



Background Paper

Involvement of relevant stakeholders in health technology assessment development

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Background to the selection of the topic and objectives of this document

This document provides information that will serve as a starting point for the discussions that will be held in the HTAi Latin American policy forum on "Involvement of relevant stakeholders in Health Technology Assessment development".

At the first Health Technology Assessment (HTA) Policy Forum, one of the main challenges identified by representatives of countries in the region for HTA initiatives included difficulties in involving the different stakeholders in the process. The inclusion of relevant interested parties in the HTA process is a good practice principle widely recognized by the HTA community at a global level. However, during the first forum, participants concluded that all identified international good practice principles require adaptation to the local context, and the decision on which of them and to what extent they should be implemented depends on the state of development of HTA in each country, available resources and characteristics of the health system and the decision-making process. The main challenge identified by the countries participating in the first forum was finding an appropriate balance between proposed improvements to HTA processes and available resources (personnel, budget and time) in each country, especially to prevent these improvements from hindering report production-times and responsiveness to the needs of decision makers. Some participants felt that stakeholder involvement should be implemented without delay as it was deemed essential to give legitimacy to the HTA process and decision making and could reduce the risk of conflicts and appeals. The need to involve stakeholders (mainly patients and health technology manufacturers) as early as possible, from the prioritization of technologies to be evaluated, was also mentioned. However, other participants felt that, at the present stage of HTA development in the region, stakeholder involvement was not necessarily a priority, since the legitimacy of the process and decision-making could still be improved by other means (for example, by the use of appropriate methodology, or by the involvement of scientific societies). Concern was also expressed over the complexity of stakeholder involvement in the HTA process, which would require appropriate methodologies and, if not done properly, could expose the HTA process to undesirable influences and represent a burden of excessive workload, delaying the production of HTA reports and making it difficult to provide timely answers to decision-makers.

These different views reflect the situation in the region: many countries in Latin America have not yet implemented mechanisms to involve stakeholders in HTA processes and in many others available mechanisms are still limited to involving only some of the stakeholders or only involving interested parties in certain stages of the HTA process and decision making, but not in all of them.

For this reason, the aim of this second forum will be to discuss the best way in which HTA agencies in the region can move forward with the involvement of relevant stakeholders in Health Technology Assessment development; both in terms of the conceptual framework, as well as methodological and operational aspects.

Introduction

Health technologies are now an indispensable part of any health system and their use has increased in recent decades. The introduction of new technologies has usually led to significant benefits in terms of disease prevention, safety, improvement of health and quality of life or reduction of adverse events. However, in a resource-limited context, appropriate incorporation and dissemination of health technologies has become a challenge and, in some cases, a serious problem.

The rapid emergence of technologies and the increasing volume of available evidence have become a challenge for health systems to overcome. Providing health services involves making decisions about what interventions should be offered, how the health system should be organized, who will pay for interventions, and how and who should provide them. The challenge is to achieve adequate health outcomes with the available resources, taking into account the expectations and demands of the population.

Many countries are currently committed to reaching universal health coverage (UHC) for their population and this is one of the goals prioritized by the World Health Organization (WHO). In the context of UHC, prioritization of interventions is a fundamental strategy, and the documents developed by WHO about this goal, propose that a deliberative process that takes into account social values is of fundamental importance.^{1,2} In this context, health policy makers have an increasing need for reliable and detailed information to enable them to make transparent and legitimate decisions when setting priorities in their quest to maximize benefits with limited resources. The growth and development of HTA reflects this demand for solid and transparent information that supports decision-making on the development, incorporation and diffusion of health technologies. In fact, HTA has its origins in this growing concern for the expansion of new and expensive health technologies in the 1970s and the ability of health systems to finance their use. Health technology assessment has evolved since the 1970s to become a multidisciplinary field with the purpose to synthesize the available evidence in order to help health decision makers, health professionals and patients to understand the relative value of technologies.³ There is no single definition of HTA. One of the definitions used is that it is a multidisciplinary field of policy analysis that incorporates the medical, social, ethical and economic implications of the development, diffusion and use of health technologies.⁴

To understand the different aspects of decision-making and technology assessment, we must first make a distinction between terms that might seem similar but mean different things:⁵

