Background Paper

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Defining the value of health technology in Latin America: developments in value frameworks to inform the allocation of health care resources

Introduction

Many times, health decision makers must make decisions that involve funding costly interventions with a limited budget.

Health Technology Assessment (HTA) is a systematic approach to assess the value and potential impact of implementing a specific technology in benefit packages.[1]

HTA involves the use of implicit or explicit criteria to assess the value of the technologies to be funded. On the other hand, choosing some technologies over others means giving priority to specific populations and interventions. Therefore, in addition to health budget implications, HTA has important social and political consequences. Initially, HTA was used only to prepare isolated reports with a minimum impact (if any) on health decisions. During the last decades, however, HTA has played a crucial role in decision-making processes to allocate health resources.

This has created the need for an explicit definition of the role of technologies and decision-making processes. HTA agencies and health systems across the world are making steady progress towards defining the dimensions to be considered to assess a technology, the methods and criteria to assess the performance of a technology in each along said dimensions, and the way in which all this information should be assessed and used to inform decisions.

In this context, the recent emergence of "value frameworks" is aimed at more explicit and inclusive decision-making processes (i.e. a more precise definition of relevant criteria and stakeholders).

Health Technology Assessment (HTA)

Today, health technologies are a central part of health systems. During the last decades, their use has increased significantly. In general, the implementation of new technologies has brought substantial benefits in prevention, safety, health, quality of life and lower rates of adverse events. In settings with limited resources, however, the correct and widespread implementation of technology poses a difficult challenge and, sometimes, a serious problem.

The rapid development of new technologies and the huge volume of available evidence pose a new challenge for health systems. Providing healthcare services means making decisions about the type of interventions that will be offered, the organization of the health system, who will pay for the interventions, and who will provide them and how. The challenge is to use available resources to achieve adequate health outcomes, while considering the population's expectations and demands.

Many countries have made a firm commitment to reaching universal health coverage (UHC) for their populations. UHC is one of the main objectives of the World Health Organization (WHO). Therefore, prioritizing interventions is a basic strategy. According to WHO documents, social values should be at the center of all deliberative processes.[1,2] In this context, health decision makers have a growing need for more reliable and detailed information to make better and more transparent decisions. They need to maximize benefits and set priorities to overcome budget limitations. HTA's growth and development reflects this need for sound and transparent information to inform decisions on the development, incorporation and use of health technologies. The history of HTA can be traced back to the '70s and is closely linked to this growing concern about the emergence of expensive technologies and health systems' (limited) capacity to fund their use. Since the '70s, HTA has evolved to become a multi-disciplinary field. The objective of HTA is to gather available evidence to help decision makers, healthcare practitioners and patients understand the relative value of technologies.[3] There are many definitions of HTA. One of them defines HTA as a multi-disciplinary field of policy analysis that studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology.[4]

During the last 15 years, the development of HTA has been remarkable. Today, HTA is an essential part of the health systems of many countries. Latin America and the Caribbean (LA) have undertaken several HTA initiatives. Argentina, Brazil, Colombia, Chile, Mexico and Uruguay have their own HTA agencies—and are INAHTA members. At present, there are many LA countries that use HTA (to different extents) in their decision-making processes to allocate health resources.

HTA has the potential to become an extremely useful tool for decision makers. However, an inadequate use of HTA may result in inefficient resource allocation, coverage of interventions that offer minimum benefits (if any), delays in patients' access to useful health technologies, unnecessary risks for patients, and sending wrong messages to technology manufacturers and developers, among others.[4] In addition to this, HTA is not a purely technical process. Decision-making processes must consider broad dimensions. HTA decisions have the potential to affect a large number of people and organizations. Therefore, to be fairer and more transparent, HTA processes must be based on a series of basic principles. These principles include transparency, involving all key stakeholders, having a clear system for setting priorities and a clear link between HTA findings and decision-making processes. In this context, value frameworks have emerged as a way to respond to these demands.

