



DEVELOPING AN APPROACH FOR USING HEALTH TECHNOLOGY ASSESSMENTS IN REIMBURSEMENT SYSTEMS FOR MEDICAL PRODUCTS

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Executive summary

A two day meeting was held to discuss the use of health technology assessment (HTA) in low and middle income countries (LMIC), including aspects of its use in relation to medicine and health technologies, pricing policies and reimbursement decisions. The meeting brought together experts in HTA and pharmaceutical economics from academia; WHO regional advisors from Europe (EURO), Africa (AFRO), Eastern Mediterranean (EMRO) and the Americas (PAHO), as well as representatives from LMIC that have started using elements of HTA, or are working towards doing so. (Annex 1). In addition, the meeting discussed possible follow-up actions, including a proposed larger consultation to be held late in 2015.

A key discussion point was to identify the future role for WHO in supporting the development of HTA, particularly given the WHA resolution from 2014 (67.23) on the topic that called on WHO to develop global guidance on methods and processes for health intervention and technology assessment in support of universal health coverage.

As has been well described in extant literature, currently HTA is used as a tool in many high income countries as part of a process of selecting pharmaceuticals, clinical procedures and medical devices for reimbursement, budgeting, and insurance programs as well as public health interventions. A wide variety of different organizations and structures have been set up in order to use aspects of HTA, ranging from large institutions to small advisory committees and secretariats in ministries of health. Common elements in advanced systems are staff or personnel with capacity to critically appraise clinical and economic evidence, availability of data on cost and resource utilization, integration in some way with decision-making processes about budgeting, benefit packages, or reimbursement lists. In some countries, pricing of pharmaceuticals or technologies is explicitly linked to HTA (most often narrowed down to economic evaluations), but in combination with other policies such as reference pricing, generic substitution, and control of supply chain mark-ups.

Meeting participants discussed some of the current work of the WHO relating to aspects of HTA. This includes the work on health financing, guidance on cost-effectiveness of interventions and the selection of essential medicines and devices. Results of a large WHO survey of countries with respect to their reported use of and capacity for HTA were presented. Participants from Morocco, South Africa, Indonesia, Slovenia and Jordan, shared their experiences. A broad overview of European work on pricing and reimbursement was presented. Representatives from the WHO regional offices, AFRO, EMRO, EURO and PAHO, presented the regional activities and status of HTA. Some academic perspectives on models of using HTA, education and training program needs, and how to localize the use of HTA in different health care systems were also presented.

Based on the discussion, the priority areas of work for WHO were proposed as:

- Coordinating the many activities in relation to HTA that are currently being undertaken by different agencies for LMIC to ensure that countries get the support that they need and to avoid duplication of effort or conflicting messages;
- Consolidating the existing guidance from WHO, with that in development by other groups, by providing a 'clearing house' for resources, networks, training programs and capacity development;
- Defining the roles and components of HTA holistically for countries so that scientific and organizational components are understood and used appropriately and consistently;
- Promoting that the roles of HTA are understood in the context of other aspects of health system decision making and that HTA is not seen as a 'magic bullet' solution to priority setting, financing and decision-making needs of countries moving towards universal health coverage;
- Promoting that the use of HTA is appropriately linked to other policy tools for managing resources efficiently, especially with regard to pricing and reimbursement policies;
- Setting standards for technical tools used in HTA, such as economic models, to ensure that they are fit for purpose especially when used in LMIC settings
- Clarify the role of the so-called WHO 'cost-effectiveness threshold';
- Supporting countries to define sources of local data for evaluation, and for use in priority setting, managing expenditure and finances in the context of developing universal health coverage.
- Supporting countries in using assessment reports from existing HTA systems
- Developing guidance for countries that are moving towards systems for using HTA, such as a set of possible approaches (laws, regulations, functions, processes, policies to establish and update over time) based on national health care, financing systems, institutional organization and other aspects at a given time.

The objectives for the proposed follow-up consultation are:

- To ensure that the approach under development is consistent with a broader group of stakeholders' views, including a larger sample of countries, HTA agencies, civil society and academic institutions
- To create a platform for coordinating activities with other partners
- To develop drafts of pathways to using HTA over the next 3 months, based on a sample of existing country case studies of successful development and implementation of HTA
- To communicate and obtain feedback on initial approaches for WHO guidance, including the use of the cost-effectiveness threshold
- To develop methods for defining local data sources for use in priority setting and the needs for capacity for analysing and using these data for decision-making
- To launch a 'clearing house' of information on capacity development and methodological guidance
- To establish a process for setting the quality standard of technical tools.

The participants in this first meeting have agreed to work as the initial Reference Group for this work.

This meeting was organized with the financial contribution of the European Commission through the EU/ACP/WHO Renewed Partnership on Pharmaceutical Policies . The outcome of the HTA consultations will provide guidance to the 15 African ACP countries part of this project and more particularly those establishing reimbursement systems.

