Background Paper

Good Practices in Application of Health Technology Assessment For Decision-Making Worldwide

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Good Practices in Application of Health Technology Assessment For Decision-Making Worldwide

Purpose of this document

This document contains useful information to open up discussions at the Latin American HTAi forum on "Good practices in the application of Health Technology Assessment to decision making in Latin America".

The document begins by summarizing the reasons that gave rise to health technology assessment as a discipline and the need for good practice principles in the application of HTA to decisions about covering/ funding new health technologies. After that, we describe principles mentioned in a series of international documents that we consider relevant to Forum discussions. We also discuss points of consensus and controversy among the principles included in the documents reviewed. Finally, we outline the current situation as regards implementation of these principles in Latin America and worldwide.

It is worth noting that Forum discussions will focus mainly on the application of HTA to decision making processes, rather than methodological aspects of assessment. This is why, even though methodological principles are mentioned, central focus is on principles related to procedures used to formulate HTAs and HTA adoption by competent authorities.

As additional information for meeting participants, this document includes an appendix with data on Latin American healthcare systems and the role of HTA in LAC countries.

Methodology used for topic selection and manuscript development

Steps taken to select the topic ("Good practices in the application of Health Technology Assessment for decision-making worldwide") of the First Latin American Forum on HTA policies:

1. A list of potentially relevant topics to be discussed in Latin America was prepared using several sources: list of topics discussed at Global Policies Fora held by HTAi during the last years and relevant topics suggested by people who attended previous Global Policies Fora, HTAi authorities, organizers, the Forum's scientific secretariat, and representatives from countries considered for inclusion in this first Latin American Forum.
2. Selection of the five most relevant topics. Forum organizers and the scientific secretariat selected these topics to be sent to participants after a consultation process with potential participants.
3. This short list of five topics was ranked according to participants' responses.
4. The organizing committee[1] used this information to reach a final decision.

After selecting the topic to prepare this manuscript, a search was conducted to identify documents with general information on HTA principles and good practices. The strategy included specific databases (MEDLINE, CRD, LILACS), internet generic search engines, websites of relevant organizations, and expert consultation. Selected publications included information about HTA criteria that could be regarded as principles or good practices or that referred to their adoption worldwide and specifically in LAC. Reports and documents devoted exclusively to methodological aspects were not included.

1 Made up by three representatives of HTA agencies in LAC, one representative of a payer, two industry representatives (one for medical devices and one for pharmaceuticals), the chairman of the event, scientific secretary, HTAi vice-chair, chairman of the global policies forum.

Background to the topic

Today, health technologies are a key element in all healthcare systems and, during the last decades, their use has increased significantly. In general, the introduction of new technologies has brought significant advantages in terms of prevention, safety, health and quality of life improvements or less adverse effects. However, in contexts of limited resources, correct introduction and diffusion of technologies poses a challenge and, in some cases, a serious problem.

The rapid emergence of technology and the increase in available evidence have become yet another obstacle healthcare systems must face. Providing healthcare services entails making decisions about what interventions will be offered, how to organize healthcare systems, who will pay for interventions, and who will provide them and how. The challenge is to obtain good health outcomes with available resources, while considering population's expectations and demands.

In this context, health decision-makers need more and more detailed and reliable information to inform transparent and legitimate decisions to identify priorities in their quest to obtain the best possible outcome with limited resources. This demand for sound transparent information to inform decisions about the development, addition, and diffusion of health technologies led to the current growth and development of Health Technology Assessment (HTA) as a discipline. In fact, HTA emerged in the '70s from this growing concern for the diffusion of new and expensive health technologies and healthcare systems' capacity to fund their use.

After the '70s, HTA evolved to become a multidisciplinary specialty, with the purpose of gathering available evidence to help healthcare decision makers, professionals, and patients understand the relative value of technologies.[1] There is no single definition of HTA. According to one of the definitions used, HTA is a multidisciplinary field of policy analysis, which incorporates the medical, social, ethical and economic implications of development, diffusion, and use of health technology.[2]

Currently, many countries are committed to reach universal health coverage (UHC) for their populations. Since all healthcare system have limited resources, it is necessary to set priorities and decide what services to offer, for whom, and at what cost. For this purpose, in 2013, the Pan-American Health Organization (PAHO) and then, in 2014, all WHO member states passed a resolution on HTA and universal health coverage calling upon states to enhance HTA capacities in the region and include HTA principles in their strategies and WHO fields of work.

In order to understand the different elements involved in decision-making and technology assessment, we have to differentiate between seemingly similar terms:[3]

- ***Assessment***: technical assessment of health technologies to develop or summarize evidence about benefits, needs, impact, costs, context, etc. These assessments are carried out by HTA experts.
- ***Appraisal***: analysis of evidence obtained through HTA. This process may be formal or informal and involves analyzing other relevant information such as availability of financial resources (or other type of resources), political priorities and/or healthcare system mission, among others. The result of this process is a recommendation issued to health authorities (final policy makers) about the advantages/ disadvantages of funding the technology, target patients, and conditions (e.g. type of facilities that can prescribe and use the technology).
- **Official decision-making**: process used to explicitly decide which health technologies will be offered or provided. These decisions are made by duly appointed people or agencies within each healthcare system.

Decision making processes based on HTA and other relevant evidence may be complex. Policy makers assess recommendations on their own or with the advice of technical consultants or official bodies, such as experts' committees, independent bodies, or relevant stakeholders.

During the last 15 years, HTA has developed rapidly, becoming a key element of healthcare systems in many countries. Several initiatives have appeared in Latin America and the Caribbean (LAC). Argentina,

Brazil, Colombia, Chile, Mexico, and Uruguay have HTA agencies that are INAHTA members; and many Latin American countries currently use HTA—to a different extent—to make resource allocation decisions.

HTA has the potential to become a very useful tool for policy makers. However, inappropriate conduct and use might lead to inefficient resource allocation, covering useless or low-benefit interventions; delay access or prevent patients from accessing useful health technologies, expose patients to unnecessary risks, and send wrong messages to health technology producers, among others.[2]

In order to meet policy makers' needs satisfactorily, HTA documents—and processes used to prepare them and to implement HTA results—must fulfill some requirements. To meet the objectives of all stakeholders, some mechanisms must be in place to assure assessment quality. Since these principles or good practices and their relevance to the Latin American context were selected as the topic for this forum, this document will provide information about the contributions made by several authors and working groups.

Sets of guiding principles for Health Technology Assessment worldwide

Using the previously described search methodology, we identified eight main documents about good practice principles for the development and use of HTA. Table 1 shows the selected documents in chronological order. The following section includes additional information about these documents. Selected lists of criteria or goods practices are aimed at both HTA developers and users and should not to be regarded as an exhaustive review of this topic.

