Framework proposal for the collaborative development of a multi criteria assessment for medical and diagnostics devices in Brazil

2023 MAI

ABiMED
Associação Brasileira da Indústria de Tecnologia para Saúde

ABIMED

ABIMED – Brazilian Association of the Health Technology Industry, an entity with 27 years of experience, brings together 200 companies of different sizes and capital sources, which represent around 65% of the market for medical equipment and devices in Brazil. This market is equivalent to approximately 0.6% of the national GDP and generates approximately 100.000 direct jobs. Its core principle is the promotion of a healthy and sustainable environment, conducive to technological innovation and competitive edge of its associates in the local and global markets, whilst contributing to the development of the health sector in Brazil. ABIMED is guided by precepts of ethics and integrity and focuses its efforts on patients, providing the Brazilian population with access to high-tech and innovative health care technologies.

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Presentation

The adequacy and reliability of the usability, clinical and economic evidence used to evaluate and support decisions for the incorporation of medical devices into health care services and systems are objects of an evolving discussions around the world. Given the size of its population, the precepts of the Unified Health System (SUS), as well as its socioeconomic particularities, Brazil has a role to play in the vanguard of said discussions.

To contribute to the qualification of the assessment processes and the incorporation of procedures that involve the use of medical devices in Brazil, ABIMED – Brazilian High-Technology Health Product Industry Association - commissioned this study believing registration, assessment, and decisions on the incorporation of technologies to the SUS and to the List of the National Supplementary Health Agency (ANS) can be prepared with greater technical-scientific rigor, with more transparency, broader social participation and faster. We honestly believe the country can evolve to provide more equitable and fair access to a health care system which promotes the intelligent use of technology, in both public and private care, focusing on the adoption of technologies that grant better correlation of outcomes and costs.

Hence, it is with great satisfaction that we deliver this study to the Academia, the Health Technology Assessment Centers (NATS), the National Commission for the Incorporation of Technologies in the SUS (CONITEC), the Permanent Committee for the Regulation of Health Care of the ANS (COSAÚDE), among other social stakeholders. We believe the adoption and the use of custom-built health technology assessment tools (HTA) for the assessment of medical procedures and devices, as well as deliberations of the most appropriate outcomes for the assessment of such technologies, will considerably contribute to the qualification of HTA processes in Brazil, reducing the time frame for the availability of more effective technologies and new technologies to solve health needs not met by the technology currently available to the population.

The study also highlights the need for companies who manufacture and market medical devices to provide stakeholders with robust and quality evidence in a clear and structured way, generated, whenever possible, in light of the Brazilian reality. However, in this context, it is important to highlight that the specificities in the framework of clinical research of medical devices and the obstacles in conducting clinical research

in Brazil need to be known to all actors involved and interested in the topic, and thus be considered while assessing and incorporating these technologies. Ethical and methodological barriers must be highlighted in order to always provide the best possible evidence, privileging the use of real-world data, vis-à-vis ideal evidence not always feasible due to such specificities.

With this structured study and its with replicable methodologies, we intend to foster dialog, sharing of information and knowledge and mutual collaboration between all stakeholders interested in this topic. We made a point on safeguarding various goals and purposes related to utilization, clinical evidence, costs, budget impact, among others factors. Our intention is to access technologies that deliver greater value to health care services, operators, professionals, technology manufacturers and traders and, ultimately, to patients, thus representing palpable progress from a social standpoint.

The future scenario of health care will be marked by digital transformation and technological advances in the socalled 4th Industrial Revolution. It is vital that the decision-making processes for the incorporation and acquisition of technologies in health care advances towards privileging value-based health care models, aiming at the rationalization of the use of limited resources and, consequently, the sustainability of health care services and systems.

Fernando Silveira Filho
Chief-executive officer at ABIMED

Content

Introduction

In Brazil, according to RDC 579/2021[1] a Medical Device is any instrument, device, equipment, implant, device for in vitro diagnosis, software, consumable or other object intended by the manufacturer to be used on its own or in conjunction, on human beings, for any of the following specific medical purposes:

a) diagnosing, preventing, monitoring, treating (or alleviating) a disease;

b) diagnosing, monitoring, treating, or repairing an injury or impairment;

c) investigation, replacement, alteration of the anatomy or of a physiological or pathological process or state;

d) bear or sustain life;

e) control or support to gestation;

f) provide information through in vitro examination of samples from the human body, including organ and tissue donations;

g) and whose main intended action is not achieved by pharmacological, immunological, or metabolic means in the human body, but which may be aided in their intended action by such means.

Notes: a) active medical devices (equipment) specifically intended for cleaning, disinfecting, or sterilizing medical devices are considered medical devices; b) active medical devices (equipment) indicated for aesthetic correction and beautification purposes are considered medical devices.

It is important to highlight that these medical and diagnostics devices can be categorized in diverse ways, including implantable medical devices, external devices, devices used in surgical or diagnostic procedures, in vitro diagnostics and, more recently, combinations of drugs/devices/diagnostics

which bring even more complexity to the assessment of treatment and attribution of the effect on clinical outcomes. Consequently, the primary applications are diverse, ranging from early detection to action on outcomes, such as predictive tests, screening tests (e.g., endoscopies), diagnostics (MRI, USG, PET), procedures (pacemaker, bariatric, endometriosis), prognostic tests (USG to detect any post-surgical complications), laboratory tests for monitoring purposes or genetic or non-genetic biomarkers as well as software use.

Complexity is also seen in decisions involving the incorporation of new health technologies in healthcare systems. Limited financial resources, existing options, and clinical data, or even the lack of such data, make the decision-making process difficult. The specificities in the assessment of the public health system (SUS) and Health Plans (ANS), especially when considering economic aspects and the population that will be affected by each decision, are factors that demand special attention from evaluators and policy makers. decision.

Given this context, decision makers will always prefer to establish direct evidence proving causal relationships between the device and the outcomes in health. However, many factors can make this goal difficult. In the case of diagnostic technologies, the paths between early diagnosis and the outcomes may involve different decision-makers and more than one exam or complementary exams depending on the chosen medications, which would require significantly large samples of the target population, long-term follow-up and complex research designs. For example, c ollecting direct evidence correlating diagnostic procedures and primary clinical outcomes is complex because usually, the therapeutic device that should have a direct relationship can be influenced by other factors linked to the procedure itself (learning curve, facility, adoption of clinical protocols and therapeutic guidelines), which do not depend on the characteristics of therapeutic medical devices.

Thus, analytical frameworks or clinical journeys are generally used to understand the connection of an intervention with outcomes along a health continuum, as they try to understand a broader view, beyond just focusing on technology, changing the look at the intervention. within health care, considering the various stages of disease progression and the impact of other factors on these outcomes.

As of 2010 there has been an increase in the use of MCDA in health care. This upward trend may have been driven by the emergence and consolidation of HTA agencies across Europe. A growing concern for national and local governments are justifying investment, licensing decisions and the use of MCDA in emerging decision contexts (for example in research and development). The use of MCDA in regulatory decisions arose between the years of 2009 and 2012. It coincides with the publication of the first report by the European Medicines Agency (EMA) in 2010, recognizing MCDA as a quantitative approach conducting risk-benefit assessment processes.[2]

Within this context, the Multiple Criteria Decision Analysis (MCDA) is a tool that allows systematic and explicit consideration of multiple factors that influence decision making, through identified criteria, and named framework, so that a weight is assigned and makes its values and objectives explicit.[3] The MCDA was originally developed for the application in decision-making processes used in different economic sectors and later, adapted the use in the health sector, for it rationally and prudently organizes the multiple criteria involved in this process, promoting: transparency; systematic assessment; consistency of arguments and decisions; higher quality discussions; knowledge transfer/ alignment; interaction between those involved in the decision-making process and a solid basis for decisions.

The use of this methodology in health technology assessment processes promotes the assessment of complex problems based on a comprehensive set of criteria, organizing the discussion among stakeholders, and allowing all to access the same set of information. The organization of this assessment process defines the most relevant and impacting criteria for decision makers, with results that transcend economic issues due to its multi factorial perspective.

This framework proposal will be used in the educational process of ABIMED associates and its main objective is to give room to dialog involving market stakeholders and pave the way for this specific kind of research on medical devices in Brazil.


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Methodology

This practical guide was developed in Brazil, based on the results of a comprehensive qualitative and quantitative survey on the world's best practices in the assessment of medical devices and diagnostic medical devices (described in Table 1) and the consulting with Brazilian health care specialists and professionals **[the document "Incorporation of procedures or medical and diagnostics devices: ABIMED's contributions to the Brazilian health system" (annex 1 of the document) presents the research results in detail]** and in the guides to good practices for the development of MCDA processes for decision-making in health, edited by the International Society for Pharmacoeconomics and Outcomes Research – ISPOR.[4,5]

TABLE 1. References in the assessment of medical devices in the world.

