

A framework for action to improve patient and public involvement in health technology assessment

Aline Silveira Silva¹ , Karen Facey² , Stirling Bryan^{3,4}  and Dayani Galato¹ 

¹University of Brasilia, Campus Universitário, s/n, Centro Metropolitan, Brasilia, Distrito Federal, Brazil; ²Usher Institute, University of Edinburgh, NINE Edinburgh BioQuarter, 9 Little France Road, Edinburgh, UK; ³School of Population and Public Health, University of British Columbia, Vancouver, British Columbia, Canada and ⁴Centre for Clinical Epidemiology and Evaluation, Vancouver, British Columbia, Canada

Method

Cite this article: Silva AS, Facey K, Bryan S, Galato D (2022). A framework for action to improve patient and public involvement in health technology assessment. *International Journal of Technology Assessment in Health Care* 38, e8, 1–9. <https://doi.org/10.1017/S0266462321000647>

Received: 28 April 2021

Revised: 4 October 2021

Accepted: 6 October 2021

Key words:

Health technology assessment; Patient involvement; Public involvement; Framework

Author for correspondence:

Aline Silveira Silva, E-mail: alinefarunb@gmail.com

Abstract

Background. Patient and public involvement (PPI) in the Brazilian Health Technology Assessment (HTA) process occurs in response to a legislative mandate for “social participation.” This resulted in some limited patient participation activities, and, therefore, a more systematic approach was needed. The study describes the development of a suggested framework for action to improve PPI in HTA.

Methods. This work used formal methodology to develop a PPI framework based on three-phase mixed-methods research with desktop review of Brazilian PPI activities in HTA; workshop, survey, and interviews with Brazilian stakeholders; and a rapid review of international practices to enact effective patient involvement. Patient partners reviewed the draft framework.

Results. According to patient group representatives, their involvement in the Brazilian HTA process is important but could be improved. Different stakeholders perceived barriers, identified values, and made suggestions for improvement, such as expansion of communication, capacity building, and transparency, to support more meaningful patient involvement. The international practices identified opportunities for earlier, more active, and collaborative PPI during all HTA stages, based on values and principles that are relevant for Brazilian patients and the public. These findings were synthesized to design a framework that defines and systematizes actions to support PPI in Brazil, highlighting the importance of evaluating these strategies.

Conclusions. Since the publication of this framework, some of its suggestions are being implemented in the Brazilian HTA process to improve PPI. We encourage other HTA organizations to consider a systematic and planned approach with regular evaluation when pursuing or strengthening involvement practices.

Introduction

In Latin America, Health Technology Assessment (HTA) started to become a part of an important health sector reform in the late 1990s (1). In 2012 and 2014, the Pan American Health Organization (PAHO) and the World Health Organization (WHO) approved resolutions on HTA and universal health coverage, calling for a strengthening of HTA capacities in this region (2). Currently, Argentina, Brazil, Colombia, and Uruguay have HTA bodies that are members of The International Network of Agencies for Health Technology Assessment (INAHTA). Additionally, many other countries from Latin America and the Caribbean region are a part of The Health Technology Assessment Network of the Americas (RedETSA).

The national HTA body in Brazil, the National Committee for Health Technology Incorporation into Unified Health System—Conitec, is composed of an Executive-Secretariat (SE) and a Plenary group with thirteen members, with voting rights, representing the seven Brazilian Ministry of Health secretariats and six other national health institutions (3).

Stakeholder involvement has been developing in several HTA agencies (4) including in Latin America, with Brazil and Colombia implementing formal mechanisms to involve citizens (2;5).

In Conitec, this occurs in response to the constitutional requirements for citizens’ participation and a legislative mandate for “social participation” in all parts of the public health system. With this basis, one of Conitec’s plenary members is a representative of the National Health Council (*Conselho Nacional de Saúde*—CNS), which ensures 50 percent of places for citizen entities, 25 percent for health worker entities, and 25 percent for government representatives and service providers. Besides this, the public, who could be patients or patient groups with an interest in a particular health technology, can be officially involved (3):

- submitting HTA topic proposals;
- *via* the public consultation issued for each recommendation;
- in public hearings when the Brazilian Ministry of Health Secretariat of Science, Technology and Strategic Inputs determines they are necessary.

This is a good starting point, but it was recognized by the Ministry of Health that there was a need for more extensive patient participation in the various stages of HTA and use of processes that are applied consistently across different HTA topics.

Hahn *et al.* (6) outlined the characteristics of tokenism (*i.e.*, perfunctory or uninformed gestures toward engaging with patients), such as low stakeholder diversity, late participation, lack of role definition and appropriate training, and poor scheduling, time frame and format. On the other hand, *meaningful* patient engagement is described by Hamilton *et al.* (7) as a planned approach that involves patients, with these individuals perceiving it as a rewarding and productive experience.

All this reinforces the need to systematize involvement approaches and evaluate them to promote constant improvement. As a result, this research was commissioned by the Brazilian Government and supported by the Ministry of Health and Conitec to collaboratively develop a comprehensive framework for action that could serve as a vehicle to drive improvement of *patient involvement* in the Brazilian HTA process, building on the public involvement approaches that already exist.

