

STAKEHOLDER INVOLVEMENT IN THE HEALTH TECHNOLOGY ASSESSMENT PROCESS IN LATIN AMERICA

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Objectives: Latin American countries are taking important steps to expand and strengthen universal health coverage, and health technology assessment (HTA) has an increasingly prominent role in this process. Participation of all relevant stakeholders has become a priority in this effort. Key issues in this area were discussed during the 2017 Latin American Health Technology Assessment International (HTAi) Policy Forum.

Methods: The Forum included forty-one participants from Latin American HTA agencies; public, social security, and private insurance sectors; and the pharmaceutical and medical device industry. A background paper and presentations by invited experts and Forum members supported discussions. This study presents a summary of these discussions.

Results: Stakeholder involvement in HTA remains inconsistently implemented in the region and few countries have established formal processes. Participants agreed that stakeholder involvement is key to improve the HTA process, but the form and timing of such improvements must be adapted to local contexts. The legitimization of both HTA and decision-making processes was identified as one of the main reasons to promote stakeholder involvement; but to be successful, the entire system of assessment and decision making must be properly staffed and organized, and certain basic conditions must be met, including transparency in the HTA process and a clear link between HTA and decision making.

Conclusions: Participants suggested a need for establishing clear rules of participation in HTA that would protect HTA producers and decision makers from potentially distorting external influences. Such rules and mechanisms could help foster trust and credibility among stakeholders, supporting actual involvement in HTA processes.

Keywords: Universal coverage, Health economics, Evaluation of biomedical technologies, Public health policy, Stakeholder involvement, Health priorities

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Latin American countries are taking important steps to broaden and strengthen universal health coverage (UHC) (1). Health decision makers, in their efforts to maximize health benefit within constrained budgets, have begun to require more and more information that is reliable and relevant to allow them to make better decisions in priority-setting (2;3). This has placed health technology assessment (HTA) in a more prominent role. From an initial stage where HTA was primarily a series of isolated reports with little or no impact on decisions, it has recently come to take a central role in decision making for health resource allocation in many countries in the region. This has been more evident in countries such as Brazil, Chile, Colombia, and Mexico, but it is beginning to spread to many other countries in Latin America and the Caribbean (4).

In the early days of HTA in Latin America, the focus was primarily to develop human resources to produce HTA reports and related aspects such as evidence synthesis and health economics (5;6). More recently, however, as the region began to develop greater technical capacity, other priorities arose for making improvements to the process and quality of HTA. In this context, given that decisions made through the HTA process have the potential to affect a large number of people and institutions, the participation of all relevant

stakeholders has become a priority to make the HTA-based decision-making process more transparent and legitimate (7).

The First Latin American HTA Policy Forum of Health Technology Assessment International (HTAi) was held in 2016 in Costa Rica, and the topic of good practice principles to guide HTA in the region was discussed. One of the highest priority principles that was identified by participating country representatives related to stakeholder involvement (8). The involvement of relevant stakeholders in the HTA process is a good practice principle largely recognized by the international HTA community (9–16). However, many Latin American countries have not yet implemented formal mechanisms for stakeholder involvement in the HTA process, and in many other countries in the region implementation is still partial, involving only certain groups or involving them only in some, but not all, components of HTA and decision-making processes.

Also during the first Forum, it was emphasized that the local context must be taken into account for all of the good practice principles. Thus, determining when and how to implement these principles depends upon the state of HTA development in each country, the resources available, and the characteristics of the health system and the decision-making process. This insight informed the selection of the topic for the second Latin American HTA Policy Forum held in 2017, which was: “Stakeholder Involvement in the Health Technology Assessment Process.” The objective of the Forum was to debate the best way for HTA agencies in the region to improve stakeholder involvement, both in terms of the conceptual frameworks as well as in the methodological and operational aspects of HTA.

METHODS

The Second Latin American HTA Policy Forum was held in-person in Lima, Peru, on April 24–25, 2017, and it included a total of forty-one participants: ten representatives of HTA agencies; seven representatives of funders of the public, social security, and private insurance sectors; seventeen representatives from industry (pharmaceuticals, medical equipment, and diagnostic tests); one representative of the Pan-American Health Organization and six academics and organizers, and members of the event’s scientific secretariat. In total, there were ten countries in the region represented and ten companies. In the acknowledgements section of this study is the list of participants, including their affiliations and countries.

The scientific secretariat developed a background document summarizing the state of knowledge on the topic; establish shared understanding among participants; harmonize the definitions of key terms; and support discussions during the in-person meeting. This document was created with input from the Forum Organizing Committee and the members of the Forum (17).

