3.3 Assessment: National health technology assessment unit

3.3.1 Introduction

Health systems throughout the world are struggling with the challenge of how to manage health care delivery in resource-constrained conditions to achieve Universal Health Coverage. Healthcare policy, practice and decisions are needed to maximize the positive impact of health care interventions on population health, while optimizing the value from the cost of providing the interventions (see Fig. 3.3-1).

In this context, alongside health technology regulation and health technology management, health technology assessment (HTA) is a key component in supporting evidence based decision-making by promoting technologies that increase the quality of the health system and by preventing the uptake of technologies that are of doubtful value at the same time. Health systems are strengthened when HTA is integrated into 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 HTA to provide a policy approach that is accountable to the population for its decisions.

In other words, alongside health technology regulation and health technology management, HTA is needed to ensure the appropriate, effective, and safe introduction and use of health technologies. During the 67th World Health Assembly in 2014, resolution WHA67.23 was approved, recognizing the importance of HTA in support of universal health coverage. HTA can be defined as the “systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.” Here, “health technologies” refers to the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life.

HTA started out as a response to the technological breakthrough of computer-assisted tomography due to the very high costs per unit, and HTA processes nowadays are used to inform the decision-making process concerning the introduction of new technologies to a health system. In a well-defined scientific process, criteria such as the health technology’s medical efficacy, safety and cost are analysed in relation to social, economic, organizational and ethical aspects. Here, HTA relies on disciplines such as epidemiology, biomedical sciences, behavioural sciences, clinical effectiveness studies, health economics, implementation science, biomedical engineering, and health impact analysis and evaluation. The multidisciplinary and interdisciplinary nature of HTA is what gives it its strength commensurate with the call to action that the WHO research for health strategy has articulated. In the case of medical devices,
Fig. 3.3-2 explains the domains of regulation, assessment and management, and illustrates the distinction of the regulatory and management aspects of health technologies for drugs and devices, and the position of HTA being independent of both. The complementary function of regulation 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 (Fig. 3.3-3).

Fig. 3.3-2. Domains of health technology regulation, assessment, and management for drugs and devices

In response to the need for formal organization to structure and undertake reviews of the safety, efficacy and effectiveness of health technologies, various HTA agencies have emerged during the past years. The agencies are often established with a mission and provided with financial and human resources to undertake systematic assessment of public policy questions with a defined set of objectives. There are several international agencies supporting the advancement of HTA on the global stage, as shown by the following examples:

- The International Network of Agencies for Health Technology Assessment (INAHTA)
  is a non-profit organization that has grown to 46 member agencies from 26 countries. All members are non-profit organizations producing HTAs, and are linked to regional or national governments.

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

- The International Information Network on New and Emerging Health Technologies (EuroScan International Network)
  “is a collaborative network of agencies for the sharing of information and development of methods for the early identification and assessment of key new and emerging health-related technologies”.

- The European network for Health Technology Assessment (EUnetHTA)
  is a European collaboration launched in November 2008 with 25 founding partners from 15 European countries. Its aim is to facilitate efficient use of resources available for HTA, create sustainable systems of HTA knowledge sharing, and promote good practices in HTA methods and processes.

Fig. 3.3-3. From performance to use in health care: layers of questions
HTA agencies are, however, not limited to government institutions; there are also HTA agencies that produce assessments in the academic sector. HTA 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, but networking is essential for finding ongoing HTA research. Furthermore, the development of the capacity to use HTA information often poses a challenge. Also, many HTA agencies and scientists from high-income countries seek to help HTA in developing countries by supporting local HTA activities and helping to build up local expertise.

### 3.3.2 Global facts

The Baseline Country Survey on Medical Devices collected information on the existence of a unit at national/federal level that is responsible for health technology assessment for medical devices. Results are visualized in Fig. 3.3-4. However, as the degree of HTA done in the corresponding countries is very variable – ranging from committees or units not formally called HTA, to specialized HTA agencies – the numbers only give an approximate idea of global HTA implementation.

