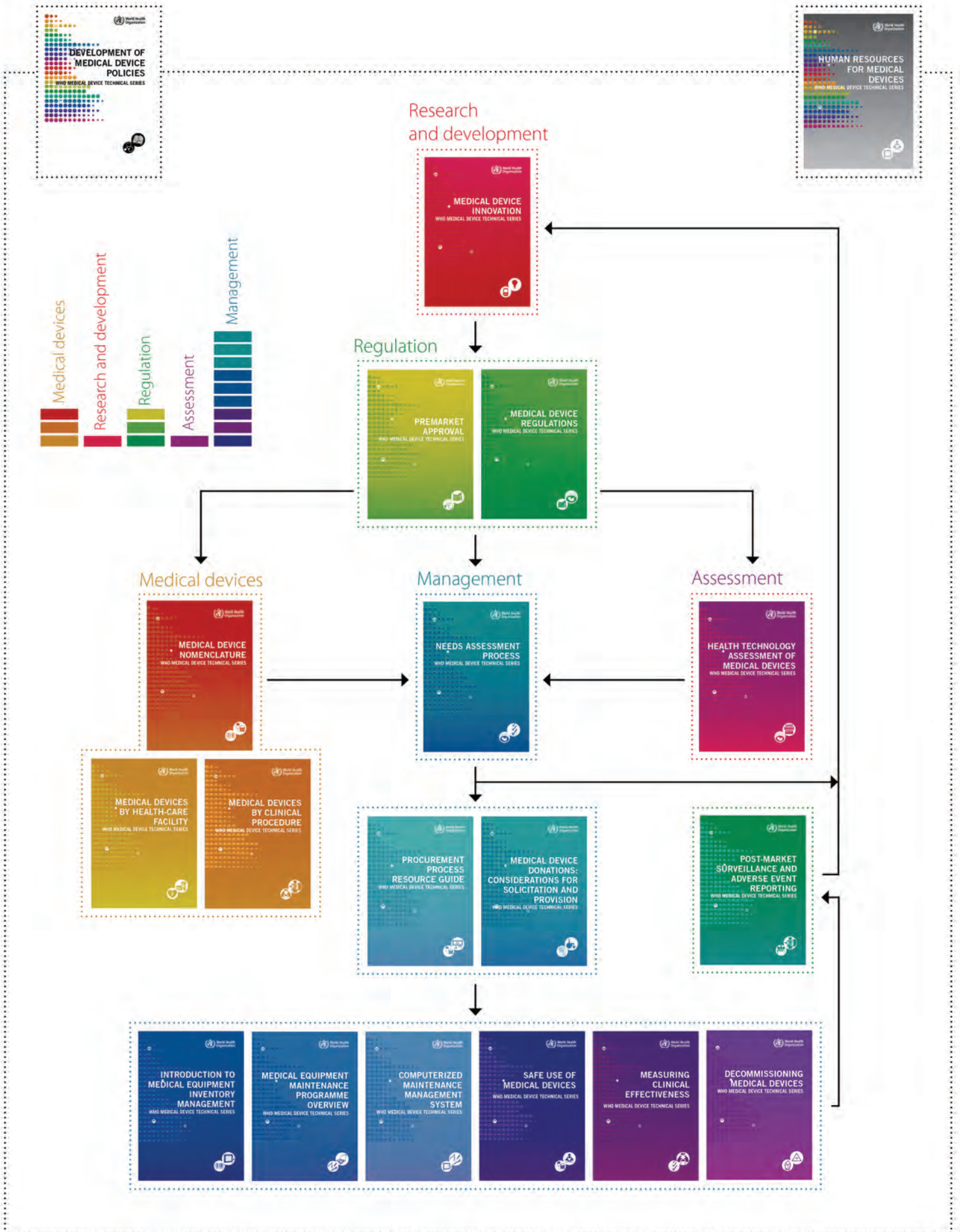




Health technology assessment of medical devices

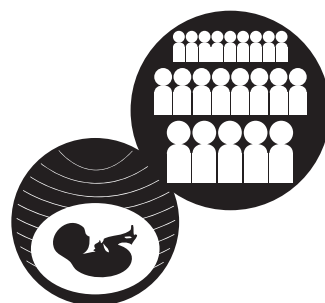
WHO Medical device technical series





Health technology assessment of medical devices

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Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
 - › needs assessment of medical devices
 - › medical device procurement
 - › medical equipment donations
 - › medical equipment inventory management
 - › medical equipment maintenance
 - › computerized maintenance management systems
- medical device data
 - › medical device nomenclature
 - › medical devices by health-care setting
 - › medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.¹

All meeting participants and persons involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

¹ *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

² World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_who60_29-en1.pdf, accessed March 2011).

³ Information document concerning the definition of the term “medical device”. Global Harmonization Task Force, 2005 (<http://www.ghhf.org/documents/sg1/sg1n29r162005.pdf>, accessed March 2011).

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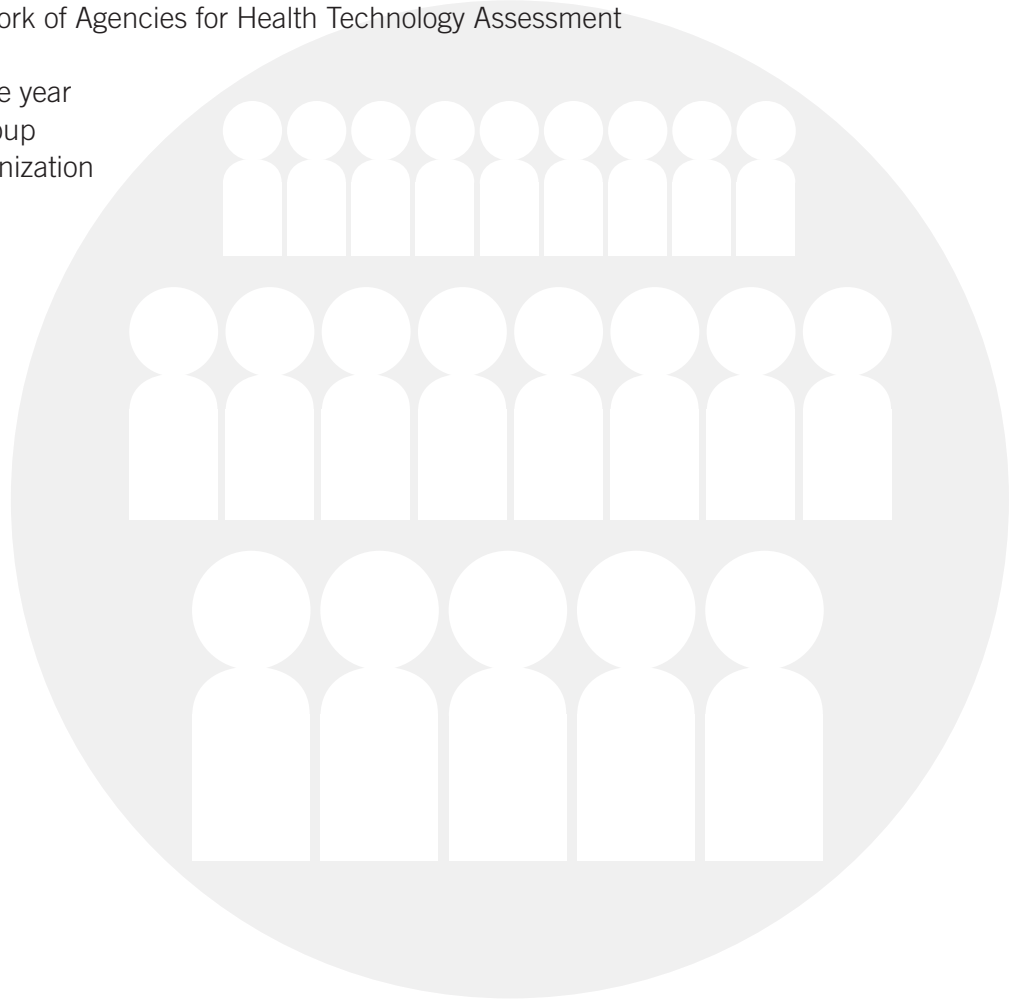
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Declarations of interests

Conflict of interest statements were collected from all contributors to and reviewers of the document. Donald Juzwishin declared his employment at the Alberta Health Services and as a consultant with McMaster University as remuneration from an organization with an interest related to the subject. Maria Benkhalti declared her position with Knowledge Transition and Health Technology Assessment in Health Equity, University of Ottawa as representation of interests related to the subject. Janet Hatcher-Roberts declared receipt of funding for a global conference on health equity which was unrelated to health technology assessment. Joseph L Mathew declared the Health Technology Assessment International (HTAi) travel grant award to participate in the annual meeting of the scientific society as well as his interest in the publication of the report in question to benefit health care professionals and people in developing countries with whom he has substantial professional interests. None of these declared conflicts influenced the content of the document.

Acronyms and abbreviations

TAGHT	Technical Advisory Group on Health Technology
COHRED	Council on Health Research for Development
CSIH	Canadian Society for International Health
DALY	disability-adjusted life year
EUnetHTA	European network for Health Technology Assessment
EVIPNet	Evidence-Informed Policy Network
GIHT	Global Initiative on Health Technologies
HTA	health technology assessment
HTAi	Health Technology Assessment international
HTM	health/health-care technology management
HTR	health technology regulation
INAHTA	International Network of Agencies for Health Technology Assessment
ISG	interest sub-group
QALY	quality-adjusted life year
SIG	special interest group
WHO	World Health Organization



Executive summary

Health technology assessment (HTA) has emerged as an important tool for supporting the core functions of an effective global health system.¹ Actions by the World Health Organization (WHO) and other global health organizations are necessary to support regional and national initiatives for the advancement of HTA in developing and emerging countries (i.e. nations in the process of rapid growth and industrialization). This document describes an approach for how the multiple players in the global community can come together to advance the knowledge and effective uptake of health technology assessment in local settings.