Methods

The development process of this framework was inspired by the works of Abelson (8) and Greenhalgh (9) and followed a three-phase mixed-methods approach, involving critical reflection on the descriptive and evaluative results, as shown in Figure 1 and described below.

The first author (ASS) was a technical advisor to Conitec responsible for patient and public involvement (PPI) activities between 2014 and 2020, which allowed a detailed observation and review of the activities in this context.

Phase A: Review of PPI in the Brazilian HTA Process

Phase A sought to elucidate gaps, feasibility, and implementation considerations for PPI in Conitec based on a desktop review of existing practices since its establishment in January 2012 until December 2017 as described by Silva *et al.* (6). It focused on the following questions: (i) *In what stages of HTA in Brazil can patients and the public be involved?* (ii) *In what stages could there be greater patient participation?*

Phase B: Stakeholders' Perspectives and International Best Practices

This phase aimed to address the following questions: (i) *What are the barriers to overcome and suggestions to improve PPI in the Brazilian HTA processes?* (ii) *What are the values and principles that should guide this involvement in Brazil?* (iii) *What international strategies could be applied or adapted to this context and how should they be evaluated?*

To understand stakeholders' perspectives on questions (i) and (ii), a workshop and survey with patients and patient groups and semistructured interviews were undertaken with a range of

stakeholders. For questions (iii), a rapid review of the international practices of involvement in HTA was conducted.

The methodological details are described below.

Patients and Other Stakeholders' Perspectives about PPI in HTA in Brazil

A patient workshop organized by Conitec SE in collaboration with Oswaldo Cruz German Hospital (HAOC) was held in Sao Paulo in October 2017 (3;10). It involved 103 patients and representatives from 98 patient groups. An online survey applied at the beginning of this event collected data outlining their perspectives about the existing PPI approaches in the Brazilian HTA. Questions in the instrument were informed by the literature and constructed using a multiple-choice Likert agree-disagree scale.

In addition, suggestions on how to improve PPI were received through a group consensus activity that involved all attendees divided into nine groups. The workshop inputs were documented by a range of approaches, including graphic facilitation. These suggestions were compiled and posteriorly analyzed and described (ASS and DG).

Semistructured stakeholder interviews with diverse stakeholders involved with HTA in Brazil were conducted face-to-face or by phone between May and August 2018 to capture perspectives, values, barriers, and suggestions to improve the PPI. Twenty-five participants were recruited using a convenience strategy determined by theoretical saturation and snowball sampling.

The Research Ethics Board of the University of Brasilia approved this research project, and all participants signed a consent form. Quantitative data analysis (survey) was descriptive, using Microsoft Excel. Qualitative data was transcribed and analyzed using Qualitative Solutions Research (QSR) NVivo 12 and thematic content analysis based on the principles of constant comparison and qualitative description (ASS, DG and SB) (11).

Rapid Review of PPI in HTA: Practices and Evaluation

A gray literature search for PPI practices in HTA was undertaken on the Web sites of nine HTA organizations (ASS and SB): Health Technology Assessment International (HTAi) and eight selected agencies from the INAHTA members' list, selected by a consensus of the researchers involved in this rapid review. The search resulted in twelve weblinks for the initial review. Three were finally included, from the National Institute for Health and Care Excellence (NICE), CADTH, and HTAi (Supplementary File 1).

A rapid review to explore how patient involvement practices have been evaluated was undertaken in April and May 2019 (ASS and SB). HTA organizations and relevant journals were also searched. The inclusion criteria were studies that addressed the evaluation of patient involvement in HTA, in English, published from 2008 (Supplementary File 2).

Phase C: Developing a Framework for Action

Phase C developed the framework for action to improve PPI, integrating the findings from Phase A and Phase B applied to the whole Brazilian HTA process mapping.

The framework development followed the assessment criteria of the Canadian Centre for Excellence on Partnerships with Patients and Public (CEPPP), that is, to encompass scientific rigor, incorporation of the perspectives of the public and the patient, scope, and usability (9;12).

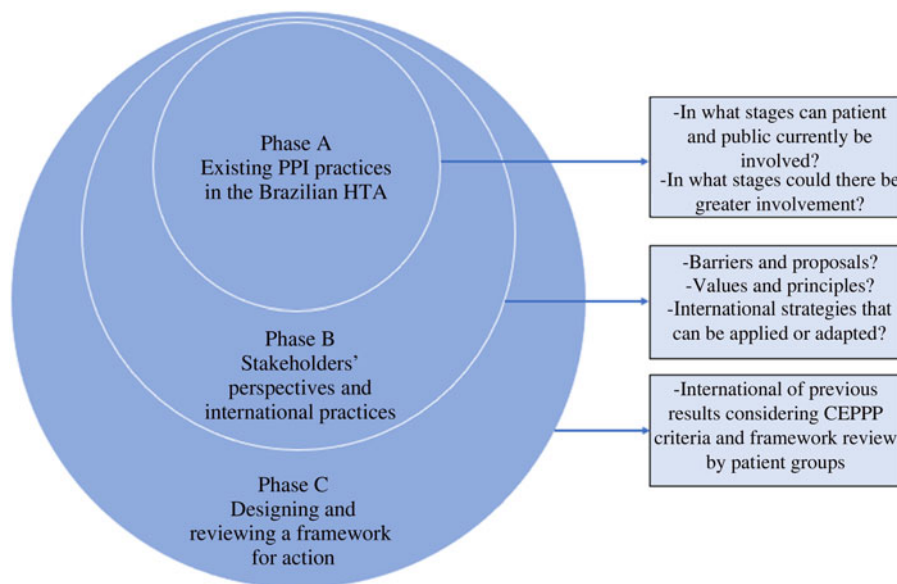


Figure 1. Three-phase approach to building the framework for action to improve PPI in the Brazilian HTA. Abbreviations: CEPPP, Canadian Centre for Excellence on Partnerships with Patients and Public; HTA, health technology assessment; PPI, patient and public involvement.

