



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



28th PAN AMERICAN SANITARY CONFERENCE 64th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 17-21 September 2012

Provisional Agenda Item 4.6

CSP28/11 (Eng.)
16 July 2012
ORIGINAL: SPANISH

HEALTH TECHNOLOGY ASSESSMENT AND INCORPORATION INTO HEALTH SYSTEMS

Introduction

1. One of the major challenges of health systems based on primary health care is the pursuit of equity, quality of care, and efficiency. In this context, health technologies¹ play an important role. On the one hand, they are essential in the provision of quality care and, on the other, they are generating an ever-growing budgetary impact that can threaten health system sustainability. For this reason, the decision on what technologies should be provided by health systems is vital so that countries can optimize benefits in the health sphere. This document proposes that countries establish processes for the incorporation of health technologies based on health technology assessment (HTA),² using an approach that integrates health technology related functions into the cycle of regulation – incorporation – rational use.

Background

2. The Declaration of Alma-Ata (1978) defines primary health care as “...essential health care based on practical, scientifically sound, and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford [...]. It forms an integral part both of the country's health system, [...] and of the overall social and economic development of the community” (2).

¹ The definition of “health technology” encompasses all products used in health services delivery, procedures, and systems, concept adopted in Resolution WHA60.29 (1).

² HTA is the systematic evaluation of properties, effects, and/or impacts of health care technology. It should include medical, social, ethical, and economic dimensions, and its main purpose is to inform decision-making in the health area (definition adapted from the glossary of the International Network of Agencies for Health Technology Assessment [INAHTA] and Health Technology Assessment international [HTAi]).

3. HTA commenced in the mid-1970s, with assessments carried out in the United States and in Sweden (3-5). However, the first country in the Region of the Americas to formalize the use of HTA in decision-making was Canada, which established governmental HTA institutions in the late 1980s (6). From then until the late 1990s, the advancement of HTA in other countries of the Region remained very limited (7, 8). At that point, interest in the subject increased and countries began to institute significant change, as described later in this document.

4. In the last decade, there has been significant progress in the supply and availability of health technologies in the countries. However, this progress has important budgetary and planning consequences since many of the new technologies are expensive, without, in many cases, offering comparative advantage with respect to technologies already in use. At the same time, in most countries the increase in the availability of health technologies has not been accompanied by the development of capacity in priority setting, institutional processes for comparative assessment of health technologies, and their rational and planned incorporation into health systems.

5. The expansion of access to essential medicines and other health technologies is a global priority and should be considered within the context of the importance of the right to health for all and the recognition that this right has received.³ In some cases, even though health technologies have been shown to be cost-effective, the system does not make them available to all citizens in a manner that is equitable and affordable. In these cases, one option has been to turn to the judicial system to enforce access to health technologies. An example of this was the request for precautionary measures submitted to the Inter-American Commission on Human Rights (IACHR) that guaranteed access to antiretroviral medicines in 10 countries of the Region.⁴ However, regular use of the judicial system to require national health authorities to ensure access to health technologies, often without having verified their effectiveness, can distort the process of incorporating new technologies. This practice, known as ‘judicialization,’ has become increasingly frequent in recent years throughout the Region. It is a complex phenomenon that should be examined from different perspectives, especially with regard to the fulfillment of the right to health and other related human rights by the States, with a focus on the principles of equity, equality, and solidarity. The establishment of transparent

³ See General Comment No. 14 “The right to the highest attainable standard of health” (Article 12 of the International Covenant on Economic, Social, and Cultural Rights). United Nations Committee on Economic, Social, and Cultural Rights. Available at:

[http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) See also PAHO Directing Council Concept Paper CD50/12, “Health and human rights,” available at: www.un.org/disabilities/documents/paho_mh_concept_paper.pdf

⁴ For more information on the measures adopted by the Inter-American Commission on Human Rights (IACHR) with regard to access to antiretroviral drugs in Bolivia, Colombia, Ecuador, Guatemala, Honduras, Nicaragua, Peru, and the Dominican Republic, see the IACHR Annual Report 2002. With regard to measures adopted for Chile and El Salvador, see the IACHR Annual Report 2001. Reports available at: www.cidh.org/annual.eng.htm

decision-making processes based on HTA should help to safeguard the right to health and other human rights anchored in these principles.