HTA is the systematic evaluation of properties, effects, and/or impacts of health technology. Its main purpose is to inform technology-related policy-making in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system. It is one of three complementary functions to ensure the appropriate introduction and use of health technology. The other two components are regulation, which is concerned with safety and efficacy, and assessment of all significant intended as well as unintended consequences of technology use, including clinical and cost-effectiveness; and management, which is concerned with the procurement and maintenance of the technology during its life-cycle. The performance of health systems is strengthened when the linkages and exchange among these elements are clearly differentiated but mutually supportive.

This document integrates health technology assessment into the WHO framework for evidence-informed policy-making (2). Health systems are strengthened when HTA is integrated into the human and material resources, data, transparent decision- and policy-making, and linked to the overall vision of equity and accountability. Good governance can rely on health technology assessment to provide a policy approach that is accountable for its decisions to the population.

Organizations specializing in health technology assessment are becoming institutionalized elements of health systems, not only to help identify health-care interventions that may not be effective, but also to identify promising technologies that can stimulate innovation.

There are several international agencies supporting the advancement of HTA on the global stage. Health Technology Assessment international (HTAi) and the International Network of Agencies in Health Technology Assessment (INAHTA) have a demonstrated commitment to advance and collaborate on health technology assessment with WHO and any country or community that is interested. WHO collaborating centres and their global network – specifically the Global Network of WHO Collaborating Centres for HTA – have made a commitment to promote international dialogue, collaboration and strengthen existing projects.

¹ The global health system has been defined as the constellation of actors (individuals and/or organizations) “whose primary purpose is to promote, restore or maintain health” and “the persistent and connected sets of rules (formal or informal), that prescribe behavioral roles, constrain activity, and shape expectations” among them. Such actors may operate at the community, national or global levels, and may include governmental, intergovernmental, private for-profit, and/or non-profit entities (1).

There are several strategies for overcoming challenges and advancing health technology assessment in developing and emerging countries. In all, sensitivity for contextualizing to the resource capacity and capability is encouraged. One approach for advancing HTA is to build on the 1990 report of the Commission on Health Research for Development and the 2003 commentary by the Council on Health Research for Development, both of which encourage the strengthening of national institutions supported through regional and international networking.

The strategy of introducing focal points for health technology assessment in a developing or emerging country will be dependent on many factors – appropriate location, human resource capability, and organization capacity to name a few. Good governance, funding, and effective collaboration with partners will be essential ingredients for building HTA capacity. This document demonstrates that there are many international organizations and professionals willing to work with WHO and developing and emerging countries to advance HTA to strengthen health systems. Alignment of HTA capacity building initiatives with the WHO strategy on research for health will create synergies for promoting evidence-informed decision-making to improve health systems and population health.



1 Introduction

Health systems throughout the world, whether in developed or developing countries, are struggling with the challenge of how to manage health-care delivery in conditions of resource constraint. Health-care policy, practice and decisions are needed to maximize the positive impact of health-care interventions on population

health, while maximizing the value from the cost of providing the interventions. This document explores how health technology assessment can be adopted and adapted in developing and emerging countries in an attempt to foster health equity.

2 Purpose

Health technology assessment of medical devices provides a background to the concept and programme of health technology assessment (HTA) around the world, and highlights the contribution that HTA can make to informed policy- and decision-making, particularly for developing and emerging countries. It aims to describe strategic actions for advancing HTA into developing and

emerging countries, and to support informed decision-making on the introduction of HTA into the health systems of these countries.

This document was commissioned by WHO for the advancement of health technology assessment in developing and emerging countries.

3 Approach

This document builds on the work of the WHO Department of Essential Health Technologies, the Global Initiative on Health Technologies (GIHT), the Global Network of WHO Collaborating Centres for Health Technology Assessment, Health Technology Assessment international (HTAi), the International Network of Agencies for Health Technology Assessment (INAHTA), and others committed to the use of high-quality

evidence to inform health-care policy and decision-making. The authors have based their work on a personal knowledge of the international literature on the concepts and practice of health technology assessment (HTA) as well as on the available literature and past experiences of introducing HTA into developing and emerging countries. Consultations with key groups and international experts in HTA have contributed to the text.

4 Definition of health technology assessment

The paradigm of HTA emerged as a response to decision-makers' questions about the uncontrolled diffusion of costly medical equipment. HTA began in the early 1970s, when the rapid demand for computer-assisted tomography (CT-scans) became a public policy issue due to the very high cost per unit, often in excess of US\$ 300 000 (3).

In February 1975 the US Senate Committee on Labor and Public Welfare (on behalf of its Subcommittee on Health) invited the recently established Office of Technology Assessment to conduct a study of the justifications required before the implementation of costly new medical technologies and procedures. The concepts of health technologies and HTA have developed very broadly since.

A health technology is “any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care” (4). It thus encompasses medical devices ranging from simple wooden tongue depressors and assistive devices, to the most sophisticated implants, medical imaging systems, drugs, medical and surgical procedures, and the organizational and supportive systems within which such care is provided.

HTA is “the systematic evaluation of properties, effects, and/or impacts of health-care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods” (4).

Depending on the issues involved, the time frame of decision-making, and the availability of resources, HTAs can take different forms such as a full-scale HTA report, contextualization of HTA reports produced elsewhere, rapid reviews, health technology information services or horizon scanning reports. HTA is always policy-oriented, context-embedded and methodologically sound (5).

As outlined in a document from the Organisation for Economic Co-operation and Development (6), countries can successfully manage the opportunities and challenges arising from health-related technology by optimizing decision-making processes, recognizing the value of innovation, dealing with uncertainty, and producing and coordinating HTA.

5 Methods in health technology assessment

As stated in a policy brief by the European Observatory on Health Systems and Policies, “in order to give an evidence-based solution to the problems outlined in the policy question, the researchers undertaking the assessment will need to specify the policy question in terms of safety, efficacy, effectiveness, psychological, social, ethical, organizational, professional and economic aspects. These research questions determine how the rest of the assessment will be conducted, the aspects that will be evaluated and those that will not ... Formulating research questions is a crucial part of the assessment, since they transpose the original decision-making problem, the policy question, into questions that can be answered by evaluating scientific evidence” (5). Depending on the specific context of the decision-making, the dimensions needed by the decision-maker may vary. For example, hospital-based HTA tends to focus much more on specific organizational dimensions, compared with HTA for decision-making by a ministry of health.

The *Health technology assessment handbook* by the Danish Centre for

Health Technology Assessment provides an excellent overview of most of the methods needed and used internationally in HTA (7). It is important to note that an economic analysis is often, but not always, part of an HTA. The economic dimensions may include cost-benefit analysis, cost-utility analysis, cost-effectiveness analysis, cost-minimization analysis, and also budget impact analysis and other forms of economic assessments. As always in HTA, the method must be appropriate for the decision-making process to be informed by the HTA. Quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs), as used in cost-utility analyses, are often seen as the hallmarks of HTA, but in many situations budget impact is much more important and useful for decision-makers.

Formal methods for using HTAs produced in one setting and putting them into the context of another setting are receiving increasing attention. One example is the *HTA adaptation toolkit* developed as part of the European Network for HTA (EUnetHTA) collaboration (8).

6 Links between health technology regulation, health technology management and health technology assessment

Health technology regulation (HTR), health technology assessment (HTA) and health technology management (HTM) are complementary functions to ensure the appropriate introduction and use of medical devices.

While the regulatory processes concern all medical devices and drugs to some degree, HTA is usually reserved for complex problems. Table 1 summarizes some of the differences and complementary roles of health technology regulation and HTA.

Table 1. Comparison of health technology regulation and health technology assessment

Characteristics	Health technology regulation	Health technology assessment
Perspective	Safety and efficacy	Efficacy, effectiveness and appropriateness
Requirement	Mandatory	Recommendation on complex technologies
Role	Prevent harm	Maximize clinical and cost effectiveness

Practitioners from HTM and HTA have had only very limited interactions in the past. However, as requested in the World Health Assembly resolution WHA60.29 on health technologies, Member States are urged “to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering” (9).

It is useful to compare the dimensions of HTM and HTA to gain an appreciation of their respective contribution to policy decisions that ensure the most appropriate diffusion of health-care technologies, such as medical devices. Table 2 compares HTM and HTA along several very broad dimensions. Understanding and supporting the synergy between HTM and HTA will be a major factor for the success of national health technology policies.