MedTech Europe. Medical Device Industry Position on HTA.2022.
Australian Government. Department of Health. Therapeutic Good Administration. Clinical evidence guidelines for medical devices. Version 3.1, June 2022.
Guía para la Evaluación Clínica de Dispositivos Médicos. Mexico: Secretaría de Salud, Centro Nacional de Excelencia Tecnológica en Salud (CENETEC), 2017.
WHO Global atlas of medical devices 2022. Geneva: World Health Organization; 2022.
Onwudiwe, NC, Charter, R, Gingles, B, et al. Generating Appropriate and Reliable Evidence for Value Assessment of Medical Devices: An ISPOR Medical Devices and Diagnostics Special Interest Group Report. Journal of Medical Devices (ASME Digital Collection) 2022; 16(3):03470110.

Due to the scarcity of references in the area and to avoid loss of content published by health technology assessment entities that only present their guidelines on their website, the search for these references was conducted in a semi-structured and non-systematic way. The following terms were used as search keys: HTA, Medical Devices, Value Based Health Care, Clinical evidence, Value assessment, Clinical evaluation.

This framework proposal for a multi-criteria evaluation of medical devices and diagnoses in Brazil was developed based on results obtained throughout the above mentioned process and sources.


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Selection and structuring of the evaluation criteria

To start the evaluation process and fully and assertively identify the aimed technology, we **developed the proposal for a scope defining basic panel**. Table 2 presents the proposal.

TABLE 2. Proposal for a scope defining basic panel.

Analysis Application*	"Technology name" evaluation process for incorporation into the Brazilian "public OR private" health system
Type of decision	Assessment for inclusion in the reimbursement/coverage system
Characterization of the new technology	Summarize the characteristic of the employed medical technology, considering the following specificities: 1. **Devices** - describe the safety, effectiveness, and efficacy of the device. — Implantable medical devices — Therapeutic devices 2. **Procedures** - describe the safety, effectiveness and efficacy of the device and the conditions for performing the procedure (ambulatory/day hospital/hospital; required infrastructure, medical technique, type of intervention (minimally invasive, open surgery, robotic), surgeon volume, size of the team, specific training, consumable surgery instruments): — Medical device surgically implanted — Therapeutic device used in surgical procedures — Diagnostic device for surgical procedures — Combination of device/drug/diagnostic (such as minimally invasive diagnostic equipment that promotes targeted drug delivery of chemo) 3. **Tests** - describe the safety, effectiveness and efficacy of the test, target population, reference standards, innovation, social and non-clinical impact, fairness, test performance proven through safety and efficacy tests) — Diagnostic device — Combined drug/diagnostic devices (such as insulin pumps/glucose monitors)
Risk Assessment	Which risk class was attributed by ANVISA to the medical device?

TABLE 2. (continued) Proposal for a scope defining basic panel.

Currently covered alternatives	Describe, if any, the alternatives currently financed by the paying source, focused on the assessment.
Recommendation**	Describe the indication for use and the involved technology, considering: — In the case of procedures, what are the existing clinical protocols or guidelines for use, and the devices involved, detailing the ANVISA registration number — In the case of tests, describe the target population, reference standards, innovation, social and non-clinical impact, fairness, test performance proven through safety and efficacy tests — In the case of an implantable medical device, describe its ANVISA registration number and indication for use
Question guiding this assessment	Define the question this assessment wants to answer. Example: Is the use of XXXXXX in the XXXX procedure more effective and/or safer than treatments currently covered by XXX and should it be considered for incorporation into the XXXXX system?

* In the question related to the application of the analysis, the characteristics of the devices must be considered;

** The off-label use can only be proposed by technical areas of the Ministry of Health, as provided for by Law No. 14.313, of March 21, 2022

The next step was the development of a **proposal of domains and basic criteria, based on literature, which would help who develops the content for the assessment process** and those who will conduct the decision process, so that the relevant points for the assessment of medical devices are present in the process.

To organize this proposal for the assessment of medical devices, five domains were created based on what is found in the literature: disease, technology, clinical, economic and value in health and innovation, each with its own evaluation criteria.

The proposed base criteria listed below correspond to the various applications previously mentioned (exams, procedures, orstandalones), as well as the purpose and patient population for which they are used, including clinical and non-clinical variables. **The criterion value in health and innovation was based on the work published by Onwudiwe NC et al., as it is a large ISPOR study to assess the specific health value of medical devices.**

a Medical device for the exclusive use of instruments regulated as medical devices, which is not marketed for individual use and only has a medical application if connected to the instrument, such as software.

All proposed base criteria were characterized according to levels or categories and based on findings in the sources described in Table 1. Each level defined or explained one of the characteristics or values that a criterion could have in relation to the medical/diagnostics device. These levels can be quantitative or qualitative, exclusive, and differentiated within this criterion in relation to the scope of the study; that is, the definition of a criterion at one level or another may reflect a change in decision-making.

Thus, all the criteria identified in the literature for each of the domains listed below were grouped according to their respective level. **Next, a validation process was conducted, based on the publication by Souza AB et al[6] carried out in Brazil, allowing for modification and inclusion of criteria, according to the context of the Brazilian market and health technology under evaluation**. Tables 3 to 7 present the proposed domains (Disease, Technology, Clinical, Economic and Value in Health and Innovation) and corresponding base-criteria.

The proposed domains and base criteria are the result of the study findings, being subject to inclusions and exclusions, depending on the elaborated question, assessed technology, specific assessment process of medical devices that may be published by the Brazilian authorities and the technical group in charge of conducting and interpreting the assessment.

TABLE 3. Proposed domains and base criteria: ILLNESS.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Size of population affected by the disease	— Description of the disease and epidemiology (what it is, how it is diagnosed and progresses, what are its consequences on mortality, morbidity, and quality of life for the patient) — What are the characteristics of the group of patients (subpopulation) that could benefit the most from the proposed intervention? — What is the estimated rate of patients per year that would benefit the most from the proposed intervention?
Treatment protocol	Is there a protocol (national and/or international) for the treatment/diagnosis of this group of patients?
Existence of treatments/ technologies currently incorporated into the health system	— Is there any treatment for the disease? If so, is this treatment covered by the paying source? — If so, what treatments are covered by the paying source? What is the group of patients who could benefit the most from the new treatment/diagnosis currently treated/diagnosed?
Do currently incorporated treatments/ technologies meet the treatment needs?	If so, do the currently covered treatments/ diagnoses meet the patients' needs?
Equity	— Is the disease listed in any official program? Is it considered a priority by the paying source? — Is the disease listed in any official program? Is it considered a priority by the paying source?
Impact on patient life expectancy/lifespan	— How much does the disease impact the patient's life span? — With the progression/lack of control of the disease, what are the main health complications it causes?
Impact on the patient's quality of life	— How much does the disease impact the patient's quality of life? — How severe is the disease? — How much does the disease affect the patient's life? — With the progression/lack of control of the disease, what are the main health complications? — What are consequences of the disease on the patient?

TABLE 3. (continuation) Proposed domains and base criteria: DISEASE.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Economic burden of disease	— What is the resulting economic burden considering direct and indirect (social) costs — How much is currently invested in the treatment of the group of patients who could benefit the most from the proposed intervention? — How does the disease affect patients in their daily activities? — What indirect costs does the disease lead to? Absenteeism, presenteeism, work productivity, caregiver burden, current treatment burden (palliative care or home care, etc.

TABLE 4. Proposed domains and base criteria: TECHNOLOGY.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Clinical Use	Was the clinical use of the medical device established as preventive, diagnostic, therapeutic, rehabilitative or a combination?
Technical specifications	— Is there safety data registered with ANVISA, FDA and EMA? — Was the data made available for the ATS process?
Description of the technology	— What are the characteristics, in addition to those of the technical/engineering development process, of the medical device being assessed? — For what purpose was the medical device created? — How does the medical device work? — Can the medical device substitute another existing device? Is the divestment/deaccession of technologies possible?
Principles of operation or function	— What are the physical means, techniques, procedures, or algorithms used/ performed by this medical device in order to generate an action or reaction in the human body? — Does it require assistance of another technology (for example, medication or software) to achieve its purpose? — Are accessories and consumables needed to make the technology operational (e.g., sensors, equipment, etc.)
Installation / infrastructure	— Does the medical device require any special facilities or conditions for its use? — Does it require internet/communication support?

TABLE 4. (continued) Proposed domains and base criteria: TECHNOLOGY.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Training	— Which health care professional(s) will use the medical device? — Does the use of the medical device require professionals to under go training? — Who will be responsible for providing training?
Maintenance and calibration	What is the maintenance and/or calibration requirements of the medical device once it is installed?
Organizational and non-clinical aspects	— Impact on the health care system – does the implementation of this technology require a change in infrastructure or logistics? — Impact on clinical pathway – is there any operational efficiency benefit such as reduced length of stay, reduced operating room time, reduced resource utilization, or promotion of additional studies with the incorporation of this technology (mainly if in qualified/specialized centers) — Patient and caregiver experience – are there any benefits for caregivers and families in implementing the technology? Will patients have faster diagnosis / treatment, facilitating their therapeutic choice and post-intervention management?

Specifics to assist in the analysis of devices within the TECHNOLOGY domain

ANVISA classifies devices into different classes, and this classification depends on their risks and the invasiveness to the body. The more invasive the medical device, the higher the risk class, as well as the higher the data requirement. This criterion plays a role in the beginning of the assessment process, as it guides decision makers regarding the validity and need for data, including when to apply randomized controlled studies.

