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Relevant domains for health technology assessment of medical device reimbursement in Brazil's unified health system: a survey and Delphi panel study on stakeholder preferences

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Abstract

Aims: Health technology assessment (HTA) for medical devices (MDs) is essential for adoption decisions, but the sector's particularities studied here defy regulatory frameworks. In Brazil, the National Policy for Health Technology Management (PNGTS) provides guidelines for HTA, but the reimbursement of MDs in the Brazilian National Health System (SUS) still faces challenges. This study aimed to identify and validate relevant domains and attributes for HTA of MDs in the SUS, considering the perspectives of various stakeholders.

Objectives: To analyze and validate the essential domains and attributes for conducting HTA studies focused on the reimbursement of MDs in the SUS.

Methods: A baseline systematic review was performed, which was followed by two additional stages: a survey with 115 participants and a Delphi panel with 33 experts. Likert scales were used to assess the importance of the domains and attributes, along with open questions to collect suggestions and comments.

Results: The domains "clinical benefits," "evidence ecosystem," and "budget impact" were considered fundamental. "Social participation" showed high variability in response, indicating the need for greater engagement and clarity in participation mechanisms. The inclusion of the "public policy" domain emphasizes the importance of aligning government policies with population needs.

Conclusions: This study reinforced the relevance of a multidisciplinary and participatory approach in HTA for MDs, with a focus on clinical outcomes, real-world evidence, and continuous monitoring. Overcoming the identified challenges, such as information gaps and the need for robust methods, is crucial for improving the reimbursement of MDs in the SUS.

Introduction

Medical devices (MDs) are essential technologies for health care and service delivery. Health technology assessment (HTA) of MDs challenges regulatory frameworks because of the sector's particularities, such as extensive heterogeneity, often highly context- and user-dependent, the need for local adaptation, and rapid technological evolution (1).

There are approximately 2 million types of MDs available globally, grouped into more than 7,000 generic device categories, used in techniques ranging from simple procedures, such as measuring temperature, to highly complex surgical interventions (2).

HTA for high-complexity MDs has to consider their critical interdependence and interactions with other technologies. It may involve specific configurations required for their implementation, and it needs to align to prevent risks, including the underutilization of devices (3).

The adoption and reimbursement of these technologies should consider several prerequisites for their proper implementation in healthcare services. It is important to evaluate the degree of innovation and regulatory approval status and, within the HTA process, to assess equity, social, clinical, and economic aspects, along with the requirements for health technology management. Evidence-informed decision making ensures that the acquisition, installation, training, and safe use of technologies are conducted efficiently, safeguarding patient safety. Financing models must also be evaluated to ensure service delivery efficiency in healthcare systems (2).

In Brazil, the National Policy for Health Technology Management (PNGTS), published in 2010, defines HTA as "a continuous process of analysis and synthesis of health benefits, economic and social consequences of technology use, considering aspects such as safety,

accuracy, efficacy, effectiveness, cost, cost-effectiveness, equity, and ethical, cultural, and environmental impacts." The PNGTS situates HTA within the health technology management context, encompassing evaluation, reimbursement, dissemination, and use, until technology decommissioning in the Brazilian National Health System (SUS). This process should be guided by population health needs, public budget constraints, responsibilities at the three government levels, and social control, as well as the principles of equity, universality, and comprehensiveness to underpin health care in the country (3).

Since the publication of the PNGTS, incremental steps have been taken toward its implementation. However, following the COVID-19 crisis in 2020, emergency governmental initiatives were launched to strengthen the management of HTA and MDs.

In 2021, the Brazil National Health Surveillance Agency (Anvisa) established the Technical Committee on Techno Surveillance (4), specifically to monitor postmarketing actions of MDs registered under emergency provisions during the COVID-19 pandemic. That same year, Anvisa updated the resolution governing health technology management in healthcare facilities, replacing Resolution 2/2010 with Resolution 509/2021 (5). Additionally, during this period, there was a revision and publication of Resolution 548/2021 regulating clinical trials with MDs in Brazil (6).

In August 2022, the National Committee for Health Technology Reimbursement in the SUS (Conitec) structure was reorganized. The previously single plenary was divided into three specialized thematic committees, with one created specifically for products and procedures, responsible for making recommendations on the inclusion, alteration, or exclusion of MDs from SUS coverage (7).

Later that year, the Ministry of Health established the Subcommittee on Products and Procedures, mandated to (i) analyze methodologies and proposal flows for MDs to be submitted to Conitec; (ii) contribute to the development of guidelines and frameworks for HTA; (iii) monitor technology implementation in the SUS, including updates to the SUS procedures table (SIGTAP) and the national equipment and permanent material list (Renem); (iv) require cost composition studies from relevant departments to inform Conitec's deliberations; and (v) provide HTA support for innovative products to be included in Renem (8).