Table 2. Comparison of health technology management and health technology assessment

Dimension	Health technology management	Health technology assessment
Perspective	Health facility	Societal
Orientation	Community served	Population health
Method	Project management, technology life-cycle	Systematic critical review, meta-analysis
Criteria	Needs analysis, alternatives, specifications	Clinical effectiveness, cost effectiveness, appropriateness
Outcome	Decision	Policy/decision/practice

HTR, HTA and HTM are distinct actions for enabling the best use of health technologies, especially medical devices, for better health care and better population health. Close links need to be established between the three, but it is essential to keep these activities separate. For example, in order to support decision-making for complex problems, HTA examines all significant intended as well as unintended consequences of

technology use through multidisciplinary analysis, whereas the regulation process focuses on safety and effectiveness. Therefore, the timing, procedures, objectives and resources needed are different for each of them. Regardless, it is important that the outcome from each is considered as part of decision-making in national health technology policies. Very close links between regulation and HTA on a country level will lead to a very superficial use of HTA not conducive to evidence-informed decision-making. Furthermore, as described on page 21, HTA cannot support innovation if it is

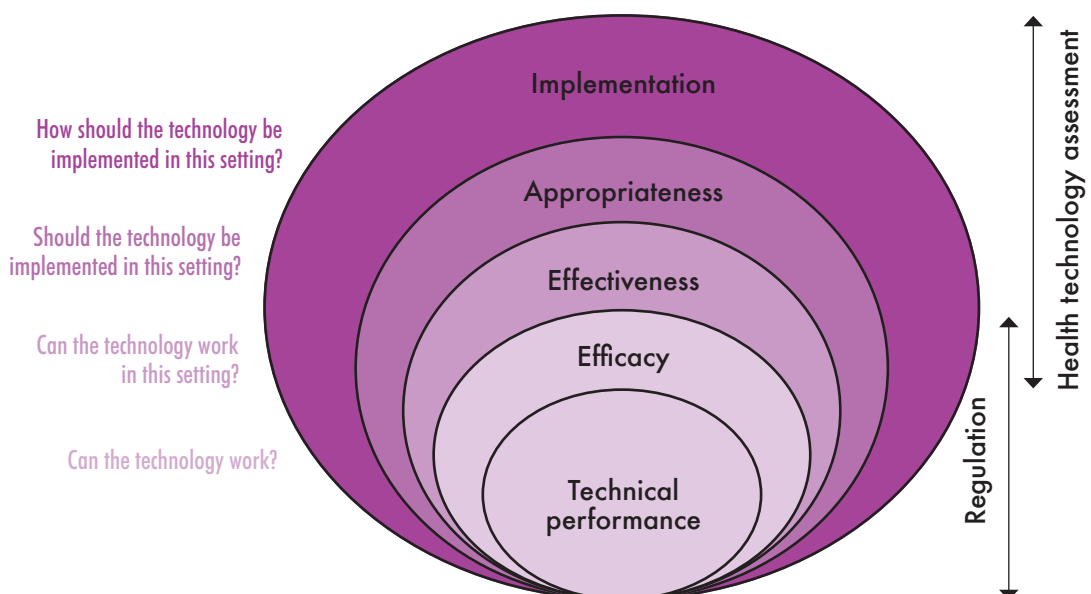
amalgamated with regulation. HTR, HTA, clinical engineering and surveillance are all essential, but have specific roles in this life-cycle of technologies (10). Figure 1 illustrates the distinction of the regulatory and management of health technologies for drugs and devices, and the position of HTA being independent of both.

The complementary function of HTR and HTA is related to a set of questions that must be answered for the coherent introduction of technologies, especially medical devices, into health systems (Figure 2).

Figure 1. Domains of health technology regulation, assessment and management for drugs and devices



Figure 2. From performance to use in health care: layers of questions



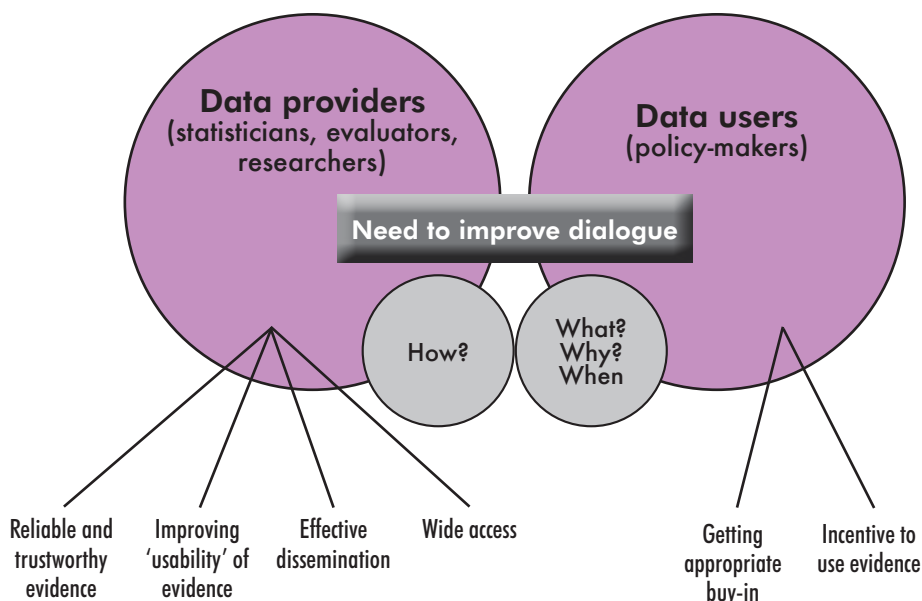
7 Health technology assessment for evidence-informed context-based decision-making

Different concepts and processes have been promoted to increase the contribution of science to decision-making. Over the last 20 years, the concept of evidence-based and evidence-informed decision-making has received ever increasing attention.

The technical rigour of the evidence must be matched to the policy relevance as illustrated in Figure 3.

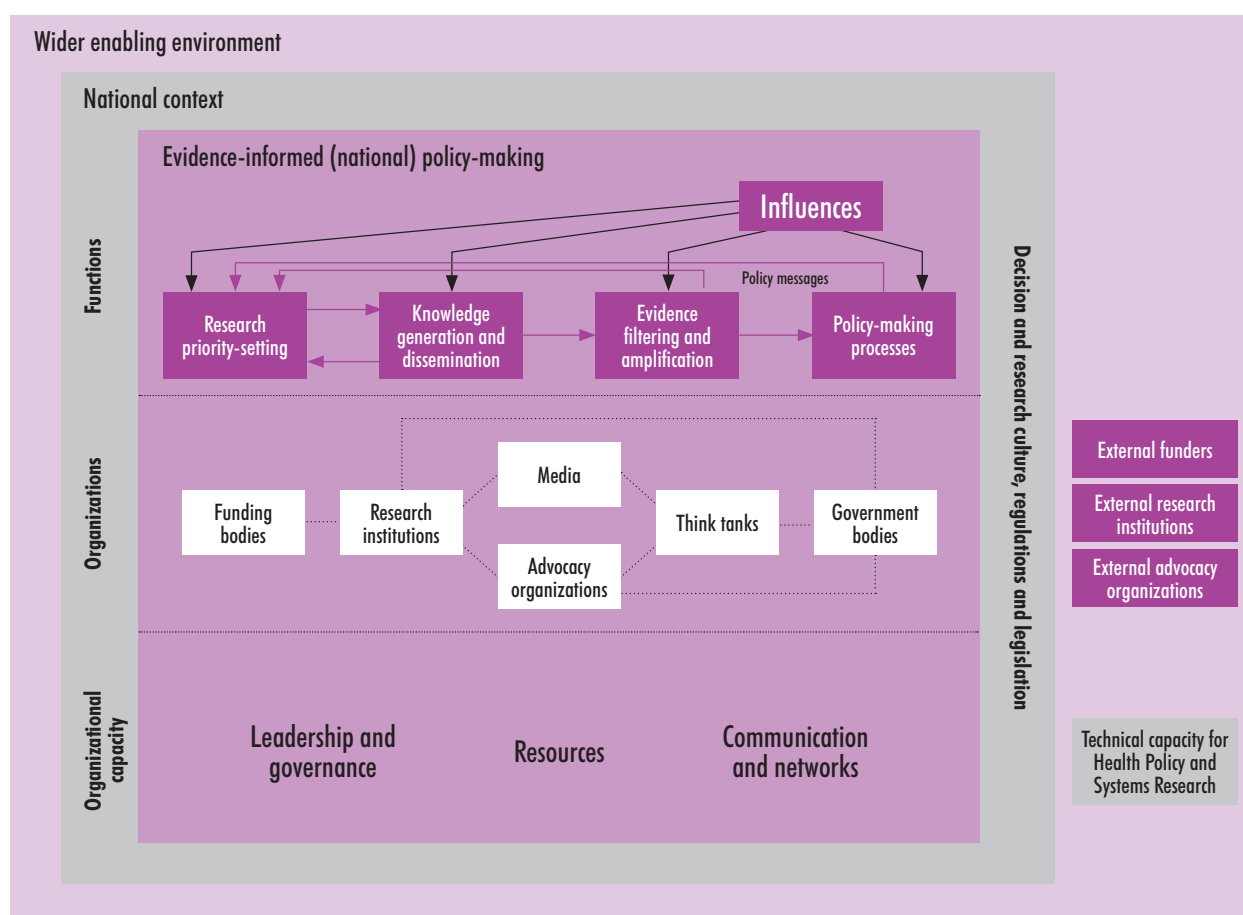
Figure 3 underscores the importance of the need for those who create information and knowledge to be accessible, reliable and effective in the communication and dissemination of the facts. On the other hand, those who use the information and data must demonstrate a commitment to use the evidence and create policy frameworks that incentivize appropriate behaviour and practice (11).

Figure 3. Good quality evidence. Matching technical rigour to policy relevance



Source: (11)

Figure 4. Framework for evidence-informed policy-making



Source: (2)

The WHO Alliance for Health Policy and Systems Research proposes a model that takes into account the multiple interacting dimensions for enhancing capacity for evidence-informed health policy (Figure 4).