Relevant stakeholders were defined as those individuals, organizations or communities who have a direct interest in

the process and results of an assessment of a health technology, in other words, all the people potentially affected by a health technology coverage (reimbursement) decision (18). The Forum focused discussion on two stakeholder groups deemed to be of highest priority in the region: (i) patients and caregivers in general, and (ii) health technology producers.

To facilitate presentations and debate, two areas where involvement could occur were defined: one relating to the general structure, policies, and values of the HTA process; and the other relating to the development and production of HTA.

The keynote speaker, Edward Clifton, shared the experiences of Healthcare Improvement Scotland, an institution with a long history of stakeholder involvement in HTA. This was followed by presentations on the current state and main barriers to the implementation of stakeholder involvement in each of the countries represented at the Forum. In turn, two representatives from industry (medicines and devices) presented their perspectives on the topic, one providing a global perspective, the other a regional view. These presentations were the basis for breakout group discussions that led to the results of the Forum.

Both the supporting materials and presentations, along with the breakout group discussions were developed to: (i) discuss stakeholder involvement experiences in different countries, (ii) assess the current situation in the region, and, (iii) discuss possible next steps toward involving stakeholders in HTA processes in the region.

The Forum was conducted following the Chatham House Rule (19), which permits participants to share information obtained during the meeting but without revealing the identity or affiliation of the person who provided the information.

After the Forum, the scientific secretariat developed a summary report of the activities, results, and conclusions, which was circulated to all participants for input and comment. This study is based on this summary report and presents the main points debated during the Forum. It is not a formal consensus of Forum participants and, therefore, it should not be construed as representing the views of the participants or the organizations where they work.

RESULTS AND DISCUSSIONS HELD DURING THE FORUM

The background document summarized the main mechanisms of, and experiences with, stakeholder involvement in HTA from around the globe, with examples from countries in the region where possible. Mechanisms for involvement were described in each of the two aforementioned areas: first, in the definition of the structure of HTA bodies, policies, and values of the HTA process; and, second, in the different stages of the HTA processes (e.g., prioritization of topics for assessment, formulation of recommendations and their implementation and/or revision) (17). Forum participants

agreed that the background document provided a good base to support discussions about stakeholder involvement in Latin America.

Presentations by members about the current state of the situation in the region showed that Latin America has made tremendous progress in HTA in the past few years. Nevertheless, opportunities for improvement remain, particularly in aspects related to the use of HTA in decision making. [Table 1](#) provides an overview of the state of stakeholder involvement in the ten Latin American countries represented at the Forum, with a special focus on patients/users and industry. It shows a high level of heterogeneity, ranging from countries systematically involving stakeholders, to others where there are no formal mechanisms in place for stakeholder involvement in HTA. Even in countries that have been able to move forward in this respect, implementation is mostly either limited to a subset of all relevant stakeholders, or it applies only to certain phases of the HTA process, for example, the assessment phase but not decision making.

Presentations by industry emphasized that the participation of patients in the HTA process is a critical success factor and could be seen as the third pillar of evidence along with clinical and economic evidence. It was noted that this involvement should follow two key principles: involving the right patients or patient groups at the right time, and involving them in the right way.

In subsequent discussions the importance of stakeholder involvement in HTA was reaffirmed. It was seen as a way to provide a broader perspective that would prevent a narrow focus limited to the viewpoints of technocrats and health professionals only. It was also seen as a way to engage various groups in dialogue thereby increasing the legitimacy of both the process and the resulting decisions.

Throughout the meeting, different types and degrees of stakeholder involvement were discussed. These ranged from passive involvement, for example, publicly available HTA documents open for comments through formal mechanisms and the incorporation of social values in the weighting of criteria used in the assessment, to active participation, for example, where representatives are present at committee meetings involved in decision making.

The Forum did not reach a consensus on the stages of HTA to be prioritized for involvement. However, there was agreement that stakeholder involvement could enrich many of these stages, except for those that are purely technical. Many attendees believed that such stages should be the responsibility of HTA staff who are appropriately trained and that social values should not influence this work, which should be protected from external influences. However, it was noted that the items for technical assessment could be prioritized in previous participatory stages, and the results of the technical assessment should be appraised in a deliberative process including nontechnical stakeholders.

In the exploration of the issues and barriers to the implementation of stakeholder involvement, one main barrier mentioned was their lack of knowledge about HTA processes and methods. Other barriers identified by Forum participants were the lack of trained staff and dealing with the additional cost and time burdens arising from changes made to the HTA process to achieve greater participation.