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In general, value frameworks include criteria to estimate the level of benefit brought by a specific technology and its cost-effectiveness. Value frameworks may also include other criteria or values (which may or may not be included in conventional HTA), such as the implications for potential stakeholders and other ethical, legal and social consequences.[3] Each technology is assessed according to its performance on each relevant criterion. Then, the process offers a final (explicit or implicit) definition of the value of the technology based on its performance under each criterion and the relative (objective or subjective) importance attached to each criterion or dimension.

Decisions may be based on a more quantitative approach (if selected criteria and information are quantified with formulas or scores) or a deliberative process (if a group of people make an informed decision based on the performance of a technology in different dimensions).

During recent years, the use of value frameworks has spread to different fields and countries. Higher health costs, the emergence of more complex technologies, cost-benefit inconsistencies associated with some technologies, changes in social values, and the inclusion of more stakeholders (e.g. physicians and patients) in HTA processes account for this phenomenon.

The main objective of this Third Latin America Policy Forum is to explore contemporary experiences in the use of value frameworks to inform the incorporation of health technologies and discuss the potential implementation of value frameworks in Latin American HTA systems.

The objective of this document is to offer useful information to stimulate in-depth discussions during the HTAi's 2018 Latin America Policy Forum. This document presents basic information about value frameworks, their use in decision-making processes to allocate health resources, and a series of examples and experiences in the use of value frameworks.

The information presented herein is the result of a bibliographic search and an Internet search of the websites of many organizations involved in the development of value frameworks. This document is also based on the documents prepared after HTAi's 2017 Global Policy Forum: "From theory to action: developments in value frameworks to inform the allocation of Health care resources".

Background

HTAi created the Policy Forum as a neutral venue to hold strategic discussions about the present state of HTA, its development and its implications for health care systems, industry, patients and other stakeholders. HTAi's Policy Forums are attended by representatives of three main groups: (1) decision makers involved in health system decisions about coverage, pricing or reimbursement for drugs and devices; (2) organizations that carry out HTA to inform said decisions; and (3) biomedical companies and manufacturers of medical technology. The Policy Forum has been held for 13 years in Europe and the US and for four years in Asia. In 2016, Latin America held its first Policy Forum and this year [2018], it will hold the third Latin America Policy Forum.

The Forum's approach, agenda and logistics were defined by an Organizing Committee made up of representatives of participating institutions (three representatives of the public sector and three representatives of technology manufacturers). Argentina's Institute of Clinical Effectiveness and Health Policy (IECS, iecs.org.ar) is serving as the Scientific Secretariat for this third Latin America Policy Forum.

The process to select the Forum's central topic involved the following steps: (1) preparing a list of potentially relevant topics using different sources of information; (2) selecting the five topics regarded as more relevant (these topics were chosen by Forum organizers and the Scientific Secretariat after consultation with potential Forum participants); (3) sending this shortlist to participants and using their feedback to prepare a ranking; and (4) final selection of the central topic by the Organizing Committee.

The topic selected for this third Policy Forum is: "Defining the value of health technology in Latin America: developments in value frameworks to inform the allocation of health care resources".

To prepare this document, the Scientific Secretariat searched the literature and the websites of several organizations involved in the development of value frameworks, as well as the documents prepared after HTAi's 2017 Global Policy Forum: "From theory to action: developments in value frameworks to inform the allocation of Health care resources". The purpose of this document is to review and describe the characteristics of existing value frameworks from a global and regional perspective. This is not an exhaustive review. The main objective of this document is to spread basic knowledge and stimulate the discussions to be held during the 2018 Policy Forum.

The third Policy Forum is closely linked to the two previous Forums. The first Latin America Policy Forum, which was held in Costa Rica in 2016, dealt with "Good practices in the application of Health Technology Assessment for decision-making in Latin America". This Forum prioritized the following principles as the most relevant to promote HTA in Latin America:[4]

HTA processes must be transparent and HTA findings must be adequately communicated.
HTA processes must involve all relevant stakeholders.
Appeals: there must be a mechanism to challenge decisions.
There must be a clear system for setting priorities.
The link between HTA findings and decision-making processes needs to be clear.