- **Assessment:** refers to the technical assessment of health technologies including developing or summarizing the evidence on benefits, needs, impact, cost, context, etc. These assessments are carried out by specialists in HTA.
- **Appraisal:** refers to the evaluation of the evidence provided by HTA. This process can be done in a formal or informal manner and it includes the assessment of other relevant information, such as the availability of financial or other resources, political priorities and/or the health system's mission, among others. It leads to a recommendation to the health authorities (who make the final decision) on whether the technology is to be financed, for which patient groups and, sometimes, under what conditions (e.g. the type of healthcare facilities that can prescribe or manage the technology).
- **Decision making:** the process by which decisions on which health technologies will be offered or provided are made. These decisions are made by individuals or institutions with the appropriate responsibility or authority within the health system.

The development of HTA has been especially remarkable in the last 15 years. Several initiatives have emerged in the Latin American and Caribbean region (LAC). Argentina, Brazil, Colombia, Chile, Mexico and Uruguay have HTA agencies that are members of INAHTA, and various Latin American countries apply HTA to decision-making on resource allocation to different extents.

HTA has the potential to be a very useful tool for decision makers. However, if not performed and used properly, there are several potential risks: inefficient allocation of resources, coverage of interventions of little or no benefit, hindering or delaying patient access to useful health technologies, exposing patients to unnecessary risks, and sending wrong messages to technology producers, among others.⁴ For these reasons, since decisions to be made as a result of HTA development have the potential to affect a large number of people and organizations, and to make the process of decision-making based on HTA increasingly legitimate, involvement of all relevant stakeholders is proposed.

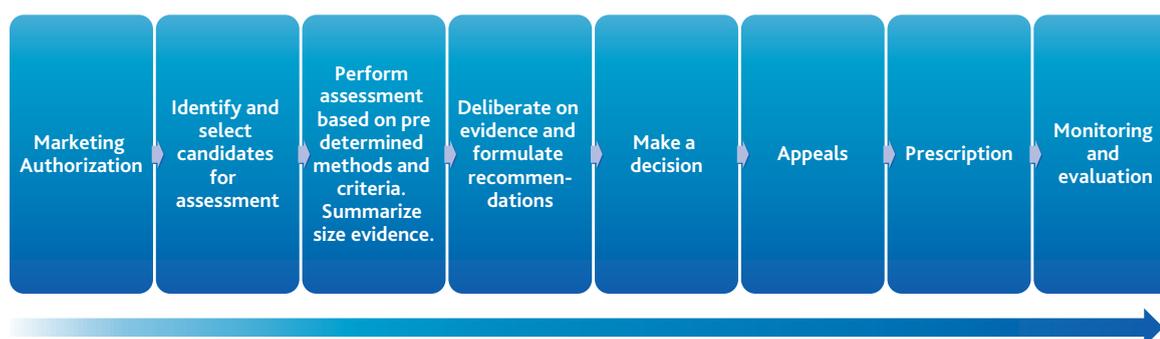
In this context, the term stakeholder refers to any interested party affected by a decision on the coverage of a health technology. More specifically, it refers to individuals, organizations or communities that have a direct interest in the process and results of a health technology assessment.⁶ EUnetHTA defines stakeholders as "groups or organizations which provide considerable insight into views of the groups they represent, and which will be affected by, or have an interest in, and may in a consultative role contribute to, the actions or aims of an HTA organization, project or policy direction".⁷

Examples of relevant stakeholders for the HTA process include:

- Individual Patients
- Disease-Specific Citizen and/or Patient Organizations
- Citizen and health system user organizations not specific to any condition or disease
- Caregiver and family member groups
- Healthcare professionals
- Organizations of healthcare professionals
- National or Regional health authorities
- Policy-makers
- Payers
- Companies and associations producing health technologies
- Academics
- Public in general

The views and needs of these stakeholders can be very relevant to the recommendations that are produced as a result of an HTA, and can highlight issues that are not easily addressed or explained by a technical analysis. These stakeholders can often provide valuable information on epidemiology, the role of each technology in disease management or a specific disease stage, clinical efficacy and effectiveness, cost and budget impact. At each stage of an HTA project, stakeholders can make valuable contributions.⁶ Figure 1 shows a diagram of the usual steps involved from when a health technology achieves marketing authorization in a country to when its used and monitored. Although every country in the world does it differently, in many countries of the world and in our region different stakeholders are actively involved, especially in the steps of prioritization of technologies to be evaluated, the compilation and summarization of the evidence and discussion about the recommendation.