Several participants expressed concern over potentially negative consequences of stakeholder involvement in HTA. Some of the main fears were that certain groups could have an excessive influence on setting the agenda for prioritization of technologies to be assessed. Specifically, some participants mentioned that stakeholder involvement would engender excessive influence by industry, which would lead to the prioritization of assessment of those interventions/technologies that have a “sponsor” promoting them and away from those technologies that are most needed by the health system, thereby leading to an increase in existing health inequalities. Forum attendees feared that stakeholders could inappropriately influence the assessment and decision making as well, and mentioned cases of pressures received from severely ill patients or patient groups highly associated with industry. This concern was more pronounced in countries with a lower level of HTA institutionalization where HTA mechanisms and structures are weaker or in the process of emerging.

Country representatives also worried that stakeholder involvement could increase demand to a point exceeding available resources, thereby causing delays in the HTA process. In this regard, the cases of Brazil and Mexico were referred to because, according to regulations, they are required to respond within a certain timeframe to requests for assessment or adoption of technologies from different stakeholders. It was argued that this could be readily applied in large countries with assessment structures equipped to respond to such demands, but for smaller countries, this would be unfeasible. This is one reason why some countries in the region are reluctant to establish formal participation processes.

Most attendees agreed that the participation of stakeholders would increase legitimacy. This, in turn, would reduce the discretion of decision makers, which was considered a positive factor to further reinforce the legitimacy of the decision-making process.

Several additional potential barriers were identified, namely, the lack of trust among different stakeholders, the judicialization of many of the HTA related decisions through individual-based appeals, the lack of education and awareness among patients about HTA, the absence of clear and accessible mechanisms to promote the participation of the general public in the HTA process, the fragmentation of many of the countries' health systems, and the lack of a culture of citizen participation in policy development in general.

For all these reasons, many participants believed that there should be certain principles and conditions already in place to

Table 1. Overview of the Involvement of Patients/Users and Industry in the Ten Latin American Participating Countries of the Forum

Country	Patients/users	Industry
Argentina	The participation of patients and users is foreseen in the bill for the creation of the HTA agency in Argentina (AGNET), but this law is not yet in force.	There is a mechanism for the industry to request the evaluation and adoption of technologies in social security, which began in 2017. Industry participation is also foreseen in the bill for the creation of the HTA agency in Argentina (AGNET).
Brazil	Citizen participation in HTA has been formalized by law since 2011. Their participation is considered in all stages of HTA through involvement in the plenary that issues recommendations, as well as public hearings and public consultation. They can also submit technologies to be assessed.	Industry participation is regulated by law since 2011. They can submit technologies to be evaluated and can ask for a private scoping meeting prior to the submission. There is an industry representative on the National Health Council. And industry can provide feedback during public consultation
Chile	A general norm has existed since 2009 that regulates citizen participation in the processes of the Ministry of Health. The law known as “Ricarte Soto” (2009) regulates patient and citizen involvement in HTA. They can request assessments, participate in the prioritization process and the monitoring of the implementation of the law. They do not participate in clinical guideline development nor in decision making.	In 2014, the Lobby Law came into effect. It has been widely used by industry. The “Ricarte Soto” Law considers industry collaboration with the assessment team to achieve shared risk agreements. Industry is not explicitly considered as a source of information.
Colombia	There are formal mechanisms to involve patients and citizens in the teams that develop health technology assessments and clinical practice guidelines.	Industry is informed about the assessments being conducted and their participation includes providing information and evidence and being involved in dissemination of HTA conclusions.
Costa Rica	There are no formal mechanisms to involve patients and citizens in the HTA process, except through the judicial system. They will be consulted in the Bill currently being discussed in the Legislative Assembly.	Industry sometimes requests assessments and adoption of technologies and provides information, but this is not formally regimented. There is a project underway to consider formalization of this process.
Ecuador	Patients and citizens are invited to participate in updating the national formulary every two years. They can also propose the adoption of technologies in special cases, such as orphan diseases or end-of-life. The agency has one month to respond to such requests.	Industry participates in the regular process every two years. They can present technologies for assessment. There are plans to train members of industry for participation in the HTA process.
El Salvador	There are no formal mechanisms for citizen involvement in the adoption of health technologies into the List of Institutional Medicines. However, applications from citizens are accepted. There are plans to work with the National Health Forum and with patient associations to create spaces for citizen participation.	Industry can present assessment requests, although there are no formal mechanisms for this. Work is underway to regulate the participation of patients and industry in the HTA process.
Mexico	There are no formal mechanisms in place, although information from patients or civil society can be accepted. Regulation by the new standards of the General Health Council will consider the possibility to give a voice to civil society, although not voting rights.	The process is well established for industry to present new technologies (technical meetings prior to the process, methodological guide, and appeal mechanisms).
Peru	No formalized participation of patients in any stage of the HTA process is in place, although on some occasions they can request assessments.	No formal process exists. In some cases, industry can present information to be assessed.
Uruguay	No formal mechanisms exist for patient/user participation in the HTA process. Patient groups are active in the demand for health technologies.	Industry can propose topics for assessment and send documentation through established mechanisms. There also exist informal mechanisms for interviews and meetings with those responsible for carrying out the HTA.