Table 1 - Selected documents about good practice principles to guide HTA's development and use

1. Accountability for reasonableness/Justice, health and healthcare	Daniels and cols.	2000/2001
2. HTA for medical devices in Europe	Siebert and cols. for Eucomed	2002
3. Position paper: the use of health technology assessment (HTA) to evaluate medicines – Key principles	European Federation of Pharmaceutical Industries and Associations	2005
4. Essential elements of a Technology and Outcomes Assessment Initiative	Emanuel and cols.	2007
5. Key principles for the improved conduct of health technology assessments for resource allocation decisions	The International Working Group for HTA Advancement	2008
6. How can the impact of health technology assessments be enhanced?	World Health Organization (WHO) in representation of the European Observatory on Health Systems and Policies	2008
7. Good practice principles for relative effectiveness assessment (High Level Pharmaceutical Forum 2005-2008 – Final Report)	High Level Pharmaceutical Forum	2008
8. Making fair choices on the path to universal health coverage	WHO Consultative Group on Equity and Universal Health Coverage	2014

1. Accountability for reasonableness/Justice, health and healthcare (Daniels, 2000/2001)

In a 2000 article (among other documents), Norman Daniels refers to the issue of legitimacy in decisions related to introducing new health technologies.[4,5] According to this author, in the absence of consensus on the ethical principles of distributive justice that should govern the introduction of new technologies, a fair decision making process allows us to agree on what is legitimate and fair. He refers to this concept as "Accountability for Reasonableness". For health resource allocation to be fair, some mechanisms have to be in place to ensure the following criteria are met:

- ***Relevance:*** *grounds for resource allocation decisions must rest on reasons that stakeholders can agree are relevant in the context.*
- ***Publicity:*** *decisions and their grounds must be publicly accessible.*
- ***Revisions/Appeals:*** *There must be a mechanism to challenge and revise decisions in light of new evidence.*
- ***Enforcement:*** *to ensure that the first three conditions are met.*

The idea underlying these criteria is that the allocation of limited resources should be based on a fair, broad and public deliberative process aimed at meeting the health needs of different populations. In addition to this, a fair process must be feasible and involve practices that can be sustained and agree with the goals of various stakeholders.

2. HTA for medical devices in Europe (Siebert and cols. For Eucomed, 2002)

In 2002, Eucomed, the European Confederation of Medical Devices Associations, published a position statement.[6] This document was the result of in-house discussions and contributions by HTA experts both from within and outside the industry. This report states Eucomed's position regarding the specific characteristics HTA should have to assess medical devices. This report presents methodological and policy-related considerations to take into account when implementing and using HTA.

Methodological Considerations

- *Considering the usefulness of HTA for the selection of the technology:* HTA can be useful to inform decisions on reimbursement or coverage of new technologies or procedures, compare technologies already available in the market, or make decisions in the light of new data or improved outcomes or costs.
- *Determining the timing of HTA according to the specific characteristics of medical devices' life cycle*: the life cycle of devices is significantly shorter than that of pharmaceuticals. There is no consensus over the optimal time to undertake HTA. This decision must be based on product and context knowledge obtained by interacting with users and manufacturers. Assessments made early into the life cycle of a device might allow early patient access but might not consider learning-curve related issues and the fact that innovation in medical devices is a continuous process. In some cases, single-point assessments should be avoided since iterative processes might be better to assess the characteristics of some technologies.
- *Research questions have to consider contextual factors related to the outcomes of the use of medical devices:* A device might be used in different contexts and outcomes will depend not only on the device itself but also on additional factors such as training and user experience. Therefore, it is essential to define the research question as clearly as possible with input of all stakeholders.
- *Specific characteristics of patient populations treated with medical devices have to be considered when defining study populations*: Sometimes, medical devices target small patient populations, whether due to epidemiological reasons or because they are considered a "last resource". In these cases, obstacles to conducting clinical trials should be considered.
- *Methodologically adequate observational studies must be considered when randomized clinical trials are not feasible:* For some devices, randomized controlled trials (RCT) are not feasible and/or have limitations. In these cases, well-designed observational studies can be useful and have high external validity. HTA including economic evaluations should adapt to a societal perspective or to the healthcare system's perspective—should the first be inappropriate or unacceptable.
- *Data collection processes must be based on health industry and expert judgment*: decisions regarding data needed for the assessment should rest on industry and health experts' judgment and consensus. Local studies should not be an absolute requirement and data from international studies should be considered valid.

Policy-related Considerations

- *Representation of stakeholders*: Both the industry and other stakeholders (e.g. patient associations) are entitled to participate in the assessment process. Technology manufacturers should take part (as peers) in all discussions and meetings about contributed data to clarify concerns and provide additional information to support coverage of their products. For patients to take part in decision-making processes, a clear process must be in place.
- *Transparency of the Process*: The whole process must be clear and transparent. Technology manufacturers should be aware of the review process steps. All HTA requirements should be published and communicated to industry and all relevant stakeholders. Technology manufacturers need access to adequate information and be able to conduct research at reasonable time and cost frames. HTA process should be entirely separate from individual interests and, therefore, from coverage decisions, which are policy-related decisions. Due to medical devices' short life cycle, coverage and reimbursement decisions should be made in less than 90 days.
- *Appeals Process*: Industry should be able to appeal adverse coverage/reimbursement decisions through a formal process. This process should include a fair hearing and be provide the setting to consider new evidence (if any), and challenge the grounds for the decision made. All stakeholders should be entitled to a hearing to voice their grounds for appeals and submit additional information prepared by medical experts of their choice.
- *If limited data is available, interim and/or regional coverage may be appropriate mechanisms*: When limited data is available, provisional coverage will allow patients to access new technologies while additional data is collected. When implementing new technologies regionally, decisions call for a flexible and patient-centered approach.

3. Position paper: the use of health technology assessment (HTA) to evaluate medicines – Key principles (EFPIA, 2005)

In 2005, the European Federation of Pharmaceutical Industries and Associations (EFPIA) published 12 principles to assess drugs through HTAs.[7] The pharmaceutical industry developed these principles for European Commission member countries. According to the EFPIA, HTAs should be used to achieve better health outcomes, rather than delay or prevent patient access to drugs. According to the EFPIA, for HTAs to be effective, pharmaceutical industry and governments must agree on the use and mechanisms of HTAs.[2]

EFPIA Principles:

1. HTAs should be based on a clear, sophisticated and differentiated view of what constitutes value in technology
2. HTAs should be transparent and balanced
3. HTAs should be based on early and inclusive dialogue, including with patients
4. Evaluations should allow new data to be considered
5. Flexibility is required in handling uncertainty
6. Comprehensive understanding of the benefits of a drug in disease management is needed to perform HTA
7. Payers should commit to rewarding added value of a technology
8. HTA outcomes should be implemented
9. HTA should apply to all healthcare interventions
10. Assessment should take place at national level
11. HTA should remain separate from regulatory review
12. Evaluations should take into account indirect benefits

4. Essential elements of a Technology and Outcomes Assessment Initiative (Emanuel and cols., 2007)

In 2007, Emanuel, Fuchs and Garber stated that to answer controversial questions and facilitate access to objective information, any assessment initiative must include six specific features:[8]

Essential elements of a technology and outcomes assessment initiative. Emanuel and cols.[8]

1. Administrative independence
2. Dedicated funding
3. Production of objective and timely research
4. Use of reliable methods
5. Widespread dissemination
6. A governance and organizational structure that lend legitimacy to the entity conducting the HTA

In 2008, several documents were published postulating principles for HTA processes. The International Working Group for HTA Advancement published the most widespread set of principles known as "key principles"[9]. That same year, the WHO Regional Office for Europe published a report, and the High Level Pharmaceutical Forum published good practice principles for relative effectiveness assessment.

