

VISIONS OF STAKEHOLDERS ABOUT INSTITUTIONALIZATION OF HEALTH TECHNOLOGY ASSESSMENT IN CHILE: A QUALITATIVE STUDY

Constanza Paz Lavín

Pontificia Universidad Católica de Chile-Department of Public Health

Rafael Alaniz

Universidad de Chile-Specialists Program in Public Health

Manuel Espinoza

Pontificia Universidad Católica de Chile-Department of Public Health

maespinoza@med.puc.cl

Objectives: The aim of this study was to explore and describe the viewpoints and beliefs with respect to a health technology assessment (HTA) process and its institutionalization in a sample of stakeholder representatives in Chile.

Methods: A qualitative study with a descriptive design, based on the model of discourse analysis, was performed. Eighteen semi-structured interviews were conducted on nineteen Chilean representatives of stakeholders in HTA. The data analysis was based on a process of open coding that allows the contrasting of the interviewees' visions.

Results: From what the interviewees mentioned, a proposal to institutionalize the process of HTA is presented for Chile. The focus is on three main areas: (i) Principles to guide the HTA, (ii) Institutional Framework for Chile, and (iii) Impacts associated with their implementation process. Transparency and participation were the main principles identified. The idea of an autonomous body for HTA, independent and publicly funded, was widely supported. However, this implementation could face potential resistance from technicians and politicians, who might impose barriers to avoid their loss of decision power.

Conclusions: There is a broad agreement about the importance of creating a national institution for HTA, independent and publicly funded. This study supplies relevant information for other countries that are currently undertaking a similar process.

Keywords: Qualitative research, Health technology assessment, Decision making, Chile

Health systems face the challenge of improving population health in a context of budget constraints, limited information, and opposite views from stakeholders. These elements make decisions on health coverage more complex and demand a socially legitimate process (1). Health technology assessment (HTA) as a multi-disciplinary field offers a comprehensive framework to support these difficult decisions (2–4).

Since the 1970s, HTA has been adopted to inform decisions about coverage of healthcare interventions in many jurisdictions (5). In Latin America, important progress has been made in Mexico, Brazil, and Colombia (6). In Chile, elements of HTA were implemented alongside the Regime of Explicit Health Guarantees in 2005, the Chilean Health benefit plan (7;8), specifically the generation of clinical guidelines following the principles of evidence-based medicine for assessing efficacy and safety (8;9). In 2013, a National Commission of HTA formed by representatives of governmental entities proposed to create a national centralized institution, independent in its technical work but publicly funded, responsible for evi-

dence assessment and elaboration of recommendations to the health authority (10). Unfortunately, this discussion has been conducted inside the institutions that depend on the health authority without any external consideration. The objective of this study is to explore and describe the viewpoints and beliefs of potential beneficiaries of HTA in Chile about its institutionalization. The main motivation is contributing to the discussion about the implementation of a legitimate HTA process in Chile.

METHODS

A qualitative study with a descriptive design, based on the discourse analysis model (11) was performed. Participants were eligible if they were representatives of groups who have some grade of participation on the decision-making process: (a) technical groups (academics and scientific societies), (b) public and private decision makers related to acquisition of healthcare technologies and implementation of HTA (payers and healthcare providers), (c) civil servants interested in HTA (patient associations, consumer associations, and NGOs) or (d) congress representatives. The exclusion criterion was to have participated in the National Commission of HTA, whose opinions are reflected in their proposal (10).

This work was supported by the Public Policy Centre of Pontificia Universidad Católica de Chile. The authors acknowledge the participants for taking part in this study.

The recruitment of interviewees followed a purposive sampling (12;13) and the sample was defined *a priori*, based on the above criteria. We invited five representatives from each group due to the limited time and budget available, and they were contacted by email or telephone. Finally, eighteen face-to-face semi-structured interviews were conducted with nineteen participants (Supplementary Table 1). The 1-hour interviews were guided and recorded on the participants' workplaces for a psychologist and a specialist in public health, and were transcribed by external social scientists. The data were analyzed using open coding. The aim of this strategy is to understand the phenomena "breaking down, examining, comparing, conceptualizing, and categorizing data", to recognize their properties and dimensions (14). A coding system was generated from the content reported by interviewees for an expert data coder and discussed with the multidisciplinary research team to facilitate the analysis of divergent visions (13). As a result, a systematic triangulation of perspectives was performed to control bias alongside the analysis (15). The Research Ethics Committee of the Faculty of Medicine at Pontificia Universidad Católica de Chile approved this research project and suggested a verbal agreement from participants. All confirmed their willingness under the conditions explained at the beginning of the interview.

RESULTS

The interviews provided viewpoints, which were categorized in three main areas. The categories and sub-categories are shown in Table 1.