In January 2023, the technical departments responsible for the Health Economic-Industrial Complex were reinstated into the Ministry of Health, to reestablish the coordination for health products, fostering a national strategy for innovation, production promotion, and public–private partnerships (9), aiming for the technological sovereignty of strategic MDs in the SUS.

Our baseline systematic review was published in 2024, entitled Domains and Methods of Medical Device Technology Evaluation, and was a central reference for this study (10). The review aimed to identify the main domains and assessment methods used in the HTA of MDs, with a focus on their practical introduction into health systems (10). Through systematic searches in MEDLINE, Embase, BVS, Cochrane Library, and Web of Science between 2017 and May 2023, 41 articles met our rigorous inclusion criteria out of 5,790 retrieved. The findings identified eight essential domains and recommended the adoption of grouping by technological characterization to improve the standardization of methods (10).

These recent initiatives underscore the importance of strengthening HTA processes involving MDs within the SUS. In this context, the present study aims to validate, from the perspective of diverse stakeholders, the domains and attributes to guide HTA studies for the reimbursement of MDs in the SUS.

Methods

This study employed, after our systematic review (10), an exploratory qualitative research design developed in two stages. The first stage consisted of a survey designed to assess the perceived importance of the proposed domains. The second stage involved a Delphi panel used to validate findings from both the literature and the survey. The flowchart of methodological steps is illustrated in the figure available in Supplementary Material 1. This study was approved by the appropriate ethics committee (CAAE 58703722.9.0000.0068). Participation was voluntary and anonymous, and all participants provided informed consent before participating in the study.

Survey

The survey employed a convenience sample to gather insights based on participants' experiences regarding key domains to be considered in HTA studies involving MDs. The goal was to reach primary stakeholders or those interested in the HTA processes and reimbursement of MDs in healthcare systems.

The survey included domains and attributes relevant to HTA studies identified from our previous "Domains and Methods of Medical Device Technology Evaluation: A Systematic Review" (10). In this survey, an online questionnaire composed of 22 items (closed and open-ended) was developed via the Google Forms platform. For the 13 items related to the domains (as presented in Table 1), a Likert scale was used, with importance rated from 0 to 5: (0) "I don't know," (1) "not important," (2) "slightly important," (3) "moderately important," (4) "important," and (5) "very important."

Table 1. Survey questions for rating domain importance on a Likert scale

Domain	Attributes	N
Clinical and nonclinical benefits	Patient-centered clinical outcomes, assessment of adverse events (severity, tolerance, frequency, and their impacts)	1
	System-level and organizational benefits (e.g., productivity gains, avoidable waste reduction, workload reduction, resource optimization)	2
	Comprehensive clinical assessment using all available evidence when randomized controlled trials are ethically or technically unfeasible (e.g., blinding infeasibility, randomization difficulties)	3
Economic evaluation	Economic assessment considering dynamic pricing from scale gains, diverse business models (leasing, loan, acquisition), rapid innovation, and market entry	4
	Full lifecycle cost evaluation, including direct and indirect costs to keep MDs functioning effectively (e.g., consumables, accessories, installation, training, logistics, maintenance, decommissioning)	5
Innovation	Innovation assessment in relation to lifecycle stage (e.g., recent regulatory approval, early diffusion, widespread use)	6
	Degree of innovation: incremental (improvements on existing technologies) or	7

(*Continued*)

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Table 1. (*Continued*)

Domain	Attributes	N
	radical/disruptive (transformational MDs that impact service delivery and clinical practices)	
	Assessment of innovation based on added therapeutic value, nonredundancy, noncumulative technology, shift in clinical/technological pathways, unmet clinical needs	8
Intrinsic characteristics	Evaluation of MD-specific attributes (e.g., sanitary risk, shelf life, body contact and exposure duration, single-use or reusable, usability, learning curve, operator dependency, place in care pathway, technical performance, interoperability, infrastructure requirements)	9
Legal requirements	Assessment of ethical and legal requirements (e.g., conflict-of-interest management, equity, comprehensive care, environmental impact, compliance with regulations)	10
Social participation	Stakeholder engagement strategies: involvement of patients/caregivers and their influence on decisions, health professional engagement, robust communication, and transparency strategies	11
	Collaborative HTA processes and exchange of technical scientific information; data repositories; involvement of health engineering professionals to inform on technical features, usability, safety, and lifecycle maintenance	12
Implementation	Clear, robust, and adaptable implementation strategies for MD adoption in health care; evaluation of funding and reimbursement; organizational support; definition of technical/clinical criteria; monitoring and evaluation of implementation	13

HTA, health technology assessment; MD, medical device; N, attribute number.