5. Key principles for the improved conduct of health technology assessments for resource allocation decisions (International Working Group for HTA Advancement, 2008)

Based on previous works, such as the Principles of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Working Group for HTA Advancement proposed a set of 15 principles to assess existing or establish new HTA activities.[9] These principles focus mainly on HTA activities linked to or involving resource allocation decisions. In these HTAs, it is essential to consider both costs and benefits in an economic evaluation. Principles are organized in four sections: structure of HTA programs, methods of HTA, processes for conduct of HTA, and use of HTA in decision making.

Key principles for the improved conduct of health technology assessments for resource allocation decisions (International Working Group for HTA Advancement, 2008)

Structure of HTA programs

1. The goal and scope of HTA should be explicit and relevant to its use

Ideally, a specific document should define the scope and objectives of the HTA, taking into account the questions to be answered through the assessment and their alignment with the decisions to be made using the HTA. This document should be sent to all stakeholders to benefit from constructive criticism and other contributions.

2. HTA should be an unbiased and transparent exercise

In order to be useful, in addition to being transparent, HTA processes must be perceived as transparent and unbiased. Therefore, independent bodies, separate from decision makers, should conduct HTA.

3. HTA should include all relevant technologies.

In addition to drugs, HTAs should assess all types of health technologies, such as devices, diagnostic methods, IT systems, etc.

4. A clear system for setting priorities for HTA should exist
Principles 3 and 4 are aimed at preventing clinical practice and policy decision making from favoring non-assessed technologies, since they would be subject to no regulatory barriers. This principle calls for a clear prioritization process because, in most cases, it is not possible to assess all health technologies.

Methods of HTA

5. *HTA should incorporate appropriate methods for assessing costs and benefits.*
6. *HTAs should consider a wide range of evidence and outcomes.*
7. *A full societal perspective should be considered when undertaking HTAs.*
8. *HTAs should explicitly characterize uncertainty surrounding estimates.*
9. *HTAs should consider and address issues of generalizability and transferability.*

Principles five through nine refer to HTA methods. Under these principles, HTA should use rigorous analytical methods to build trust, so that all stakeholders and the public rely on the process. HTA should include data from different types of studies, integrate final outcomes with validated intermediate outcomes, assess impacts, and compare existing costs and benefits at the level of different clinical, economic and social results. Assessments have to be conducted from a broad social perspective to optimize efficiency and social benefits, since clinical and health policy-related decisions based on a narrower perspective may bias result interpretation and restrict (maybe excessively) the types of evidence considered. All analytical methods are subject to uncertainty, potential bias and limitations, therefore, HTAs should explicitly characterize the uncertainty of their estimates. For this reason, it is necessary to conduct sensitivity analyses to define the strength of results and conclusions. Analysis limitations must always be acknowledged. To be useful at the jurisdictional level, HTAs should consider relevant perspectives and address issues of generalizability and transferability of HTA results to other clinical populations to account for differences in diseases, intervention responses, patient outcomes, populations, healthcare providers, healthcare centers, and healthcare systems.

Process for conduct of HTA

10. Those conducting HTAs should actively engage all key stakeholder groups.
HTA programs should actively engage all key stakeholders at all process stages. This is likely to result in more widely accepted evaluations and increased probabilities of implementation. On the other hand, an open process increases transparency and builds trust, since more stakeholders will gain a deeper understanding of used criteria and standards.

11. Those undertaking HTAs should actively search for all available information and data.
This means trying to obtain all available data, whether confidential or not. When confidential information is used, confidentiality obligations must be defined as clearly as possible. To foster understanding and make transparent reliable decisions, it is important to make all information available to the public as soon as possible.

12. The implementation of HTA results needs to be monitored.
In order to optimize HTA-related investments and ensure fair implementation of results, implementation of HTA results must be monitored.

Use of HTA in decision-making

13. HTA should be timely.
HTA timelines should be adequate to inform key decisions related to the diffusion and use of health technologies. HTAs should be updated on a regular basis. Therefore, studies should be conducted in a timely manner, or under certain circumstances, coverage or reimbursement may be conditional on the collection or production of more evidence, such as clinical trials testing safety, effectiveness and cost-effectiveness.

14. HTA findings need to be communicated appropriately to different decisions makers.
Since HTA results address a wide audience, effective communication strategies should be developed to meet the needs of different users.

15. The link between HTA findings and decision-making processes needs to be transparent and clearly defined.
The conduction of HTA should be separate from the decisions made using HTA findings. The link between assessment and decision may differ in each setting, but should always be transparent.

6. How can the impact of health technology assessments be enhanced? (World Health Organization (WHO) in representation of the European Observatory on Health Systems and Policies, 2008)

Also in 2008, the WHO Regional Office for Europe and the European Observatory on Health Systems and Policies published a document. Their objective was to issue key messages to support the development of evidence-based policies.[10] This document states that HTA is an important tool to inform effective regulation of health technology diffusion and use. This report analyzed the main challenges and opportunities of HTA in countries with existing or emerging programs. They identified measures to enhance HTA impact in three main areas (stakeholder involvement, methods and processes employed, implementation of HTA findings):

Measures to enhance HTA impact [10]

1. ***Increase stakeholder involvement***
2. ***Enhance HTA methods and processes, including***: a) reduce HTA timelines to provide decision makers with timely assessments; b) alleviate some of the uncertainty inherent to assessment and decision-making processes (e.g. approval or coverage conditional on evidence development); c) increase HTA transparency; and d) facilitate development of efficient methods.
3. ***Advancing local applicability and implementation of national decisions or guidance*:** It is necessary to implement incentives appropriately aligned with HTA recommendations. This may include adequate funding and education to effectively and equitably implement decisions, institutionalizing local political drivers (such as prior commitment by decision-makers to implement recommendations or guidance) or employing a mixed portfolio of information dissemination strategies to apprise national and local stakeholders of recent decision and policy changes. Formal links between users and producers of HTA and frequent re-evaluations may also advance implementation. Implementation is essential to ensure the existence of cost-effective products that add value.

7. Good practice principles for relative effectiveness assessment (High Level Pharmaceutical Forum, 2008)

Also in 2008, the High Level Pharmaceutical Forum (HLPF) published their principles for relative effectiveness assessments. The objective of relative effectiveness assessments is to compare two or more health interventions to classify them according to their therapeutic value.[2] Differences between the objectives and priorities of different national healthcare systems may create differences in the way in which healthcare interventions will be valued relative to one another. This means a relative effectiveness assessment is most likely to be meaningful at the level for which HTA is developed. However, there is considerable value in stimulating exchange of information, methodologies and experiences between different authorities.

Good practice principles for relative effectiveness assessment - High Level Pharmaceutical Forum (HLPF)[11]

1. Individual Member States may use relative effectiveness assessments for different purposes. Decisions on the implementation of relative effectiveness assessments, including methods and relevant stakeholders, are most appropriately made at a national level.