![Fig. 3.3-4. Unit at national/federal level responsible for Health Technology Assessment (HTA)](image)

From the 177 country survey respondents, 174 provided information on HTA. In total, 68 Member States (39% of 174) have at least one HTA unit/committee/agency within the ministry of health and 106 Member States (61% of 174) do not have any formalized HTA units (Fig. 3.3-5).

![Fig. 3.3-5. Existence of an HTA unit within the country’s MoH](image)

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9 As the degree of HTA done in the corresponding countries is very variable – ranging from occasional HTA to HTA performed in specialized HTA units – the numbers only give an approximate idea of global HTA implementation.
Presenting the data with respect to WHO regions, all regions except the European region have less than 40% of countries with at least one HTA unit (from responding countries in each region). The EUR region has 69% of countries with at least one HTA unit. Furthermore, in Eastern Mediterranean, African and South-East Asia regions, three out of four countries do not have at least one HTA unit (see figure 3.3-6).  

As a response to the WHA67.23 resolution approved in May 2014 on Health Technology Assessment for Universal Health Coverage\(^1\), in 2015, WHO did a global survey on health technology assessment as conducted by government or national institutions. Consistent with the WHA67.23 resolution, the survey included five sections that aimed to measure the utilization of HTA in public sector decision making, the scope of HTA and availability of guidelines, the institutional capacity and human resources supporting HTA, the governance of HTA processes, and the requirements for strengthening HTA capacity. The resulting report “2015 Global Atlas of Health Technology Assessment by National Authorities”\(^9\) is available here: [http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf?ua=1](http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf?ua=1).

The participation rate varied by region and country income, with higher response rates from EUR (79.2%), SEAR (72.7%), EMR (61.9%) and WPR (59.3%), than AMR (37.1%) and AFR (36.2%), with 111 respondent countries overall. Some of the most important findings are summarized in the following figures. Fig. 3.3-7 shows the distribution of the assessed types of technologies. Fig. 3.3-8 shows the considered frequency of ten pre-specified aspects of HTA regarding medical devices as estimated by the respondent countries.

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\(^9\) Global topics and facts

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**Fig. 3.3-7.** Type of technologies or interventions assessed, proportion of countries by (a) region and (b) country income (graphic from “2015 Global Survey on HTA by National Authorities”\(^9\), page 9)
As found in the survey, the preparation of HTA reports usually involves public health professionals as well as experts in clinical sciences. Fig. 3.3-9 shows the proportion of different professionals for HTA involved in the preparation of HTA reports for medical devices. Fig. 3.3-10 shows the proportion of different professionals for HTA involved in the decision-making process regarding medical devices.

Fig. 3.3-8. Frequency of covering different aspects in HTA regarding medical devices (62 respondent countries), (graphic from “2015 Global Survey on HTA by National Authorities” ix page 12)

Fig. 3.3-9. Number of professionals from different backgrounds involved in preparation of HTA reports for medical devices (from “2015 Global Survey on HTA by National Authorities” ix, page 19)

Fig. 3.3-10. Number of professionals from different backgrounds involved decision-making processes regarding medical devices (from “2015 Global Survey on HTA by National Authorities” ix, page 19)
The health technology assessment of medical devices is an area under development. In high-income countries where health systems are well developed, the HTA process is mainly to define which new sophisticated or costly technology to add to the packages of interventions or for public procurement. In low- and middle-income countries though, HTA is an important tool to consider which technologies should be included in the package of benefits of public insurance schemes, or to do prioritization when resources are limited (see Fig. 3.3-11).

**3.3.3 Further readings**

The following documents and websites contain further relevant information:

**Documents:**
- Health technology assessment of medical devices. WHO Medical Device Technical Series.x
- Resources for health technology assessment. Health Technology Assessment international and the International Network of Agencies for Health Technology Assessment, 2005.xi
- Health Technology Assessment resolution WHA67.23 on health intervention and technology assessment in support of Universal Health Coverage.xi

**Websites:**
- The International Network of Agencies for Health Technology Assessment (INAHTA).iv
- Health Technology Assessment international (HTAi).v
- Health technology assessment (HTA) database.vii

**Endnotes**