The description of the device differs from the description of drugs because it is necessary to mention the following points: indication of use (what is its purpose?); operating principle (how does it work?); elements or parts that constitute it; accessories; consumables and spare parts as appropriate. In this

way, depending on its nature, characteristics such as: sterility, special storage needs and whether the device is disposable or single-use, among others, must be mentioned.

In general, a medical device is designed for the benefit of the patient, however, its scope should not be limited to it and may provide an advantage to the user (doctors, nurses, caregivers, or family members) or even improve a process of the Healthcare System.

With regard to operation and handling, this aspect is not taken into account in medicines, while in medical devices their operation depends on the medical professional for their use in patients, a situation that implies prior training in use and/or application since the efficiency is directly related to the operator and performance depends on it.

Depending on their nature and complexity, some medical devices require special installations (electrical, hydro sanitary, medicinal gases, steam, mechanics, IT, shielding, etc.) and technology management, with traceability procedures, maintenance based on technical-scientific evidence and calibration.

For the use of a medical device, the health professional must be continuously trained for its use to be safe and efficient. Some of this training is audited by the corresponding authority and is sometimes an essential requirement for the service to function within the health care unit. This point is so relevant that even the effectiveness and efficiency in the use of medical devices improve with experience.

TABLE 5. Proposed domains and base criteria: CLINICAL.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Preclinical data	— What preclinical data of the new medical device is available? — Do the preclinical data of the new medical device present relevant information for the decision-making process? — Are there published direct comparison data of the new medical device with what is currently used in the local market?
Definition of comparator	Are there published direct comparison data of the proposed intervention with what is currently used in the local market?

TABLE 5. (continuation) Proposed domains and base criteria: CLINICAL.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Clinical Data - Efficacy	— The clinical data presented demonstrate greater effectiveness (or potential effectiveness), directly or indirectly, of the intervention proposed in relation to currently available procedures? — Are currently available procedures covered by paying sources? — Is the clinical gain provided by the proposed new intervention relevant to the disease being evaluated?
Clinical Data - Safety	— The clinical data presented show greater safety (or potential efficacy), directly or indirectly, of the proposed intervention in relation to currently available treatments? — Does the use of the proposed intervention compromise patient safety in any way? — Do the benefits brought by using the proposed intervention outweigh any undesirable effects?
Clinical experience / Real-life data	— Does clinical experience data (post-market data and real-life data) demonstrate the benefits of the proposed intervention over what already exists in the market? — Are there data on the learning curve* of the medical device? *__Learning curve:__ time invested and/or the number of procedures a health care professional needs to be able to perform a procedure independently and with an adequate result.
Quality of evidence	— Considering the characteristics of the medical device being evaluated and the specificities for medical devices*, is it possible and/or ethical to perform randomized controlled trials? — If conducting randomized controlled studies is not possible, does the medical device have other types of studies that are relevant to demonstrate its efficacy and safety? — Was the analysis of the quality of scientific evidence assessed by GRADE affected by the absence of randomized controlled trials? — Were aspects of the impact of resource use evaluated? — Were clinical experience data (previous criteria) considered in assessing the quality of evidence?

Specifics to assist in the analysis of devices within the CLINICAL domain

The existence of evidence with the same level of quality as the drugs that prove efficacy and effectiveness is scarce, since the performance of randomized controlled studies and, consequently, the availability of systematic reviews and meta-analyses is hampered due to the following situations:

— Conducting blinded studies is often complex and sometimes unethical if it is a sham procedure.
— Randomization is difficult or impossible. Patients are reluctant to participate in these studies due to concerns about being selected for an invasive surgical procedure as opposed to a minimally invasive procedure.
— Existence of learning curves (time invested and/or the number of procedures that a health professional needs to be able to perform a procedure independently and with an adequate result) associated with the use of the device, mainly those intended for surgery, in due to the fact that instead of demonstrating the differences between the procedures themselves, the difference between experience with the old surgical procedure and inexperience with the new process is demonstrated.

Evidence for devices with a higher risk profile should undergo more detailed scrutiny with a greater expectation of direct evidence and/or high-quality clinical investigation data directly related to the expected level of evidence for the risk class of the device. A factor of significant importance is the treatment of devices with limited clinical data. This limitation, which is most often due to ethical issues that prevent devices from undergoing clinical trials in the same way as medical pharmacological devices (impossibility of double-blind testing, for example), must be justified in the assessment request.

TABLE 6. Proposed domains and base criteria: ECONOMIC.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Medical device acquisition costs	— Costs involved in the acquisition of equipment and consumables inherent to the medical device — Is the equipment for purchase or use on loan? — Is there any proposal for dynamic pricing (fluctuation in relation to volume, scale, productivity, etc.)? — What is the total cost of ownership for calculating the lifetime cost of technology, encompassing cost of acquisition, operation, maintenance, training, and replacement. (If relevant to the type of technology) OR Is the device implantable or single-use? How much?
Budget impact	— In the case of lending: how it will work in daily practice with the paying source — Have infrastructure, logistics and training costs been considered? — Will any of these costs be borne by the manufacturer, or will they all come from the paying source?
Cost-effectiveness	— In the case of lending: how it will work in daily practice with the paying source — Have infrastructure, logistics and training costs been considered? — Will any of these costs be borne by the manufacturer, or will they all come from the paying source?
Need for investment in logistics for the health system to absorb the new technology	— What is the need for investment in logistics for the use of the medical device? — Who will make this investment in logistics?
Need for investment in infrastructure for the health system to absorb the new technology	— What is the need for investment in infrastructure for the use of the medical device? — Who will make this investment in infrastructure?
Need for investment in training for the health system to absorb the new technology	— What is the need for investment in training to use the medical device? — Who will make this investment in training?

TABLE 7. Proposed domains and base criteria: VALUE IN HEALTH AND INNOVATION.

Base criteria	Proposal of auxiliary questions to, if relevant, be analyzed within the criteria
Added clinical value	— How does the new device improve performance or outcomes in the care line? — How does the new device fit into the care line? — Does the device replace another treatment? — What part of the care line will become obsolete once the device is on the market?
Economic value added	— How does the new device affect the costs of the course of the procedure? — What are the average care line costs including the new device? — How can the device improve health care delivery and reduce total staff time and/or allocated resources compared to the standard of care?
Value delivery requirements	— Under what circumstances can the new device add value? — How viable and realistic are the preconditions for return on investment, infrastructure adjustments, operator training, logistics, compliance and other items of assessment? — What is the device's potential security, financial, and legal risks?
Environmental impact	Does the new medical device being evaluated have a better or similar environmental impact compared to the comparator?
Innovation	— Does the innovation brought by the medical device have a positive impact on the patient's health? — Does the innovation brought by the medical device have a positive impact on the health system? — Was monitoring of the technological horizon conducted to verify if there are other technologies under development? — What stage of the technological life cycle is the medical device under review?


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Method of evaluation/capture of the decision process

Hierarchical analytical process (AHP)

The methodology used to capture the analysis conducted by decision makers regarding the information presented is called hierarchical analytical process (AHP), where the alternatives are compared in terms of importance of each evaluated criterion. In this method, the participant is presented with a specific scale, directly related to each of the criteria under evaluation.

The *Decision Support Systems Glossary DSS* defines AHP as: an approach to decision making that involves structuring multiple-choice criteria into a hierarchy, analyzing the relative importance of those criteria, comparing alternatives for each criterion, and determining an overall ranking of the alternatives.[7]

The levels/scales proposed in the reviewed articles were adapted within the AHP concept, in order to offer flexibility for grading the individual assessment and avoid targeting the participants.

All proposed scales were developed within the AHP concept, in order to offer flexibility for individual assessment graduation and avoid any direction of the participants.

Weight establishment for the evaluated criteria

Continuing with the application of the AHP, the format for assigning weight to each criteria was established. When developing a performance evaluation, there are several factors to consider, the most important of which is determining how many levels (or points) the rating scale needs to have to be effective.

In the case of evaluations that seek flexibility, as well as generating a situation/ opportunity to obtain greater differentiation between the scores, a scale of 5 points is the most appropriate to achieve this goal. In this way, the scale of 5 points presents enough points to extract significant data in relation to the weight that the participants attribute to each evaluated criterion, in the situation in which the exercise is being applied.

The weight scale used considers 1 least important (low) and 5 the most important (high). Thus, before starting the performance measurement, the evaluators should assign a weight from 1 to 5 for each criteria that will be analyzed.

Tables 8 to 12 present the proposal on how to select the criteria that are adequate to the question and/or technology being evaluated and the weight that each of the selected criteria should have in this specific evaluation process.

The proposed base criteria can be considered or not, as well as new criteria can be added, depending on the question elaborated or the technology evaluated, this decision being part of the evaluation process.
Once the criteria are defined, its weight for the analysis and decision-making process also needs to be defined.

TABLE 8. Selection of base criteria and criterion weight in the decision process: DISEASE.