The central topic of the second Latin America Policy Forum, which was held in Lima in 2017, referred to the inclusion of different stakeholders in HTA processes.

The topic of the third Policy Forum is closely linked with the conclusions of the two previous Forums because the use of value frameworks is a strategy to facilitate the implementation of the above-mentioned principles, and to promote the transparency of HTA processes and the participation of different stakeholders throughout the process (including patients, healthcare practitioners, technology manufacturers, etc.).

In 2017, HTAi carried out the Global Policy Forum in Barcelona. This important event also focused on the development and use of value frameworks. The conclusions of the 2017 Global Policy Forum were:[5]

- To specify the difference between the criteria used to determine the value of a technology from the criteria or values of decision making processes.
- To define the core components of a value framework (for this purpose, HTA Core Model may be used as a starting point).
- To use both quantitative and qualitative methods to assess different diseases and technologies.
- Value frameworks must adhere to the principles of transparency, predictability and active involvement of stakeholders, and be consistent across a wide range of decisions.
- Decision makers are responsible for explaining and clarifying how they use value frameworks in their decision-making processes.

Exhibit I includes all the conclusions drawn at the 2017 Global Policy Forum.

What are the lessons that Latin America could learn from these international experiences? Is it possible to extrapolate these experiences to our region? What is the present state of development and use of value frameworks in Latin America? These questions will be discussed during the third Latin America Policy Forum to be held in Montevideo.

Value Frameworks

Decision-making processes need to define and measure the value of the assessed technology. This task may be based on or facilitated by the use of "value frameworks". Value frameworks consider different criteria to define or measure the "value" of technology.[6]

In general, the method used to define or measure the value of technology is to assess the performance of the technology under different domains or criteria. In this way, it is possible to measure the overall performance of technology. The final result may derive from a deliberative process with a qualitative outcome (usually an appraisal) or a quantitative outcome with a final score (multiple-criteria decision analysis (MCDA), which is less frequent but preferred in academic settings).

The criteria used to define or measure the value of technology vary across different decision-making contexts (political and cultural) and are defined by different stakeholders (i.e. those potentially affected by eventual decisions).

Most value frameworks include the following criteria: disease burden, effectiveness, cost-effectiveness and budget impact.[7]

In addition to this, criteria include value judgements. These value judgements are formed when selecting comparators, the outcomes that will be considered relevant to assess the effectiveness of a technology, and aspects to be considered when assessing the quality of evidence, for example. On the other hand, different stakeholders are expected to assess said criteria differently (e.g. patient representatives, healthcare practitioners, decision makers, funding entities, researchers, technology manufacturers or civil society representatives).[8]

The 2017 Global Policy Forum expressed concern regarding the low degree of involvement of some stakeholders in current value frameworks (making special mention of patients' values). Forum participants mentioned the need to identify and include criteria relevant for patients in value frameworks.

Specifying and listing the criteria used in HTA processes promotes transparency and improves the quality of decision-making processes.[9]

MCDA is an older process related to the current use of value frameworks. This process, which has

become more popular during recent years, specifies the criteria to be used in decision-making processes and the relative importance of each criterion. Then, it is necessary to prepare a framework to assess the behavior of assessed technology under such criteria and this information is used to inform decisions. If value is defined or measured using formulas and scores, decisions will have a higher degree of quantitative rigor. Otherwise, decisions may be based on a deliberative process (when a group of people make a decision using the information obtained from the above-described process).