From the beginning of its development in October 2019, the first author made the draft framework available to the Conitec SE team and received insights from its director and coordinators through personal communications.

Five patient group representatives, previously engaged on the interviews as participants, were invited to review a draft framework and a plain language summary of this study. Three of them, called our patient partners—patients and informal caregivers who provide a patient perspective in health research (7), sent their revisions in July 2020, which were considered by two researchers (ASS and DG). They gave informed written consent and indicated whether they wanted to be explicitly acknowledged in this paper.

Next, the framework was translated to English and reviewed by two other researchers (SB and KF).

Results

Phase A

Review of PPI in the Brazilian HTA Process

Figure 2 depicts the HTA process in Brazil and indicates the stages in which patients and the public are entitled to be involved according to the legal mandate: (1) HTA topic proposals; (4) CNS as a committee member; (5) public consultations; and (8) public hearings (3).

To evaluate how these legal entitlements were put into practice, we reviewed and mapped all existing PPI practices during the period analyzed (10). This identified a range of different strategies that had been trialed by Conitec, in addition to those established by the law.

Submission of HTA topic proposals requires a dossier of evidence, and so, it is difficult for citizens, patients, or patient groups to suggest a topic given the complexity of the process.

Conitec's seat for one public member of the CNS committee is valuable, but international best practice suggests that at least two public members should be involved.

Public consultation was the main tool for PPI and almost half of the consultation responses were from people who were directly affected by a particular condition or health technology (patients

or their informal caregivers). However, no information is available about the methodology used to review the consultation responses and incorporate them into the HTA deliberation. PPI impact was simply measured according to the number of consultation comments received (10).

Public hearings were instigated but not used during the period analyzed.

Activities additional to those legislated include communication initiatives to support PPI (10), such as plain language summaries of recommendation reports, a guide for patient involvement in HTA launched in 2016, the workshop for patients in 2017, and informative video conferences held between 2016 and 2017. Some PPI initiatives, such as social media accounts and a video conferencing program to the public, were discontinued, but there are no records of evaluation of PPI strategies.

Phase B

Patients and Other Stakeholders' Perspectives about PPI in HTA in Brazil

A majority of the workshop attendees who completed the survey ($n = 82$, 90.1 percent) had a disease (55.6 percent) and were not engaged in HTA (53.2 percent), probably because they consider PPI in Brazilian HTA difficult (59.5 percent). However, the majority agreed that Conitec involves patients and public (59.6 percent). From all attendees' perspectives, PPI in Brazilian HTA is important and can be improved.

The group consensus suggestions on how to improve PPI (Supplementary File 3) were analyzed and synthesized and some were grouped together according to different forms of barriers.

Twenty-five semistructured interviews were conducted and are fully reported elsewhere (3). The participants were grouped into four groups by type of audience: pharmaceutical industry ($n = 5$), patients or patient group representatives ($n = 5$), researchers ($n = 7$), and health professionals, including Conitec members ($n = 8$).

Drawing on perspectives and themes arising from the workshop and interviews, barriers to overcome and suggestions for improvement were identified (Table 1).

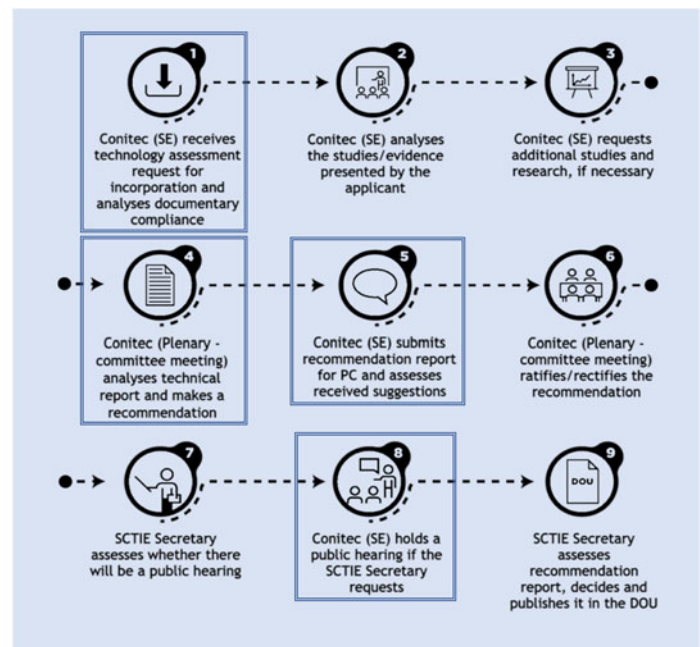


Figure 2. HTA stages in which PPI can occur in Brazil. Source: Silva (2020). Abbreviations: DOU, *Diário Oficial da União* (federal government official journal); PC, public consultation; SCTIE, *Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde* (secretariat of science, technology and strategic inputs); SE, executive-secretariat.