As depicted in Figure 4, the national context plays an important role in patterning the overall conditions for evidence-informed policy. For example, “the policy environment may vary from a closed and corrupted society to an open, accountable and transparent one. Political and social systems influence use of evidence. Issues such as the timing of evidence and availability of resources; values, beliefs and ideology affect its use” (2). Many countries are labelled as “vicious circle countries” where “evidence is weak and policy-makers make little use of it. Evidence-based policy-making is not practiced, which results in poor policy decisions

and poor development outcomes. In this case, it is necessary to adopt measures which will simultaneously increase both the demand and supply of evidence, as well as improve the dialogue between producers and users of evidence” (2).

If a “knowledge pull” from decision-makers is present, HTA has shown the potential of informing decision-making under a great variety of conditions. Introducing HTA into a health system can change the decision-making dynamics over time. For example, in Thailand, HTA has developed from being a provider of technical information to having a transforming role in decision-making where “experience gained among academics, health officials, and civil society organizations [was] helpful not only in sustaining the momentum but also in improving formal HTA systems in the future” (12).

8 Health technology assessment in health systems

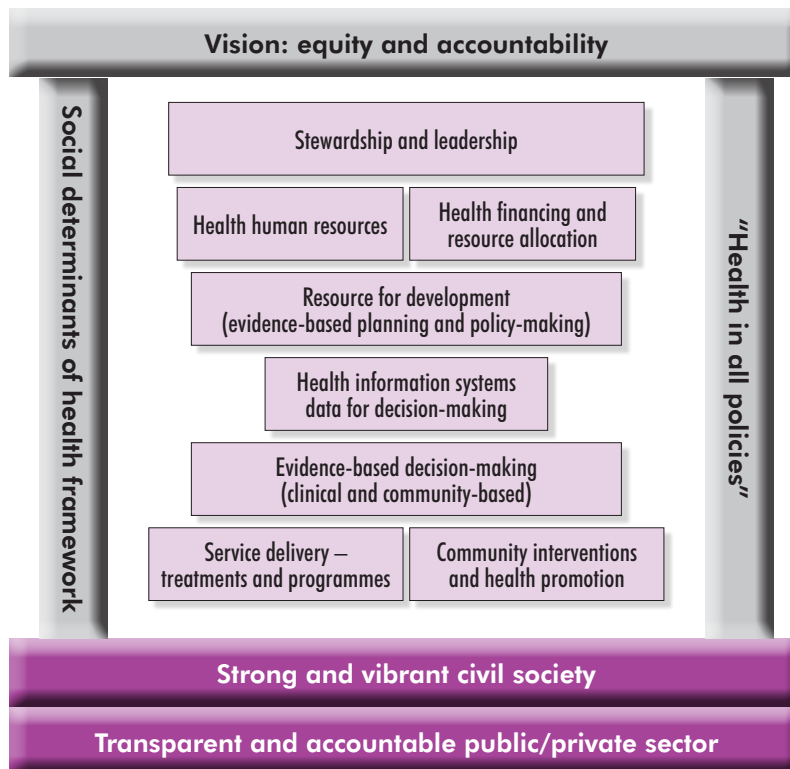
8.1 Decision-making and governance

The policy-oriented nature of HTA calls for a close integration into the functioning and governance of health systems. Strengthening the health systems of the global health community is one of the prime objectives of the Canadian Society for International Health (CSIH). The health system model of the CSIH emphasizes the central role of evidence-based decision-making, both on the level of service delivery/community intervention as well as for planning and policy-making. The CSIH framework is reproduced in Figure 5.

The best practice of HTA draws upon a number of elements of this model.

- HTA contextualizes global knowledge into the different elements of the health system such as human and material resources, as well as relevant data from the health system setting.
- HTA supports transparent decision-making, and therefore participation from all stakeholders including civil society.
- Equity and needs-based HTA enables decisions to be linked to the overall vision of equity and accountability.

Figure 5. Canadian Society for International Health (CSIH) framework for strengthening health systems



Source: (13)
©JHR/CSIH 2004

Decision-making in health systems is patterned by governance. For example, in health systems with hospital autonomy, an important part of new technologies are introduced at the hospital level on the basis of decision-making by hospital authorities. In such health systems, it can be valuable for some form of HTA to be used not only at the national level, but also at the hospital level. The same reasoning applies to regionalized health systems. If HTA is to maximize population health impact, it must take into account the governance structure of the specific health system.

8.2 Institutionalized health technology assessment

HTA agencies have emerged in response to the need for a formal organization to structure and undertake reviews of the safety, efficacy and effectiveness of health technologies. The agencies are often established with a mission, and provided with financial and human resources to undertake systematic assessments of public policy questions with a defined set of objectives. Most HTA activity in high-income countries is linked to such agencies – most being members of the International Network of Agencies in Health Technology Assessment (INAHTA). This non-profit organization has grown to 46 member agencies from 26 countries including Australia, New Zealand, and countries in North and Latin America, and Europe. All members are non-profit organizations producing HTAs, and are linked to regional or national governments. HTA agencies are, however, not limited to non-profit organizations; there are also HTA agencies that operate in the for-profit sectors.

Over the last few years, other models of institutionalized HTA have emerged, such as hospital-based HTA (14) or HTA

in regional health authorities. These more localized forms of HTA are following the principle of a close linkage of HTA to the levels of decision-making as patterned by the governance mechanisms of the health system.

One of the authors of this document has developed a framework for the development and introduction of HTA to inform practice and governance decisions in local health authorities (15). In addition to a framework, the author has developed a screening procedure for determining which technologies are worthy of consideration for a HTA (16).

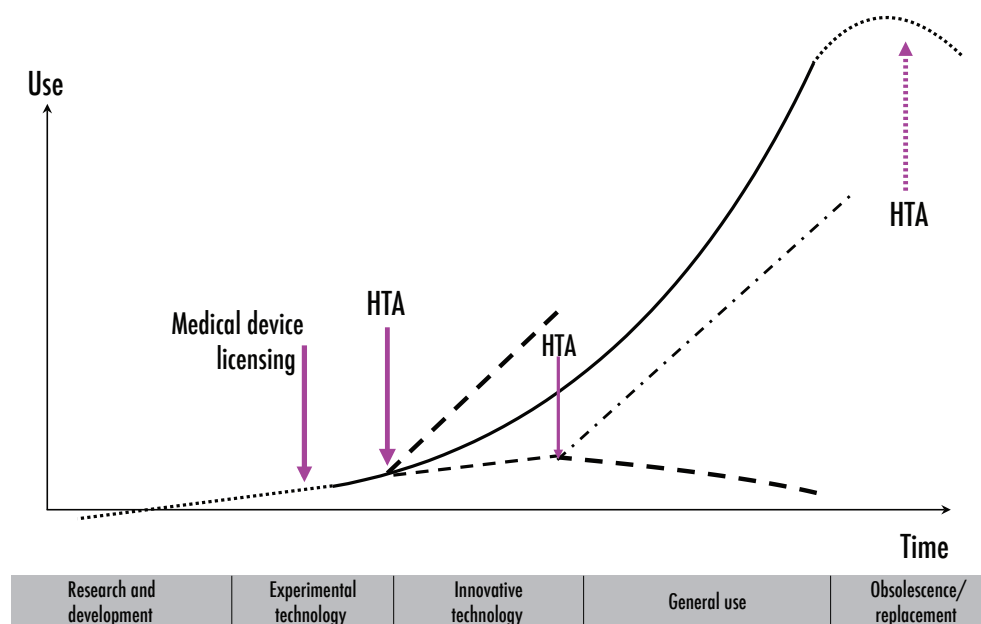
HTA institutions are often linked to universities. For instance, in Canada, the Newfoundland and Labrador Centre for Applied Health Research is linked to the Memorial University of Newfoundland and is an innovative example of explicitly contextualizing existing research synthesis from HTA or other sources. As a direct result of the ever increasing role of HTA in health decision-making, industry also harbours an increasing number of HTA-related activities.

8.3 Health technology assessment and innovation

The processes of HTA and innovation are intertwined. HTA started as a response to the technological breakthrough of computer-assisted tomography (CT-scans) in the early 1970s. HTA is still very much used to inform the decision-making process concerning the introduction of new technologies to a health system. Figure 6 captures the natural life-cycle of technologies in health care.

HTA is aimed at improving the uptake of cost-effective new technologies, preventing the uptake of technologies that are of doubtful value for the health

Figure 6. Health technology assessment and diffusion of health technologies



system, and slowing the uptake of technologies that seem promising but have persistent uncertainties.

For some, especially industry, HTA is perceived as a hurdle to the introduction of innovative technologies into the health system. In this perspective, HTA is sometimes classified as the “fourth hurdle”, after the assessment of safety, efficacy and quality that are part of the regulatory requirements in many countries (17). This view of HTA as an additional hurdle is sometimes used as a synonym for an additional requirement of demonstrating cost-effectiveness for coverage decisions (18). The term “fourth hurdle” is most commonly used in relation to the coverage of new drugs, where it becomes increasingly evident that not only cost-effectiveness, but also budget impact is an important dimension in decision-making (19). However, it is becoming increasingly clear that HTA can be a highly beneficial additional step for moving technologies from the laboratory to the bedside (20).

There is general concern among medical device manufacturers about the timing

of HTAs in relation to the innovation process. The 2008 Eucomed position paper on HTA states that:

Policy makers should consider the implications of HTA on the environment needed to foster innovation of medical devices. If HTA introduces significant new challenges to market entry then there is a potential that this may impact on the rate of innovation in the device sector which already faces a number of challenges. Intellectual property associated with medical devices is less well protected than patents on new medical compounds. In addition to this, medical device development is characterized by iterative improvement of technologies resulting in a more rapid life-cycle and increased competition (21).