The questionnaire was divided into three sections. The first addressed informed consent. If consent was not granted, the respondent could not proceed. The second section collected general participant profile data, including region (state), academic background, professional area, age, and years of experience. The final section presented the domains for HTA of MDs, including brief definitions and conceptual alignment. Two open-ended questions were included: one invited suggestions for additional relevant domains, and the other provided space for general comments.

As a pretest, the form was reviewed by five external collaborators (not participants of the study), including a methodologist, an industry representative, a Ministry of Health official, a university professor, and a patient advocate. Based on the pretest, adjustments were made to improve text clarity and comprehensibility.

Sampling for the survey was nonprobabilistic and was based on convenience. No sample size calculation or effect size estimation was conducted.

The survey was disseminated via social media and e-mails starting on 14 August 2023 and remained open until 4 October 2023. The dissemination channels included WhatsApp groups of clinical engineering professionals, HTA centers (NATSs), regulatory professionals, professional associations in clinical and biomedical engineering, the Conitec Product and Procedures Committee, industry associations, the Anvisa's Sentinel Network, and LinkedIn.

E-mail invitations were sent to the Brazilian Network for Health Technology Assessment (Rebrats). The Radiology Program of the University of São Paulo Medical School and the São Paulo State Department of Health also promoted the study via their institutional channels.

Delphi panel

A structured Delphi panel was performed with the domains identified in the prior systematic review (10), enriched with the empirical contributions gathered during the survey. The objective was to validate the domains from the perspective of subject-matter experts and to gather additional input.

The purpose of the sampling was to include official representatives from government agencies, industry associations, patient associations, professional associations in clinical and biomedical engineering, research funding agencies, and coordinators of the Health Technology Assessment Centers (NATSs) affiliated with Rebrats. The instrument was sent to 60 invited participants, 10 of each 6 categories: regulators/government; productive/regulatory sector; methodologists/academia; science, technology, and innovation funding agencies; healthcare services/managers; and patient associations/councils/advocacy groups. All the responses were provided individually and anonymously.

The questionnaire was structured into three sections. The first addressed informed consent, and without agreement, the respondent could not proceed. The second section offered guidance and collected general profile data, including location (federative unit), educational background, professional area, years of experience in HTA, and level of knowledge about HTA involving MDs. The participants could also select the option "I have never heard of this subject and do not feel comfortable continuing," which terminated their participation. The following section addressed the domains to be considered in HTA studies on MDs. A Likert scale ranging from 0 to 5 was used to rate importance: "I don't know," "not important," "slightly important," "moderately important," "important," and "very important." Each domain was presented with a brief definition and conceptual alignment. The final section listed the main challenges to conducting HTA studies on MDs, as reported in the previous survey phase. The respondents could select "agree," "disagree," or "partially agree." Additionally, three open-ended questions invited suggestions for new challenges, new domains, and general comments.

The instrument was pretested by six external collaborators not involved in the study, one of each six categories: methodologist, industry professional, government official, university professor, research funding agency representative, and patient representative. On the basis of their feedback, suggested adjustments were incorporated to enhance the instrument's clarity.

Three Delphi successive rounds were conducted. After each round, the responses were summarized and presented in the subsequent round, allowing the participants to reflect on the feedback and revise their opinions if desired. For analytical purposes, respondents' academic backgrounds were grouped into the following categories:

- Health sciences: medicine, nursing, pharmacy, dentistry, physical therapy, biomedicine, and psychology.
- Basic sciences: chemistry, biology, physics, and medical physics.

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- Engineering: biomedical, clinical, electrical, mechanical, chemical, production, and materials engineering.
- Human sciences: administration, economics, museology, and communication studies.

Results

Survey

A total of 116 responses were received for the survey. One respondent did not consent to participate and was therefore excluded, resulting in 115 complete and valid responses.

Among the 115 participants, the majority were from the Southeast region (67.8 percent), with São Paulo State being predominant. The remaining participants were from the Midwest (13.9 percent), Northeast (4.3 percent), and South (3.5 percent) regions. Regarding the participants' educational backgrounds, there was a predominance of respondents from health sciences (43.5 percent) and engineering (42.6 percent), as illustrated in Figure 1. The profile data of the respondents are illustrated in figures available in Supplementary Material 4.

In terms of the professional sector, the majority worked in hospitals and healthcare services/clinical engineering (50.43 percent), followed by the MD industry (12.17 percent), HTA centers (NATSs) (11.30 percent), higher education and research institutions (9.57 percent), and government management (7.83 percent). Other sectors included research funding agencies and specialized consulting (1.74 percent each). Regulatory agencies, pharmacies, public service management through social organizations, armed forces, clinical research, and health plans were each represented by 0.87 percent.

Concerning their academic qualifications, 41.74 percent held a specialization degree, 25.22 percent had a master's degree, 17.39 percent held a PhD, 8.70 percent had a bachelor's degree, and 6.96 percent had a technical degree.