In the stakeholder interviews, several of the key themes could be categorized as values or principles, which were used to guide the building of the framework.

Transparency was continuously cited in the interviews and also appears among the suggestions received at the workshop. Participants stated the need to clarify the HTA process as well as how PPI occurs throughout it.

Another key theme was *capacity building*. In the opinion of several stakeholders, the Brazilian public needs more information about the HTA process so that they can be effectively involved in it.

In both the interviews and workshop, there was a desire to involve patients who would be directly affected by the decision in HTAs. In several interviews, there was concern about the lack of representativeness and disparity within the Conitec plenary (seven of the thirteen members represented the Ministry of Health, and only one represented citizens). These perspectives led to a call for these processes to be based on *justice* and *equity*, the latter being one of the principles of the Brazilian public health system itself.

Rapid Review of PPI in HTA: Practices and Evaluation

Information on PPI activities in HTAi, CADTH, and NICE provided important insights for the elaboration of this framework.

The HTAi Interest Group for Patient and Citizen Involvement in HTA (HTAi PCIG) presents values and quality standards for PPI in HTA that are directed to HTA agencies and have been recognized, referenced, and when applicable, translated by agencies in England, Scotland, France, Belgium, Colombia, and Canada (13). The HTAi values to support PPI in HTA are relevance, fairness, equity, legitimacy, and capacity building. Canada has recently reflected on its PPI practice and how it aligns with these values and standards (CADTH Framework for Patient Engagement in Health Technology Assessment | CADTH) (3). Both NICE and CADTH have a published strategy that describes the processes and responsibilities of those working in HTA to effectively involve patients; designate appropriate resources to ensure and support such involvement; HTA staff receive training

on how to involve patients throughout the HTA process; patient groups also have training opportunities so that they can contribute optimally; and finally, the processes of patient involvement in HTA are evaluated and reviewed regularly in order to continually improve them.

The rapid review of evaluation processes included three articles that met the inclusion criteria. They not only focused on the evaluation of patient involvement in HTAs but also described international experiences of PPI in HTA, and we observed what could be feasibly adapted to the Brazilian context.

Gagnon et al. (14) reviewed PPI practices and evaluation strategies internationally. In terms of international PPI practices, they found that countries such as the United Kingdom, the United States, the Netherlands, Canada, Denmark, New Zealand, and Australia consult and use data provided by the public and patients. Qualitative methods used to capture these data are interviews, focus groups, questionnaires (willingness to pay or discrete choice questionnaires, for example), and weblogs (gray literature). Several agencies in these countries also allow patient participation in the stages of selection of HTA topics, assessment, and in the dissemination of results. For this, the most frequent methods are interviews, focus groups, questionnaires, document analysis, and citizens' jury to develop criteria guiding the definition of priorities. Gagnon et al. concluded that in addition to systematizing the approaches of PPI in HTA, it is also necessary to evaluate these strategies.

Dipankui et al. (15) evaluated patient involvement in HTA via interviews and literature review and identified that some HTA bodies presented patient input and research into patient aspects in a separate section of their reports, allowing an explicit consideration of those inputs and evidence, which could sometimes be shown to directly influence recommendations.

Weeks and colleagues (16) showed that HTA organizations that support PPI involve both patient and public, but some HTA bodies only involve patients. The study reported that, among the surveyed organizations, PPI was performed in a series of activities, such as involving patients in working groups or

Table 1. Synthesis of main barriers and suggestions to improve PPI in the Brazilian HTA

Barriers	Suggestions
Lack of prioritization (difficult for society to request HTA)	Create listening channels for patients and public requests
Lack of transparency	Broadcast or make committee meetings public
	Make processes more transparent
	Disclose the committee meeting agenda earlier
	Expand communication and dissemination strategies
Lack of information about the HTA process	Hold events/workshops for patients more frequently
	Provide training and inform patients and public about how to get involved
	Improve knowledge translation
Lack of communication	Disclose the committee meeting agenda earlier
	Expand communication and dissemination strategies
	Create listening channels for patients and public requests
Lack of interest to get involved	Get closer to society and representative groups
Lack of patient and public representation (SUS user representation only through CNS as a unique member)	Amplify public representation in committee meetings
	Enable patient representation in committee meetings
	Undertake work with decision makers to demonstrate the value of PPI
Possible conflicts of interest and lobbying	Get closer to society and representative groups
Litigation	Create listening channels for patients and public requests
Public consultation form issues	Improve public consultation forms
Lack of quality, analysis, and acceptance of public consultation submissions	Provide training and inform patients and public about how to get involved
	Improve knowledge translation
	Define the PPI methodology process
	Undertake work with decision makers to demonstrate the value of PPI
Lack of public hearings	Undertake work with decision makers to demonstrate the value of PPI
	Establish criteria for when public hearings should occur

Abbreviations: CNS, *Conselho Nacional de Saúde* (National Health Council); HTA, Health Technology Assessment; PPI, Patient and Public Involvement; SUS, *Sistema Único de Saúde* (Unified Health System).

committees to provide opinions and perspectives, identifying HTA topics, refining HTA scope, identifying clinical outcomes, making recommendations, and helping to disseminate results. According to the authors, a small but diverse set of HTA organizations evaluate their PPI activities using a range of strategies.