Background

The resolution on Health Intervention and Technology Assessment in Support of Universal Health Coverage (WHA67.23, 2014) called on the World Health Organization (WHO) to develop global guidance on methods and processes for Health Technology Assessment (HTA). HTA is described WHO Executive Board EB134/30 as:

'.....is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies. It may be applied to interventions, such as including a new medicine into a reimbursement scheme, rolling-out broad public health programmes (such as immunization or screening for cancer), priority setting in health care, identifying health interventions that produce the greatest health gain and offer value for money, setting prices for medicines and other technologies based on their cost-effectiveness, and formulating clinical guidelines.'

Recent requests from countries to WHO also reinforce the need for guidance and support for structures and systems to establish HTA processes and policy frameworks. Countries also are in need of tools to develop benefits packages for insurance programmes and require capacity to undertake the technical aspects of HTA. Existing guidance from WHO being used as a starting point include:

- the WHO Model List of Essential Medicines¹;
- WHO clinical treatment and policy guidelines²;
- benefits package and health financing strategies;
- selected national health strategic plans and or national medicines policies; and
- WHO-CHOICE.

Some upper-middle and high-income countries, have developed guidance documents that are intended to contribute to facilitate decisions made in different areas, including:

- provision of new services;
- reimbursement of technologies in insurance processes;
- pricing of medicines and technologies (and its associated budget impact);

¹ www.who.int/medicines/publications/essentialmedicines/en/

² www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/

- geolocation of sites of provision of new services and technologies;
- associated health system investments to provide the new services and technologies that are to be provided or reimbursed; and
- de-commissioning/dis-investment of superseded technologies.

In the context of several projects managed by EMP/PAU³ aimed at improving access to medicines and health technologies, a number of countries have requested support for developing ‘road maps’ for initiating and enhancing HTA-informed reimbursement systems for medicines, health interventions and technologies.

Within WHO, there have been initial activities to map current HTA activities carried out internally, as well as mapping of the international organisations undertaking HTA activities. Some of the WHO Regional Offices have established regional networks of interested Member States as well as working with existing well-established networks, such as EUnetHTA. Key international professional associations including HTAi, INAHTA and EuroScan also have official links with WHO.

Currently, some independent technical support is being provided to selected countries by established HTA agencies, including NICE (UK), through its consultancy arm, NICE International and HiTAP (Thailand). The Bill and Melinda Gates Foundation is funding some of this work. In addition, there are many academic institutions contributing evidence and capacity strengthening for decision making, for example, the London School of Economics, Harvard Medical School and Mahidol University.

Meeting objectives

In line with resolution WHA 67.23, WHO aims to establish a coordinating and convening role for these many different activities and stakeholders, to ensure that the requirements of the WHA resolution are carried out effectively and efficiently and that the needs of Member States are met. In view of this, the objectives of this initial consultation were:

- developing (or collating if they already exist) a series of country case studies that describe the development of HTA, pricing and reimbursement systems, and highlight what has or has not worked in different contexts
- developing a ‘roadmap’ for countries to use as a guide for establishing HTA in systems of decision-making
- taking an inventory of existing WHO publications that are potentially useful to guide countries

³ EU/ACP/WHO Renewed Partnership to strengthen pharmaceutical systems and improve access to quality-assured medicines in 15 African ACP countries:

www.who.int/medicines/areas/coordination/en/

Medicines Transparency Alliance <http://www.who.int/medicines/areas/coordination/meta/en/>

- identifying and defining options for capacity development required for initiating HTA in decision-making; and
- discussing and exploring country needs for WHO technical collaboration in HTA

Summary of presentations

Brief update of the work of the WHO

Any global activities or program of work on HTA must be set in the context of global work on priority setting and health financing, and similarly in countries, HTA needs to be set in the context of the health system. Therefore, an overview of the work on health financing being undertaken by the WHO was provided. Health financing is a key factor in countries' efforts to progress towards universal health coverage. The WHO provides technical and policy advisory support to countries in their assessment of health financing system performance. This serves as the basis to identify and explore policy options for health financing reform. WHO has also been involved in assisting countries to develop their health financing strategy with a view to clarify a country's vision for UHC, objectives, targets and specific reform measures. A key area of work is capacity development in health financing policy analysis and guidance. The link between HTA and health financing is related to strategic purchasing and benefit package design. Benefit package design, however, is not just about defining a list of interventions to be covered. It is a policy instrument with the aim of improving equity, increasing efficiency (e.g., health value for money), "more health for money"), improving financial protection, and increasing transparency in health care, medical product purchasing and financing systems. HTA as one component of benefit package design is relevant in health insurance systems, as well as in other health financing arrangements.

As requested in the WHA Resolution 67.23, an assessment of the status of health intervention and technology assessment in Member States has been conducted. A survey of Member States has been completed, including data on the methodology, human resources, institutional capacity, governance, linkage between health

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