Indeed, industry is one of the main contributors to innovation in health technology. However, the innovation process goes beyond the development of a new device for regulatory approval. Innovation comprises both invention and exploitation, meaning an invention only

becomes an innovation if it is somehow adapted by the market and integrated into a technology, process or organizational landscape. Any innovation comprises three dimensions.

1. Kind of innovation: What is new? Product, process, input, organizational, social.
2. Subjectivity of innovation: New for whom? Individual, group, organization, industry, society.
3. Degree of innovation: How new? Market, technology, organization, environment.

The Global Forum for Health Research proposes this very short working definition of innovation: “Innovation encompasses the entire process from the generation of new ideas to the transformation of those ideas into useful things (health services, products, methods, management practices and policies) to their implementation” (22). In accordance with this concept of innovation, HTA plays a major role in innovation by shaping the conditions of successful implementation in health systems.

Overall, the use of HTA to inform national coverage policies leads to a more explicit and transparent resource-allocation process, improving not only technical or allocative efficiency, but also health equity. A case study of Argentina illustrates the importance of HTA for transparent resource allocation in countries with fragmented health systems (23). A context-oriented concept of innovation may also explain the increasing use of HTA in different levels of decision-making within health systems, including hospitals. In order to support innovation, HTA must support decision-making not only on what to implement, but also on how to implement a new technology.

It is valuable for any discussion of innovation to take into account the overall objective of the use of health

technologies for a population. In a case study of the Israeli health system, the investigators state, “Innovation plays a key role in medical progress, and contributes significantly to public health. Reimbursement provides a significant incentive for innovation, with the two forming a feedback cycle. Nevertheless, it should be kept in mind that it is health that people desire, and health technology utilization is merely the means to achieve it” (24).

8.4 Health technology assessment as part of good health governance

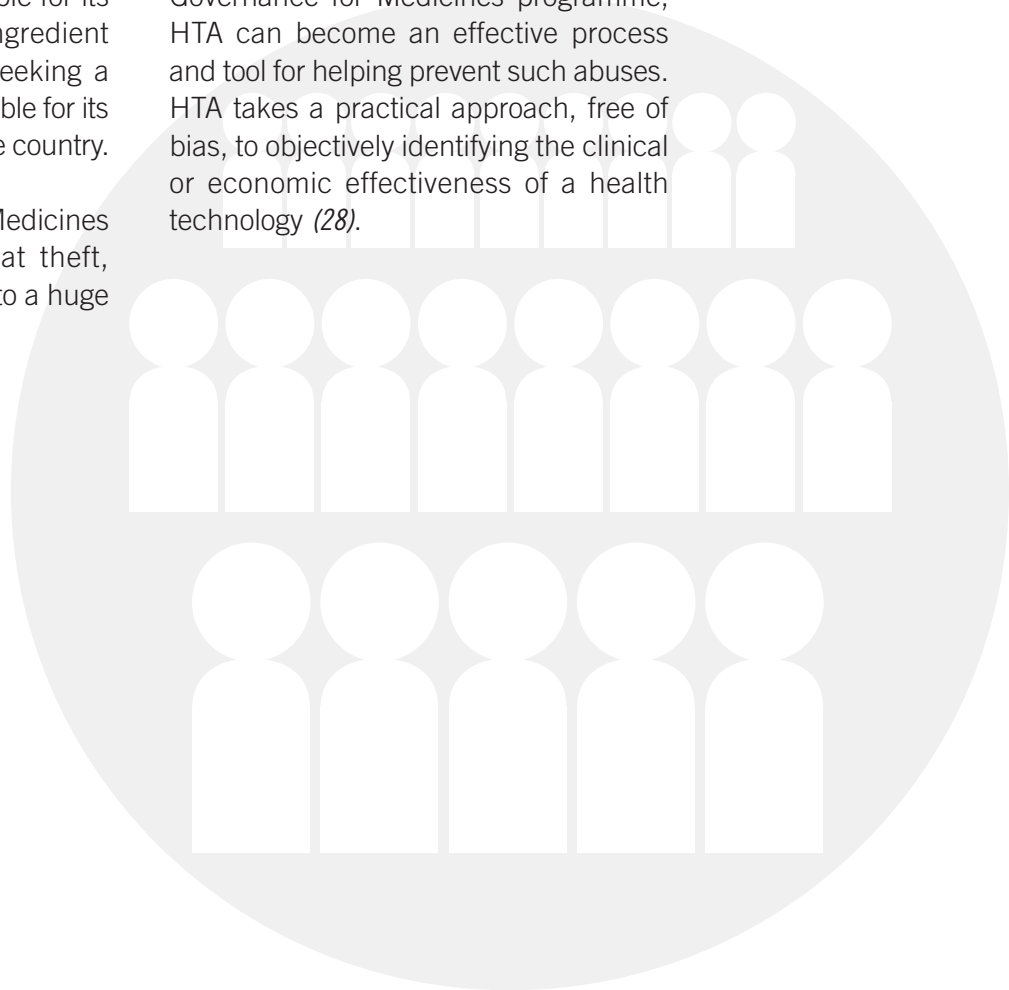
In their 2008 book *Access: how do good health technologies get to poor people in poor countries?* Laura Frost and Michael Reich from the Harvard Centre for Population and Development Studies illustrate a number of barriers to an equitable access to beneficial health technologies. Their case studies “highlight the importance of expert consensus, both within the directly involved international technical agencies and the broader international public health community” (25). The vision of HTA as an interdisciplinary, context-informed approach for evidence-based consensus building should be promoted. This will help build a stronger community of practice and discourse between the producers of HTA and the policy and decision-makers who use the information. This sets the stage for the need for good governance and leadership.

Arminee Kazanjian and Carolyn Green, from the University of British Columbia, Canada, pointed out that health technology assessment is a necessary part of the public accountability framework in a health system (26). The World Bank recently released a report stating that “good governance as an entry point can help to focus on performance in

health care delivery, and in turn, provide policymakers and program managers with a basis upon which to raise performance” (27). The report goes on to describe the importance of standards, incentives, information and accountability to ensure strong system governance and performance (27). HTA is a standards-based practice built on the foundation of the highest quality evidence and can be held up to and be accountable for its claims. HTA is an essential ingredient in any health system that is seeking a policy approach that is accountable for its decisions to the population of the country.

WHO’s Good Governance for Medicines programme has identified that theft, extortion and abuse contribute to a huge

loss of value in health services worldwide. Corruption has been identified as the single greatest obstacle to economic and social development. The programme is raising awareness of abuse in the pharmaceutical sector and promoting good governance. Its ultimate aim is to ensure that essential medicines reach people – not the black market. Building on the momentum of WHO’s Good Governance for Medicines programme, HTA can become an effective process and tool for helping prevent such abuses. HTA takes a practical approach, free of bias, to objectively identifying the clinical or economic effectiveness of a health technology (28).



9 International collaboration in health technology assessment

There are several international agencies supporting the advancement of HTA on the global stage. The following section reviews each of these agencies in turn to provide an appreciation of their mission, goals and activities.

9.1 Health Technology Assessment international (HTAi)

HTAi is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi embraces all stakeholders, including researchers, agencies, policy-makers, industry, academia, health service providers, and patients/consumers, and acts as a neutral forum for collaboration and the sharing of information and expertise. HTAi has over 1200 members from 59 countries.

The mission of HTAi is to support and promote the development, communication, understanding and use of HTA around the world, as a scientifically-based and multidisciplinary means of informing decision-making regarding the introduction of effective innovations and the efficient use of resources in health care.

HTAi serves as a hub for a range of collaborative work. Its major activities include:

- annual international meetings, which serve as a major gathering point for global networking, information sharing, and dissemination of latest advances in policy, methods, and other areas of HTA research;
- the HTAi Policy Forum, which

provides a venue for open discussion between global leaders from HTA bodies and industry in areas of shared strategic interest;

- in a number of interest sub-groups (ISGs), acting as international networks for information exchange in specific focus areas;
- active collaborations with WHO and related international societies;
- maintenance of a web site (www.htai.org) to share information and resources and to act as an online work platform for ISGs and other collaborations;
- publication of regular online resources, including a newsletter and webcasts;
- publication of the *International Journal of Technology Assessment in Health Care*, HTAi's official academic journal.

Through its ISG on HTA in developing countries, and through collaboration with INAHTA, HTAi has made a clear commitment to explore and promote strategies and tools to advance access to, and application of, HTA in developing countries. In 2005, the HTAi special interest group (SIG) of experts in HTA produced a report with INAHTA, which was presented to WHO as an expression of support. In the report, the authors state:

One of the most important challenges to improving the quality of health systems worldwide is the need to establish mechanisms for transferring knowledge to action, (i.e. for bridging the “know-do” gap). Such mechanisms require

the involvement of many different constituencies, all of whom are committed to achieving evidence-based health policy and practice. The HTA community, with its agencies, associations, and researchers, has developed its role around contributing to this effort (29).