6. A health system based on primary health care is comprised of a set of essential structural and functional elements that guarantee coverage and universal access to services that are acceptable to the population and promote equity. The coordination and establishment of an institutional framework for decision-making with respect to the incorporation of health technologies will assist in addressing one of the principal obstacles to achieving universal coverage identified in the World Health Report 2010 (9): the inefficient use of resources. HTA-based processes for prioritizing and incorporating health technologies contribute to universal access through: improvements in the quality of health care; assessment of true therapeutic innovation; increased spending efficiency; expansion of access to technologies that are effective, safe, cost-effective, and form part of the right to health; and the rational use of health technology.

7. A comprehensive approach to HTA is proposed, in accordance with the recommendations of resolutions CD45.R7 (2004) (Access to Medicines), CSP27.R10 (2007) (Quality of Health Care), CD48.R15 (2008) (Public Health, Innovation, and Intellectual Property), CD50.R9 (2010) (Strengthening National Regulatory Authorities for Medicines and Biologicals), CD50.R8 (2010) (Health and Human Rights), CD49.R10 (2009) (Research for Health), CD44.R6 (2003) (Primary Health Care), CD49.R22 (2009) (Integrated Health Services Delivery Networks Based on Primary Health Care), CD47.R10 (2006) (Regional Strategy for Sustaining National Immunization Programs in the Americas), WHA60.16 (2007) (Progress in the rational use of medicines), WHA63.21 (2010) (WHO's role and responsibilities in health research), and WHA60.29 (2007) (Health technologies) (10-20, 1).

8. This policy proposal is also in accordance with the Health Agenda for the Americas 2008-2017 (21), the WHO Medium-Term Strategic Plan 2008-2013 (22), and the PAHO Strategic Plan 2008-2012 (23), with specific links with Strategic Objectives 7, 10, 11, 12, and 14 (see Annex C).

Current Situation Analysis

9. HTA began to gain momentum in the Region in the late 1990s (24). PAHO contributed to this through the dissemination of publications and the organization of workshops with experts and decision-makers in national and subregional settings. In some countries, significant organizational changes began to take place in the 2000s, with the creation of structures devoted to HTA and decision-making, as well as important legislative reforms. A recent study showed that decision-makers consider HTA to be a key element in the decision-making process, although they do identify gaps in their countries, especially the lack of clear linkages between HTA and decision-making (25).

10. Countries have adopted different models for HTA and the incorporation of health technologies. In 2009, Argentina created the Coordinating Unit for Health Technology Assessment (UCEETS), composed of 14 institutions involved in the incorporation process. Brazil, which adopted a national health technology policy in 2009 (26), has an HTA unit in its national regulatory agency—the *Agência Nacional de Vigilância Sanitária* (ANVISA)—responsible for using HTA to guide decisions on pricing of new medicines (27), as well as an HTA unit in the Ministry of Health; both units were established in 2003. It also has a National Commission for the Incorporation of Technologies (CONITEC), which was redesigned in 2011. In Colombia, the new Health Technology Assessment Institute (IETS) was created in 2011. The HTA unit in the Ministry of Health of Chile (ETESA), created in 1997, was the first entity from Latin America to join the International Network of Agencies for Health Technology Assessment (INAHTA).⁵ Mention should also be made of the establishment in 2004 of the National Center for Health Technology Excellence (CENETEC-SALUD) in Mexico, designated a PAHO/WHO Collaborating Center⁶ for health technologies in 2009, as well as the establishment in 2011 of the Sectoral Commission for the Assessment of Health Technology and High Cost Diseases in Peru in the Ministry of Health.⁷

11. Economic assessments (cost-effectiveness, cost-utility, cost-benefit), as part of HTA, are key for supporting the introduction of appropriate and efficient technologies into health systems. In 2006, PAHO launched the ProVac Initiative to develop economic assessment tools for vaccines, provide support for their use, and strengthen institutional decision-making capacity (28, 29). Although economic assessments are still underutilized in the Region, there is increasing interest in incorporating such assessments into the decision-making process (30, 31). Some countries (e.g. Brazil, Mexico, and Uruguay) require the submission of economic assessments as a part of the process for the incorporation of technologies into health systems.