Two studies (15;16) mentioned that an evaluation of PPI in HTA could be categorized around three topics: (1) patient satisfaction, (2) process evaluation, and (3) impact evaluations. Evaluation of PPI in HTA processes found that in most instances, patient involvement has enriched the content of the HTA report and its recommendations, introduced additional perspectives, and served as a mechanism to validate the findings from the stakeholder views.

Phase C

Developing a Framework for Action

To build this framework to improve PPI, the following learnings, informed by phases A and B, were integrated to the whole Brazilian HTA process mapping by the researchers (ASS and DG):

- the stages of the Brazilian HTA process in which there could be greater involvement;

- barriers to overcome;
- the values and suggestions identified in the stakeholder's perspectives;
- international strategies that could be adapted/applied to the Brazilian context.

For better organization of the strategies proposed in each HTA stage, the typology of engagement mechanisms by Rowe and Frewer (17) was adopted, which includes three levels of involvement that are commonly cited: communication, consultation, and participation. The resulting framework is presented in Figure 3.

An analysis of the PPI activities in the Brazilian HTA process up to 2017 identified that there is potential for greater involvement, starting from stages 1, 2, and 3. Some HTA agencies involve patients and the public in HTA prioritization, scoping, and data collection (14;16), which would lead to an earlier involvement in Brazil. Conitec could seek to achieve this through conducting prioritization workshops (using consensus methods) based on SUS health priorities and encouraging HTA topic proposals from patients and public through its Web site. In stages 2 and 3, studies using Patient-Reported Outcome Measures (PROMs) (18) could be encouraged, as well as a search for qualitative