Base criteria	Should the Criterion be considered in this evaluation process?	For those considered, what should be the weight of the criterion in the decision process
Size of population affected by the disease	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Treatment protocol	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Existence of treatments/ technologies currently incorporated in the health system	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Do currently incorporated treatments/ technologies meet the treatment needs?	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Equity	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Impact on expectancy / patient lifetime	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Impact on the patient's quality of life	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Economic burden of disease	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
INCLUDE relevant additional criteria		1 2 3 4 5 Less important — More important

TABLE 9. Selection of base criteria and criterion weight in the decision process: TECHNOLOGY.

Base criteria	Should the Criterion be considered in this evaluation process?	For those considered, what should be the weight of the criterion in the decision process
Clinical Use	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Technical specifications	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Description of the technology	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Principles of operation or function	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Installation / infrastructure	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Training	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Maintenance and calibration	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
Organizational and non-clinical aspects	☐ Yes ☐ No	1 2 3 4 5 Less important … More important
INCLUDE additional relevant Criteria		1 2 3 4 5 Less important … More important

TABLE 10. Selection of base criteria and criterion weight in the decision process: CLINICAL.

Base criteria	Should the Criterion be considered in this evaluation process?	For those considered, what should be the weight of the criterion in the decision process
Preclinical data	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Definition of comparator	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Clinical Data - Efficacy	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Clinical Data - Safety	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Clinical experience / Real-life data	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Quality of evidence	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
INCLUDE additional relevant Criteria	☐ Yes ☐ No	1 2 3 4 5 Less important — More important

TABLE 11. Selection of base criteria and criterion weight in the decision process: ECONOMIC.

Base criteria	Should the Criterion be considered in this evaluation process?	For those considered, what should be the weight of the criterion in the decision process
Medical device acquisition costs	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Budget impact	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Cost-effectiveness	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Need for investment in logistics for the health system to absorb the new technology	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Need for investment in infrastructure for the health system to absorb the new technology	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Need for investment in training for the health system to absorb the new technology	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
INCLUDE additional relevant Criteria	☐ Yes ☐ No	1 2 3 4 5 Less important — More important

TABLE 12. Selection of base criteria and criterion weight in the decision process: VALUE IN HEALTH AND INNOVATION.

Base criteria	Should the Criterion be considered in this evaluation process?	For those considered, what should be the weight of the criterion in the decision process
Added clinical value	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Economic value added	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Value delivery requirements	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Environmental impact	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
Innovation	☐ Yes ☐ No	1 2 3 4 5 Less important — More important
INCLUDE additional relevant Criteria	☐ Yes ☐ No	1 2 3 4 5 Less important — More important


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Establishing the score for the evaluated criteria

To support the evaluation criteria for the distinct categories to which medical devices are submitted, a source document must be developed, and its results used to provide data in order to meet each of the criteria evaluated in the proposed evaluation exercise.

For the evaluation to take place completely and coherently with the MCDA proposal, the source document must contain the answers to all the questions listed within the domains. This source document serves as a basis for summarizing the results, in the form of a structured and objective summary of each evaluated item, and the complete documentation must be available to the evaluators.

After assigning weight to each criteria, the result of the new medical device is measured against the existing alternatives using an evaluation scale. For this, the criteria evaluated in the exercise were classified into two groups:

NON-COMPARATIVE CRITERIA – Those that generate a graduation of the participants' evaluation, but do not deal with the comparison between alternatives and do not present negative scales.

Example:

3	2	1	0
Proper protocol			There is no protocol

COMPARATIVE CRITERIA – Those that generate a graduation of the participants' evaluation from the comparison of alternatives and present negative scales.

Example:

3	2	1	0	–1	–2	–3
Result(s) superior to comparator			Result(s) similar to comparator			Lower result(s) than the comparator

After the measurement via evaluation scales, the calculations must be aggregated in order to obtain the analysis of the new medical device and the importance and evaluation of the different criteria that involve the process of analysis of medical devices.

Tables 13 to 17 below present a proposed score for each proposed base-criteria, within a specific process for evaluating medical and diagnostics devices in Brazil.

TABLE 13. Scoring proposal for each base criterion established: DISEASE.

Base criteria	Proposal of punctuation
Size of population affected by the disease	3 Ultra rare disease; 2; 1; 0 Common disease
Treatment protocol	3 It exists and is adequate to reality of the update in Brazil; 2 It exists, but need disease; 1 Exists, but does not suitable for reality of the disease in Brazil; 0 Does not exist
Existence of treatments/ technologies currently incorporated in the health system	3 Exist; 2; 1; 0 Does not exist
Currently incorporated treatments/technologies meet the treatment needs	3 Fully meets; 2; 1; 0 Does not attend
Equity	3 Totally neglected; 2; 1; 0 Health system does not neglect the disease
Impact on patient life expectancy/lifespan	3 High impact; 2; 1; 0 No impact
Impact on the patient's quality of life	3 High impact; 2; 1; 0 No impact
Economic burden of disease	3 High economic load; 2; 1; 0 No economic load
INCLUDE additional relevant Criteria	Include scores appropriate to the criteria

TABLE 14. Scoring proposal for each base criterion established: TECHNOLOGY.

Base criteria	Scoring proposal
Clinical Use	3 Established · 2 · 1 · 0 Not established
Technical specifications	3 Fully available data · 2 · 1 · 0 Data not available
Description of the technology	3 Description is enough · 2 · 1 · 0 Not enough description
Principles of operation or function	3 Description is enough · 2 · 1 · 0 Not enough description
Installation/Infrastructure	3 It is not necessary · 2 · 1 · 0 Need a lot
Training	3 It is not necessary · 2 · 1 · 0 Need a lot
Maintenance and calibration	3 It is not necessary · 2 · 1 · 0 Need a lot
Organizational and non-clinical aspects	3 High impact · 2 · 1 · 0 No impact
INCLUDE additional relevant Criteria	Include scores appropriate to the criteria

TABLE 15. Scoring proposal for each base criterion established: CLINICAL.

Base criteria	Scoring proposal
Preclinical data	3 Enough data · 2 · 1 · 0 Not enough data
Definition of comparator	3 Established comparator · 2 · 1 · 0 Comparator not established
Clinical Data - Efficacy	3 Result(s) superior to comparator · 2 · 1 · 0 Result(s) similar to the comparator · –1 · –2 · –3 Lower result(s) than the comparator
Clinical Data - Safety	3 Result(s) superior to comparator · 2 · 1 · 0 Result(s) similar to the comparator · –1 · –2 · –3 Lower result(s) than the comparator
Clinical experience / Real-life data	3 Result(s) superior to comparator · 2 · 1 · 0 Result(s) similar to the comparator · –1 · –2 · –3 Lower result(s) than the comparator
Quality of evidence	3 High · 2 · 1 · 0 Low
INCLUDE additional relevant Criteria	Include scores appropriate to the criteria

TABLE 16. Scoring proposal for each base criterion established: ECONOMIC.

Base criteria	Scoring proposal
Medical device acquisition costs	3 2 1 0 –1 –2 –3 Overall cost(s) lower than comparator … Overall cost(s) similar to comparator … Overall cost(s) greater than comparator
Budget impact	3 2 1 0 –1 –2 –3 Lower budget impact than the comparator … Budget impact similar to comparator … Higher budget impact than comparator
Cost-effectiveness	3 2 1 0 –1 –2 –3 Dominant … Cost-effective … Not cost-effective
Need for investment in logistics for the health system to absorb the new technology	3 2 1 0 High level of payer investment … Low level of payer investment
Need for investment in infrastructure for the health system to absorb the new technology	3 2 1 0 High level of payer investment … Low level of payer investment
Need for investment in training for the health system to absorb the new technology	3 2 1 0 High level of payer investment … Low level of payer investment
INCLUDE additional relevant Criteria	Include scores appropriate to the criteria

TABLE 17. Scoring proposal for each base criterion established: VALUE IN HEALTH AND INNOVATION.

Base criteria	Scoring proposal
Added clinical value	3 2 1 0 –1 –2 –3 Superior to comparator … Similar to comparator … Lower than comparator
Economic value added	3 2 1 0 –1 –2 –3 Superior to comparator … Similar to comparator … Lower than comparator
Value delivery requirements	3 2 1 0 –1 –2 –3 Superior to comparator … Similar to comparator … Lower than comparator
Environmental impact	3 2 1 0 –1 –2 –3 Superior to comparator … Similar to comparator … Lower than comparator
Innovation	3 2 1 0 –1 –2 –3 Superior to comparator … Similar to comparator … Lower than comparator
INCLUDE additional relevant Criteria	Include scores appropriate to the criteria

Aggregation calculations

To arrive at the result of the analysis, the following calculations are performed:

I. Normalized weight of domains: through this calculation, the relative importance of each category per participant was obtained.

$$\frac{\textit{Weight assigned to the category}}{\textit{Sum of assigned weights for all categories}}$$

II. Normalized weight of the criteria: through this calculation, the relative importance of each of the criteria was obtained.

$$\frac{\textit{Weight attributed by criterion* normalized weight of the category of this}}{\textit{criterion Sum of weights attributed to the criteria of the same category}}$$

Value measurement models use additive models to aggregate results. In compositional methods, such as the one used in this exercise, the score obtained in each criterion is multiplied by the weight attributed to each of the evaluated criteria. Thus, the final (or adjusted) score of a criterion will be obtained by the formula:

$$\frac{\textit{Score attributed to the criterion* normalized weight of the criterion}}{\textit{Number of categories evaluated}}$$

Each alternative's criteria score is multiplied by the weights, and the weighted results are then summed to obtain a "total value" for each alternative. Through a joint analysis of the participants' responses, the performance of the alternatives is incorporated into the evaluation function to estimate the value of each criterion or its probability of being the preferred criterion.