Figure 1: Life cycle of a health technology



Source: Modified from Gutiérrez Sourdis C, Giedion U, Muñoz AL, Ávila A. Serie de notas técnicas sobre procesos de priorización en salud: Banco Interamericano de Desarrollo (BID); 2015. Available from: <https://publications.iadb.org/bitstream/handle/11319/7097/Nota-2-Un-enfoque-sistem%C3%A1tico-Serie-de-notas-t%C3%A9cnicas-sobre-procesos-de-priorizaci%C3%B3n-en-salud.pdf?sequence=1>.

Stakeholder involvement is also a response to the problem of the legitimacy of decisions in health technology assessment policies. Norman Daniels, in a 2000 editorial (among other documents), refers to this issue and argues that, given the impossibility of establishing a consensus on a group of ethical principles of distributive justice that could guide the incorporation of new technologies, the existence of a fair decision-making process is what will allow a consensus to be reached on what is considered to be legitimate and fair, and calls this concept "Accountability for Reasonableness". He proposes that decision-making on the use of limited resources should become part of a broader public deliberative process that would allow for a fair protection of the health of populations with diverse needs.^{8,9} Daniels proposes that for decision-making in health resource allocation to be appropriate, four criteria should be taken into account and applied: revisability or appealability (existence of explicit mechanisms for appeals and reviewing decisions); Publicity (decisions and their reasons must be made public); Relevance (decisions and their rationale should be relevant to the context and agreed upon by stakeholders); and Application (ensuring application of the three previous criteria). The criterion of relevance implies that the values of society as a whole must be taken into account. Some countries and health systems have developed mechanisms and studies to make these social values explicit.

Baltussen et al., in a 2017 article, state that the establishment of priorities in health systems is a complex process and that it's heavily dependent on considerations of social values.¹⁰ However, in many cases, HTA agencies use value frameworks for health technology assessment that do not grasp the scope and diversity of the values of relevant stakeholders, thereby compromising the legitimacy their recommendations. These authors propose an "evidence-based deliberative processes" as an alternative framework, with the aim of improving said legitimacy. This framework integrates two increasingly popular and complementary approaches to prioritization: multicriteria decision analysis and the aforementioned "Accountability for Reasonableness". Evidence-based deliberative processes are, on the one hand, based on early and continuous deliberation with relevant stakeholders to understand the importance of social values. On the other hand, they rely on rational decision-making through evidence-based assessment of the extent to which the technology in question optimizes the identified social values.

For the purposes of this document, the HTA process will be considered comprised of the following parts:

- Global delineation of the structure, policies and values of the HTA process
- HTA process for specific technologies:
 - Identification, selection of technologies for evaluation (prioritization) and steps prior to the assessment: This stage identifies, through various procedures, the technologies that can be evaluated and selected, through a prioritization process, those that will proceed to the following stages. This stage can also include discussions among stakeholders regarding evidence development.
 - Conduction of the Assessment (including "scoping"): This stage is comprised of the determination and delimitation of the question to be answered during the evaluation (intervention or technology to be evaluated, population and indication for which it will be evaluated, outcomes to be included and suitable comparators) and then the conduction of the evaluation itself.
 - Formulation of recommendations (appraisal) and decision-making: The results obtained in the previous stage are evaluated and recommendations formulated.
 - Implementation of recommendations/decisions: The recommendations resulting from the assessment are put into practice in the health system.

Involvement of stakeholders is desirable and can occur in all these stages. For the purpose of this document, we will focus the analysis mainly on the principles and mechanisms proposed for the involvement of two kinds of stakeholders: 1. Patients and citizens in general, and 2. The health technology industry. In the next section we will review the proposed ways for these two stakeholders to engage in the HTA process in its different stages, adding examples of international or regional experiences.