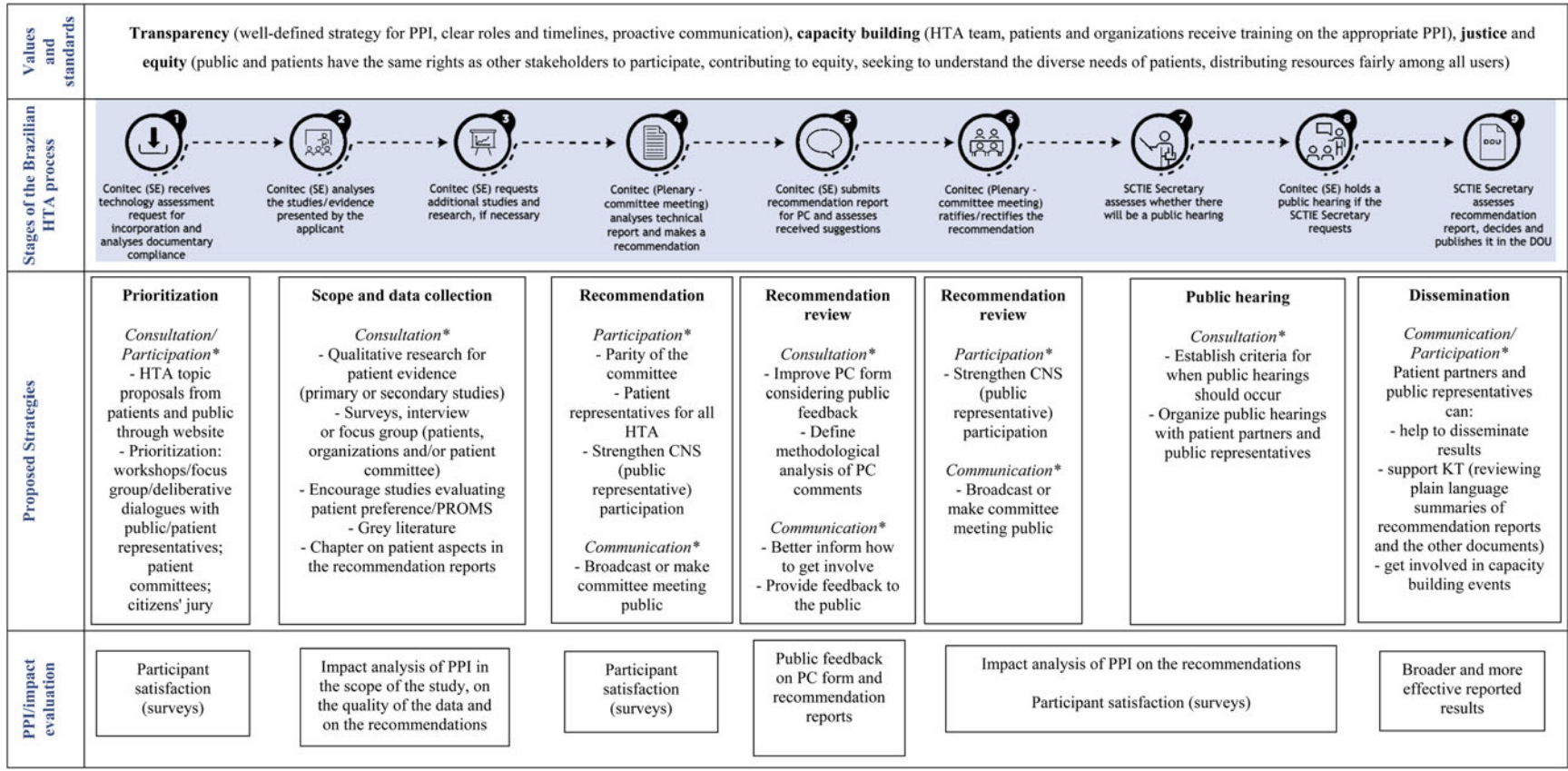


Figure 3. Proposed framework for action to improve patient and public involvement (PPI) in the Brazilian health technology assessment. Abbreviations: CNS, *Conselho Nacional de Saúde* (national health council); DOU, *Diário Oficial da União* (federal government official journal); HTA, health technology assessment; KT, knowledge translation; PC, public consultation; PPI, patient and public involvement; SCTIE, *Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde* (secretariat of science, technology and strategic inputs); SE, executive-secretariat. *Based on Rowe and Frewer (2005): communication, consultation, and participation mechanisms.

research about patients' experiences and perspectives with the technology or disease, and adding a separate chapter in the recommendation report on patient aspects (15).

The Brazilian stakeholders identified barriers and proposals to support more meaningful involvement. Because transparency was a concern raised in several interviews as a barrier and is an important value for the Conitec HTA process, one suggestion was to broadcast committee meetings or make them public (stages 4 and 6). In addition, there were proposals to make the whole process more transparent, expanding communication strategies and defining how patient and public inputs would be considered, taking account of the international examples. We suggest observing transparency as a transversal value throughout the whole HTA process, as well as capacity building.

Capacity building is reported in the literature as a support factor for participation (14). At CADTH and NICE, staff, committee members, and patients/patient groups receive training on appropriate patient involvement. Training/support for public consultation users and participation instruments improvement (stage 5) are strategies that have already been developed in Brazil. However, these could be expanded to overcome reported barriers such as a lack of information about HTA and quality of public consultation comments.

Listening effectively to the voices of patients and the public in the HTA process was observed as an issue to be addressed. Patients (and other stakeholders) pointed to a lack of public representation on the Conitec plenary and during its meetings. Active participation of patient group representatives in the committee meetings for all HTA, with an appropriately defined methodology and focused invitations, is suggested (14). In addition to this, the participation of the public representative (CNS member) through a careful selection of an individual who can represent the public with credibility should be strengthened. This could be achieved with greater dialogue and interaction with patient groups (stages 4 and 6).

Another proposal is to establish the criteria for when public hearings, stages 7 and 8, should occur. Furthermore, knowledge translation improvement and dissemination of results (stage 9) were suggested by stakeholders and international practices (14).

There was no evidence of PPI evaluation or any analysis of the consultation comments nor of these inputs' impact on Conitec's recommendations. The number of submissions received through public consultation is usually the measure of PPI impact, according to Official Information from Conitec's Web site, "Conitec in numbers." The findings of the rapid review reinforce the importance of this evaluation (14–16), which was added as a continuous activity throughout the suggested framework. The approaches vary widely, from participation in interviews to something more simplified, such as the participants' satisfaction survey, with questionnaires being applied regularly during work processes, and even the possibility of using storytelling to reflect on the impact of patient involvement in HTA (19).

Analyzing Brazilian patients' and other stakeholders' perspectives, we identified values (transparency, capacity building, equity, and justice) that align with the HTAi PCIG Values and Quality Standards for Patient Involvement in HTA. As Conitec is an active HTAi member, acknowledgment and observation of the identified values during its PPI process should be encouraged.

Beyond the insights from Conitec SE, the review by patient partners complemented our perspective and added value to this framework, reinforcing the possibility of public and patients to

submit HTA topic proposals as an involvement mechanism that should be improved, besides the lack of use and criteria for public hearings.

Discussion

According to Facey (20), early involvement, training, an appropriate participation method and support from HTA organizations may help ensure that patients contribute meaningfully to the HTA process and output. For Whitty (21), even though evaluative processes are relatively recent, encouraging HTA organizations to publish narratives of their experiences with public engagement can support the development of systematic yet pragmatic approaches and frameworks.

Following the CEPPP guidance, this three-phase mixed-methods approach framework was based on a critical reflection of (phase A) the existing PPI practices and feasibility for greater involvement; (phase B) relevant values, barriers, and proposals identified through a thematic analysis of data from different stakeholders and literature review; (phase C) an integration of previous results to the whole Brazilian HTA process mapping in consultation with Conitec SE; receiving final review by patient partners to make sure it was built on Brazilian needs.

In the first phase, Silva (10) showed the gradual implementation of PPI actions by the Brazilian HTA agency. However, like many other HTA bodies, the strategies do not go beyond consultation level (22). Considering the current trend to broaden the spectrum of involvement to increase genuine participation (6) and the findings from this study, the involvement strategies already used in Brazil should be expanded, for an earlier, more direct, and active participation. Involving patients and patient groups in ways by which, and at times when, their input can influence decision making and generating a dialogue to use their unique experiential knowledge are needed (23). Thus, the development of a broader strategy adapting international best practices, involving patients and the public from the beginning and along all the HTA process could be helpful.