This statement of commitment has been offered to WHO and other agencies wishing to extend HTA into their jurisdictions. The authors of the report also recognized the need for respecting local contextual settings and advancing the field of HTA at a pace that is most appropriate for the recipient country, stating:

HTA aims to “globalize the evidence, localize the decision”, and, therefore, involves 2 steps. The first comprises a systematic synthesis of the global evidence base (i.e. systematic reviews). The second involves an appraisal of this evidence within a local or jurisdictional context,

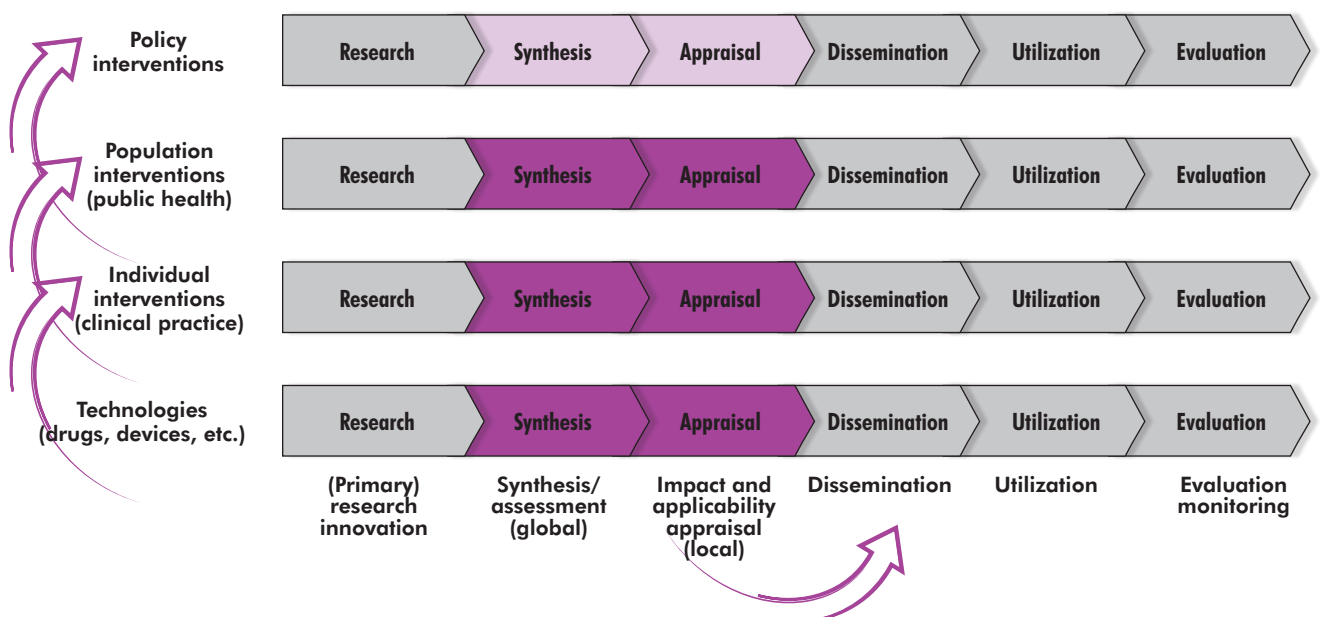
engaging local experts and decision-makers who play important roles in the dissemination and utilization of the intervention. It may also include an examination of the intervention’s potential impact on the higher population and policy levels (29).

The authors provided a graphical representation of how HTA can be used to inform different levels of practice, policy and decisions (Figure 7), which shows how the chain of evidence can be operationalized along an iterative loop of continual learning.

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

The International Network of Agencies in Health Technology Assessment (INAHTA), established in 1993, is a non-profit organization that in 2010 had grown to 52 member agencies from 26 countries.

Figure 7. Knowledge chains and learning loops: health technology assessment as a tool



Source: (29)

All members are non-profit making organizations producing HTAs, and are linked to regional or national governments. Most INAHTA activities are coordinated by a secretariat. The membership meets yearly and participates in various working groups throughout the year. The annual meeting is held in conjunction with the HTAi conference. The Executive Committee and Board are elected for two-year terms.

INAHTA's key communication forum is the Internet. The INAHTA web site at www.inahta.org includes information about ongoing activities and HTA reports. INAHTA Briefs are published regularly on the site, and are intended as a forum for member agencies to present overviews of recently published reports. Also on the web site are HTA checklists, which are an aid to furthering a consistent and transparent approach to HTA.

The web site also has information on joint projects that involve member agencies in collaborative efforts to evaluate medical technologies of mutual interest. As an example, the INAHTA report on positron emission tomography (PET) was updated and published in the *International Journal of Technology Assessment in Health Care* in 2006 (30, 31). A synthesis report was published in 2000 and contains a summary and analysis of five reports on preoperative evaluation from INAHTA agencies (32). A members-only section of the site provides a platform for ongoing work of the membership.

INAHTA also produces a newsletter, which includes news on current initiatives and activities among member agencies, new projects within the Network, recent developments and trends in health policy research, publications in the field, and upcoming events. Other means of dissemination include participation in international conferences, workshops,

exhibitions, and educational activities and seminars.

9.3 WHO collaborating centres and their global network

WHO collaborating centres are institutions such as units in ministries of health, research institutes, universities or academies, which are designated by the WHO Director-General to carry out activities in support of WHO's programmes. In 2010, there were over 800 WHO collaborating centres in 90 Member States working with WHO on areas such as nursing, occupational health, communicable diseases, nutrition, mental health, chronic diseases and health technologies.

In 2009, the Global Network of WHO Collaborating Centres for HTA was launched during the HTAi annual meeting in Singapore. This is a network of WHO collaborating centres involved in research and implementation of HTA worldwide. The aim of the network is to connect the various collaborating centres across the world involved directly or indirectly in HTA to promote international dialogue and collaboration and to strengthen existing projects. This networking will lead to increased capacity for using HTA as a key tool in decision-making and policy-making processes, especially in developing and emerging countries.

The network holds annual meetings of members in conjunction with the HTAi annual meetings. It also facilitates communication between its members via its web site hosted by the University of Ottawa (<http://www.cgh.uottawa.ca/htanet/>) and newsletters. In addition, it actively seeks opportunities for collaboration between its members via projects and internships.

There are currently 14 WHO collaborating centres with full membership to the network whose work is either directly or indirectly linked to HTA.

- National Center for Health Technology Excellence (CENETEC), Ministry of Health – WHO Collaborating Centre in Health Technology in Mexico.
- Fudan University Shanghai – WHO Collaborating Centre for Health Technology Assessment and Management in China.
- Catalan Agency for Health Technology Assessment and Research (CAHTA) – WHO Collaborating Centre for Health Technology Assessment in Spain.
- Swedish Council on Technology Assessment in Health Care (SBU) – WHO Collaborating Centre for Health Technology Assessment in Sweden.
- Fundação Oswaldo Cruz Instituto Oswaldo Cruz (FIOCRUZ) – WHO Collaborating Centre for Education of Health Technicians in Brazil.
- Institute of Population Health – WHO Collaborating Centre for Knowledge Translation and Health Technology Assessment in Health Equity in Canada.
- WHO Collaborating Centre for Oral Health Research in Ireland.
- WHO Collaborating Centre for Mental Health Research and Training in Egypt.
- Emergency Care Research Institute – WHO Collaborating Centre for Patient Safety, Risk Management and Health Care Technology in the United States of America.
- College of Nursing at Ribeirao Preto University of São Paulo – WHO Collaborating Centre for Nursing Research Development in Brazil.
- DHI Water and Environment and Health – WHO Collaborating Centre for Water and Health in Denmark.

- Norwegian Centre for Telemedicine (NST), University Hospital of North Norway – WHO Collaborating Centre for Telemedicine in Norway.
- Curtin University of Technology – WHO Collaborating Centre for Environmental Health Impact Assessment in Australia.
- CES University – WHO Collaborating Centre for Health Technology in Colombia.

The network also aims to work in synergy with other existing HTA networks, including HTAi and INAHTA, in order to galvanize the international HTA community as a whole.

9.4 European network for Health Technology Assessment (EUnetHTA)

EUnetHTA is a European collaboration launched in November 2008 with 25 founding partners from 15 European countries. Focusing on HTA collaboration in Europe, EUnetHTA:

- facilitates efficient use of resources available for HTA;
- creates sustainable systems of HTA knowledge sharing;
- promotes good practices in HTA methods and processes.

In addition, EUnetHTA implements project tools and processes, explores relative effectiveness principles and methodology, and develops transparent and broad balanced engagement with identified HTA stakeholder groups. In 2009, the EUnetHTA collaboration joined forces with European Union Member States and the European Commission to implement the results of the EUnetHTA project through a Joint Action on HTA 2010–2012 (33).

10 Challenges for using health technology assessment in developing and emerging countries

The institutional dimensions are essential for enhancing the use of knowledge by decision-makers. A multi-method case study by Lavis et al. examined these institutional dimensions of evidence-informed health policy in developing countries. The authors point out:

Seven recommendations emerged for those involved in establishing or leading organizations that support the use of research evidence in developing health policy: 1) collaborate with other organizations; 2) establish strong links with policymakers and involve stakeholders in the work; 3) be independent and manage conflicts of interest among those involved in the work; 4) build capacity among those working in the organization; 5) use good methods and be transparent in the work; 6) start small, have a clear audience and scope, and address important questions; and 7) be attentive to implementation considerations, even if implementation is not a remit (34).

The Health Technology Assessment international interest sub-group (HTAi ISG) on the use of HTA in developing countries highlighted in their 2005 paper the special challenges of advancing HTA for policy, decision-making and practice in developing countries (29). The authors of the paper state:

Whether within or among countries, HTA should be context-specific. Although it originated in and has

been used mostly in the wealthier nations, HTA is increasingly used in low- and high-resource nations to provide findings to inform health-care policies and decisions. Further, there is increasing international sharing of HTA expertise, information, methods, and findings. It is also an aim among HTA agencies and scientists in the developed countries to assist low-income countries by “adopting” future local HTA activities and helping to build up local expertise (29).