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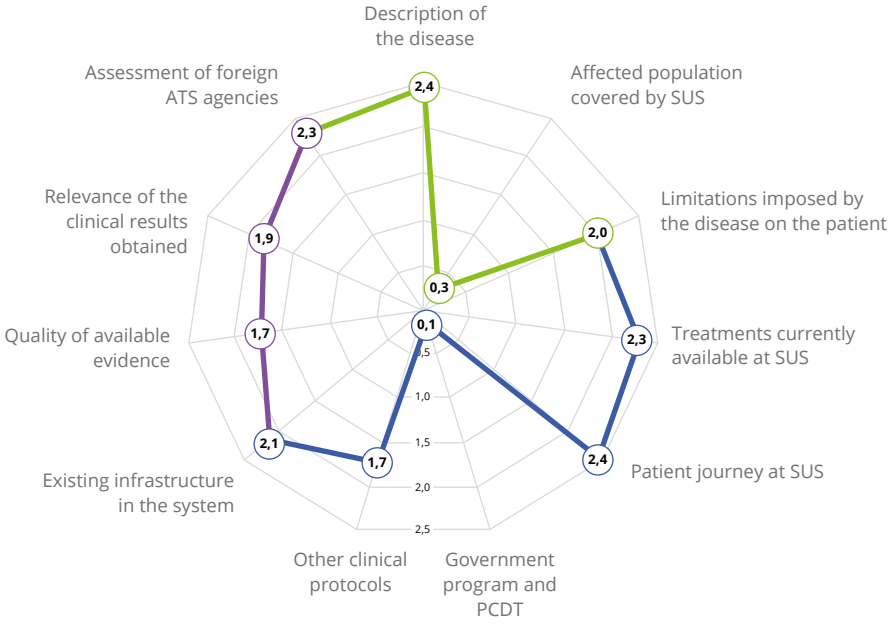
Results presentation

The results obtained after the aggregation calculations can be presented both in the form of tables and figures, the most used being the forest graph and the web graph.

FIGURE 1. Forest graphic example.

FIGURE 2. Web graphic example.



Presenting the statistical results in the form of measures of central tendency and data dispersion allows for an expanded view of the responses obtained. The measures of central tendency used should be average, minimum, and maximum. To measure data dispersion, the standard deviation must also be calculated.

Analysis of uncertainties and use of results

All assessment processes are subject to a degree of uncertainty. The identification and description of possible uncertainties identified and associated with the process are essential for the reliability of the results. The uncertainty associated with the heterogeneity of preferences of the participants involved is mitigated by assigning weights to each alternative.

Promote a discussion with participants before applying the questionnaires to detail and clarify any doubts about the entire process - including the objectives of the process, structuring of the method, data sources used, and data treatment is a fundamental step to guarantee the good application of the MCDA and to obtain well-grounded data.

The objective of the MCDA result is to provide transparency on how each item related to the evaluation process was considered and how the performance of the new medical device compared to what already exists on the market. Thus, it is still up to decision makers, based on the set of data presented, to decide on the incorporation of a new medical device and/or procedure.

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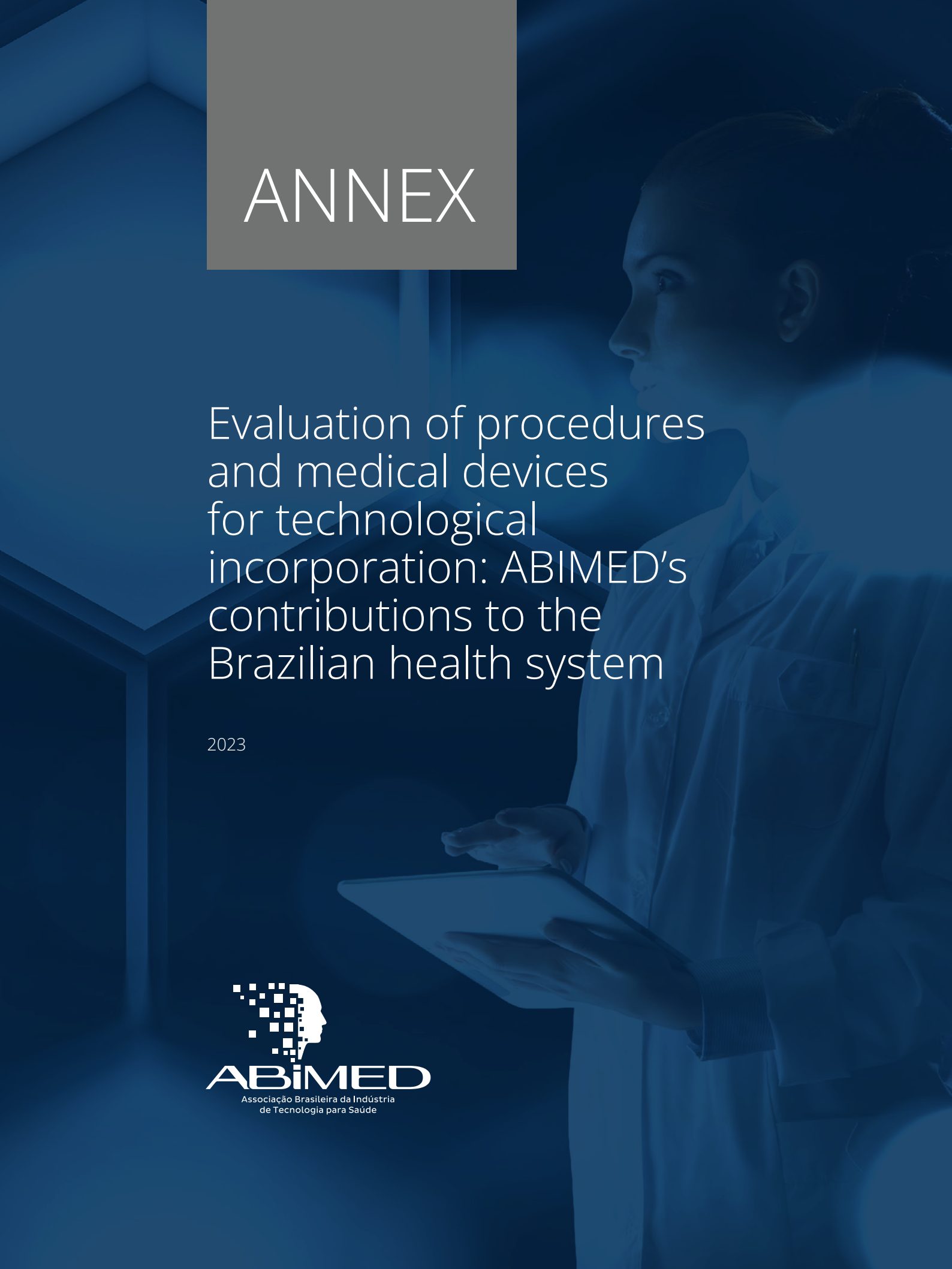
ANNEX

Evaluation of procedures and medical devices for technological incorporation: ABIMED's contributions to the Brazilian health system

2023



ABiMED
Associação Brasileira da Indústria de Tecnologia para Saúde

Content

Abimed Proposals (summary table)

Proposal	Abimed Performance	Actions	Expected outcome
Development of a Good Practice Guide for evaluating procedures and medical devices	Preparation of Proposal framework for the collaborative development of a multi-criteria assessment for medical and diagnostics devices in Brazil.	Search for active participation in forums related to the theme, aiming at dissemination and adoption of the Guide by actors and institutions that conduct HTA in Brazil.	Gain in speed and quality of assessments, allowing the technologies that bring real value to Brazilian patients are incorporated.
Expansion of specific structure and plenary for the discussion of medical procedures and devices	Formal participation in CONITEC and COSAUDE.	Presentation of proposals, technical explanations, providing additional data and answer for these new technologies.	
Fostering the composition and training of teams multidisciplinary teams of evaluators of procedures, medical devices, with technical fluency and a 360° view	Distance Education Program (EAD).	Classes with a theme focused on the evaluation of procedures, medical devices, based on good practices. Articulation with SBEB, Abeclin and SBIS that train professionals in Biomedical, Clinical and Informatics Engineering in Health containing the discipline of ATS.	Increase knowledge of the actors involved in the evaluation and decision process about procedures, medical devices, as well as providing training for professionals duly qualified to perform ATS in medical procedures and devices.
Increase and intensification of dialog between actors and institutions that carry out HTA in Brazil	Organization of seminars and workshops.	Promote the interaction of interested parties, thus allowing the exchange of knowledge and unique perspectives of each actor on the subject.	Increase interaction between the parties and build solutions and a positive agenda for all involved in the events.
Shorten the learning curve time, generating local experience	Promotion actions with companies associated with ABIMED.	Educational and market access activities that generate interest and incentives for the development of real-life studiesand the generation of local experience.	Shorten the distance between new technologies and the local market, especially patients.
Actively participate in the Brazilian digital health strategy in Brazil	Regular schedule with the Ministry of Health, composing a working group	Presentation of proposals and experiences already lived, both in other jurisdictions and in the private health market in Brazil.	Implement the ESD28 plan and, above all, meet the health needs of the Brazilian population.