An analysis of different stakeholders' perspectives in Brazil shows that some identified barriers are similar to those identified internationally (14;15;22;24). International strategies for stimulating and evaluating PPI in HTA, plus patient and stakeholders' suggestions, made it possible to identify several promising actions that could feasibly be addressed by Conitec, and bringing these actions together creates the systematic approach presented in this framework. Conitec SE first received these recommendations in June 2020 and subsequently moved toward implementing some of them. The final version was shared in August 2020 with Conitec and other interested stakeholders, including all participants of this research.

To overcome the lack of transparency, pointed as an involvement barrier, we suggested making the committee meetings public, which was started by the agency in July 2020, through making meeting recordings available online.

Patient representatives' participation in the committee meetings was suggested as an improvement of a strategy sporadically used by the agency since 2014 (10;19;25). Gagnon (14) reported that issuing focused invitations (inviting people with experience related to the topic discussed in HTA) is a success factor in patient engagement. Since December 2020, Conitec started issuing public

calls for patient representatives for each topic discussed in the committee meetings.

Also, since the publication of this framework, two public hearings have taken place for the first time. The first one discussed a health technology for spinal muscular atrophy in March 2021 and the second one discussed the Brazilian guidelines for hospital treatment of patients with Covid-19 in July 2021.

The main strength of this study was our collaborative approach to ensure that the framework was grounded on the experiences and views of patients and other stakeholders who engage in the HTA process. However, it had some limitations, such as the rapid review searches, which were conducted in only one database (MEDLINE) and narrowed on the evaluation of patient involvement. Besides these, the search engines on the agencies' Web sites were not specific. Finally, it was not possible to implement a rigorous validation method for the proposed framework, so we attempted to minimize this limitation by inviting previously enrolled patient representatives to review it.

Conclusion

This article is a response to the reported need for a pragmatic approach and more systematic PPI at the Brazilian PPI in HTA. It reports on the findings of different study phases: a review of Brazilian PPI activities in HTA up to 2017; an elicitation of perspectives and values of patients and other stakeholders captured by surveys, interviews, and workshop; and a rapid literature review.

Using this mixed-methods approach involving all interested stakeholders, it was possible to build a framework for action to improve the involvement of patients and the public during all the HTA stages, considering important values and principles for the Brazilian context.

This framework defines and systematizes involvement actions and highlights the importance of evaluating these strategies and their impact to enhance PPI in the Brazilian HTA process.

We encourage other HTA organizations to consider and demonstrate a systematic and planned approach with regular evaluation when pursuing or strengthening patients and public involvement.

Supplementary Material. The supplementary material for this article can be found at <https://doi.org/10.1017/S0266462321000647>.

Acknowledgments. Our acknowledgments to all Brazilian Ministry of Health collaborators who contributed to PPI in HTA since the beginning of its implementation, and specially, to those who supported the workshop in Sao Paulo and this framework building. Many thanks to all stakeholders involved in this research, mainly the following patient partners, Gustavo San Martin, Simone Arede, and Tiago Farina, for reviewing the presented framework and the plain language summary of this study. We also would like to thank Dr. Kathiaja Miranda Souza (National Consultant of Health Technology Assessment and Management at Pan American Health Organization—PAHO, Brazil) for reviewing this manuscript.

Author Contributions. ASS and DG developed the initial outline. ASS, DG, and SB obtained funding. ASS and DG contributed to the workshop, survey, and interview development. ASS and DG analyzed the free-text data. ASS, DG, and SB contributed to the survey analysis. ASS and SB contributed to the rapid review. SB and KF contributed to the English translation of the study and framework. All authors wrote the manuscript, contributed to the interpretation and narrative of the paper, reviewed, and revised the content, approved the final version, and agreed to be accountable for all aspects of

the work in ensuring that questions related to the accuracy or integrity of the work.

Funding. The work for this manuscript is a result of the doctorate project entitled “The patient and public involvement in the Brazilian health technology incorporation process” from the University of Brasilia, having the Department of Management and Incorporation of Technologies and Innovation in Health (Conitec SE) from the Brazilian Ministry of Health as a co-partner institution. A part of this study was conducted at the Center for Clinical Epidemiology & Evaluation (C2E2) and supported by the University of British Columbia, Canada. It received funding from the Brazilian Government through the *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* – Brazil (CAPES), process number 88881.188553/2018-01 of 2018.

Conflict of Interest. Dr. Silva served as a civil servant at the Department of Management and Incorporation of Technologies and Innovation in Health (Conitec SE), Brazilian Ministry of Health between 2014 and 2020. Dr. Facey reports personal fees from Swii.ch, BMS, Health Technology Wales, NICE, Ministry of Health/Czech Republic, Pfizer/Lilly, Novartis, and imi Paradigm project, outside the submitted work. The other authors declare no conflicts of interest.