2. Relative effectiveness assessment processes, selection of products to be assessed, working methodologies, and quality assurance processes should be transparent to all parties and evidence-based.

3. Relevant stakeholders should be able to contribute to the development of assessment methodologies. The purpose of relative effectiveness assessments and the organization(s) responsible for its conduct should be clearly identified.

4. Relative effectiveness assessment processes should remain separate from product market authorization procedures (though this does not mean that they are necessarily performed by different organizations).

5. Relative effectiveness assessments should be time-framed, and should minimize or avoid causing unnecessary procedural delays consistent with any associated transparency directive requirements where applicable.

6. Relative effectiveness assessments should be capable of addressing transparently uncertainty in the evidence base, and the methodological challenge of translating evidence on relative efficacy into conclusions on relative effectiveness.

7. The sources of evidence which are to form the relevant relative effectiveness input should be specifically discussed among the identified key stakeholders, who should each be able to submit evidence or argumentation for appraisal.

8. Relative effectiveness assessment should include comparison with the most appropriate healthcare interventions. Such comparison should build on the results of controlled clinical trials, where available.

9. When concluded, outcomes should be communicated in a clear and timely manner to all interested parties. Communication by means of publishing the supporting evaluation on a publicly accessible website is strongly encouraged.

10. Relative effectiveness assessments should be capable of subsequent revision and updating as the evidence base develops.

11. Relative effectiveness assessments should aim to identify areas in which the evidence base on an intervention could most usefully be developed in the future.

8. Making fair choices on the path to universal health coverage (WHO Consultative Group on Equity and Universal Health Coverage, 2014)

This is the final report of the WHO Consultative Group on Equity and Universal Health Coverage. In 2015, WHO member states ratified universal health coverage as a major objective and determined that healthcare systems should advance to assure access to needed services, while protecting people from financial risks. The consultative group was created to develop guidelines (for the states) to address the issues of fairness and equity that arise on the path to universal health coverage.

The document states the need to categorize services into priority classes. For this purpose, relevant criteria include cost-effectiveness, priority to the worse-off, and financial risk protection.

In the process of expanding coverage, the document highlights the importance of reaching the population with services considered as high-priority services, in the first place, making sure no disadvantaged groups are left behind.

The document also mentions a series of decisions regarded as "unacceptable", such as expanding coverage for low- or medium-priority services before there is universal coverage for high-priority services; or giving high-priority to very costly services when the health benefits are very small; or expanding coverage to well-off groups before doing so for worse-off groups when costs and benefits are not vastly different.

In the path to UHC, reasonable decisions and their enforcement can be facilitated by public accountability and participation mechanisms. These mechanisms should be institutionalized, for example, through a standing national committee on priority setting. The design of legitimate institutions can be based on the Accountability for Reasonableness framework. A monitoring and evaluation system is needed to promote accountability and participation and is essential for effectively pursuing UHC.

Points of consensus between documents about principles for HTA development and use

A 2005 WHO document highlights the confusion and difficulty to establish the best way to implement HTA in healthcare systems and the use of HTA in decision-making processes.[12] Even though principles' applicability and desirability are still under debate, there is a general consensus on the basic characteristics HTA should have. HTAs should:

a. Use adequate methods
The use of adequate methods is essential in any HTA process. Many entities even develop their own methodological guidelines, in addition to the ones in the literature.

b. Be aligned with decision makers' questions about technology coverage/reimbursement
This factor is essential to assure HTA's applicability. Only those able to answer decision makers' questions will be useful. Therefore, one recommendation calls for the development of a document clearly defining questions to be answered, objectives and scope of assessment. Decision makers should be involved in preparing this document.

c. Be timely
Assessment depth, stakeholders' engagement, and assessment opportunities should be well balanced. This means that HTA processes that do not provide timely answers or are conducted at irrelevant times cannot be used properly and therefore, will have no impact on practices and policies.

d. Be the result of a transparent and unbiased process
This feature is essential to assure acceptability of HTA programs and their findings.

e. Involve different stakeholders
Different stakeholders may engage at different stages of the assessment process, but it is necessary to have a mechanism in place to consider their perspective.

f. Be separate from decisions made based on HTA findings
The general consensus is that roles should be clearly defined, especially regarding those who conduct HTAs and those who appraise HTA findings to inform decisions.

Points of controversy

When the International Working Group on HTA Advancement published their principles in 2008, these were widely debated. In a later publication (2012), among other things, the Group suggested analyzing whether all principles should be weighted equally or not, trying to strike a balance between them.[13] For example, including more groups of stakeholders probably entails longer assessments and larger processes that are more complex.

The role or responsibility of an organization or agency may also limit their potential to adopt a certain principle. This concern is raised both by the authors of the Key Principles and other authors as well.[14-16] Principle 3 is an example of this. According to Principle 3, "HTA should include all relevant technologies". Clearly, HTA bodies that restrict their activities to pharmaceuticals cannot assess all technologies. Of course, to maximize the benefits from resources allocated to the assessment of health technologies, adherence to this principle is important at the level of a given jurisdiction. However, most likely, these issues must be settled at the jurisdictional level, expanding the powers of a single organization or creating a network of bodies or agencies—each covering different types of heath technologies. For example, in Washington, USA, there are at least three separate bodies devoted to HTA with limited remit to assess a specific group of health technologies.[13]

There is also discussion about whether principles—both those of the International Working Group and others—should be regarded as universal objectives or if some of them should be considered in light of the cultural or social context. Probably, those related to methodological quality are adaptable to most contexts, while others may depend not only on the remit of the organization conducting or using HTA, but also on prevailing social values. In this regard, according to Eddy, decision-making includes two basic steps: the analysis of the estimated outcomes of all possible choices; and the desirability of the outcome of each option.[17] The first is a scientific evidence-based analysis; while the second is more subjective and takes into account the preferences and values of society as a whole. Since the second step is largely subjective, its guidelines should adapt to context characteristics. A context-related factor that may affect principles' desirability is the type of organization developing or using HTA. Most organizations engaged in developing or using HTA are publicly funded, but some of them are private. Principle No. 2 states "HTA should be transparent and unbiased", and usually the procedures of publicly funded organizations are expected to be transparent. However, since private organizations are run with private funds and operate in a competitive economy, they may be reluctant or unable to disclose certain information, such as the price they pay to purchase technology.[13, 15] According to Henshall, we have to distinguish between the transparency of assessments and the transparency of programs in charge of conducting assessments.[15]

Principles worldwide

In 2010, Neumann and cols. published an article on the level of acceptability and implementation of the principles of the International Working Group for HTA Advancement in 14 selected HTA organizations worldwide.[14] A principle was considered accepted when the HTA organization included said principle in written guidelines or made explicit reference to it, regardless of actual implementation. On the other hand, a principle was considered implemented when reports and HTA-based decisions evidenced adoption. Table 2 summarizes results. Documents showed significant variability in principles' acceptability. Some principles were widely accepted (such as the one stating that HTA should have explicit objectives and a clear scope and adequate timelines); while others were relatively neglected, such as those related to generalizability and transferability, transparency in the link between HTA findings and decision-making processes, taking a societal perspective, and monitoring the implementation of HTA results. Differences in principle implementation also turned out to be significant. Most widely implemented principles were those related to explicit objectives and a clear scope, unbiased and transparent HTAs, and the use of a broad range of evidence and outcomes. Least used principles were those related to transparency, the link between HTA findings and decision-making processes, using a societal perspective, and monitoring the implementation of HTA results. This study only included one Latin American country: Brazil.