Even though value frameworks are becoming increasingly popular, their implementation in different countries is still very recent. MCDA technology has been used in different countries. Many of these experiences are mentioned by the ISPOR MCDA Task Force[10] (Definition of universal coverage in Thailand, Implementation of EUnetHTA Core Model in Lombardia or the local allocation of resources to a Primary Care Trust in the United Kingdom, among others). The use of value frameworks to specify criteria and measure the performance of assessed technology promotes transparency and informed decisions.[10]

International experiences in the use of value frameworks

The use of value frameworks is linked to decisions about coverage or funding. In general, value frameworks are used by HTA agencies to inform decisions by funding entities. During recent years, however, value frameworks have been linked to clinical decisions and have been used by healthcare practitioners and patients.

Funding entities usually define or measure value considering the benefits offered by a technology and its incremental cost-effectiveness relative to current treatments, relating this value to the possibility, feasibility or willingness to pay and the uncertainty related to mentioned criteria.[11]

In some countries like the UK, Australia and Canada, among others, funding decisions (technology appraisal) are made by discussion committees.

In the UK, for example, the Advisory Committee of the NICE is made up of physicians, patients, the technology's manufacturer and members of the civil society. First, the committee reviews the evidence about the technology's clinical benefits and cost-effectiveness. Then, all stakeholders can voice their concerns and opinions. Finally, the Committee makes a recommendation about the assessed technology.[12]

In Australia, this function is carried out by the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is made up of 18 persons who hold regular meetings. The PBAC includes at least one representative for each of the following categories: patients, economists, pharmacists, general practitioners and specialists.[13]

In Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) carries out Common Drug Reviews and issues recommendations to the different provinces. Just like in the UK and Australia, they have a special committee (Drug Expert Committee) that meets regularly to issue said recommendations.[14]

HTA Core Model[15] is another widespread model. According to this model, HTA processes should consider the following domains:

1. Health problem and current use of the technology
2. Description of the technology and its technical characteristics
3. Safety
4. Clinical effectiveness
5. Cost and economic evaluations
6. Ethical considerations

7. Organizational aspects
8. Social and patient-related aspects
9. Legal aspects

Table 1 shows some of the value frameworks used by different countries in their decision-making processes. This table summarizes six cases from countries with well-established HTA processes and two cases from the US that focus largely on technology purchase and price decisions.

In general, these cases relate to the assessment of different types of technology including drugs, devices and procedures. Most processes require information on interventions' effectiveness, safety and cost. In this regard, all processes consider quality of evidence, comparators and degree of uncertainty attached to observed outcomes. With regard to economic information, almost all of them prefer cost-effectiveness studies above other methods and the preferred outcome measure is QALY quality of life. Sometimes, processes include information on budget impact. Processes also consider other aspects such as the prevalence and severity of the health problem, availability of alternative treatments, ethical and legal considerations, and willingness-to-pay thresholds.

Table 1. Characteristics of selected value frameworks

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
Types of assessed technologies/interventions								
• Drugs		+	+	+	+	+	+	+
• Devices	Permanent implants, only indirectly, when a new procedure is necessary		+	+	+	+	+	+
• Procedures, diagnostic tests, surgeries	+		+	To some extent	+	+	+	+
• Public health interventions	Theoretically, but very rarely in practice		+			+		+
• Systems, services	Theoretically, but very rarely in practice		+		+	+ (e.g.: service guidelines)		+

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
• Information requirements	Clinical Benefit and relative safety, cost information to determine value for money, budget impact, other aspects mentioned below when relevant	Clinical Benefit and relative safety, cost information to determine value for money, budget impact, other aspects mentioned below when relevant	Clinical Benefit; cost information to determine value for money. Additional information on equity, public health, and budget impact may be submitted.	Clinical Benefit; cost information to determine value for money. Additional information about disease burden and severity or impact on equity may be submitted.	4 criteria: Need, Effectiveness, Cost-effectiveness, Adequacy. This includes disease burden, budget impact, and legal, ethical, and organizational aspects.	Clinical Benefit; cost information to determine value for money. Additional information on social values, impact on equity, innovative characteristics, and budget impact may be submitted.	Clinical assessment considering benefits and damages to estimate net benefit. This is a dichotomic process, either there is or there isn't evidence of a clinical benefit. BCBSA considers but has not implemented assessments of net benefit levels.	KP considers published clinical trials, information from their own records, and opinions of their own experts. These expert opinions are used to frame the questions to be answered, understand common practices, operating considerations, and existing treatment considerations.
Value criteria assessed								
• Size of effect	+	+	+	+	+	+	+	+
• Quality of evidence	+	+	+	+	+		+	+
• Disease burden/ prevalence	+	+	+	+	+			+
• Relevant clinical outcomes	+	+	+	+	+		+	+
• Uncertainty attached to clinical benefit	+	+	+	+	+	+		+, Qualitatively