For many health-care interventions, the medical evidence on safety and efficacy is applicable across populations in different communities or countries. Indeed, evidence used in HTA can be rapidly and easily shared around much of the world. However, the desirable or acceptable levels of safety, effectiveness, cost-effectiveness, and other attributes of a technology, as well as acceptable trade-offs among these, may vary in different communities, countries, or other circumstances. As such, in HTA, it can be useful to “globalize the evidence, localize the decision” (35).

In a presentation at the 2009 HTAi conference in Singapore, entitled *National planning and regulation under pressure*, Akiko Maeda from the World Bank presented the following conclusions concerning the challenges for applying HTA in developing countries.

- HTA offers critical information on technology solutions but to date, most HTA applications have been

developed for high-income countries with relatively well-established planning and regulatory systems in place.

- To be useful for developing countries, there is a need to:
 - › find ways to lower the cost of establishing and maintaining HTA functions and capacities;
 - › better link HTA with governance and organizational reforms in developing countries to generate appropriate demand (36).

At the opening ceremony of the HTAi 2009 meeting, the Minister of Health of Singapore, Khaw Boon Wan, stressed the importance for developing countries to adapt global knowledge to local contexts. He urged participants to “not re-invent the wheel’ and reaffirmed that:

Asians welcome such objective, authoritative assessments of health technology. Many do not have as many resources for such research, but this is where the global collaborative approach can benefit us. We can adapt your technology assessments for our local context. And some Asian countries in a position to do so, should also contribute to this body of knowledge. I hope that this conference will be a useful forum for mutual learning in developing and enhancing decision-making systems which integrate evidence from HTA, and that are sensitive to local factors (37).

The HTAi ISG on HTA in developing countries was aware of the sensitivity and different challenges of advancing the application of HTA in developing countries. The authors of the paper recognized this challenge by observing that:

Certainly, implementing health interventions in developing countries that have been proven in wealthier nations has been difficult and often disappointing. In the completion of HTA and the transfer of findings from one country to another, there can be substantial differences in:

- *epidemiological environments (e.g. relative prevalence of communicable vs. noncommunicable disease; acute vs. chronic disease);*
- *physical environments;*
- *financial resources;*
- *health-care financing and distribution mechanisms;*
- *cultural acceptance of health-care interventions;*
- *values for personal choice, efficiency, and equity;*
- *technology maintenance capacity;*
- *civil and health-care infrastructure;*
- *skilled human resources;*
- *training and education;*
- *regulatory environment;*
- *health professional standards; profitability of health-care markets (e.g. for technology companies) (29).*

HTAi has made an explicit commitment to collaborate on advancing HTA around the globe. In the paper from the HTAi ISG on developing countries, the authors state, “Partnership – HTAi welcomes the opportunity to work in partnership with other agencies to develop resources for promot(ing) the use of HTA around the world” (29). The challenge is now for the global community to work with HTAi to advance scientific evidence to inform health practice, and to facilitate policy- and decision-making for the benefit of people in developing and emerging countries.

The Global Network of WHO Collaborating Centres for HTA also recognizes many of these challenges and has come forward with approaches and next steps to address them. In addition, some WHO collaborating centres have developed toolkits that will assist in capacity building to incorporate HTA into decision-making and allocate resources within local health

systems. One such example is the *Equity-oriented toolkit for HTA* (38) developed by the WHO Collaborating Centre for Knowledge Translation and HTA in Health Equity, which assesses existing HTA tools by their capability to detect differences in impact by taking into consideration vulnerable populations.



11 Strategies for developing health technology assessment

11.1 Adapting the strategy to the specific context

Health technology assessment can be used and introduced in countries based on their capability, capacity and need. Any country can access HTA knowledge through the international HTA database (39), but networking is essential for finding ongoing HTA research. The biggest challenge however is not to *find* information, but rather to develop the capacity to *use* HTA information. Institutional capacity for assessing the need for HTA, finding the information, analysing this information in relation to the specific context, and supporting decision-makers to use the information will be described in this section.

The appropriate use of health technology assessment in a country matched against its resource capacity can be thought of as being located along a continuum of development:

- i. researchers, scientists and policy-makers become familiar with the international scientific literature;
- ii. researchers, scientists and policy-makers become familiar with the appraisal, interpretation and potential application(s) of scientific literature in the local settings;
- iii. a critical mass of professionals is developed so that the country has the capacity and capability to create new knowledge in HTA;
- iv. formalized mechanisms are established for linking the creation of knowledge to decision-making processes, eventually leading to formal organizations.

The foundation for advancing health technology assessment to developing countries can be signalled with the 1990 report of the Commission on Health Research for Development, entitled *Health research: essential link to equity in development* (40). The report states, “For the health field, international functions can be better achieved by strengthening national institutions within developing countries to play both national and international roles, buttressed by regional and international networking, rather than by creating new autonomous international health research centres” (40). When developing HTA in a specific country or region it is important to identify existing reputable and autonomous national research organizations in the country to develop the HTA capacity.

Health research systems should be considered as part of the country’s health system and take into account the large variety of stakeholders within the country’s national context. A commentary by the Council on Health Research for Development (COHRED) reflects this sentiment in their statement:

Furthermore, by defining a health research system as “the people, institutions and activities whose aim is to generate detailed and reliable knowledge”, its boundaries are restricted to research producers. This retrogressive definition is contrary to the broad thrust for inclusiveness that has characterized the movement for health research for development during the last two decades: by moving towards a demand-driven model of health research, decision-makers, users of

research, civil society and mediators have been acknowledged as equally important actors (41).

The most current and important contribution to the advancement of health research on the international stage is the WHO strategy on research for health, which was approved by the World Health Assembly in May 2010. The strategy focuses on the management and organization of research activities within WHO and on support provided to countries in organizing health research when required (42). Since this is such an important piece of work it is being used to inform the structure and approach for developing country HTA capacity.

11.2 Priority setting for health technology assessment

Making choices of resource allocation in health care is a complex and contested matter. Approaches using cost-effectiveness, QALYs, programme budgeting marginal analysis, and deliberative discourse are recommended. The optimal approach for priority setting in health care however is far from clear, as each technique has its own strengths and weaknesses. A deliberative approach using summaries of costs and benefits of options as a basis for discussion may be preferable as it is inclusive of a wide array of participants.

A balance sheet approach has been shown to be very promising in study of a low-income setting. The authors of the paper *Combining evidence and values in priority setting: testing the balance sheet method in a low-income country (43)* concluded that evidence-based and deliberative decision-making does change priorities significantly in an experimental setting. Their use of the balance sheet method was meant as a demonstration project but could, if properly developed,

be feasible for health planners, experts and health workers; although more work is needed before it can be used by laypersons (43, 44).

11.3 A strategy of health technology assessment focal points

HTA could be introduced gradually by identifying individuals with a capacity for accessing and understanding HTAs and making these individuals the “focal points” of HTA and scientific evidence of effectiveness of health-care interventions. Focal points could be located in a national research organization, a national government department, a university or other non-profit agencies concerned with advancing the use of HTA for good governance in policy- and decision-making. These individuals – hereafter referred to as “HTA focal points” – would serve as knowledge mobilizers or ambassadors of the relevant information that they would bring to the attention of policy- or decision-makers.

The basic role of the HTA focal point would be to develop awareness of health technology assessment and increase the uptake and use of HTA within a designated country by:

- developing and supporting a network of HTA stakeholders within the country that find HTA useful in the policy- and decision-making;
- facilitating the flow of HTA information from the international HTA community to the country;
- acting as the primary contact in the country for HTA resources and information;
- organizing or facilitating meetings, providing presentations and conducting workshops to help potential users of HTA to interpret and disseminate HTA information;

- identifying and articulating the HTA needs and priorities of key audiences;
- facilitating interaction between HTA producers and HTA users to develop an ongoing relationship, and maintaining linkages to the international HTA community.

The HTA focal point can also take health technology assessments from the international literature and customize them for appropriate utilization in their communities. They would work with the data and information in the HTAs and with the country-specific data and information, and then merge the two so that they provide a credible source of information to inform the policy question.

Another strategy would be to introduce and develop HTA capacity within an existing organization, such as a university or government, or to establish an independent agency with the capacity to undertake health technology assessments. The elements that contribute to an independent high functioning HTA agency have been identified and described elsewhere in the literature (45).

11.4 Building on synergistic linkages

On page 24, synergies were identified between and among HTAi and INAHTA initiatives in advancing the international community's advancement of HTA. These will be important partners and linkages available to WHO at all levels as well as the national research organizations, which function in support of the country health systems.

The WHO strategy on research for health (42) focuses on the management and organization of research activities within WHO and on support provided to countries in organizing health research when required. A fundamental component

of the strategy is that WHO becomes more familiar with using evidence-based decision-making methods such as health technology assessment, at its headquarters, and in its regional and country offices. This demonstrates a substantive commitment to HTA and evidence-based policy-making, and increases the likelihood of HTA gaining traction in the lower-income countries.

The commitment of WHO to health research and to HTA will support capacity building in health research and health technology assessment, and strengthen the advocacy for these fields. It will also provide an improved platform for communicating its involvement in the commitment to health research and health technology assessment.

For the HTA projects to be successful and for the WHO infrastructure to be appropriately aligned and supportive, four ingredients are necessary. Figure 9 illustrates the importance of these ingredients – good governance, funding, adequate staffing and good collaboration with partners – for a successful implementation of HTA projects at the country level.