1. Involvement of Patients and Citizens in general

General delineation of the structure, policies and values of the HTA process

In this instance, the social values of a particular health system or country are established, which will guide the development of tools and methodological approaches to be used by those who develop HTAs. This level is also related to establishing the framework within which technologies to be evaluated will be prioritized.

In England and Wales, the National Institute for Health and Care Excellence (NICE) has a Citizens Council, which is a panel of 30 members of the public that reflects the demographic characteristics of the UK. Members serve for up to three years. This body provides NICE with the public's perspective on general moral and ethical issues that NICE needs to take into account. The recommendations and conclusions of the council are incorporated in documents, such as the one referred to as "Social Value Judgments" and, where appropriate, in the NICE methodology.¹¹ Members meet once a year for 2 days and discussions are organized and conducted by independent facilitators. The meetings are open to public observers. During the meetings, Council members listen to the views of the experts on an issue, examine the issues in detail, and discuss their own views in depth. The views and conclusions of the members are captured by an independent rapporteur and the report is circulated to the members for comments and amendments before being finalized. After a meeting, the report is made available for public comment. Summaries of these comments along with the report are presented to the NICE board for discussion. Other examples of issues addressed by the Citizens council are the balance between efficiency and equity; the role of innovation in the health system, or the importance of disease severity beyond the gain of healthy years.¹¹ In general, the perception of this mechanism in NICE is positive, with the exception of concerns about possible conflicts of interest of members of this council. In response to these concerns, NICE has implemented a strict conflict of interest policy that extends to the immediate family of members of the Citizens Council.

In our region, Colombia conducted an experience using a multi-criteria decision-making framework (Evidence and Value: Impact on Decision Making, EVIDEM) in 2012-2013 to assess what the criteria valued by society were for prioritization and assessment of the technologies to be incorporated their benefits package (POS, Spanish acronym for Plan Obligatorio de Salud). Of the 15 pre-selected criteria, disease severity, the size of the affected population and the effectiveness of the new technology were the most relevant criteria.¹² In Mexico, the People's Health Insurance (Seguro Popular de Salud) was designed within a framework of accountability for reasonableness, seeking greater public participation in decision-making in health.¹³

HTA for specific technologies:

Identification, selection of technologies for evaluation (prioritization) and steps prior to the assessment¹⁴

By incorporating patients or the community in general, greater legitimacy and breadth of perspective can be achieved in the identification and selection of technologies. In this manner, those that are "really important" (that is, those that matter to people suffering from a disease and will therefore have a health impact) will be selected for evaluation. This could also change the perception of HTA as a barrier for cost containment, for that of a facilitator for incorporation for new and effective technologies. Currently, the criteria for identifying and selecting technologies for assessment are generally developed or adopted and used by HTA agencies without the direct participation of patients or the public.

Some agencies accept assessment proposals from any stakeholder, while others limit the submissions to patients/caregivers (the Netherlands and the United States) or patient/caregiver organizations (Australia and France).

In relation to the selection of technologies to be evaluated among all those identified, there are different approaches. Within NICE, decisions about which technologies will be evaluated are made by a panel whose members include representatives of patients and/or caregivers. In the US, at the Centers for Medicare & Medicaid Services (CMS), potential technologies to be evaluated are posted on the website, and feedback is accepted from anyone.

An example in our region is Chile, where the promulgation of the Ricarte Soto Law for the financial protection of high cost diseases in 2015, established an explicit process and methodology for the incorporation of high cost health technologies not contemplated by other available funding schemes. The law states that citizens have to be involved in the prioritization of the technologies to be assessed.¹⁵

Conduction of the Assessment¹⁴

Completing an HTA report involves several steps, including: identifying the "right" questions to be answered; selecting appropriate outcomes; collecting, analyzing and summarizing information; and drafting a report for decision-makers. The definition of questions to be answered is closely related to considerations on what aspects are given value. Patients' opinions about what constitutes "value" may not be the same as those of clinicians or researchers. Not including this different perspective can lead to the identification and selection of outcome measures that do not capture critical beneficial aspects for patients. Active engagement of patients in this stage avoids these potential problems.