12. Despite the importance of economic studies, the results of these assessments should not be the only consideration in the decision-making process, for example at the expense of other considerations, such as equity. By assessing the many ways a given technology will make an impact, including on equity, HTA can contribute to making health systems increasingly efficient and fair.

13. Pharmacotherapeutics committees play an important role in the assessment of medicines in the countries of the Region, despite variations in the level of functionality and quality. However, most of the countries have no equivalent entity to assess other

⁵ The Latin American country members of INAHTA are the HTA units in the ministries of health of Argentina, Brazil, and Chile; the National Center for Health Technology Excellence (CENETEC) of Mexico; and the Institute for Clinical Effectiveness and Health Policy (IECS) of Argentina.

⁶ In the Region, the following are also collaborating centers on HTA and/or health technology management: *Universidade Federal de Santa Catarina* (Brazil), *Universidad CES* (Colombia), and the University of Ottawa (Canada).

⁷ Ministerial Resolution No. 463-2011 of the Ministry of Health of Peru.

health technologies. The Ministry of Health of Barbados, with PAHO/WHO technical support, performed a review of its national drug formulary using HTA criteria. As a result of this review, the country reduced medicines expenditures by US\$6 million in the first six months following adoption of the changes (April to September 2011), without compromising the quality of health care (32). Since 1977, WHO, with the technical assistance of a group of experts, has prepared and periodically updated a list of essential drugs. WHO recommends that countries adapt the list to their own health needs. By 1995, over 120 countries had adopted national essential medicines lists.

14. At the subregional level, the successes achieved by the MERCOSUR, the Andean Community of Nations (CAN), and CARICOM integration mechanisms should be highlighted. The MERCOSUR countries have advanced in the design of an HTA strengthening project; for its part, the Andean Community adopted a subregional HTA policy (33), while in 2010, the Council for Human and Social Development (COHSOD) of the Caribbean Community adopted the subregional Caribbean Pharmaceutical Policy, whose model lists and therapeutic guidelines are based on HTA.

15. Regional cooperation in HTA has gained momentum. During the Regional Meeting on Health Technology Assessment held in Buenos Aires in October 2010, representatives from 12 countries and a total of 20 institutions, among them ministries of health of the countries, Pan American Health Organization/World Health Organization (PAHO/WHO) Collaborating Centers, and other networks and institutions, agreed to establish the Health Technology Assessment Network of the Americas (RedETSA). This Network, launched officially in June 2011 in Rio de Janeiro, will facilitate information sharing, promote the adoption of common methodologies, and set priorities for joint capacity-building in HTA. PAHO, in consultation with the Member States, is creating a Regional Platform on Access and Innovation for Health Technologies, aimed at supporting the development of regional HTA networks and providing information on health technologies in fields such as regulation, HTA, and rational use.

16. Despite this progress, most countries in the Region need to strengthen processes for the assessment and incorporation of health technologies into health systems.

Proposal

17. For the purpose of: *a*) strengthening the link between HTA and quality of care and patient safety; *b*) ensuring respect for the right to health based on the principles of equity and solidarity; *c*) strengthening evidence-based decision-making processes; and *d*) contributing information to support the organization of cost-effective services for health systems, a comprehensive approach to HTA and the incorporation of health technologies into health systems is proposed, with the elements mentioned below.