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
Assessment of therapeutical value (preferred/required approach)								
• QALY	+	+	+	+	+	+		
• SMR/ASMR						+ (previously described)		
• Benefit estimation categories								
Assessment of economic value (preferred/required approach)								The review of evidence does not require an assessment of economic value. Upon a positive review of evidence, the economic value is addressed when considering implementation.
• Cost-effectiveness	+, preferred	+, preferred	+	+	+	+		
• Cost- effectiveness	In some cases	In some cases	+	In some cases	In some cases	In some cases		
• Cost-minimization	In some cases	In some cases	+	+	seldom	Yes (new summary process)		
• Cost- effectiveness				In some cases				

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
• Patient subgroup analysis required or considered	+	+, if applicable	+	+	+	+		Considered if method-ologically applicable or for relevant populations.
• Cost-effectiveness (uncertainty about cost-effectiveness information)	+	+	+	+	+	+		Only good-quality economic evaluations are considered after a positive review of clinical evidence when KP is evaluating incorporation.
• Quality of evidence used in economic evaluations	+	+	+	+	+			The quality and relevance of economic information is considered after the review of clinical evidence if KP is planning to implement the technology

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
• Budget impact	+	+	+	In some cases	+			Considered upon a positive review of clinical evidence if KP is planning to implement the technology
• Severity of disease	+	+	+	+	+		+	+
• Availability of alternative treatments	+	+	+	+	+	+	+	+
• Impact on public health	+	+	+					+
• Innovative characteristics	Focused on interventions with a clinical benefit	Focused on interventions with a clinical benefit						Not explicitly, only considered if KP plans to implement the technology.
• Legal/ethical or equity considerations	+	+	+	+	+			+
• Patient accessibility	+	+			+			Considered (quantitively) upon a positive review of clinical evidence if KP plans to implement the technology.
• Preferences and social values	+	+			+	+		Quantitative evaluation

	Australia		Canada	Sweden	The Netherlands	UK	USA	
	MSAC	PBAC	CADTH	TLV	ZIN	NICE	BCBSA TEC	KP
Cost-effectiveness threshold	Not set.	Not set.		Not set. E.g. approx.. 500,000 SEK (USD $74,000)	Not set but there are 3 categories based on disease burden: 0.1 – 0.4 DALY: up to 20,000 per QALY 0.41 – 0.7 DALY: up to 50,000 per QALY 0.71 – 1.0 DALY: up to 80,000 per QALY	Cost/QALY threshold approx. £20,000 - £30,000	Cost-effectiveness analyses are not performed. However, in drug evaluations, some members use QALYs to evaluate cost-effectiveness These are 4-category packages that assign lower out-of-pocket expenses to drugs regarded as high-value drugs.	

Source: This table was prepared using the Background Paper of the 2017 Policy Forum (From theory to action: Developments in value frameworks to inform the allocation of health care resources)

On the other hand, during recent years, the cost of oncology drugs led to the development of many value frameworks to measure their benefit. The objective was to help physicians make prescription decisions and to facilitate price negotiations between funding entities or practitioners and technology manufacturers, especially by private health funding entities in the US.