Table 2 – Example of Acceptability and use of the Key Principles of the Working Group for HTA Advancement and selected institutions (see footnote)

Principle	CMS 1999	Medicaid/ DERP 2003	WellPoint 2009	BCBS TEC 1985	NICE 1999		IQWiG 2004	DIMDI 2000	TLV 2002	SBU 1987	CADTH 1990	HIRA 2008	PBAC 1992	Anvisa 1999	DHTA 1998
	US				UK		Germany		Sweden		Canada	Korea	Australia	Brazil	Taiwán
Structure of HTA program															
1 The goal and scope of the HTA should be explicit and relevant to its use	++	++	++	++	++		++*	+	+	+	++	++	++	+	++
2 HTA should be an unbiased and transparent exercise	++	++		++	++		++	++	++	++	++		+	+	
3 HTA should include all relevant technologies	++		++		++		++	++		++		+		+	
4 A clear system for setting priorities for HTA should exist	+	+			++		+	++	+	++			++		++
Methods of HTA															
5 HTA should incorporate appropriate methods for assessing costs and benefits			+		++		+*	++	++	+	++	+	++	+	
6 HTAs should consider a wide range of evidence and outcomes	++	+	+	++	++		++*	++	++	++	++		+	+	++
7 A full societal perspective should be considered when undertaking HTAs								+	++		++	+			
8. HTAs should explicitly characterize uncertainty surrounding estimates				++	++		+	+			++	+	++	++	
9 HTAs should consider and address issues of generalizability and transferability			+	++				+		+	++	+	+	+	
Process of conducting HTAs															
10 Those conducting HTAs should actively engage all key stakeholder groups	++	+			++		++		++	+	++		+	+	
11 Those Undertaking HTAs should actively seek all available data	++		+	++	++		++	+		++	++	+	++	+	++
12 The Implementation of HTA findings needs to be monitored			+		+								++		
Use of HTA in decision making															
13 HTA should be timely	++	++	+		+		++	+	++	+	+	+	+	+	++
14 HTA findings need to be communicated appropriately to different decision makers					++		++	++	+	++	++		+	+	
15 Link between HTA findings and decision-making processes needs to be transparent and clearly defined.					+		+	+	++	+	++		++		

Note: information included in this table was sourced from published scientific documents. In some cases, this information might be outdated or have changed. However, this table is included as an example to show the existence of heterogeneity in HTA practices between different organizations worldwide.

"+" signifies that the organization "supported" the principle in question in written guidelines or other form, regardless of whether they actually follow it.
"++" means that the organization "implemented" the principle in published reports and decisions based on these reports demonstrate adoption of the specific principle.
CMS = Centers for Medicare and Medicaid Services.
DERP = Drug Effectiveness Review Project.
BCBS TEC = Blue Cross Blue Shield Associations, Technology Evaluation Center.
NICE = National Institute for Health and Clinical Excellence.
IQWiG = Institute for Quality and Efficiency in Health Care.
DIMDI = German Agency for Health Technology Assessment at the Institute for Medical Documentation and Information.
TLV = The Dental and Pharmaceutical Benefits Agency.
SBU = The Council on Technology Assessment in Health Care.
CADTH = Canadian Agency for Drugs and Technologies in Health.
HIRA = Department of Health Technology Assessment, Health Insurance Review Agency.
Anvisa = National Health Surveillance Agency (Office of Economic Evaluation of Health Technologies).
PBAC = Pharmaceutical Benefits Advisory Committee.
DHTA = Division of Health Technology Assessment.
*: There was disagreement in the group about whether IQWiG warranted a "plus" for principles 1 and 6, and whether methods for assessing costs and benefits (principle 5) were appropriate. Moreover, at the time of the evaluation, IQWiG had not yet performed a cost-effectiveness assessment so implementation of this principle could not be judged.
Source: Modified from: Neuman . INTL. J. OF TECHNOLOGY ASSESSMENT IN HEALTH CARE 26:1, 2010

Latin American context

Most LAC countries have fragmented healthcare systems, where different subsystems coexist with public, private and social security systems—each of them with their own decision-making process. However, the influence and use of HTA has increased considerably.[15] Argentina, Brazil, Chile, Colombia, Mexico, and Uruguay have HTA agencies that are members of INAHTA. [16]

In 2010, Pichón-Riviere et al. published a study to test the relevance of the International Working Group for HTA Advancement principles in Latin America, and measure the extent of their use in the region.[15] To do this, they sent a survey to 11,792 researchers and decision makers. They received 1,142 answers. Table 2 describes the results of this study. All principles were considered relevant, with an average relevance/usefulness score between 8.3 and 9.2 (on a 1-10 scale). On the other hand, scores related to principle implementation were much lower, with mean scores between 3.2 and 4.9. The bigger gaps between perception of relevance and implementation were observed in principles related to the use of HTA in decision-making and processes for conduct of HTA.

Table 3 – Mean relevance scores for each principle of the International Working Group for HTA Advancement (Key Principles) in Latin America

Principle	Mean relevance	Mean Implementation	Mean Gap between relevance and Implementation
Structure of HTA program	**8.52**	**3.85**	**4.65**
1 The goal and scope of the HTA should be explicit and relevant to its use	8.46	3.77	4.69
2 HTA should be an unbiased and transparent exercise	8.43	3.88	4.54
3 HTA should include all relevant technologies	8.32	4.03	4.30
4 A clear system for setting priorities for HTA should exist	8.97	3.85	5.19
Methods of HTA	**9.00**	**4.02**	**4.98**
5 HTA should incorporate appropriate methods for assessing costs and benefits	9.24	4.85	4.41
6 HTAs should consider a wide range of evidence and outcomes	8.98	4.28	4.71
7 A full societal perspective should be considered when undertaking HTAs	8.90	3.41	5.55
8 HTAs should explicitly characterize uncertainty surrounding estimates	8.97	3.80	5.18
9 HTAs should consider and address issues of generalizability and transferability	8.95	3.74	5.25
Process of conducting HTAs	**8.58**	**3.35**	**5.26**
10 Those conducting HTAs should actively engage all key stakeholder groups	8.45	3.42	5.09
11 Those Undertaking HTAs should actively seek all available data	8.30	3.21	5.20
12 The Implementation of HTA findings needs to be monitored	8.95	3.34	5.66
Use of HTA in decision making	**9.94**	**3.39**	**5.32**
13 HTA should be timely	9.03	3.77	5.34
14 HTA findings need to be communicated appropriately to different decision makers	8.71	3.26	5.29
15 Link between HTA findings and decision-making processes needs to be transparent and clearly defined.	9.09	3.67	5.50
Source: Pichón-Riviere INTL. J. OF TECHNOLOGY ASSESSMENT IN HEALTH CARE 26:4, 2010			

As regards the implementation of principles in the region, no additional literature has been found—apart from the already quoted—showing the degree of adoption. However, when checking economic assessments and HTA guidelines of different countries and processes followed to adopt new technologies, we observed that some good practice principles are being met.