Integration of HTA into Public Policies on Health Technologies

18. HTA is an integrating force in health policy; for example, national pharmaceutical policies, science, technology, and innovation policies, and health research policies. HTA promotes access, quality, and the rational use of health technologies and is essential as a means to measure the value added of technological innovation. Regulation is an essential public health function and is crucial to the process of technology incorporation. It encompasses different levels, from the assessment of safety, quality, and efficacy by the national regulatory authority to post-marketing surveillance. The latter produces information on effectiveness and adverse events, which in turn provides feedback for the health technology assessment and incorporation system. Research policies support HTA processes in setting research priorities, in strengthening information collection systems (data processes and quality), as well as in analytical capacity to carry out quality research studies at the national level. It is necessary to strengthen the coordination between HTA and public policies related to health technologies at the national, subregional, and regional levels.

Establishment of an Institutional Framework for HTA-based Decision-making

19. Although there is no single institutional framework for the incorporation of health technologies in health systems based on HTA, it is necessary to develop a regulatory and operational framework adapted to the national context that includes the following elements: *a)* establishment of explicit links between HTA and decision-making on incorporation by means of national laws and norms; *b)* definition of a transparent decision-making process that specifically sets out the relationships and responsibilities of the different stakeholders; and *c)* institutional capacity-building. In addition to an adequate institutional framework, advocacy between stakeholders and decision makers is crucial in mobilizing the necessary political will to ensure that outcomes of HTA are taken into account in decisions relating to the incorporation of health technologies.

Human Resources Development

20. Training of necessary human resources is an essential component of HTA and the incorporation of technologies into health systems. It is important to train assessment teams in both the methods for conducting HTA studies and in the critical analysis of assessments submitted. It is also important to offer continuing education applied to the context and based on case studies. In addition to capacity building at the level of the national authorities, strengthening the technical capability of universities and other research institutions is also recommended.

Promote the Production of Evidence and Dissemination of Information

21. In the Region, there are considerable gaps with regard to the availability of data, the production of evidence, and the quality of research studies. Effective communication

of relevant information to decision-makers is another significant obstacle. To overcome these challenges it is necessary to: *a)* develop methodological tools related to country needs; e.g. economic assessment models; *b)* identify gaps in information availability and quality, in order to adapt existing studies and carry out new studies tailored to local and regional contexts; *c)* promote clinical trial registration; and *d)* promote dissemination of study results among stakeholders and decision-makers, through the Regional Platform on Access and Innovation for Health Technologies and other relevant platforms.

Rational use of Health Technologies

22. Integrated health services delivery networks develop systems for guaranteeing and continuously improving quality of care with the objective of promoting a culture of clinical excellence at all levels. These networks are designed to centralize and integrate service delivery functions that require health technologies as a means of promoting overall efficiency. At the same time, they incorporate management and assessment systems to rationalize the use of medical technology (34). The experience that the countries throughout the Region have acquired in the rational use of medicines and some other technologies offers a solid basis for the promotion of the rational use of all health technologies in national health systems. In addition to strengthening selection processes, it is necessary to: *a)* develop and implement the use of medicine formularies and clinical practice guidelines that govern the use of health technologies in integrated service networks; *b)* evaluate the performance and use of health technologies in health services, including continuous monitoring of adverse events (post-marketing surveillance); *c)* promote the use and availability of independent information on health technologies for health professionals and civil society; and *d)* train human resources for health on the prescription, dispensing, and management of health technologies.

Promotion of Network Collaboration

23. Network collaboration can strengthen HTA outcomes. A network-based approach to research, supported by national and regional academia, aims to improve quality and efficiency both in the production of studies and in their use in decision-making. Experience sharing among institutions, and especially among countries, helps to strengthen the HTA capacity of institutions and human resources, and facilitates the dissemination and comparison of national information and experiences. In this context, the creation of RedETSA in the Region of the Americas provides an opportunity to the countries for information sharing, training, and strengthening the processes to incorporate health technologies based on HTA.

24. Considering the above, the development of a regional strategy and plan of action for HTA is envisaged, to provide support for decision making processes related to the incorporation of health technologies in health systems.