Category 1: Principles to Guide HTA

Interviewees said the main criteria that should govern HTA are transparency and participation:

"It is not because participation and transparency are popular, but we are talking about a topic that has two aspects... First, health technologies are controverted, complex and have [sic] scientific uncertainty; and second, affect to several groups in different ways" (Healthcare provider)

The 89 percent agreed to consider all social groups influenced by these decisions. These groups are shown in Table 2. However, interviewees proposed different levels of participation. The 68 percent considered that patients and manufacturers have conflicts of interest, which might introduce bias. They should be restricted to provide information through qualitative methods, such as focus groups, opinion surveys, hearings, and Advisory Councils. Ninety-five percent mentioned that the process should be public and understood by all citizens, with clear rules, transparent management of funds, and disclosure of stakeholders' conflicts of interest to improve credibility and legitimacy. Fifty-eight percent included equity as a principle to integrate a nondiscriminatory basis. Others perceived that HTA is only to estimate cost-effectiveness, and equity

Table 1. Interview themes: open coding

| Category/theme | Subcategory/subthemes |
|---|--|
| C1: Principles of HTA | <ul style="list-style-type: none"> ■ Transparency ■ Participation ■ Equity ■ Based on evidence ■ Technical rigor ■ Independence ■ Pursuing efficiency |
| C2: Institutionality for HTA in Chile | <ul style="list-style-type: none"> ■ Organizational nature ■ Role ■ Regulatory/normative effect ■ Resources and Funding |
| C3: Effects of the implementation of HTA in Chile | <ul style="list-style-type: none"> ■ Benefits |
| C4: Emergent topics | <ul style="list-style-type: none"> ■ Challenges ■ Issues of the current Chilean health system (without HTA) ■ Relevancy and priority of HTA |

Table 2. Groups of stakeholders to be represented in HTA process.

| Groups of Stakeholders | Participation mentioned by respondents* |
|---|---|
| Academy (Universities and Research Centres) | 79% |
| Technology developers | 68% |
| Patients | 63% |
| Technical professionals (doctors, economists, bioethicists, epidemiologists and social science professionals) | 53% |
| Civil society (foundations, corporations and consumer societies) | 47% |
| Government health entities and state health organizations (Ministry of Health and Public Health Institute) | 42% |
| Scientific societies | 37% |
| Financers (Ministry of Finance) | 26% |
| Providers (Health Centres) | 21% |
| Insurers (Isapres and Fonasa) | 16% |

* Eighteen interviews were conducted on nineteen Chilean representatives of stakeholders in HTA.

ought to be considered in subsequent instances of decision making. However, most participants said that installing this process would make the health system more equitable. Finally, some interviewees incorporated principles such as technical rigor, process based on evidence, efficient use of resources, and independence.

Category 2: Institutional Framework

The 84 percent proposed to create an autonomous public entity, which should link governmental, private, and nonprofit organizations:

“(the organization) will be autonomous, independent in their duties, lines of work, strategies, research and results; (...) If it is not autonomous, it will face political influences of powerful groups and stakeholders, affecting the outcome, which will produce damage to the country”
(Scientific society)

To ensure independence, they suggested the creation of a Board formed by social representatives. Some believed that any HTA model should be embedded in the health organizations processes and led by the Ministry of Health. Furthermore, the 68 percent thought in a Center for decision making, whereas 32 percent indicated that its scope should be limited to perform evaluations, studies, and formulate indications for use, that is, a Centre of collection of evidence.

Regarding its indications, half of participants believed that this institution should provide recommendations for public and private decision makers, becoming a national referent. Others believed that only compulsory mandates would safeguard decisions based on evidence and with strict scientific standards. Although, 68 percent supported an appealing process focused on technical aspects, others mentioned that it should be directed to decision makers or legal instances; thus, the process is not contaminated. They emphasized that a participative and transparent process will minimize prosecution of cases.

All agreed that the main duties of the institution should be guaranteed with public funds and the 32 percent considered a strict normative to incorporate private funds to avoid conflicts of interest. Finally, they also expressed the need of a law to safeguard the regulation of their processes and funds:

“According to our culture and tradition is through a law that this organization should be created to guarantee its stability over time and avoid changes... we have examples of good policies, that after being implemented, when the government changes, they are suspended and eliminated.”
(Public decision maker)

Category 3: Impacts of the implementation of this HTA institution

Participants acknowledged some challenges. Thirty-seven percent mentioned that Chile does not have human capacities to support this process, and it should be included as part of health professionals' training. Another challenge is to make HTA a necessity for the country rather than a technical exercise. Also, some argued that HTA represents a cultural change, because it will modify the decision making:

“I think you will have resistance of technicians and politicians for implementing the model, because it will remove their power... If you do all with methodology and participation, you distribute power”
(Public decision maker)

With respect to benefits, 63 percent said HTA would allow decision planners to assign resources efficiently, improving public expenditure and avoiding overspending on the incorporation of technologies. Second, 53 percent said it will produce a systematization of the decision-making process and it will work as a filter, able to guarantee the use of scientific evidence as a requirement and to promote the enrichment of democracy. Finally, only 26 percent believed that the creation of an agency to guide HTA in Chile is a priority.