Only 0.9 percent of the respondents were under 25 years old. The age distribution was as follows: 25–34 years (21.7 percent), 35–45 years (34.8 percent), 45–59 years (32.2 percent), and over 60 years (10.4 percent).

With respect to professional experience, 37.4 percent had more than 15 years of experience; 26.1 percent had 10–15 years; 20 percent had 5–10 years; 10.4 percent had 3–5 years; and 6.1 percent had less than 2 years.

The distribution of responses regarding the importance of the domains was primarily concentrated in the "very important" and "important" categories, as shown in Table 2.

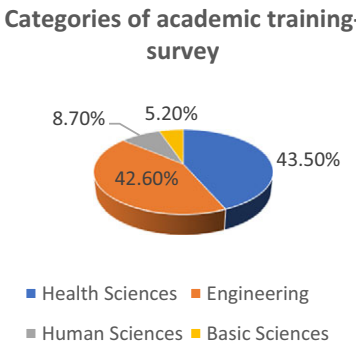

Figure 1. Survey respondents: categories of academic training.

In the open-ended question ["Do you suggest any other domain as important or essential for HTA studies on medical devices?"], 48 suggestions were submitted. Of these, 24 respondents felt that the proposed domains were comprehensive and sufficient. Supplementary Material Table 2 details the suggestions for new domains and attributes.

In summary, contributions emphasized the need for assessments to be conducted by professionals with technical (normative and regulatory), scientific, and clinical expertise. The respondents also highlighted the importance of lifecycle cost considerations, including infrastructure investments, complementary technologies, and disposal or decommissioning.

The responses further stressed the complexity of safety evaluations, which demand institutionalization and a strong HTA culture. The registration of adverse events, corrective actions, recalls, and modifications was noted as essential, although it was limited by data scarcity and heterogeneity of evidence. In this context, postmarket surveillance studies were deemed critical, especially for evaluating appropriate implementation, effectiveness, performance, continuous access, and educational impact. These studies are considered particularly important for rare disease populations, such as those using implantable ventricular assist devices for rare pediatric cardiomyopathies or specialized infusion pumps for enzyme replacement therapy in lysosomal storage disorders, where robust postmarket evidence is essential.

Additionally, there were suggestions for fiscal incentives (e.g., tax exemptions for imported equipment) and funding to establish regional centers linked to the SUS with consolidated metrological capabilities – especially for high-tech equipment – regardless of cost-effectiveness.

In the "Comments" field, 24 statements were received. Nine praised the study's relevance and quality, whereas the others addressed challenges in managing and conducting HTA studies. The key obstacles cited included limited data availability and the incipient culture of evaluating the effectiveness and economic aspects of MDs, which hinders more in-depth analyses and the development of robust clinical studies. The full comments are available in Supplementary Material 3.

Delphi panel

The first round of the Delphi panel was completed by 33 participants, with 13 responses in the second round and 20 in the third round.

Among the 33 participants in the first round, the majority were from the Southeast region (67 percent), most of which were from the São Paulo State. The remaining participants were from the Midwest (21 percent), Northeast (3 percent), and South (9 percent) regions.

There was a predominance of professionals from health sciences and engineering fields. Regarding their professional sector, most respondents worked in hospitals and healthcare services, while some were affiliated with funding agencies and research institutions (Supplementary Material 4).

With respect to professional experience, 30.3 percent reported more than 15 years of experience, whereas another 30.3 percent had between 10 and 15 years of experience. Additionally, 21.2 percent had 5–10 years of experience, 15.2 percent had 3–5 years, and only 3.0 percent had less than 2 years of experience.

Regarding their level of knowledge of HTA involving MDs, the majority of respondents (60.6 percent) reported having substantial knowledge or practical experience in the area. Another 24.3 percent

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Table 2. Responses regarding the degree of importance – survey

Domain	Attributes (N)	Very important (5)	Important (4)	Moderate (3)	Unimportant (2)	Not important (1)	I do not know
Clinical and nonclinical benefits	1	84.3%	13%	1.7%			0.90%
	2	68.7%	27.8%	3.5%			
	3	60%	28.4%	9.6%			2%
Economic evaluation	4	63.5%	27.0%	8.6%	0.9%		
	5	64.4%	30.4%	5.2%			
Innovation	6	51.3%	35.7%	11.2%	0.9%		0.9%
	7	42.1%	36%	19.2%	0.9%	0.9%	0.9%
	8	42.1%	39.5%	15.8%			2.6%
Intrinsic characteristics	9	55.7%	34.8%	7.8%			1.7%
Legal requirements	10	54.4%	34.2%	4.4%	6.1%		0.9%
Social participation	11	47.4%	36%	12.2%	3.5%		0.9%
	12	63.5%	27.8%	7.8%	0.9%		
Implementation	13	65.3%	30.4%	4.3%			

Note: N = sequential number of the attributes as presented in Table 1. Mean percentage of responses – "very important": 58.67 percent; "important": 31.00 percent.

had intermediate knowledge, and 12.1 percent had basic knowledge. Only one respondent reported no knowledge of the subject and therefore terminated his participation.