Purpose of the study

In August 2022, through Decree 11,161, a restructuring of the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC) was determined. With the change, in addition to the Executive Secretariat, three committees: Medicines, Medical Devices and Procedures, and Clinical Protocols and Therapeutic Guidelines. Especially in the case of medical devices, the creation of a specific committee (Medical Devices and Procedures) is undoubtedly a great advance for the evaluation of this type of technology in health. The publication of Ordinance GM/MS No. 4.228/202, which amends Ordinance of Consolidation GM/MS No. 1, of September 28, 2017, defines the new administrative process for the incorporation of health technologies in the Unified Health System - SUS, but does not consider an evaluation process with specific requirements for medical devices.

The generation and analysis of valid scientific evidence are essential to assess the value of medical devices within the scope of the procedures in which they are used. Used, as well as understanding the opportunity costs of resource allocation and determining the impact of the medical device to justify coverage. This need, together with the ethical and methodological specificities inherent in clinical trials for medical devices, as well as significant differences between the dynamics of this market compared to the pharmaceutical market, led to the development of specific health technology assessment guidelines for medical devices in other countries such as Australia and Mexico, and the need of a broad criterion of value in health that can also support the institutional decision-making process of payers[1–3]. At this point, it is important It should be noted that the processes and methods used to evaluate pharmaceutical medical devices do not reliably assess the value of most medical devices[3–6].

The main recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), a scientific entity that brings together specialists in the evaluation of health technologies from around the world, for the evaluation process of a medical device, include the following items presented in summary form[7]:

— Support the use of evidence generation through robust, high-methodological quality real-life studies for medical devices, at all stages of the medical device life cycle, and adapt traditional evidence hierarchies to include real-life data at a higher level appropriate of importance;

— Develop cost-effective methods as part of the medical device development process and further define the applicability of published recommendations for conducting, methodological practices, and reporting cost-effectiveness analyzes for evaluating medical devices[8];

— Develop value-based access programs (sometimes known as "risk-sharing agreements") as a means of supporting the introduction of medical devices with limited evidence at launch;

— Ensuring that evidence generation includes assessment domains other than medicines, including evidence to demonstrate the importance of the learning curve of health care professionals and the impact of the medical device on the organization of patient care;

— Assess the current state of value frameworks to be considered for medical technologies and propose possible best practices for designing a value framework suitable for medical devices.

In Brazil, this scenario of discussions is similar to the rest of the world, and the process of evaluating health technologies has been a reality since the establishment of CITEC in 2008. With the change in 2011 to CONITEC, a formal health technology assessment process still valid today, where medicine, procedures and medical devices are evaluated under the same rules and criteria. This scenario, even with its particularities, is repeated in the evaluation process of the ANS, and the recommendations and decisions taken in the context of CONITEC for the SUS are also used as part of the evaluation parameters in the scope of supplementary health through the analysis of the ANS mandatory coverage list.

The use of CONITEC's opinion by ANS is a fact supported by legislation, since in addition to CONITEC's opinions being public, the supplementary system of health in Brazil, which regulates the activities of private health plans, as its name says and defined in the Brazilian constitution as follows: In Article 197 of the Federal Constitution of 1988, health actions and services are considered of "public relevance, (...) and their execution must be carried out directly or through third parties, and also by individuals or legal entities governed by private law". That same article defines that it is incumbent upon the Government to "regulate, supervise and control" the execution of the health services provided, regardless of the legal nature of the provider.

Given the new organization of CONITEC, and with the aim of collaborating with the process of implementing policies and regulations that provide the population with quick and efficient access to new technologies in medical devices in an ethical business environment, ABIMED conducted a study focused on achieve the following objectives:

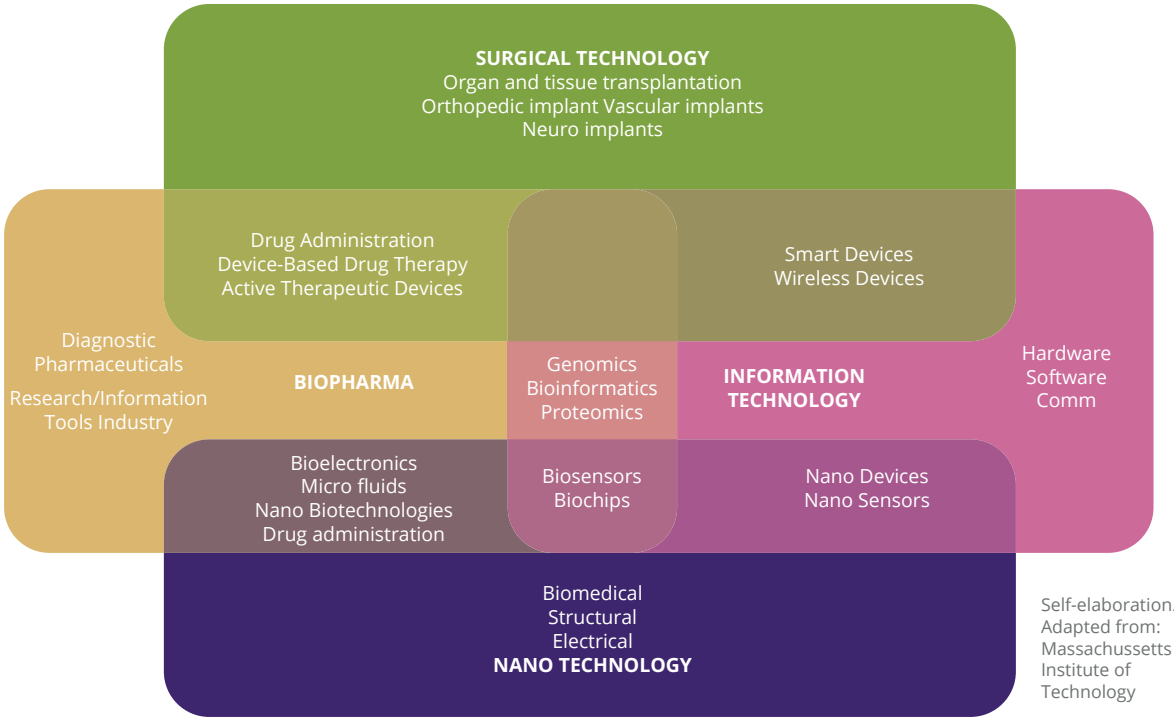
— To analyze how medical devices, as well as the procedures connected to them, in general, are evaluated in Brazil and in the world.
— Understand how the Health Technology Assessment (HTA) methods and procedures currently used in Brazil for procedures and medical devices impact the population's access to technologies, both in the public and private spheres.
— Identify the factors that remain under discussion about incorporation, evaluation and remuneration, their gaps, and opportunities for improvement.
— Exchange knowledge and experiences with other participants in the Brazilian health market.
— Solidify dialog channels with the main actors and institutions that conducts HTA in Brazil.
— Foster and collaborate with the training and qualification of labor specialized in Good Practices of evaluation of health technologies for procedures and medical devices.
— To elaborate a structural proposal for the collaborative development of a multicriteria evaluation for medical and diagnostics devices in Brazil.

Definition of medical devices for health

The convergence revolution happened to the health area in the 2000s. Convergence is the merging of disparate technologies, processing disciplines, or devices into a unified whole that creates a series of new paths and opportunities. It involves bringing together different areas of study – particularly engineering, physical sciences, and life sciences – through collaboration between research groups and the integration of approaches that were originally seen as distinct and potentially contradictory[9].

In the area of health, we also have traditional surgical technology that dates back to the dawn of humanity. The fusion of these technologies had an important impact on the health market, as the technological revolution resulting from this convergence led to the emergence of different health solutions, as shown in Figure 1.

FIGURE 1. Convergence of medical revolutions.



Self-elaboration. Adapted from: Massachussetts Institute of Technology

Therefore, a medical device can be any instrument, apparatus, implement, machine, implant, reagent for in vitro use, software, material or similar article or related, intended by the manufacturer to be used, alone or in combination, for medical purposes[10], its value, within the context in which the medical technology is used, is determined by its ability to meet the needs of patients and caregivers.

The universe of possible solutions to long-standing problems has expanded radically with the convergence revolution.