Retrieval and summarization of information provided by patients raise a series of methodological questions and potential challenges. Conventional HTA is based on methods of clinical epidemiology and biostatistics for data aggregation and weighing of the value of the sources and types of data. There are well-accepted methods for collecting data from clinical trials, scales for assessing the quality of clinical trials, and guidelines for conducting economic assessments. However, information on patient experiences is, at least to some extent, qualitative, requiring different methodological approaches (e.g. focus groups and interviews). Although published literature encourages the collection and use of such information, it offers little guidance on rigorous approaches to achieve this, given the time and resource constraints most HTA agencies are faced with.

Some agencies include patient representatives on the committees responsible for defining the scope of the evaluation (Australia and France). Others seek the perspective of patient / caregiver organizations (England and Wales), and others accept opinions from anyone in the general public (Germany). Several agencies invite anyone (eg. Germany) or patient representatives (eg France and the UK) to comment on HTA protocols drafts.

In some agencies, patients / caregivers can submit information directly to the organization responsible for preparing the assessment (Germany), through a group presentation of patient / caregiver organizations (eg Canada, France and NICE), or through an appointed patient representative to the advisory group overseeing the evaluation (eg, Australia). In Scotland patient input is facilitated through a participation subcommittee which includes three members of the general public. In New Zealand, submissions are only accepted at the request of decision-makers.

Formulation of recommendations and decision-making¹⁴

In general, progress towards public and patient engagement in health policies extends beyond HTA to include decision-making. The formulation of recommendations or decisions is typically the task of a body or committee designated for that purpose. It has been proposed that patients and / or the public should have the opportunity to review HTA's reports and present their views on recommendations or proposed decisions.

Some mechanisms to ensure consideration of the patient's perspective during the deliberations of the committee / decision-making are as follows:

Membership in the committee - Designation of at least one patient / user to the committee responsible for coverage recommendations (eg Australia, France, Germany).

Presentation of oral or written patient testimonials (Consumer impact statements) either by invitation of the committee (eg Australia or the Netherlands) or at the request of a patient/caregiver or patient/caregiver organization (eg United Kingdom);

Opportunity to review the HTA draft report and proposed recommendations. (eg. France and the United Kingdom). Less frequently, consultations are undertaken through the internet or mass media. In New Zealand, patient feedback on HTA is by request. In some cases the role of the public at this stage is limited to membership in the designated committees (Canada) or to the opportunity to comment on the proposed recommendations (Germany and the United States and in our region, Brazil¹⁶). Finally, some agencies hold committee meetings that are partly open to the public (eg the UK).

Implementation of recommendations / decisions¹⁴

In general, participation of the public or patients / users in the implementation of the recommendations is limited to the presentation of appeals to them. In most cases, with the exception of some countries such as the UK, only someone representing the person who submitted the request for assessment can initiate an appeal (Australia). In our region, the absence of systematic and legitimate mechanisms for incorporating technologies into the health system often means that the usual way of expressing disagreements with existing health policies is through appeal to the courts to claim the coverage of a given service that a health professional prescribed, leading to the judicialization of the health system being a major problem in different countries of our region.¹⁷

2. Industry Involvement

Global delineation of the structure, policies and values of the HTA process¹⁸

In collaboration with other stakeholders, the industry can contribute to defining the role and purpose of HTA development, including the criteria for selecting the technologies to be assessed and the methodologies used during the HTA process.

There are many different examples of how the industry is formally involved in HTA processes. In Switzerland, health insurers and the pharmaceutical industry began to develop a Swiss consensus on the use of HTA in 2010. Industry was an equal partner in the process. In the Ontario Drug Strategy Review (Canada), industry, represented by an association, was part of the development of recommendations to the government on the future of the drug plan. In Scotland, two representatives of an industry association are part of the Scottish Medicines Consortium (SMC). In addition, the SMC User Group Forum, including representatives of the pharmaceutical industry, aims to identify, address and resolve process issues related to the SMC's work. When NICE developed the new assessment path for medical devices and diagnostics, industry was involved, with representatives serving as formal co-chairs on the steering committee overseeing the development process and being consulted in detail on all elements of the methods and processes.