Many of these oncology value frameworks were developed in the US. Most of them include a clinical benefit analysis to assess efficacy and adverse events, quality of evidence and cost. Some of them then suggest an overall composite score based on a numerical formula, while others use expert opinions.[16]

Table 2 shows some value frameworks developed by scientific societies like the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO), healthcare centers like the Memorial Sloan Kettering Cancer (MSKCC) and the National Comprehensive Cancer Network (NCCN) or private academic institutions that offer consultancy service to different states, like the Institute for Clinical and Economic Review (ICER).

Table 2. Comparative chart. Comparison between different Value Frameworks in Oncology (US)

	ASCO	ESMO	ICER	MSKCC	NCCN
1. Health Benefit component					
Measurement of efficacy	Relative risk of overall survival (progression-free and disease-free survival)	Relative risk of overall survival (progression-free and disease-free survival). Minimum observed survival (months)	Characteristic: survival is assessed in QALYs	Improvements in survival	Outcomes vary depending on experts' opinions
Adverse effects	Grade 3-4 adverse events	Analysis through multiple definitions	Serious adverse events	Grade 3-4 adverse events; treatment discontinuation	Outcomes vary depending on experts' opinions
Other factors	Disease-related symptoms Treatment-free interval	Quality of life	Early return to work, disease unmet need, QALY	Treatment novelty, R&D cost, health burden, treatment duration	Outcomes vary and are considered on a case-by-case basis.
2. Quality of evidence					
Sample size (clinical trials)	No	Yes*	Yes	Yes	Yes
Number of clinical trials	No	No	Yes	No	Yes
3. Method to estimate overall composite score					
Formula vs expert opinion	Formula	Formula	Formula and expert opinion	Formula	Expert opinion
It includes patients' preferences	No	No	No	Yes	Yes
4. Costs					
Cost analysis	Cost of drug Patients' out-of-pocket expenses	Not specified, depends of funding entity's	Cost per person, Total cost of funding entities&	Average wholesale price	Total cost of treatment
It includes out-of-pocket payments	Yes	No	No	No	No

* Indirectly through the lower limit of the confidence interval & It considers the number of patients that will need treatment
& It considers the number of patients that will need treatment

An ISPOR Task Force summarizes the recommendations to the US health system on the use of value frameworks.[17]

Value frameworks are designed for specific categories of technology (e.g. oncology drugs).

Value frameworks for decisions about medical devices are now under development. Medical devices are different from other technology categories, both in terms of the generation of evidence about effectiveness and legal aspects for their approval.

Training needs for the use of the technology and the organizational impact of implementation are usually disregarded when estimating the value of medical devices.

In 2017, the Organization for Economic Cooperation and Development (OECD) published a document about access and assessment of emerging technologies.[18] This document includes a chapter on the different regulatory aspects applicable to medical devices and the difficulties faced by this category as compared to other technology categories. The document explains how the use of value frameworks may be influenced by different uses for the same medical device and the potential evolution of these uses in the long term.

Below, we describe some value-framework initiatives to assess medical devices.

AdvaMed: Initiative to determine the value of medical technology and diagnostic tests

AdvaMed is a consortium of medical technology companies that manufacture medical devices or diagnostic tests. During the last year, they developed value frameworks for decision-making processes referred to medical technology in general[19] and one for decisions related to diagnostic tests.[20]

For this initiative, they sought the opinion of many stakeholders (funding entities, healthcare practitioners, patient groups and manufacturers). HTA agencies, however, were not included. AdvaMed identified four main categories of value criteria: clinical impact, non-clinical impact (e.g. caregivers' time and out-of-pocket expenses), implementation and social benefits (e.g. impact on employers or in the health system as a whole).

With regard to diagnostic technology appraisal processes, they specify the need to assess the impact of the information about the technology on the chain of decisions derived from the use of said information in usual care.

AdHopHTA

AdHopHTA was a European Union-funded project on HTA in hospitals.[21]

Sometimes, hospitals need to make health decisions that defer from usual coverage decisions in term of context, technologies and involved stakeholders. Sometimes, these decisions involve medical devices and, more frequently, diagnostic tests. Thus, when comparing conventional value frameworks with those developed by AdHopHTA, we observe that some criteria were regarded as more relevant in this context.