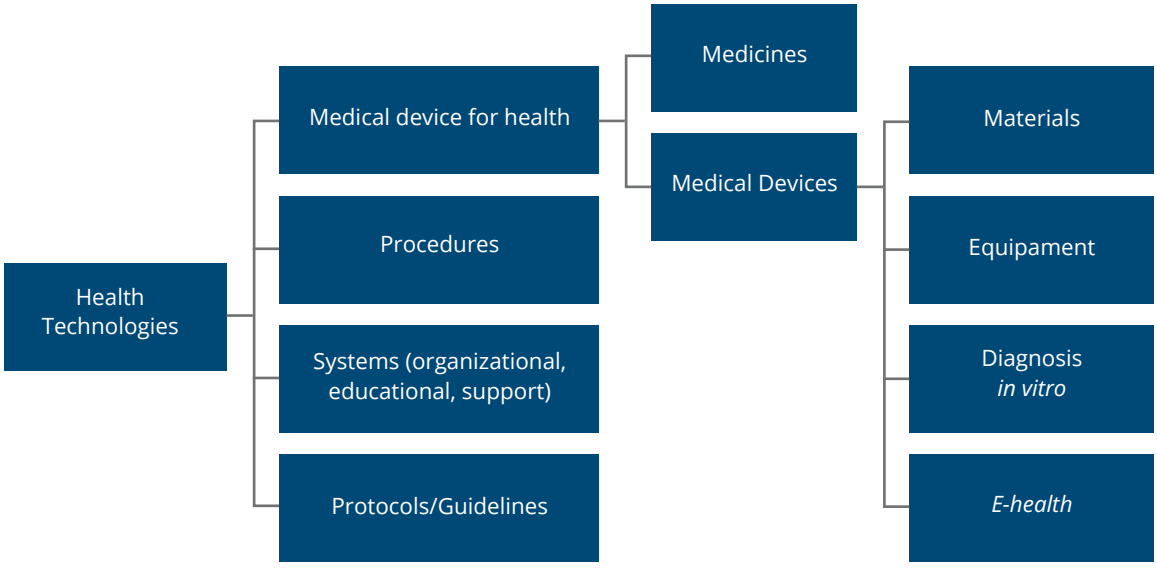
The health environment in the 21st century demands new proposals for health care that are aligned with a market dynamic where the incentive for innovation and its research investments adequately capture the needs, anticipate the vision, pressures and needs of healthcare providers and especially of patients, and how they can influence the incorporation and use of available health technologies.

The concept of medical devices for health encompasses all tools used for the prevention, diagnosis, treatment, monitoring and recovery of diseases and health conditions.

Thus, the definition of medical devices for health includes everything from simple medications such as analgesics to computerized tomography, including disposable gloves, stethoscopes, and prostheses, for example. In order to better organize the understanding of the different medical devices for health, there are categories where we can separate the diverse types of medical devices for health, as shown in Figure 2.

The group of drugs is a unique group within a medical device for health, since to be included in this group the medical device must have a common characteristic among them: they are biologically active, that is, they interact directly through different mechanisms of action (form how the medicine relates to the human body) with the molecules of the human body. Medical devices, on the other hand, act through a physical action on the organism, evaluating a parameter, in the case of diagnostic tests, or repairing the functioning of an organ or tissue, in the case of devices used in procedures for the treatment of diseases. Additionally, the developed software is also about medical devices.

FIGURE 2. Classification of types of health technologies.



Self-elaboration.

Thus, this difference between the mechanisms of action of drugs and medical devices must be observed very carefully. Until the 1990s, medical devices used in medical procedures were called "related" in Brazil, and during this period they were called "medical devices for health" and "medical devices". Recently, following the international movement on the subject, the term "medical devices" is the most appropriate term for these medical devices[11]. Medical devices are still classified by the level of risk they offer - intrinsic risk that the technology represents to the health of the consumer, patient, operator or third parties involved[12]. This classification is generally based on the following characteristics[12,13]:

— Indication/Purpose of use
— Consequences of possible failures
— Use of Associated Technologies
— Duration of contact with the patient
— Degree of invasiveness
— Part of the human body involved

Through the analysis of these data, risk classification is carried out. For example, a stethoscope is a class 1 medical device, low risk, and a coronary stent is a class 4 medical device, maximum risk[12,13].

This classification method is used in many countries, including Brazil, which has its classification rules described in RDC 185/2001, (updated by RDC 751/2022) which establishes the technical regulation for registration, alteration, revalidation, and cancellation of registration of medical devices/medical devices at the National Health Surveillance Agency (ANVISA)[12]. Officially in Brazil there are 4 risk classes, as shown in Table 1.

When a medical device is submitted by the manufacturer to ANVISA, in order to define the type of registration that must be made for the medical device to be legally in Brazil and information requirements, the device is classified into one of the classes described in table 1, of according to its technical characteristics. It should be noted that within the same type of medical device we can have items with different risk classifications.

The risk classification in Brazil is similar to the process that takes place in the United States through the analysis of the *Food and Drug Administration* (FDA) and the *European Medicines Agency* (EMA), the only difference being that the FDA combines the 3 risk classes and 4 in a single class[14].

An important fact to be highlighted is that when a medical device is formally made available on the Brazilian market, it has been compulsorily evaluated and approved by ANVISA and in most cases also by the FDA and/or the *European Medicines Agency* (EMA). Thus, one to three of the most important and reputable agencies in the world, which have well-established and recognized review processes, evaluated the respective device.

TABLE 1. Risk classification of health technologies.[12]

Medical Device/Risk	Class 1 Low risk	Class 2 Medium risk	Class 3 High risk	Class 4 Maximum risk
Non-invasive				
No patient contact or touch	All			
Used for conducting, storing, or transporting body fluids or tissues, liquids or gases for introduction into the body		All		
Modifying the chemical or biological composition of body fluids or other liquids for administration to the body		By filtration, centrifugation, exchange of gases or heat with fluids or liquids	Another medical device	
That contacts the injured skin	Used as a barrier mechanical, for compression or absorption	Intended to act in the micro-environment of the wound and other cases	In wounds that caused the rupture of the dermis and only heal by ulterior motive	

Source: Own elaboration, adapted from RDC 185_2001/ANVISA 11.
Usage times: transitory (less than 60 min.); short term (< 30 days); long term (> 30 days)

TABLE 1. (continued) Risk classification of health technologies.[12]

Medical Device/Risk	Class 1 Low risk	Class 2 Medium risk	Class 3 High risk	Class 4 Maximum risk
Invasive (Medical device that penetrates wholly or partially into the human body, either through a body orifice or through the body surface				
No patient contact or touch	Transitional; Short term in the oral cavity, nose, or external auditory canal	Too short-term medical device; Long term in the oral cavity, nose, or external auditory canal; With connection to class II or higher active medical device	Too long-term medical device	
Surgically invasive medical device for transient use	Reusable (surgical instruments)	Another medical device	Which supplies energy in the form of ionizing radiation; that produces a biological effect or is absorbed by the body; Administering drugs in a potentially dangerous way to the body	For diagnosing, monitoring, or correcting cardiac or central circulatory system dysfunction by direct contact
Short term surgically invasive medical device		Another medical device	Which supplies energy in the form of ionizing radiation; Who undergoes chemical changes in the body or administers medication	Which produces a biological effect or is absorbed by the body; in direct contact with the Central nervous system; Diagnosis, monitoring or correction of cardiac or central circulatory system dysfunction, by direct contact
Long-term implantable or surgically invasive medical device		Placed in the teeth	Another medical device	In direct contact with the heart, central circulatory system, or central nervous system; that produces a biological effect or is absorbed by the body; Who undergoes chemical changes in the body or administers medication

Source: Own elaboration, adapted from RDC 185_2001/ANVISA1.
Usage times: transitory (less than 60 min.); short term (< 30 days); long term (> 30 days)

TABLE 1. (continued) Risk classification of health technologies.[12]

Medical Device/Risk	Class 1 Low risk	Class 2 Medium risk	Class 3 High risk	Class 4 Maximum risk
Active (Any medical device whose operation depends on a source of electrical energy or any other source of power other than that generated by the human body or gravity, and which works by converting this energy. Are not considered active medical devices, medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without causing significant alteration)				
Active medical device for therapy by administering or exchanging energy		Another medical device	Potentially dangerous to the body; generated by ionizing radiation; Active medical device intended to control or monitor Class III active medical devices	
Active medical device for diagnosis or monitoring		By administration of energy to be absorbed by the organism; by image "in-vivo" delivery of radio pharmaceuticals; Other medical devices of vital physiological parameters	Of vital physiological parameters whose variations result in risk to life; by administering ionizing radiation to the body; Active medical device intended to control or monitor Class III active medical devices	
Active medical device intended for administering or extracting body fluids, drugs, or body fluids		Another medical device	Potentially dangerous to the body	
Other active medical devices	All			

Source: Own elaboration, adapted from RDC 185_2001/ANVISA1.
Usage times: transitory (less than 60 min.); short term (< 30 days); long term (> 30 days)

TABLE 1. (continued) Risk classification of health technologies.[12]

Medical Device/Risk	Class 1 Low risk	Class 2 Medium risk	Class 3 High risk	Class 4 Maximum risk
Special Rules				
Medical device incorporating medicine with complementary action in the body				All
Medical device used for contraception or prevention of sexually transmitted diseases			Another medical device	By long-term invasive means
Medical device intended for disinfection, cleaning, washing, or moisturizing		Of other medical technologies	Of contact lenses	
Non-active medical device intended for recording radiographic images		All		
Medical device that uses tissues of animal origin and their inert derivatives				All
Blood bags			All	

Source: Own elaboration, adapted from RDC 185_2001/ANVISA1.
Usage times: transitory (less than 60 min.); short term (< 30 days); long term (> 30 days)

How procedures involving medical devices are currently evaluated within the processes of incorporating health technologies in Brazil

In order for a procedure involving a medical device to be officially covered by paying sources (excluding the patient) in Brazil, there are technical and decision-making processes established and in force in the same format since 2011, with the establishment of the National Commission for Incorporation of Technologies in the Unified Health System (CONITEC)[15]. Recently, changes were made through Law No. 14.313/2022 and Decree No. 11.161/2022, which, despite creating a specific subcommittee for medical devices and procedures, did not define a specific technical rule for their evaluation.