Most of the responses regarding the importance of the domains were categorized as "very important" (62.28 percent average) or "important" (mean 26.34 percent), as shown in Table 3. The complete list of detailed attributes is available in Supplementary Material 5.

In the open-ended fields for suggestions on indispensable domains for the HTA of MDs, the additional domain "public policy" was proposed. Several challenges were also identified, which were summarized and grouped into five categories, which is presented in Table 4. Supplementary Material 6 provides its detailed information.

Survey considerations

Among the six domains assessed (as shown in Table 2), the overwhelming majority of respondents rated the Likert scale items "very important" or "important," reinforcing the validity of the domains and attributes identified in the literature (10), within the Brazilian

Table 3. Responses regarding the degree of importance – Delphi panel

Domain	Attributes (N)	Not important (1)	Unimportant (2)	Moderate (3)	Important (4)	Very important (5)	I do not know
Clinical benefit	Patient perspective: Clinical outcomes				7.7%	92.3%	
	Impact: Adverse events and tolerability				7.7%	92.3%	
	Clinical purpose of the device			23.1%	30.8%	46.2%	
	Components of the burden of disease				46.2%	53.8%	
	Target patient age group			38.5%	38.5%	23.1%	
Nonclinical benefit	Impact: For the health system and organization			7.7%		92%	
	Adequacy: Target level of care delivery			7.7%	46.2%	46.2%	
Evidence ecosystem	Qualification: Available clinical evidence			5.0%	5.0%	90%	
Economic evaluation	Economics: Dynamic pricing versus scale		5.0%	5.0%	35.0%	55%	
	Business models and contracting		5.0%	10.0%	35.0%	50.0%	
	Competitiveness versus innovation dynamics		5.0%	5.0%	55.0%	35.0%	
	Total cost of ownership		5.0%	15.0%	5.0%	75.0%	
	Direct and indirect costs in the lifecycle		5.0%	10.0%	20.0%	65.0%	
	Allocative efficiency and installed capacity		5.0%	5.0%	25.0%	65.0%	

(*Continued*)

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Table 3. (*Continued*)

Domain	Attributes (N)	Not important (1)	Unimportant (2)	Moderate (3)	Important (4)	Very important (5)	I do not know
Innovation	Assessment of the degree of innovation in the lifecycle		5.0%	20.0%	35.0%	40.0%	
	Type of innovation: incremental or disruptive		5.0%	20.0%	20.0%	55.0%	
	Added therapeutic value X clinical route		5.0%			95.0%	
	Source of innovation (demand or supply)		15.0%	45.0%	25.0%	15.0%	
Intrinsic characteristics	Assessment of the degree of health risk		7.7%	7.7%	15.4%	69.0%	
	Assessment of specific technical requirements			7.7%	46.1%	46.2%	
	Requirements/use: technical and user context			7.7%	23.1%	69.2%	
	Incidents in use: Safety and maintenance			7.7%	7.7%	84.6%	
	Predict investments: Supplementary technology(ies)		7.7%	15.4%	23.1%	53.8%	
Legal requirements	Ethical requirements and promotion of equity		7.7%		15.4%	77.0%	
	Requirements/regulation X regulatory compliance		7.7%		23.1%	69.2%	
	Environmental impact characteristics X risk		7.7%	7.7%		84.6%	
Social participation in decision making	Patient/caregiver participation		3.0%	13.0%	31.0%	50.0%	3.0%
	Involves professionals and managers of use	3.0%		3.0%	34.0%	59.0%	
	Involves professionals/engineering, chemistry, and physics	3.0%			47.0%	50.0%	
	Technical scientific information and database: Exchange and sharing of studies		3.0%	13.0%	25.0%	59.0%	
	Social impact/use X autonomy in life and practice			13.0%	16.0%	71.0%	
	Early assessment X stakeholder guidance	3.0%	3.0%	31.0%	34.0%	28.0%	
Implementation	Solid/adaptive strategy X new technologies			8.0%	0.23	69.0%	
	Necessary financing X operational costs			8.0%	8.0%	85.0%	
	Support organizations to enable adoption			16.0%	38.0%	46.0%	
	Technical assistance parameters/adoption			8.0%	15.0%	77.0%	
	Monitoring and evaluating results			8.0%	15.0%	77.0%	
	Postreimbursement: monitoring + performance				30.0%	70.0%	
	Studies for disreimbursement of technologies			23.0%	54.0%	23.0%	
Budgetary impact	Probabilities of market dynamism	5.0%		5.0%	20.0%	70.0%	
Public policy	Alignment with other SUS public policies				20.0%	80.0%	

context. Although the sample was nonprobabilistic and based on convenience, this approach was justified because of the specificity of the HTA of MDs and required familiarity to provide informed opinions. The sample included professionals from diverse academic backgrounds and all five Brazilian regions.