Industry has had different participation and involvement in the countries of our region in the delineation of HTA processes. In defining HTA's structure and mechanisms, many countries have incorporated industry views as a relevant stakeholder to varying degrees. However, most of these consultations have not followed a formal process or are not properly documented. An example of how the industry promotes the implementation of HTA principles is a position paper published by the regional chamber (FIFARMA), in which they advocate a broad participation of all relevant stakeholders, including but not limited to industry and patients, in the HTA process as well as in the assessment of specific technologies.

HTA for specific technologies:

Identification, selection of technologies for evaluation (prioritization) and steps prior to the assessment¹⁸

The producer of a technology can provide information and the rationale for the submission of a technology to be evaluated and eventually incorporated into the benefit package. In fact, in many systems, the industry is the stakeholder who usually submits technologies for evaluation. In addition, providing manufacturers with the opportunity to discuss evaluation documents with the agencies could improve the overall quality of assessments, providing opportunities to discuss the initial study designs and models submitted as evidence for the assessment. There are also experiences in which HTA and regulatory agencies work together with the industry in the pre-authorization phase of the technologies, so that the evidence produced by clinical trials is useful to satisfy the needs of decision makers.¹⁹

In 2009 NICE modified the process of evaluation of medical technologies. In this program, manufacturers can now notify and submit to NICE new technologies that are suitable for evaluation at national level, and a Medical Technologies Advisory Committee (MTAC) then determines whether this technology is appropriate to initiate an assessment process. This advisory committee includes industry representatives that provide their knowledge about the technology being assessed.

Most countries accept industry submissions to incorporate technologies to the existing benefit packages. In the region, Brazil and Mexico are two countries that currently have mechanisms in place that allow industry to submit evidence for the incorporation of technologies, and the health system is required to respond to these requests within pre-determined deadlines. Industry submissions account for the majority of the technologies assessed in these countries, to which those prioritized by the government, scientific societies or patients are added.

The case of Australia is also an example of the industry being allowed to apply for technology assessment, but this request involves a payment by the applicant company. This amount is used by the government of Australia to fund the assessment (usually by an independent academic institution) of the material submitted by the applicant. In Canada, the industry must also accompany each application for assessment with a payment for an amount that covers about 40% of the cost of the assessment. NICE has also recently started to consider charging companies 100% of the costs involved in the assessment process, which in this case were estimated at values of between 100,000 pounds for a quick review and 280,000 for a complex review of multiple technologies.²⁰

The case of the Brazilian agency is interesting. In its beginnings, industry applications were accepted without any prior discussion on the application and evidence submission. This led many of the submissions to be inadequate. A few years ago, the agency instated a period of discussions and consultations prior to the submission, which was well received by industry and lowered the percentage of inadequate presentations.¹⁶

Conduction of the Assessment¹⁸

Discussion with industry representatives can address, in accordance with available methodological guidelines, the choice of the comparator or the endpoints to use in the assessment, the sources of evidence used and the methods developed to overcome the gaps of evidence in the evaluation. This will also provide an opportunity to clarify any pending questions from those in charge of the assessment on the content of the presentations.

In England and Wales, the NICE Technology Assessment Committees are composed of members of the National Health Service (NHS), patient and caregiver organizations, academics, and the pharmaceutical and medical industries.

In Australia, the pharmaceutical industry association Medicines Australia is represented on the main Pharmaceutical Benefits Advisory Committee (PBAC), sub-committees such as the Economic Subcommittee and the Subcommittee on Drug Use.

In the National Commission for the Inclusion of Technologies into the Unified Health System (CONITEC), in Brazil, beyond the possibility of pre-submission advice, and the submission itself, the agency occasionally requests the manufacturers of the technology to provide clarifications or new information, if necessary. CONITEC has a legal deadline to provide a recommendation within 180 days, which may be extended for an additional 90 days, if necessary.²¹ Then, if the Ministry of Health recommends and endorses the incorporation of the technology into the benefits package, there is a period of 180 days to implement it.

Formulation of recommendations and decision¹⁸

In some countries, such as Australia, there is a formal exchange of assessment reports and responses. The sponsoring company is allowed to appear before the committee within a limited time-frame and there is an opportunity for the sponsor to meet with the president of said committee if the application is rejected.

Implementation of recommendations / decisions¹⁸

The relative impact of a technology on the health of patients and the health system can change over time because of usage patterns and product developments after its inclusion.