Disseminating knowledge and skills in HTA should be based on a progressive strategy, starting with raising awareness by attending workshops to become familiar with the concept, methods and results of HTA, and participating in HTA and policy networks. As experience and understanding is gained, the next step will be toward improving individuals' capability in accessing, assessing, applying and contextualizing the HTA for the country setting. The next stage would be an attempt to build self-sufficiency in the knowledge and skills by capacity building with individuals in the country through mentorships, distance education, in situ graduate study or post-doctoral work. Implementation involves gaining

Figure 8. Building health technology assessment awareness and capacity in WHO and in countries

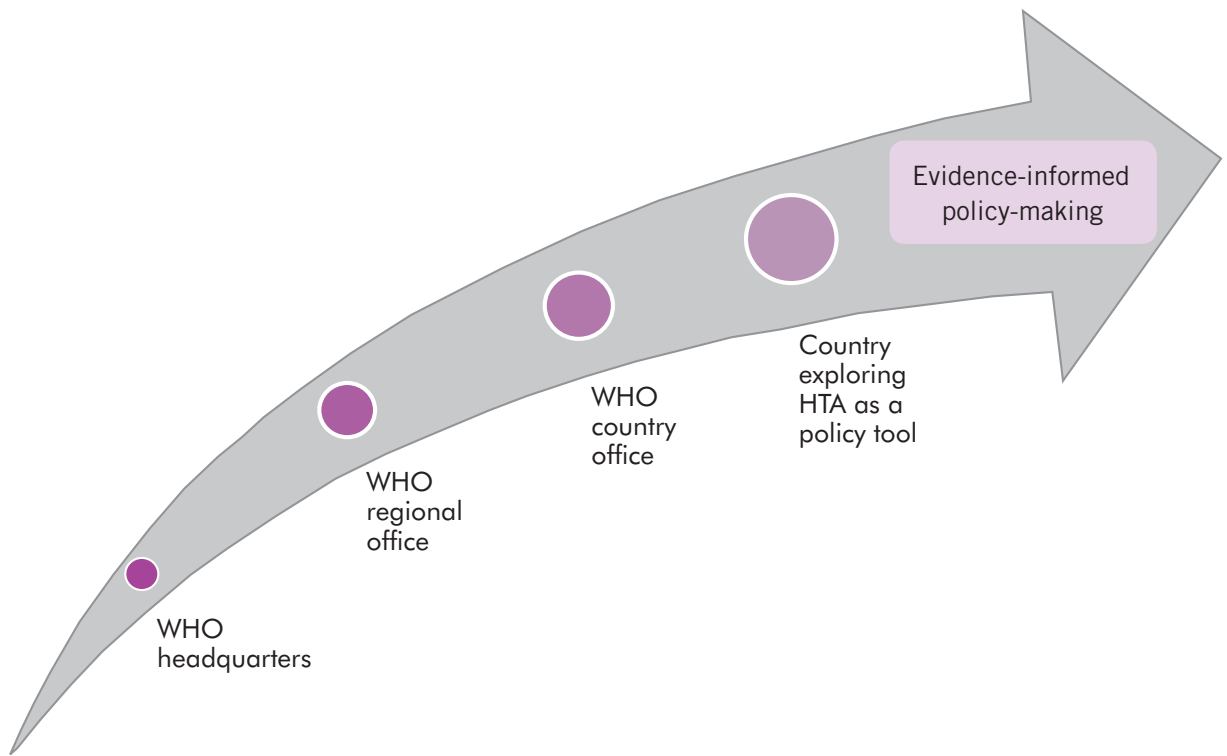


Figure 9. Ingredients for successful implementation of health technology assessment projects



the experience, knowledge and skills that would permit countries to begin considering the introduction of agencies to undertake HTAs to solve local health-care issues. Significant experience has been gained by INAHTA member agencies on mentoring individuals from developing countries who are interested in learning HTA. One study demonstrated that success in implementing an HTA presence in a country setting depends on factors such as local political, economic, and educational support (46).

Health technology assessment works in concert with, and relies on, many scientific disciplines to advance its work – epidemiology, biomedical sciences, behavioural sciences, clinical effectiveness studies, health economics, implementation science, health impact analysis and evaluation are a few of many. The multi-

disciplinary and interdisciplinary nature of HTA is what gives it its strength in being a valuable tool to inform health-care decisions and policy about what works and what does not. This character and strength is commensurate with the call to action that the WHO research for health strategy has articulated (42). Figure 10 shows how health research spans five generic areas of activity, all of which are supported by HTA.

The WHO research strategy (42) has five interrelated goals.

1. Organization – strengthening the research culture across WHO.
2. Priorities – reinforcing research as essential (at national, regional and global levels, and within WHO) in response to priority health needs.

Figure 10. WHO call to action on health research: the five generic areas of activity



Source: (42)

3. Capacity – providing support to the strengthening of national systems for health research.
4. Standards – promoting good practice in research, drawing on WHO’s core function of setting norms and standards.
5. Translation – strengthening the links between the policy, practice and products of research.

The actions identified in the WHO research for health strategy are commensurate and supported by the approach of HTA to inform practice, policy and decisions. HTA can help to achieve the goals and objectives of WHO’s research for health strategy through specific initiatives established within the country projects. Regional WHO-supported networks supporting evidence-informed decision-making, such as the Evidence-Informed Policy Network (EVIPN: <http://www.who.int/rpc/evipnet/>) should be linked to HTA projects.

Figure 11 illustrates the relationship between the five goals of the research for health strategy and how they converge with HTA to support WHO’s objectives in health research.

Figure 11. Convergence of the goals of WHO’s research for health strategy and the goals of health technology assessment



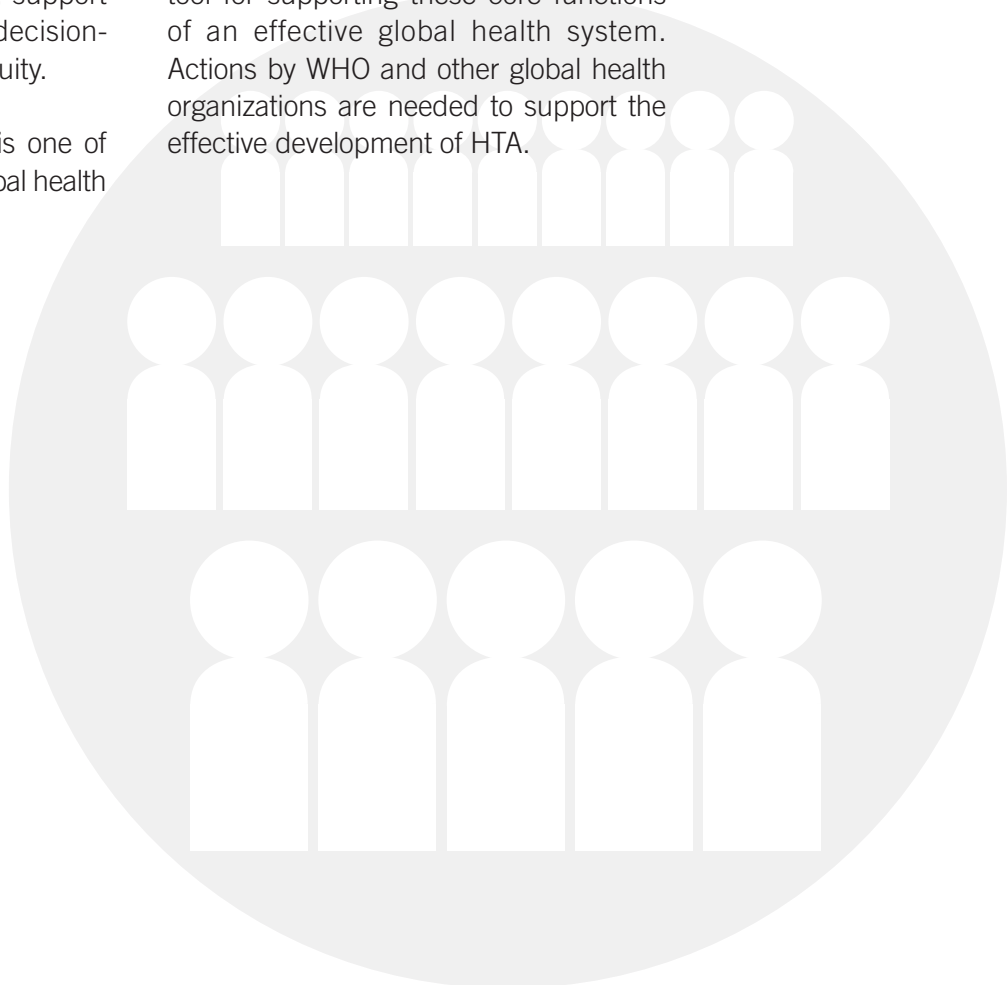
Source: adapted from (42)

12 Concluding remarks

Over the last decades, HTA has emerged as a powerful paradigm for institutionalizing evidence-based and evidence-informed decision-making for health policies. Appropriate HTA strategies enable developing and emerging countries to contextualize global knowledge, support transparent and accountable decision-making, and promote health equity.

Linking knowledge with action is one of the greatest challenges of the global health

system. This linkage is often achieved through innovations, which commonly start with basic research that is translated into new health technologies. These technologies must be delivered to those in need of them (47). HTA is an important tool for supporting these core functions of an effective global health system. Actions by WHO and other global health organizations are needed to support the effective development of HTA.



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