References

1. Banta D. Health technology assessment in Latin America and the Caribbean. *Int J Technol Assess Health Care*. 2009;25:253–4.
2. Pichon-Riviere A, Soto NC, Augustovski FA, García Martí S, Sampietro-Colom L. Evaluación de tecnologías sanitarias para la toma de decisiones en Latinoamérica: Principios de buenas prácticas. *Rev Panam Salud Pública*. 2017;41:1.
3. Silva AS. *A participação social no processo de incorporação de tecnologias em Saúde no Brasil [social participation in the health technologies incorporation in Brazil]* [internet]. University of Brasilia; 2020. Available from: <https://repositorio.unb.br/handle/10482/39520>.
4. Street J, Stafinski T, Lopes E, Menon D. Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes. *Int J Technol Assess Health Care*. 2020;36:87–95.
5. Pichon-Riviere A, Soto N, Augustovski F, Sampietro-Colom L. Stakeholder involvement in the health technology assessment process in Latin America. *Int J Technol Assess Health Care*. 2018;34:248–53.
6. Hahn DL, Hoffmann AE, Felzien M, LeMaster JW, Xu J, Fagnan LJ. Tokenism in patient engagement. *Fam Pract*. 2017;34:290–5.
7. Hamilton CB, Hoens AM, Backman CL, McKinnon AM, McQuitty S, English K, et al. An empirically based conceptual framework for fostering meaningful patient engagement in research. *Heal Expect*. 2018;21:396–406.
8. Abelson J, Wagner F, DeJean D, Boesveld S, Gauvin FP, Bean S, et al. Public and patient involvement in health technology assessment: A framework for action. *Int J Technol Assess Health Care*. 2016;32:256–64.
9. Greenhalgh T, Hinton L, Finlay T, Macfarlane A, Fahy N, Clyde B, et al. Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot. *Heal Expect*. 2019;22:785–801.
10. Silva AS, de Sousa MSA, da Silva EV, Galato D. Social participation in the health technology incorporation process into unified health system. *Rev Saude Publica*. 2019;53:1–11.
11. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3:77–101.
12. Boivin A, L'Espérance A, Gauvin FP, Dumez V, Macaulay AC, Lehoux P, et al. Patient and public engagement in research and health system decision making: A systematic review of evaluation tools. *Heal Expect*. 2018;21:1075–84.
13. Wale JL, Scott AM, Bertelsen N, Meade N. Strengthening international patient advocacy perspectives on patient involvement in HTA within the HTAi patient and citizen involvement interest group – Commentary. *Res Involv Engagem*. 2017;3:1–10. Available from: doi:10.1186/s40900-016-0053-8
14. Gagnon M-P, Desmartis M, Lepage-Savary D, Gagnon J, St-Pierre M, Rhainds M, et al. Introducing patients' and the public's perspectives to

- health technology assessment: A systematic review of international experiences. *Int J Technol Assess Health Care*. 2011;**27**:31–42. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21262085>
15. **Dipankui MT, Gagnon MP, Desmartis M, Légaré F, Piron F, Gagnon J, et al.** Evaluation of patient involvement in a health technology assessment. *Int J Technol Assess Health Care*. 2015;**31**:166–70.
 16. **Weeks L, Polisen J, Scott AM, Holtorf AP, Staniszewska S, Facey K.** Evaluation of patient and public involvement initiatives in health technology assessment: A survey of international agencies. *Int J Technol Assess Health Care*. 2017;**33**:715–23.
 17. **Rowe G, Frewer LJ.** A typology of public engagement mechanisms. *Sci Technol Hum Values*. 2005;**30**:251–90.
 18. **Bryan S, Davis J, Broesch J, Doyle-Waters MM, Lewis S, Mcgrail K.** Choosing your partner for the PROM: A review of evidence on patient-reported outcome measures for use in primary and community care. *Healthc Policy*. 2014;**10**:38–51.
 19. **Single ANV, Facey K, Livingstone H, Silva AS.** Stories of patient involvement impact in health technology assessments: A discussion paper. *Int J Technol Assess Health Care*. 2019;**35**:266–72.
 20. **Facey K, Boivin A, Gracia J, Hansen HP, Lo Scalzo A, Mossman J, et al.** Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation. *Int J Technol Assess Health Care*. 2010;**26**:334–40.
 21. **Whitty JA.** An international survey of the public engagement practices of health technology assessment organizations. *Value Health* 2013;**16**:155–63.
 22. **Gagnon MP, Tanchou Dipankui M, Poder TG, Payne-Gagnon J, Mbemba G, Beretta V.** Patient and public involvement in health technology assessment: Update of a systematic review of international experiences. *Int J Technol Assess Health Care*. 2021;**37**:1–16.
 23. **Facey K.** As health technology assessment evolves so must its approach to patient involvement. *J Comp Eff Res*. 2019;**8**:549–54.
 24. **Facey KM, Developing the mosaic of patient participation in HTA.** In: **Facey KM, Hansen HP, Single ANV**, editors. *Patient involvement in health technology assessment*. Singapore: Springer Nature; 2017, 56–57.
 25. **Silva AS, Petramale CA, Rabelo RB, Santos VCC. Brazil.** In: **Facey KM, Hansen HP, Single ANV**, editors. *Patient involvement in health technology assessment*. Singapore: Springer Nature; 2017. p. 245.