Action by the Pan American Sanitary Conference

25. The Conference is requested to review the information provided in this document and consider the possibility of adopting the proposed resolution presented in Annex A.

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Annexes



PAN AMERICAN HEALTH ORGANIZATION
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28th PAN AMERICAN SANITARY CONFERENCE **64th SESSION OF THE REGIONAL COMMITTEE**

Washington, D.C., USA, 17-21 September 2012

CSP28/11 (Eng.)
Annex A
ORIGINAL: SPANISH

PROPOSED RESOLUTION

HEALTH TECHNOLOGY ASSESSMENT AND INCORPORATION INTO HEALTH SYSTEMS

THE 28th PAN AMERICAN SANITARY CONFERENCE,

Having reviewed the report *Health Technology Assessment and Incorporation into Health Systems* (Document CSP28/11);

Recognizing that in the Health Agenda for the Americas 2008-2017 the ministries and secretaries of health recognized that human rights are part of the principles and values inherent to the Health Agenda, and declared that, to make the right to the enjoyment of the highest attainable standard of health a reality, the countries should work toward achieving universality, access, integrity, quality, and inclusion in the health systems, available to individuals, families and communities;

Taking into account the growing number of health technologies in the Region and the limited institutional capacity for their prioritization and comparative assessment;

Recognizing that the incorporation of new health technologies may have growing budgetary implications that place pressure on the management of health system resources;

Taking into account the practice in some countries of using the judicial system to require national health authorities to ensure access to health technologies without a prior evaluation of their effectiveness or a comparative assessment with those health technologies already offered by the health system;

Recognizing the benefit of incorporating health technologies into health systems based on health technology assessment (HTA), defined as the systematic evaluation of

properties, effects, and/or impacts of those technologies, including medical, social, ethical, and economic dimensions;

Recognizing the achievements and progress of the Health Technology Assessment Network of the Americas (RedETSA), established in 2011 by PAHO, as well as subregional health technology assessment networks,

RESOLVES:

1. To urge Member States to:
 - (a) encourage the establishment of decision-making processes for the incorporation of health technologies based on HTA, including safety, effectiveness, cost, and other relevant criteria;
 - (b) encourage the use of HTA to inform public health policies, including public health system coverage decisions and the development of clinical guidelines and protocols for new technologies;
 - (c) promote efforts to analyze and strengthen institutional frameworks for the incorporation of health technologies and encourage the establishment of transparent processes and linkages with responsibilities defined among the different stakeholders, including regulatory authorities and entities responsible for the assessment and incorporation of health technologies;
 - (d) encourage public procurement transparency, including non-proprietary purchase price information and the sharing of the findings of HTA at the national and regional levels to generate information for decision-making;
 - (e) strengthen institutions and human resources, including assessment teams and decision-makers, in the use of HTA, methods for the implementation of HTA studies in the critical analysis of assessment results;
 - (f) encourage the prioritization of assessments based on national and regional needs, strengthening systems for the collection of quality data, and adapting existing HTA studies to avoid duplication;
 - (g) promote the production and dissemination of HTA results among stakeholders and those responsible for decision-making;
 - (h) promote information sharing through the Regional Platform on Access and Innovation for Health Technologies and other relevant technological platforms;

- (i) strengthen the rational use of health technologies, the development and use of drug formularies, clinical practice guidelines that govern use (including by level of care), as well as systems for monitoring use in integrated health service delivery networks;
 - (j) strengthen national, subregional, and regional HTA networks to promote exchange among institutions and countries, and the dissemination and comparison of studies and national experiences;
 - (k) actively participate in the Health Technology Assessment Network of the Americas (RedETSA).
2. Request the Director to:
- (a) lend support to the Member States in the development of health technology policies and the strengthening of institutional HTA frameworks and in the incorporation of health technologies in health systems based on primary health care;
 - (b) promote the sharing of good practices in HTA and the incorporation of health technologies in health systems among the Member States;
 - (c) promote and encourage collaboration with international organizations and existing international HTA networks;
 - (d) emphasize to the Member States and in subregional, regional, and global forums the importance of participation in RedETSA, mobilizing resources in support of this initiative together with the Member States;
 - (e) promote the development and use of the Regional Platform on Access and Innovation for Health Technologies in the dissemination of HTA results, and the development of HTA communities of practice and social networks at the regional level;
 - (f) report to the PAHO Governing Bodies in 2014 on implementation of this resolution and consider the development of a regional strategy and plan of action at that time, in consultation with the Member States, for the assessment and incorporation of health technologies into health systems.