Specifically, as compared to other value frameworks, they give more relevance to safety-related aspects, the perspective of the hospital, and organizational and strategic aspects related to the future of the hospital.

Use of value frameworks in Latin America

In Latin America, the official use of value frameworks is not as developed as in other regions.

However, some countries do have decision-making frameworks though they cannot be strictly defined as value frameworks.

Below, we describe some of the decision-making processes used by some Latin America countries.

Uruguay: The Health Technology Assessment Division of Uruguay's Department of Health prepares their own reports. These reports are based on effectiveness, safety and cost-effectiveness, and are used to inform coverage decisions for technologies to be included in the National Integrated Health System.[22]

Peru: Peru performs comparative analysis based on effectiveness, safety and economic impact. These analyses are used to inform coverage decisions for drugs included in the Official List of Drugs and Health Technologies (*Petitorio de Medicamentos*) for people covered by ESSalud when said decisions will affect approximately one third of the country's population.[23]

Brazil: Brazil performs HTA through their federal agency CONITEC. CONITEC assesses effectiveness, safety and adverse events and issues recommendations for or against the inclusion of drugs in the Unified Health System (SUS). CONITEC discussion groups are made up of representatives of all Brazilian provinces, professional societies and government agencies.[24]

Colombia: The Administration of Drugs and Medical Technology of Colombia's Health Department defines value categories based on effectiveness and safety. The classification of technologies under these categories is used to inform pricing decisions and sometimes to negotiate prices upon centralized purchases of specific drugs.[25]

On the other hand, with regard to medical devices, Mexico's National Center for Health Technology Excellence (CENETEC) developed Guidelines for Clinical Assessment[26] and Economic Evaluation of Medical Devices[27] to inform decisions referred to the inclusion of devices in the Basic Chart (list of essential medicines). This category does not include medical equipment.

Even though these processes cannot be strictly defined as value frameworks, their guidelines include specific aspects that must be considered when assessing medical devices that go beyond traditional HTA and account for difficulties and differences in decision-making processes related to funding or covering this type of technologies.

Discussion

Even though their use is increasing, the international HTA community considers that there is a need for a more precise definition of value frameworks.

Below, we have included some of the conclusions drawn by the Global Policy Forum about the present state of development of value frameworks and the challenges of their implementation.

Present challenges to the use of value frameworks include the inclusion of other criteria and values beyond cost and clinical benefit, such as equity and transparency in decision-making processes. Another aspect to be considered is the official inclusion of the values of all stakeholders involved (e.g. patients). On the other hand, the development of specific methods to assess the quality of evidence of different diseases or technologies is a complex issue. To face these challenges, it would be necessary to develop quantitative and qualitative methods to address these issues.

In general, there is a clear consensus over the fact that value frameworks must adhere to certain principles such as transparency, predictability, active involvement of stakeholders, and having clear and consistent processes. On the other hand, these frameworks should not be too rigid or be based solely on numerical formulas; rather, supplementary deliberative processes are encouraged. HTA and participating communities play a decisive role in the use of value frameworks and the definition of core criteria.

The Global Policy Forum spoke against "reinventing the wheel". The use of decision-making criteria has always been an integral part of HTA. The more recent emergence of "value frameworks" and other methods to improve these processes is just aimed at enhancing and adding transparency to assessment and decision-making processes and to promote inclusion of key stakeholders, and relevant criteria and values.

Decision makers are clearly responsible for the transparency of decision-making processes and the description of the use of value frameworks. The use of value frameworks is not aimed at overriding conventional and deliberative processes. Actually, the underlying objective is the same. Value frameworks systematize and describe HTA agencies' recommendations more clearly for decision makers to base their decisions on more exhaustive results considering the interests and perceptions of all stakeholders.

Transparency in HTA and decision-making processes is key to promote fair access across the population.