DISCUSSION

The study revealed a broad consensus on the need for an independent and publicly funded HTA body in Chile to support decisions on health coverage, which should be built based on two main principles: transparency and participation. In addition, the processes and institutional arrangement for this institution should be framed by law to make sure they will not be modified by pure political interests.

The study has some limitations that must be acknowledged. First, the small number of participants might have left out important considerations, but despite the sample size, we were able to account for saturation in the technical group and on topics such as participation, transparency, and autonomy. Another important concern is that the implementation of an HTA process should not be based only on perceptions of stakeholders; its definition also needs a normative analysis, which in many cases is the only way to solve irreconcilable but legitimate views. A final model can be built based on the convergence of these elements.

Although it could be argued that the results provided by this study were expected based on international experience (16–18), this remains as an empirical question given the local context. Thus, the relevance of the present piece of work is to provide scientific evidence, based on which health authorities can make progress in the implementation of a legitimate HTA process.

Overall, the results of this study are quite consistent with the proposal of the National Commission of HTA. The idea of building a new HTA institution is broadly supported and, therefore, the health authority should not wait more to initiate the construction of the normative framework. However, more work is needed to clarify exactly what the process should look like.

SUPPLEMENTARY MATERIAL

Supplementary Table 1:
<https://doi.org/10.1017/S0266462317000381>

CONFLICTS OF INTEREST

The authors have no conflict of interest to declare during this research.

REFERENCES

1. Daniels N. Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles. *BMJ*. 2000;321:1300-1301.
2. The International Network of Agencies for Health Technology Assessment. INAHTA. [homepage on the Internet]. Alberta, Canada: Institute of Health Economics. <http://www.inahta.net/> (accessed March 3, 2015).
3. Banta D. What is technology assessment?. *Int J Technol Assess Health Care*. 2009;25:7-9.
4. Drummond MF, Schwartz JS, Jönsson B, et al. Key principles for the improved conduct of health technology assessments for resource allocation decisions. *Int J Technol Assess Health Care*. 2008;24:244-258.
5. Banta D. The development of health technology assessment. *Health Policy*. 2003;63:121-132.
6. Kuhn-Barrientos L. Evaluación de Tecnologías Sanitarias: marco conceptual y perspectiva global. *Rev Med Chil*. 2014;142:11-15.
7. Castillo-Riquelme M, Santelices E. Fundamentos para la Institucionalización de la Evaluación de Tecnologías Sanitarias en Chile. *Rev Med Chil*. 2014;142:50-54.
8. Estado de Chile. Ley N°19.966, Establece un Régimen de Garantías en Salud. Santiago, Chile: Biblioteca del Congreso Nacional (September 3, 2004).
9. Ministerio de Salud. Revisión del Proceso de Priorización de las Garantías Explícitas en Salud (GES). [Internet]. Santiago: Departamento de Economía de la Salud, MINSAL; 2011. http://desal.minsal.cl/wp-content/uploads/2013/09/REVISION_PRIORIZACION_INFOMEFINAL.pdf (accessed March 3, 2015).
10. Comisión Nacional de Evaluación de Tecnologías Sanitarias. Propuesta de un modelo de implementación e institucionalización de la Evaluación de Tecnologías Sanitarias en Chile. [Internet]. Santiago, Chile: Ministerio de Salud; 2013. <http://web.minsal.cl/sites/default/files/files/InformeFinalPropuestaETESACHile.pdf> (accessed March 3, 2015).
11. Jorgensen M, Phillips L J. *Discourse analysis as theory and method*. London: SAGE Publications Ltd; 2002.
12. Polit DF, Hungler BP. *Investigación científica en ciencias de la salud*. México: McGraw-Hill Interamericana Editores, SA; 2000.
13. Mays N, Pope C. Rigour and qualitative research. *BMJ*. 1995;311:109-112.
14. Strauss A, Corbin J. *Bases de la investigación cualitativa. Técnicas y procedimientos para desarrollar la teoría fundamentada*. Medellín: Editorial Universidad de Antioquia; 2002.
15. Flick U. *Introducción a la investigación cualitativa*. Madrid: Ediciones Morata, SL; 2012.
16. Instituto de Evaluación Tecnológica en Salud, IETS. *Manual Metodológico: Participación y Deliberación*. Bogotá DC: IETS; 2014.
17. Canadian Agency for Drugs and Technologies in Health, CADTH. Providing input to CADTH. [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2015. <https://www.cadth.ca/provide-input> (accessed May 7, 2015).
18. National Institutional for Health and Clinical Excellence, NICE. Social value judgments: Principles for the development of NICE guidelines; 2005. <https://www.nice.org.uk/media/default/About/what-we-do/Research-and-development/Social-Value-Judgements-principles-for-the-development-of-NICE-guidance.pdf> (accessed May 14, 2015).