Regional HTA and economic evaluation guidelines mention and adhere to most good methodological practice principles found in international literature. [17-22]

In other cases, the use of good practice principles—implemented to different extents—may be observed in the processes used by countries to incorporate technologies. In countries like Brazil, Colombia, and Mexico, decisions to cover new technologies are subject to public consultation (results are published and comments are accepted for a fixed period). Different stakeholders are invited to take part in the process at different stages in an effort to include all stakeholders in decision-making processes.

As for the principle on prioritizing technologies to be assessed through a clear system, Colombian and Brazilian HTA agencies have used the EVIDEM tool.[23] To update their mandatory health insurance plan (POS, for its Spanish acronym), Colombia used their own prioritization criteria and published their weighting methodology.[24]

In addition to this, documents are made available to the public (either fully or partially) through the websites of the agencies preparing the documents. In general, assessments are conducted at national level and are separate from regulatory assessments.

Questions for discussion

First day (April 18)

- Which international good practice principles can be regarded as important and currently relevant to Latin American countries? Which would need further discussions/adjustments before regional implementation? Justify the answer.
- Could you identify the three principles that should be prioritized for regional efforts in the next years? (priority decisions should try to identify relevant principles considering the gap between ideal circumstances and current implementation level, so as to identify those improvements that would contribute significantly to the region's HTA processes). Justify the answer.

Second day (April 19)

- Lessons learned: what success/failure experiences do you know as regards the implementation of the high-priority principles identified yesterday?
- What are the challenges and opportunities to foster the high-priority principles identified yesterday?
- What are the requirements/pre-requisites that a health system should meet to allow for the implementation of these prioritized principles?
- What are the proposed recommendations to promote good practices in the Region?

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Glossary

Indirect benefits: productivity gains from health improvement.

Efficacy: the degree to which an intervention brings about more benefits than harm under ideal conditions.

Relative efficacy: the degree to which an intervention brings about more benefits than harm under ideal conditions, as compared to one or more alternative interventions.

Effectiveness: the degree to which an intervention brings about more benefits than harm, under usual healthcare conditions.

Relative effectiveness: the degree to which an intervention brings about more benefits than harm, under usual healthcare conditions, as compared to one or more alternative interventions.

Health Technology Assessment (HTA): multidisciplinary policy analysis that addresses the medical, social, ethic, and economic implications of health technology development, diffusion and use.

Generalizability and transferability: the possibility of generalizing or transferring the results of an assessment to larger populations, different countries and different healthcare systems.

Perspective: point of view from which the costs and benefits of an intervention are assessed (e.g. a healthcare system perspective or a full societal perspective)

Brief description of participating countries' health care systems

The following descriptions were developed based on information provided by participants of the Policy Forum through a questionnaire. We thank all those who completed the questionnaires and proved information. These summaries are intended as guidelines and are not detailed descriptions of health systems or HTA processes.

Argentina

Argentina has approximately 42 million inhabitants. In 2013, its gross domestic product (GDP) and its GDP per capita were USD 258 billion and 14.528 USD, respectively. Approximately 50% of the population is covered by social security, 40% depends on the public system and 10% has private health insurance. Argentina´s public health expenditure—as a percentage of GDP—was 4,9% (with a total health expenditure of 7.3%) in 2013. Even though everyone may access public health services, mostly people without coverage under the other two subsystems use the public subsystem. The social security subsystem is made up of more than 300 organizations that provide health insurance to formal workers, pensioners, and their dependents. Lastly, the private subsystem is used by those who can afford prepaid medical care or resort to independent healthcare providers or private healthcare facilities. There is a defined package of benefits. The Mandatory Medical Program (PMO, for its Spanish acronym) defines the basic package of benefits for all inhabitants with some kind of health coverage (under social security or private subsystems), while the Single Reimbursement System (SUR, for its Spanish acronym) governs coverage of high cost technologies to be reimbursed to social security providers. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. Out-of-pocket expenditure is 21%.

The Ministry of Health has a HTA coordinating unit (UCEETS) that encompasses several public entities, but there is no formal process nor an agency explicitly responsible of defining the Mandatory Medical Program. Decision-making at the regional and local/hospital level is based on expert recommendations and formal analysis with or without HTA.

Scientific societies and the national department of health define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. The Superintendence of Health Services is the national agency in charge of establishing or recommending coverage of health technologies. They make their decisions using informal evaluations, expert recommendations, and HTA reports.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by national department of health, institutions linked to the national department of health, regional governments, hospital units, universities or independent for- profit and non-profit organizations.

Methods used to prepare HTAs for the national level include cost analysis. Industry and patients are not engaged in the process.

A HTA can be requested by the Department of Health.

Brazil

Brazil has approximately 205 million inhabitants. Its GDP and GDP per capita were 2.34 billion and 8,802, respectively. Brazil has a public health insurance system and hospitals and/or health systems are directly funded through taxes. Public subsidies are not available for private health insurance companies. 100% of the population is covered by public funds (including social security). Public health expenditure—as a percentage of GDP—is approximately 4.7%, and public expenditure per capita is approximately USD 100.98. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high cost drugs, high-complexity procedures,

prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. All drugs included in the official list (RENAME) are covered. There is a copayment system (*Farmacia Popular*) for some drugs, while the rest are free. As for health services funded with public funds, a national government agency makes decisions through formal HTA analysis.

Scientific societies and a national government agency known as CONITEC define the content of clinical practice guidelines and other documents used to inform decisions about public resource allocation and distribution. The methods used by scientific societies, for this purpose, include expert recommendations and formal analysis (with or without HTA). Government agencies use formal analysis with HTA.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by the national government (CONITEC). Conducted HTAs focus on drugs (64%), devices (15%), and procedures (21%). In addition to these focus areas, the national department of health and regional government agencies conduct HTAs on public health interventions. Hospital units, local units or healthcare centers, universities, and other independent for-profit or nonprofit organizations also conduct HTA to inform their decisions.

Methods used to prepare HTA include expert opinions, systematic reviews, clinical-economic decision-making models, cost analysis, budget impact analysis, and cost-effectiveness and cost-utility analyses. Analyses are conducted from a healthcare system perspective. During HTA processes, the industry is invited to comment on the proposed focus area, they are requested to send a dossier with a complete analysis (using HTA methods) and other data, and to make comments on the first version or draft report (public consultation). Occasionally, users (patients) are invited to provide information for the selection of technologies to be assessed, make comments on the proposed focus area, send data, and comment on the first version or draft report.

A HTA can be requested by the Department of Health, scientific societies, the industry, or patient groups.