The domain "clinical and nonclinical outcomes" emerged as the most important component of the HTA of MDs. However, the participants highlighted limitations, such as the scarcity of available evidence and methodological challenges. Additionally, they requested to include a domain addressing the evidence ecosystem, referring to the interconnected processes of generating, synthesizing, disseminating, and using health-related evidence throughout the lifecycle of MDs as real-world data, reports of adverse events and technical complaints, and continuous monitoring of device performance. The relevance of lifecycle monitoring studies and technosurveillance in data collection was emphasized. Such monitoring should encompass the entire device lifecycle, including until technology decommissioning.

Economic evaluation and technology implementation were also highly valued: 60 percent of participants rated them "very important." Also, the additional domain budget impact was proposed.

However, the domains of innovation and social participation showed greater variability in response, suggesting potential disagreement or subjectivity. Table 3 summarizes the comments from

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Table 4. Challenges in the HTA of DMs

Challenges in carrying out HTA studies and managing processes			
	I agree	I disagree	I partially agree
Gaps: Lack of transparency in pricing and information asymmetry	85%	8%	8%
Assessment: Feasibility of addressing the domains in at least some depth	100%		
Lack of participation of technical, scientific, and healthcare professionals	58%		42%
Possible redundancy of specificities in domains of the technology lifecycle	85%		15%
Explicit criteria in HTA, priorities, and transparency in the decision-making process	45%	10%	45%
Challenges mentioned regarding the topic methodological needs			
Guidelines for MD, including hospital HTA, big data, and artificial intelligence	92%		8%
Methods for synthesis and monitoring of MD effectiveness, safety, and postmarket performance	85%		15%
Tools to address heterogeneity, evidence, methods, perspectives, and the need for systems to organize data generated by the device–patient–technical staff interaction, time of use, and performance in the real world	83%		17%
Tools to align technology and clinical need, in the cultural context of application	85%		15%
Challenges mentioned regarding the topic management and governance			
Participation of qualified professionals in HTA, discussion, and deliberation on the reimbursement of technologies is essential	92%		8%
Balanced and adjusted regulation with a continuous qualification program for regulatory agents (Anvisa, among others)	69%		31%
Strategies to encourage collaboration among REBRATS members	92%		8%
Set priorities in HTA*	100%		
Challenges mentioned regarding the topic institutionalization and culture of HTA			
Disseminating the basic culture of HTA and raising awareness among professionals is crucial	100%		
Making HTA studies known and applicable to managers, decision makers, donors, and authorities	100%		
It is essential to expand the application of HTA in health institutions with medium-added value technologies	85%		15%
Bringing to light the reality of health services and the knowledge and culture of HTA applicable to activities involving the reimbursement of medium-added value technologies	92%		8%
Challenges mentioned regarding the topic promotion and new studies			
Promote longitudinal studies with a review of the use of existing devices/equipment	92%		8%
Support for conducting studies based on civil society initiatives	62%		39%
Conduct clinical studies with the local population or a critical comparative view of local versus foreign applications	62%		39%
Activity of HTA agencies in their countries with the assessment of MDs	100%		
Considering the heterogeneity and constant change of MDs, promote ongoing studies that contribute to the synthesis of HTA criteria	85%		15%

Note: *When it was suggested that prioritization should be based on explicit criteria, ensuring greater transparency in the decision-making process, and that prioritization should be conducted by the government, considering the needs of the Brazilian population, the agreement dropped from 100 percent to 45 percent.

the open-ended questions. Although Conitec mechanisms to enhance social participation are relatively recent, there is potential for improvement and broader institutionalization, particularly through strengthened collaboration with partners.

Compared to other domains, the legal requirements domain received a relatively high proportion of "slightly important" responses. Some participants may perceive legal requirements as less critical than clinical or economic factors, although this domain encompasses key elements – that is, regulatory approval by Anvisa is a mandatory prerequisite for HTA submissions to Conitec. Currently, legal requirements are well structured and consolidated, thereby reducing their visibility as a critical concern for those involved in the implementation process. Implementers benefit directly from the outcomes of the regulatory processes without necessarily engaging with their procedural steps or recognizing their inherent complexity.