Furthermore, knowledge and the evidence-base of a technology generally grow throughout the life cycle of a product. A number of data sources may be available after launching, such as intervention studies, data form postmarketing monitoring systems, registries and observational studies, many of which will be carried out and provided by the manufacturer. Regular and pre-agreed evaluation of these new data, based on the characteristics of the technologies and patient populations, will lead to an overall improvement in technology assessment. For example, in Scotland, the SMC offers the opportunity to ask for a review of the decision at any time.

This is one of the least developed areas in the world and in our region. There are some studies showing that NICE's recommendations have an important impact on the health system in England and Wales.^{22,23} Literature on this issue in our region is scarce or absent.

Barriers and facilitators

In the Latin-American HTA Policy Forum, held in 2016, involvement of all relevant stakeholders was considered as a source of legitimacy and transparency. Concern was expressed, however, about the technical (lengthening of times, development of methods and development of procedures) and ethical issues, that this might entail. One of the concerns was the potential existence of conflicts of interest on the part of patient groups, health professionals and industry representatives.

Patient advocacy organizations are non-profit organizations whose primary mission is to combat a particular illness or disability or work to improve the health and well-being of a particular patient population.²⁴ These organizations play an influential role in formulating health policies, seeking to expand coverage of drugs, devices and diagnostic procedures; Increase support for medical research; And accelerate the approval of experimental therapies.²⁴ Industry contributions can be an important source of support of these organizations, but they can also be a source of institutional conflicts of interest. Institutional conflicts of interest arise when the secondary objectives of an institution or its people generate a risk of undue influence over decisions that involve the primary objectives of the institution^{25,26} The primary objective of patient advocacy organizations is to Improve the health of the group they represent, while the secondary interests may include, among others, the collection of funds necessary for its operations. That is, secondary objectives, while they may be legitimate, can be a source of conflicts of interest. One study found that of the 104 most influential patient organizations in the United States, 83 percent reported receiving industry funding and 36 percent had an industry member on their executive board.²⁴ Because of this, the vast majority of the

agencies, and in our region the Commission of the Cuadro Básico in Mexico, IETS in Colombia and CONITEC in Brazil request each person or institution that sends material or participates in the consultation process, a declaration of conflicts of interest with greater varying levels of detail.

Regarding other potential barriers and facilitators, a 2011 systematic review identified barriers and facilitators to public involvement in the HTA process.²⁷ Among the barriers identified, the aforementioned technical complexity and effect on report production times, the review also mentions, as one barrier, that collaboration with user organizations may be hampered because, due to the presence of strongly held beliefs, participants may be less willing to be limited by the evidence presented during the assessment. Understanding the role they will have to play, and understanding the issues at hand, is not always easy for those without training in the subject. This review also reported as a potential barrier the lack of familiarity with the HTA process and technical language and acronyms of lay health system users. The lack of familiarity of health system users with research needs and, on the other hand, the lack of familiarity of researchers with user organizations and the way they work are also barriers that must be overcome.

Among the factors facilitating the participation of patients or the public in the HTA process, focused invitations (i.e., inviting people who have experience in the subject) is considered successful. Mentoring, training, the existence of support and the presence of an introductory day are identified as useful strategies. A well-defined and result-focused presentation, as well as a suitable context and timeframe for the consultation activities (accessible distance and convenient day of the week) have also been identified as facilitators. Finally, an open style of work and an innovative culture in HTA organizations are other important factors that could facilitate public participation.

Regarding barriers to industry involvement, the aforementioned concern about the presence of conflicts of interest prevails and the fear is that they may lead to biases in the evaluation of evidence, prolongation of HTA development times and greater requirement of resources by the agencies producing HTAs.

Among the facilitating factors identified for the involvement of industry representatives in the HTA process is that the agencies would have greater access to data from the submitted studies, as well as more detailed information on the methodologies used. Additionally, as mentioned, current experiences seem to indicate that working together with regulatory agencies and industry even from the stages prior to product authorization could increase the efficiency of the HTA process, as it would lead to the production of more appropriate evidence for HTA which seeks to answer the questions of decision makers.¹⁹

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