Note. Source: Developed by the authors based on data presented by participants in the Second Latin American HTA Policy Forum. HTA, health technology assessment.

facilitate appropriate involvement of stakeholders in HTA, including clear mechanisms to guide the assessment and decision-making processes. Many countries in the region still do not have HTA agencies, nor explicit benefit packages, nor defined explicit processes to incorporate technologies. If certain basic conditions are not met, the HTA process could be exposed to excessive “external” influences. [Table 2](#) presents

the basic principles and mechanisms deemed by attendees to be necessary for consideration by health systems to involve other stakeholders in the HTA process without exposing the assessors and decision makers to potentially distortive external influences.

Brazil and Mexico were mentioned as good examples where industry participation has been made clearer, which

Table 2. Principles and Basic Mechanisms to Achieve Stakeholder Involvement in HTA According to Forum Participants

Transparency in the HTA process
Clear links between HTA and decision making, with criteria and values explicitly based in social preferences
Mechanisms to assure that the prioritization of assessment topics aligns with real needs and that it is not unduly influenced by stakeholders or interest groups with lobbyist or pressure power
Methodological guidelines that outline the technical aspects of assessments and the process and instances of participation of different stakeholders
Appropriate technical staffing and resourcing of HTA agencies

HTA, health technology assessment.

happened mainly because these countries first clearly defined the role of HTA in the decision-making process.

The legitimization of the HTA process in decision making; bringing information complementary to the sources of scientific evidence traditionally considered in assessment; the broadening of perspectives beyond the health system; and fostering trust and improved dialogue among stakeholders were mentioned as the main reasons to promote stakeholder involvement.

The recognition by agencies of the importance of stakeholder involvement, the laws and institutional frameworks in countries that support and facilitate citizen participation in government decision making, and advances in stakeholder involvement experiences internationally, and awareness of these, were identified as the main facilitators to promote these changes in HTA processes in the region.

CONCLUDING REMARKS

The presentations and discussions at the Forum clearly showed the relevance of improving HTA processes in the region, which includes advancing toward the involvement of the main stakeholders in different HTA areas. Forum participants agreed that the involvement of relevant stakeholders is key to improve HTA processes, but the form and timing of how this is carried out must be adapted to the local context of each country. Participants selected patients-users and industry producers as the priority stakeholders for this edition of the Forum 2017, and future efforts should perhaps be focused on these stakeholders because others (such as health professionals or scientific societies) are already more generally involved in HTA processes in the region. [Table 3](#) provides a summary of key messages emerging from the presentations and discussions held at the Forum.

One important aspect identified as fundamental when it comes to moving forward with a mature and effective process of stakeholder involvement is to work with all groups to improve trust, which is often undermined by certain behaviors

Table 3. Main Messages Emerging during the Forum

The involvement of relevant stakeholders is key to improving the HTA process, but the form and timing of the implementation of such improvements must be adapted to the local context.

The legitimization of both the HTA and decision-making processes is an important reason to promote stakeholder involvement in the countries of the region.

For successful progress, it is important that the entire system of assessment and decision making is appropriately staffed and organized, and that certain basic conditions are met such as transparency in HTA processes and the presence of a clear link between HTA and decision making. In turn, effort should be made to foster trust and credibility among stakeholders so that involvement can become a reality.

The main recommendation was to advance towards establishing mechanisms and conditions that set clear rules for participation and which protect HTA producers and decision makers from potentially distortive external influences.

HTA, health technology assessment.

and practices. Successful methods or strategies for stakeholder involvement will not be achieved, particularly for industry, citizens, and patients, if no effort is made to foster and strengthen trust among the different groups and to establish clear “rules of the game” for all.

Many participants perceived mistrust as one of the most significant barriers to more rapid and meaningful progress in stakeholder involvement in the region. Therefore, to achieve progress, it is important that the entire system of assessment and decision making is properly organized, and that stakeholder participation is an essential part of the system. For this to happen, certain requirements and basic conditions must be met, such as adequate training in HTA and provision of resources for this in the country, transparency in the HTA process, and a clear link between HTA and decision making.

Participants agreed that the next steps should be aimed at finding the appropriate processes and/or methodologies, adapted to the context of each country, which would allow a gradual advance in improving the link between HTA and decision making and progress toward involving the relevant stakeholders in the different stages.

Attendees agreed that participation in the Forum was productive and they suggested that patient and user representatives be involved in future Forums.

CONFLICTS OF INTEREST

None declared for the authors.

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