The comments submitted by the participants emphasized barriers such as decision makers' limited HTA culture, weak integration of postmarket performance data, and underuse of technosurveillance systems. Suggested actions include targeted HTA training, standardized postreimbursement monitoring, and systematic data sharing.

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Delphi panel considerations

Ninety percent of respondents rated five attributes as "very important": two pertaining to the clinical benefits domain, and one of each belonging to nonclinical benefits, evidence ecosystem, and innovation (Table 3). It emphasizes assessing the importance of clinical benefits from the patient's perspective, including the evaluation of comprehensive benefits, adverse events, tolerability and added therapeutic value, and resolution of unmet clinical needs.

The domains clinical benefits, nonclinical benefits, and evidence ecosystem were identified as fundamental for the HTA of MDs. Of note, evidence ecosystem was added from the previous survey phase, covering real-world evidence, adverse event reports, technical complaints, and continuous performance monitoring.

The budget impact domain, first introduced during the survey, was rated "very important" by 70 percent of the participants.

In contrast to the survey results, 77 percent of experts in the Delphi panel gave high importance to the legal requirements domain. The implementation and intrinsic characteristics domains also received strong support, with 63.86 percent of participants rating them as "very important," aligning with survey findings.

The economic evaluation and innovation domains were "very important" for 55 percent of the participants. Within economic evaluation, the market competitiveness dynamics attribute received the lowest rating, with only 35 percent considering it "very important." Similarly, within the innovation domain, only 15 percent rated the "analysis of the source of innovation (demand or supply)" attribute "very important," likely reflecting the experts' low participation in research and innovation funding.

As in the survey, the social participation domain responses displayed high variability, including some ratings of "not important" and "I don't know." This evidences the knowledge gaps, disagreements, or subjectivity in participation mechanisms, as well as limitations in engagement and communication strategies.

During the Delphi process, the public policy domain was introduced, with 80% of responses considering it "very important." This result may reflect perceived misalignments between policies and public programs.

One key finding stood out amid challenges: when participants were asked whether prioritization should be based on explicit criteria to enhance decision-making transparency or whether it should be led by the government according to population needs, the agreement decreased from 100 percent to 45 percent. The comments made by the participants emphasized the importance of balancing government leadership with broader stakeholder engagement in the prioritization process, raising the following concerns:

- Need to accommodate external demands, even if they are in the minority.
- Importance of aligning government priorities with real population needs while ensuring that pressing issues are not overlooked.
- Risk that government-led agenda setting may introduce bias and delay innovation from academic, industry, or clinical actors.
- Role of social participation in strengthening decision-making processes, determined by Brazil's Federal Constitution and embedded in the SUS's bipartite and tripartite governance models.

The highlighted participant comments included the following:

> "I do not agree that the agenda should be strictly defined by the government. While the government may lead most evaluations, other actors should have the opportunity to request assessments of nonprioritized technologies, even if on a limited basis."

> "Public policies may guide government priorities on the basis of population needs, but they do not encompass all relevant problems, many of which demand technology reimbursement to reach underserved groups."

> "Government-defined HTA agendas can strategically address real health challenges and help identify safe, effective, and cost-effective technologies. However, such centralization risks budget-driven bias and resistance to policies that could hinder desirable advances stemming from academic, industrial, or healthcare innovation."

> "Agenda setting should be led by the government, as required by the Constitution, but must also consider seasonal epidemiological trends, market dynamics, and academic knowledge—a crucial link for strengthening this interdependent process."

> "HTA prioritization should follow constitutional principles of social participation and allow for some influence from citizens in selecting technology priorities."

Discussion

The findings of this study reinforce the relevance of key domains for the HTA of MDs, highlighting the patient's clinical outcomes as a cornerstone of decision making. This reiterates the international literature reviewed (10). Indeed, the benefits for patients and the healthcare system, adequate performance and safety during all its useful lifecycle, were quoted by many authors from diverse geographical locations. The inclusion of new domains, such as the evidence ecosystem and budget impact, highlights the need to expand traditional HTA approaches by incorporating real-world evidence, technosurveillance practices, and continuous monitoring throughout the lifecycle of MDs.

Although economic evaluation and innovation are recognized as important domains (11), the present results suggest persistent challenges in establishing clear criteria and in securing the effective participation of specialists, particularly in health economics and the innovation ecosystem. This is a domain also emphasized in the systematic review (10) and currently being integrated into regulatory requirements in various countries, for example Australia (12), and now being initiated in Brazil (13). Of interest, the recent two rounds of Delphi research conducted online in Portugal concluded that the knowledge of costs is fundamental along with the critical aspects of clinical effect, safety, and technical performance (14). In addition, in the Czech Republic, comparing ponderation models and multiple-criteria methods to ascertain hospitals' decision making in purchasing MDs, the authors exemplify the importance of economic evaluation for effective healthcare systems (15).