PAN AMERICAN HEALTH ORGANIZATION

Pan American Sanitary Bureau, Regional Office of the

WORLD HEALTH ORGANIZATION

CSP28/11 (Eng.)

Annex B

**Report on the Financial and Administrative Implications
for the Secretariat of the Proposed Resolution**

<p>1. Agenda item: 4.6: Health Technologies Assessment and Incorporation into Health Systems</p>
<p>2. Linkage to Program and Budget:</p> <p>a) Area of work: Medicines and Technology</p> <p>b) Expected result: Processes for the incorporation of health technologies based on health technology assessment (HTA) established in the countries of the Region and Regional Health Technology Assessment Network strengthened.</p>
<p>3. Financial implications</p> <p>(a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities): US\$700,000.00 over a period of two years.</p> <p>b) Estimated cost for the biennium 2010-2011 (estimated to the nearest US\$ 10,000, including staff and activities): US\$700,000.00</p> <p>c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities? US\$450,000.00.</p>
<p>4. Administrative implications</p> <p>a) Indicate the levels of the Organization at which the work will be undertaken: Regional, subregional, and national.</p> <p>b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile): The need for new staff is not anticipated.</p> <p>c) Time frames (indicate broad time frames for the implementation and evaluation): An estimated two years.</p>



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

CSP28/11 (Eng.)
Annex C

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.6: Health Technologies Assessment and Incorporation into Health Systems

2. Responsible unit: Medicines and Technology

3. Preparing officer: Alexandre Lemgruber

4. List of collaborating centers and national institutions linked to this Agenda item:

Health Technology Assessment collaborating centers:

- National Center for Health Technology Excellence (CENETEC, Mexico);
- University of Ottawa (Canada);
- *Universidade Federal de Santa Catarina* (UFSC, Brazil);
- *Universidad CES* (Colombia).

5. Link between Agenda item and Health Agenda for the Americas 2008-2017:

Item 50 in the Health Agenda for the Americas 2008-2017 establishes that: “Improving effective coverage of the population will require more effective and efficient service delivery. This in turn will require the use of evidence in the definition of practices and better managerial capacity in services, while monitoring fulfillment of the commitment to reorient health services toward models of care that encourage health promotion and disease prevention with a family and community approach. Quality control is a cross-cutting requirement of all health systems and services.”

6. Link between Agenda item and Strategic Plan 2008-2012:

Links with *Strategic Objectives 7, 10, 11, 12, and 14.*

RER 12.3: Member States supported through technical cooperation to promote and assure the rational and efficacious use of cost-effective medical products and health technologies based on the best evidence available; and Indicator 12.3.1: Number of countries that have norms to define the incorporation of health technologies.

7. Best practices in this area and examples from countries within the Region of the Americas:

- Canada: First country to institutionalize health technology assessment (HTA) to support decision-making; has an agency devoted to this issue— Canadian Agency for Drugs and Technologies in Health (CADTH).
- Brazil: Has HTA units in the *Agência Nacional de Vigilância Sanitária* (ANVISA) and in the Ministry of Health, and also has a National Commission for Incorporation of Health Technologies (CONITEC).
- Argentina: Creation in 2009 of the Coordinating Unit for Health Technology Assessment (UCEETS), composed of 14 institutions.
- Colombia: Creation in 2011 of the Health Technology Assessment Institute (IETS).

8. Financial implications of this Agenda item:

US\$700,000.00 over a period of two years.