Even though the development and use of value frameworks in Latin America is very recent and heterogeneous, the discussion about their implementation and relevance seems to be a high priority in the Region. The use of value frameworks is defined as a mechanism to promote transparency in decision-making processes and to clarify the link between HTA findings and decision-making processes—two principles identified as high priorities during the first Latin America Policy Forum. On the other hand, the use of value frameworks can become a mechanism to formalize the criteria to be considered by different stakeholders to facilitate their active involvement—a principle identified as a high priority during the second Latin America Policy Forum.

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EXHIBIT I

Supplementary Table 2: Complete list of key messages discussed by participants at HTAi's Global Policy Forum held in Barcelona, Spain on January 29 to 31, 2017.

Key Messages	
Value Frameworks	
Content	• There's a need for clear definition of what a value framework is. • Does the growth of alternative value frameworks mean that established generic value frameworks are losing missing important details? • There's a need for more analysis (conceptual, normative, economic, etc.) of value frameworks and their different aspects. • There's a need to improve value frameworks to meet emerging challenges (e.g. affordability). We can learn valuable lessons from emerging value frameworks. • Value frameworks and their implementation through HTA systems must be sufficiently adaptable to address technologies that are revolutionary vs. available current processes. • It may be necessary to adapt methodologies for assessing evidence to address different disease states and types of technologies. • We are not including all aspects of value. • Some value frameworks may not reflect some aspects of value that are important to patients. • Aspects of value that are economic externalities (insurance, hope, real options, etc. are tricky) need to be incorporated but are often not addressed in practice. • EUnetHTA model is considered a reasonable starting point as a core value framework. • There is a need for HTAi – unmet need – to define the core components of value frameworks. • HTA framework is not only about value for money but about including other social values. Social values are a must to adapt HTA to respond proactively to social needs. • Social values should influence value frameworks. • Progress on realizing that there is more to value than clinical and economic factors. • We need to identify "additional" components of value, and how they can be presented and incorporated. Move from the implicit to the explicit.

Key Messages	

Processes	• There is a need for clarity regarding the definition of "value" in a value framework and "values" in decision-making processes.
	• We have enough value frameworks - key principles of value frameworks can apply to all healthcare interventions:
	  • Make them predictable and transparent
	  • More from assessment and management of health
	  • Forward looking
	• New value frameworks have limited value for those jurisdictions with robust, well-defined HTA processes.
	• Not everything needs to be quantifiable; what is not quantifiable is still important and needs to be captured (explicitly) qualitatively.
	• Additional factors are incorporated (if at all) in different ways and often there is no transparency on additional factors and how they are used for decision making.
	• Progress has been made in recognizing there is more to value than [sic] what we currently capture (in existing frameworks); however, we struggle in identifying the best ways to integrate these additional aspects into the frameworks to capture various dimensions of value. Increasing transparency on the basis of value framework (being explicit on rationale) would help.
	• All HTA decision makers need to describe their value frameworks, which need to be adaptable to respond to new circumstances.
	• Legitimacy of value frameworks is needed – requires broad stakeholder involvement and expert involvement.
	• Existing value frameworks need to be adapted to ensure they are meeting the demand for civic participation.
	• Current processes to conclude on an added benefit do not currently take into consideration a robust patient point of view.
	• Need to be explicit regarding assessment and attrition processes and how they are linked.

Decision-making	• Accept duality of value frameworks and decision-making. Let us try not to put everything into one system. • We need to assess how value frameworks work in different types of payer systems. • Legitimacy of value frameworks is needed – requires final decision at a high level (Parliament) with broad political consensus. • Decision makers have a responsibility to clearly state rationale and detail behind application of value frameworks to make a decision. • A comprehensive value framework is important, but it does not annul or replace the need for a conversation/negotiation on how technologies can be made available whilst addressing issues such as affordability. • It is important to recognize that value frameworks used in HTA can have significant implications for global incentives for innovation and access to technologies.