Chile

Chile has approximately 18 million inhabitants. In 2013, its GDP and GDP per capita were approximately USD 258,1 billion and USD 14,528, respectively. Chile has a public health insurance system, and subsidies are available for private health insurance companies. Hospitals and/or healthcare services are not directly funded through taxes. 76,1% of the population is covered by public funds (including social security). Public health expenditure—as a percentage of GDP—is approximately 7.7%, and public expenditure per capita is approximately USD 1,024. There is a defined package of benefits. Currently, 80 diseases with explicit health guarantees (GES, for its Spanish acronym) are covered, including diagnosis, treatment and follow-up, when applicable, according to practice guidelines. These guarantees are geared toward inpatient and out-patient treatments and beneficiaries include people covered by public and private insurance (these are charged a premium). Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. In the case of high cost drugs, only those included in the Ricarte Soto law are covered. This law does not include copayment.

As for healthcare services funded with public funds, the national government agency informs its decisions using expert recommendations and formal analysis (with or without HTA). Regional and Local/hospital level decisions are informed using expert recommendations and formal analysis without HTA.

The national department of health and each hospital define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. The national department of health informs its decisions using expert recommendations and formal analysis (with or without HTAs). Methods used by hospitals for this purpose, include expert recommendations and formal analysis without HTA.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by the Health Technology Assessment Department of the Ministry of Health Conducted HTAs focus on drugs (10 reports/year), devices (3 reports/year), procedures (1 report/year), and public health interventions (3 reports/year) Universities and non-profits also develop HTAs.

Methods used to prepare HTAs include expert opinions, narrative reviews, systematic reviews, clinical-economic decision-making models, cost analysis, budget impact analysis, and cost-effectiveness and cost-utility analyses. Analyses are conducted from a healthcare system perspective. Neither the industry nor patients participate in the HTA processes.

A HTA can be requested by the Department of Health, scientific societies, or patient groups.

Colombia

Colombia has approximately 49 million inhabitants. In 2013, its GDP and GDP per capita was approximately USD 378 billion and USD 12,750, respectively. Colombia has a public health insurance system, and hospitals and/or healthcare services are directly funded through taxes. No subsidies are available for private health insurance companies. 97% of the population is covered by public funds (including social security). Public health expenditure—as a percentage of GDP—is approximately 6.8%, and public expenditure per capita is approximately USD 533. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. Services/interventions not included in the mandatory healthcare plan, may be funded through exceptional mechanisms. The amount of copayments (a percentage of cost of care) is fixed according to payment capacity. Copayments are subject to annual caps.

As for healthcare services funded with public funds, a national government agency and regional agencies inform their decisions using formal analysis (with or without HTA). Local/hospital level decisions are informed using expert recommendations.

Scientific societies, the national department of health and regional governments define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. Methods used by scientific societies, hospitals, and local organizations (e.g. primary care centers, clinics), for this purpose, include expert recommendations and formal analysis (with or without HTA). Government agencies inform their decisions using formal analysis (with or without HTAs).

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by an institution linked to the national government or the department of health (IETS). Conducted HTAs focus on drugs (81%), diagnostic tests and devices (16%), procedures (3%), and public health interventions (two studies to date).

Methods used to prepare HTAs include expert opinions, systematic reviews, clinical-economic decision-making models, cost analysis, budget impact analysis, and cost-effectiveness and cost-utility analyses. Analyses are conducted from a healthcare system perspective. During HTA processes, the industry is invited to comment on the proposed focus of the assessment, they are requested to send data to be considered during the HTA process, and make comments on the first version or draft report. Users (patients) are invited to make comments on the proposed focus of the assessment, send data, and comment on the first version or draft report.

A HTA can be requested by the Department of Health, scientific societies, the industry, or patient groups.

Costa Rica

Costa Rica has approximately 5 million inhabitants. In 2013, its GDP and GDP per capita was USD 61.43 billion and USD 12,900, respectively. Costa Rica has a public health insurance system and hospitals and/or healthcare services are funded directly through taxes. There are no subsidies for private health insurance companies, but services might be purchased. 85% of the population is covered by public funds (including social security). Public health expenditure—as a percentage of GDP—is approximately 7,39%, and public expenditure per capita is approximately USD 1,005. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, diagnostic tests, and surgeries, among others. To be covered, services/interventions must be included in the Public Health Plan and the Official List of Medicines prepared by the Costa Rican Social Security Fund (*Caja Costarricense del Seguro Social*). There are no copayments.

As for healthcare services funded with public funds, there is a national government agency and regional agencies that make decisions using formal analysis (without formal HTAs). Local/hospital level decisions are informed using expert recommendations only.

The national department of health, regional governments and hospitals define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. For this purpose, the department of health uses formal analysis (without HTA), while regional governments and hospitals only use expert recommendations.

When HTAs are used to inform coverage decisions or to prepare guidelines, HTAs are conducted by an institution linked to the national government or the department of health (*Caja Costarricense del Seguro Social*) and other independent organizations (Cochrane).

Methods used to conduct HTAs include expert opinions, narrative reviews, systematic reviews, and cost analysis. Analyses are conducted from a societal perspective. During HTA processes, the industry is requested to send a dossier with a complete analysis, conducted using HTA methods. Users (patients) do not take part in the process.

A HTA can be requested by the Department of Health, scientific societies, the industry, and patient groups.

Ecuador

Ecuador has approximately 16.5 million inhabitants. In 2013, its GDP and GDP per capita was USD 99.07 billion and USD 6,086, respectively. Ecuador has a public health insurance system and hospitals and/or healthcare services are funded directly through taxes. There are no public subsidies for private health insurance companies. 40% of the population is covered by public funds (including social security). Public health expenditure—as a percentage of GDP—is approximately 7.54%, and public expenditure per capita is approximately USD 370. There is no defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. There are no copayments.

As for healthcare services funded with public funds, a national government agency informs their decisions using formal analysis (with or without formal HTAs).

The national department of health defines the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution using formal analysis (with or without HTA) and expert recommendations.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by an institution linked to the national government or the department of health. These reports focus on drugs (38%), devices (15.8%), procedures (12,8%) and public health interventions (15%).

Methods used to conduct HTAs include expert opinions, systematic reviews, clinical-economic decision-making modes, cost analysis, and budget impact analysis. Analyses are conducted from a societal perspective. The industry does not take part in HTA processes, but users (patients) are invited to comment on the proposed focus area.

A HTA can be requested by the Department of Health, scientific societies, and patient groups.

El Salvador

El Salvador has approximately 6.1 million inhabitants. In 2014, its GDP and GDP per capita were USD 25 billion and USD 4,124, respectively. El Salvador has no public health insurance system and no subsidies are available for private health companies. However, hospitals/healthcare services are directly funded through taxes. In 2014, public health expenditure—as a percentage of GDP—was approximately 4.5%, and public expenditure per capita approximately USD 265. There is no defined package of benefits, just a list of drugs known as the Official List of Medicines, prepared by the regulatory agency (*Dirección Nacional de Medicamentos*)—mandatory at National Health Service institutions. This list includes few high-cost medicines. Health service coverage varies per healthcare facility depending on infrastructure and available equipment. Healthcare facilities and institutions currently work in networks. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. There are no copayments in the public sector and medicines and healthcare services are delivered for free.