The variability in perceptions of the social participation domain underscores the need for more structured and transparent mechanisms to include patients, caregivers, healthcare professionals, and civil society in the HTA processes of MDs. Effective strategies may involve: (i) early stakeholder involvement in scoping and prioritization; (ii) patient and caregiver advisory panels to inform evidence interpretation; and (iii) outreach tools to improve understanding and engagement. Strengthening these mechanisms can better align HTA decisions with population needs, enhance legitimacy, and build trust (16). However, from early HTA of MDs (17;18) through the complete one for public healthcare reimbursement (16) or innovation (19;20), there are still challenges in establishing effective mechanisms for the inclusion of patients, caregivers, and health system users.

The introduction of the public policy domain underscores the strategic role of government policies in defining HTA priorities while also revealing the need to balance government leadership

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with external demands and social participation, in line with the principles established in the Brazilian Federal Constitution (21;22). Equity is an important challenge due to the regional geographical differences to consider while deciding which MD the SUS will finance. This finding emphasizes the importance of having explicit and transparent criteria for prioritizing technologies, ensuring alignment with the needs of the Brazilian population without hindering progress in academic, industrial, or clinical innovation (23).

Building on existing knowledge, the systematic review of the literature (10) defined domains for the survey, and the participants evaluated and had additional suggestions and comments. The survey list was improved followed by three incrementally adjusted rounds of the Delphi panel. The completed three sequential methods resulted in the collection of these domains reflecting various stakeholders' perspectives. Therefore, this study presents an original contribution for the HTA of MDs regarding the identification of new domains and attributes, and it highlights challenges and opportunities to improve HTA processes within the Brazilian Unified Health System (SUS). The inclusion of the budget impact and public policy domains as relevant elements was particularly noteworthy in the Brazilian context, since there are financial sustainability concerns for the SUS.

Limitations

This study has several limitations: (1) data collection was conducted exclusively via online forms (survey and Delphi); (2) the sample was predominantly from the Southeast region; and (3) survey dissemination was conducted through social networks with a high concentration of participants linked to hospitals and healthcare services, which may have introduced selection bias.

Owing to these limitations, statistical extrapolations were not feasible. Nonetheless, these constraints highlight opportunities for future research that could adopt complementary data collection methods, more diverse sampling strategies, and broader recruitment efforts using purposive sampling across all regions and actively recruit underrepresented groups.

Conclusion

This study identified and validated relevant domains and attributes for HTA focusing on the reimbursement of MDs in the Brazilian Unified Health System from the perspective of multiple stakeholders involved in the process. Through a combined methodological approach, systematic review, survey, and Delphi panel, we consolidate a set of domains and attributes considered essential for conducting HTA studies in the Brazilian context.

The identified domains and attributes can guide updates to SUS HTA guidelines, inform Conitec deliberations, and be embedded in decision support tools. Integration into professional training and use in procurement planning can improve transparency, consistency, and efficiency in MD reimbursement decisions.

The results emphasized the central importance of clinical outcomes from the patient's perspective, the need for comprehensive assessments considering the efficacy and safety of MDs, but also nonclinical benefits, that is, organizational impacts and health system productivity gains. The inclusion of new domains, evidence ecosystem and budget impact, showed the need to broaden traditional HTA frameworks by incorporating real-world evidence, technosurveillance practices, and lifecycle monitoring of technologies.

The findings of the economic evaluation and innovation domains demand consolidating clear criteria and ensuring the effective engagement of specialists.

The social participation domain indicates the need for greater dissemination, engagement, and participation mechanisms in HTA and decision-making processes. Challenges remain in establishing effective mechanisms for the inclusion of patients, caregivers, and health system users. Overcoming these barriers is crucial for strengthening the transparency, equity, and sustainability of health decisions.

The public policy domain included in the HTA of MDs underscores the strategic role of government for setting priorities while also highlighting the importance of balancing government leadership with external demands and social participation, ensuring alignment with the population's health needs without hindering desirable innovation in academic, industrial, or clinical spheres.

The challenges identified, information gaps, need for more robust synthesis methods, and qualifications of professionals involved in HTA processes highlight the complexity of the HTA of MDs and the pressing need for continuous improvement in practices and guidelines.

To our knowledge, this is the first Brazilian multistakeholder study to validate HTA domains for MDs, integrating a systematic review, a national survey, and a Delphi panel. The results may also be relevant for low- and middle-income countries, as well as for health systems similar to the Brazilian SUS, which face comparable challenges in MD assessment and reimbursement.

In conclusion, this study can contribute to strengthening HTA of MDs in the SUS, emphasizing the importance of a multidisciplinary and participatory approach that considers the specificities of medical technologies and the needs of the Brazilian health system.

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Data availability statement. The complete search results can be made available upon request to the corresponding author.

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