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POINT OF VIEW

Patient and public involvement in health technology assessment committees: who is free from conflicts of interest?

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ABSTRACT

Scientific and technological advances have increased the capacity to prevent diseases, perform diagnoses, and develop innovative treatments. To analyze whether these technologies should be incorporated into healthcare systems, Health Technology Assessment (HTA) Committees were created.
There is a debate about who should be part of such committees. Typically, committee members are scientific experts, agents of funding entities (Ministries of Health), and patients as representatives of the community.
It is important to reflect on the conflicts of interest that each member may have.
Those who come from the scientific sector (universities, research centers) have fewer conflicts of interest and more independence for decision-making.
The agents designated as members by the Ministries of Health of each country are usually qualified professionals, but still employees of those who will later have to pay for the technology.
The third type of members are patients representing the community. This participation is considered a guarantee of neutrality, however, since patients are affected by the same health problem that is being analyzed, it exists a personal interest in expecting that a new medicine could be accepted to benefit other patients with the same condition (horizontal equity); with a potential risk of not showing the same empathy in recognizing the impact of this decision on other health problems (vertical equity).
This text discusses the composition of HTA Committees, the conflicts of interest of its members, and the potential impact of these decisions on equity in access to the population to essential goods.

Keywords: Biomedical, Citizen participation in science and technology, Conflict of interest, Health equity, Technology assessment

In recent decades, scientific and technological advances have improved healthcare, especially in terms of the ability to prevent diseases, in precision diagnostic procedures, and innovative treatments that improve efficacy and minimize risks (1). Some of these new options, based on the modulation of tissue functions using genetics, nanotechnology, robotics, telemedicine, and artificial intelligence, have had a positive impact on prolonging human life and improving quality of life.

However, these achievements have been accompanied by a "Schumpeterian" increase in prices, based on their monopolistic status, patent validity, or their irreplaceability for certain pathologies. Thus, since the beginning of the 21st century, new terms such as "high-cost or high/very high-priced drugs" have been introduced (2). The availability of these new therapeutic options created new individual demands, which, due to their high cost, put at risk the budgets of health systems, their commitment to provide collective care of the community, and the equity in health resources distribution (3).

In order to discern among the numerous therapeutic offers, which one of these options should be included in the lists of medicines provided by the public sector or social security in different Latin American and Caribbean countries (4), Committees for the Assessment of Medicines and other Health Technologies (HTA) have emerged throughout the region. Examples of these are CONETEC in Argentina; CONITEC in Brazil; ETESA-SBE in Chile; IETS in Colombia; ETS in Ecuador; and IETSI in Peru, among others; these are grouped into a continental network called RedETSA (4). These Committees, generally linked to the Ministries of Health or Social Security institutions of each country, are composed

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by their own staff (healthcare workers from the department itself), as well as experts in the subject matter, and community participation, which is carried out in most cases through patient invitations (5,6).

The characteristics sought by members to integrate these HTA Committees are their knowledge, their suitability, and their absence of conflicts of interest (COI) in order to avoid bias in the recommendations/decisions (5).

The scientific experts invited to join these Committees usually come from universities or recognized research centers in each country. The requirements to integrate the committee are their academic background, their knowledge, and the absence of COI regarding the drug under review or the pharmaceutical companies that produce it. These conditions for the members guarantee the necessary skills, hierarchy, and independence to ensure the highest level of quality in future recommendations arising from the committee.

Another type of member of the HTA Committee is an agent appointed by the Ministry of Health or Social Security of each country. While these members are often health professionals with specific knowledge of technologies (pharmacologists, pharmacists, engineers, biochemistries) or with complementary skills necessary for HTA (such as economists, epidemiologists, ethicists, among others), the fact that they will be employed by those who will later finance those technologies covered by the health system, makes their participation potentially objectionable to beneficiaries or those who market those products.

There is a third type of HTA Committee member who represents community participation, which, in the region of Latin America, is typically represented by patients suffering from the disease under study, or NGOs that include family members of patients affected by that disease. These members express their opinions on the health problem associated with the technology under evaluation (8,9).

In order to avoid this potential bias that could modify the recommendation/decision arising from analysis, a mandatory procedure is included by most of the Committees and Agencies, demanding that all its members must sign a COI (10).

Most of the HTA analysis requests that reach the Committee's secretaries arise from applications submitted by prescribers, who might be influenced in various ways by the Pharmaceutical Industry (11).

We have observed that patients often staunchly defend the prescriptions given to them by their treating physicians, even when it is proven that those physicians have a close relationship with the companies that sell the prescribed medical technology (12-15).

On the other hand, there is a valid and indisputable interest among patients affected by a specific health problem in hoping that a new medication can change the course of their illness, and therefore, they expect funders to offer this therapeutic option. However, this self-interest might constitute a form of bias in the decision-making process within the Committee. Patients suffering from health problems being analyzed by the HTA Committee will likely advocate for influencing decisions that have a direct impact on horizontal equity, that is, "treating equals equally." However, they probably do not have the same motivation to influence "vertical equity," that is, "treating those who are different differently" (16). For example, a group of patients with diabetes will advocate for all diabetics to benefit from a new drug (promoting horizontal equity), but they may not show the same interest in the cost-utility of this decision, which means that this judgment could potentially limit access to other goods by patients with other health problems (affecting vertical equity).

Community participation is extremely important to ensure that the HTA Committee's membership has the necessary validity and transparency (17). However, the current method of patient selection in many of the Latin American HTA Committees does not appear to be the best option for such representation. Just as jury trials in the justice system randomly select representatives of the whole community, ensuring the independence of those who must render verdicts and excluding those with special interests or connections among the interested parties, community members who serve on HTA Committees should be selected in the same manner. In health systems in other regions, this problem led to the creation of Citizen Councils to make decisions in which they have no direct personal or family interest (18).

Some authors took notice of this potential bias in the selection of patients in HTA processes in the Latin-American region (6) and in Europe (20). In the latter, the current concerns include potential over-representation of some expert patients, lack of guidance on organizational COIs, and ambiguities in how the size of financial interests is disclosed (19,20).

From a sociological perspective, social participation in HTA must consider the types of audiences (patients and citizens), the instances of participation during the HTA process, the organizational scope where the HTA is carried out, and the scope of policy formulation (21).

The question is whether patients, who are not impartial representatives of the community, should be part of the HTA committee. The answer is YES. So, what could be the role of patients in the assessment process? They could, for example, tell the other committee members firsthand what it's like to live with the disease and how technology could solve some of their daily problems, even when the treatment doesn't have a positive impact on endpoints such as survival or other variables that would seem clinically relevant.

We agree with current standards on HTA that recommend patient and citizen involvement as part of stakeholder engagement (22), but strongly invite reflection on the selection of community participants. The consequences of these decisions will directly impact equity in access to essential goods and supplies on which the health and life of the entire society depend.

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