As for healthcare services funded with public funds, a national government agency informs their decisions using formal analysis (without HTAs). Regional agencies and hospitals inform their decisions using expert recommendations.

The national department of health, at national level, and hospitals, at local level, define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. The national department of health uses formal analysis (without HTA) and hospitals use expert recommendations.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by the Department of Health (through the Health Technology Bureau, *Dirección de Tecnologías Sanitarias*). The manual of this recently created bureau is still under construction. Assessments will focus on drugs. Public health interventions are assessed by institutions linked to the national government or the department of health.

Mexico

Mexico has approximately 122 million inhabitants. In 2014, its GDP and GDP per capita were USD 1,295 billion and USD 10,325, respectively. Mexico has a public health insurance system and hospitals/healthcare services are directly funded through taxes. There are no public subsidies for private health insurance companies. 91.6% of the population is covered by public funds (including social security). In 2013, public health expenditure—as a percentage of GDP—was approximately 3.2%, and public expenditure per capita approximately USD 536. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. However, coverage includes only some high cost medicines and interventions listed in the Health Care Formulary and Supply Catalog. Copayment equals 47% of healthcare charge (i.e. reported as out-of-pocket expense).

As for healthcare services funded with public funds, a national government agency informs their decisions using formal analysis (with or without formal HTAs). Regional agencies make decisions using expert recommendations or formal analysis (without HTA). Local level/hospital decisions only use expert recommendations.

The national department of health, regional governments, scientific societies, hospitals and local organizations (primary care facilities and clinics) define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. Scientific societies and regional governments use formal analysis (without HTA). The national government uses formal analysis with HTA. Hospitals and local organizations only use expert recommendations.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by institutions linked to the national government or the department of health (CENETEC-Salud, IMSS, ISSSTE). Conducted HTAs focus on drugs (52 reports), devices (15 reports), procedures (variable amount), and public health interventions (3 reports to date).

Methods used to conduct HTAs include systematic reviews, clinical-economic decision-making modes, cost analysis, budget impact analysis, and cost-effectiveness analysis (CEA and CUA). Analyses are conducted from healthcare system's perspective. During HTA processes, the industry is invited to provide information for the selection of technologies to be assessed, and to comment on the proposed focus area. They are also requested to send a dossier with a complete analysis (using HTA methods) and other data, and make comments on the first version or draft report (public consultation). Users (patients) do not take part in HTAs processes. A HTA can be requested only by the government or the Department of Health.

Peru

Peru has approximately 31 million inhabitants. In 2014, its GDP and GDP per capita was USD 202 billion and USD 11,989, respectively. Peru has a public health insurance system and hospitals/healthcare services are directly funded through taxes. There are no public subsidies for private health insurance companies. 65.5% of the population is covered by public funds (including social security). In 2013, public health expenditure—as a percentage of GDP—was approximately 5.3%, and public expenditure per capita approximately USD 354. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, high-complexity or high-cost drugs, high-complexity procedures, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. As for high-cost drugs, treatment of the following types of cancer is covered: cervical cancer, breast cancer, colon cancer, stomach cancer, prostate cancer, leukemia, and lymphomas. In addition to this, there is a list of rare and orphan diseases, whose treatment is also covered, as well as chronic kidney disease. There are no copayments.

As for healthcare services funded with public funds, a national government agency informs their decisions using formal analysis (with or without formal HTAs). Regional agencies and hospitals use formal analysis (without formal HTAs).

The national department of health, regional governments, scientific societies, hospitals, and local organizations (primary care facilities and clinics) define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. They all use formal analysis, but only the national government uses HTA.

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by the department of health (National Bureau of Medicines, Medical Supplies and Drugs, DIGEMID, for its Spanish acronym; *Analysis* and *Generation* of *Evidence* in *Public Health* team, National Institute of Health, UNAGESP; comprehensive health insurance, GREP (Seguro Integral de Salud)), institutions linked to the national government or the department of health (Seguro Social de Salud, Institute for Health Technology Assessment and Research, IETSI) and universities (Pontificia Universidad Católica del Perú Tecnopolo Salud, CENGETS).

Foci of HTAs depend on the organization conducting the HTA. DIGEMID assesses drugs and devices, UNAGESP only assesses public health interventions, and GREP and IETSI assess drugs, devices, and procedures.

Methods used to conduct HTAs include narrative reviews, systematic reviews, clinical-economic decision-making modes, cost analysis, budget impact analysis, and cost-effectiveness analysis (CEA and CUA). Analyses are conducted from the healthcare system's perspective. In HTA processes, the industry and users (patients) are only invited to provide information for the selection of technologies to be assessed. A HTA can be requested by the government or the Department of Health, scientific societies, the industry, and groups of patients.

Uruguay

Uruguay has approximately 3.3 million inhabitants. In 2015, its GDP and GDP per capita was USD 54 billion and 16,511, respectively. Uruguay has a public health insurance system and hospitals/healthcare systems are directly funded through taxes. In addition to this, there are public subsidies for private health insurance companies. 89% of the population is covered by public funds (including social security). In 2014, public health expenditure—as a percentage of GDP—was approximately 6.3%, and public expenditure per capita approximately USD 1,040. There is a defined package of benefits. Services/interventions covered by public funds include primary care, community care, hospital services, basic drugs, prostheses, implantable medical devices, diagnostic imaging, and diagnostic tests, among others. 100% of the population has access to high-cost drug coverage, but the only drugs included are the ones listed in the Therapeutic Medicines Form. Copayments equal 0% for high-cost drugs and 0-50% for low-cost drugs.

As for healthcare services funded with public funds, a national government agency informs their decisions using formal analysis (with or without formal HTAs). Local/hospital level decisions are informed using expert recommendations or formal analysis (without HTAs).

Scientific societies and the department of health, at national level, define the content of clinical practice guidelines and other documents used to inform decisions on public resources allocation and distribution. Clinical practice guidelines developed by scientific societies are based on expert recommendations. On the other hand, for clinical practice guidelines´ adaptation or transfer, the department of health informs their decisions using formal analysis (with or without HTAs).

When HTAs are used to inform coverage decisions or prepare guidelines, HTAs are conducted by the department of health (that assesses drugs (50 HTA reports per year) and procedures (20 reports per year)), and institutions linked to the national government or the department of health (*Fondo Nacional de Recursos*): drugs (10 research and outcomes reports and 15 budget impact reports per year), devices (2 research and outcomes reports and 2 budget impact reports per year), and procedures (3 research and outcomes reports and 10 budget impact reports per year).

Methods used to conduct HTAs include systematic reviews, clinical-economic decision-making modes, cost analysis, budget impact analysis, and cost-effectiveness analysis (CEA). Analyses are conducted from the healthcare system's perspective. In HTA processes, the industry is invited to provide information for the selection of technologies to be assessed and comment on the proposed focus area. They are also requested to send a dossier with a complete analysis using HTA methods. Users (patients) do not take part in the HTA process. A HTA can be requested by the government or the Department of Health, scientific societies, the industry, and groups of patients.

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