It is worth remembering that the evaluation process for incorporating procedures into the List of the National Supplementary Health Agency (ANS) is based on the same technical guidelines used by CONITEC, including using the commission's opinions as a source of information in the decision-making process for mandatory coverage by health plans[16].

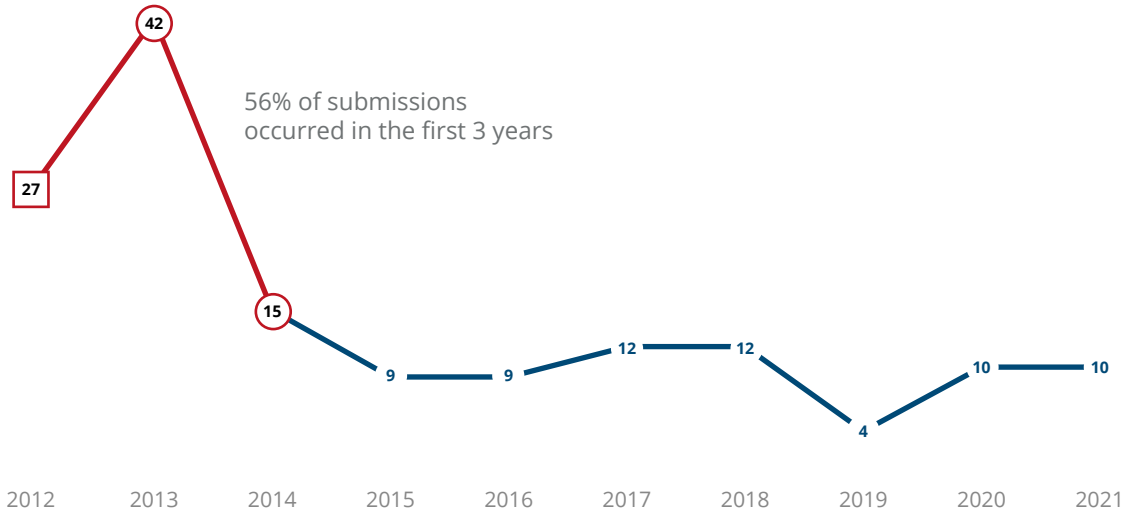
In order to understand how medical devices are currently evaluated in Brazil, an in-depth study was conducted on how the public health system (Brazilian Public Health System – SUS) and Supplementary Health (Health plans regulated by the National Supplementary Health Agency – ANS) specifically performed the medical device evaluation process.

The technical evaluation conducted aims to identify and analyze points for discussion about the HTA processes related to medical devices.

Unified health system (SUS)

In a period of 10 years (2012 to 2022), 56% of the submissions regarding procedures and medical devices made to CONITEC occurred in the initial 3 years. Figure 3 shows the quantitative evolution of submissions from January 2012 to June 2022.

FIGURE 3. Quantitative evolution of submissions analyzed by CONITEC from January 2012 to June 2022.



Over time, the number of submissions analyzed by CONITEC (which exclude health technologies incorporated/covered by lawsuits or other decisions directly conducted by the Ministry of Health) showed a large drop.

[b] National Commission for the Incorporation of Technologies in the SUS

Facts observed in the analysis process of submissions to CONITEC related to medical procedures and devices:

— Only processes that are considered complete are evaluated by CONITEC, that is, submitted with all the information determined as mandatory by CONITEC. Incomplete processes are declared as “non-compliant” and “disqualified”, not even being analyzed.

— It is essential that the form is filled out correctly. Failure to properly complete the form may result in the demand being classified as “non-compliant”, thus, the process will not be sent to CONITEC for technical analysis[17].

— The pertinence and quality of what was delivered are evaluated in a second step. The process of “how” and “what” to submit to CONITEC’s evaluation is described through methodological guidelines publicly available on the CONITEC website[18].

— The analyzes with positive recommendation responses from CONITEC, in general, do not present the details of what motivated the decision since the negative recommendation responses usually have their justifications more detailed.

— A common feature of all submissions discussed within the scope of CONITEC is the decision to recommend, or not to recommend, being directly related to the level of evidence/methodological quality of the clinical data presented. The evaluation of the methodological quality of the scientific evidence submitted to CONITEC only started to be described in documents published from 2019 onwards, and the tools/instruments presented in Table 2 used in the evaluation of the methodological quality of published scientific evidence, depending on the type of evidence, are used for this qualification.

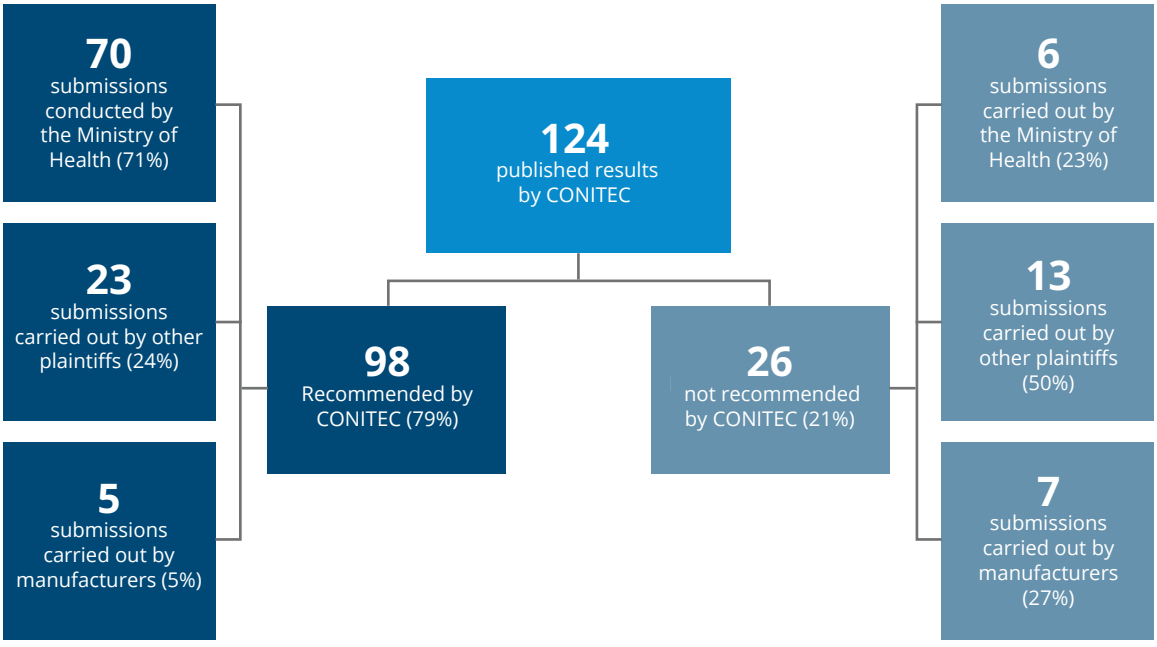
— Since 2019, both the applicant’s submission and CONITEC’s opinion have been available in full on the Commission’s website. In the same year, the opinion became more detailed, offering a broader understanding of the opinion issued.

TABLE 2. Tools / Instruments for assessing the methodological quality of published scientific evidence.

Tool / Instrument	What evaluates
GRID Grading of Recommendations Assessment, Development and Evaluation.	Universal system for grading the quality of evidence and strength of recommendations.
QUADAS Assessment of Diagnostic Accuracy Studies.	Methodological quality of studies to evaluate diagnostic tests.
AMSTAR 2 A Measurement Tool to Assess Systematically Reviews.	Methodological quality of systematic reviews of randomized and non-randomized studies.
ROBINS-I Risk of Bias in Non-randomized Studies – of Interventions	Risk of bias in estimating effectiveness and safety in non-randomized intervention studies.

Over 10 years, medical device manufacturers conducted 12 submission processes to CONITEC, corresponding to 9% of the total analyzed by the commission (124 analyses), with a success rate of 42% (5 positive recommendations). Figure 4 presents a photograph of submissions to CONITEC with results published up to June 2022.

FIGURE 4. Profile of submissions with results published by CONITEC – Procedures, devices.



Own elaboration in Nov./2022

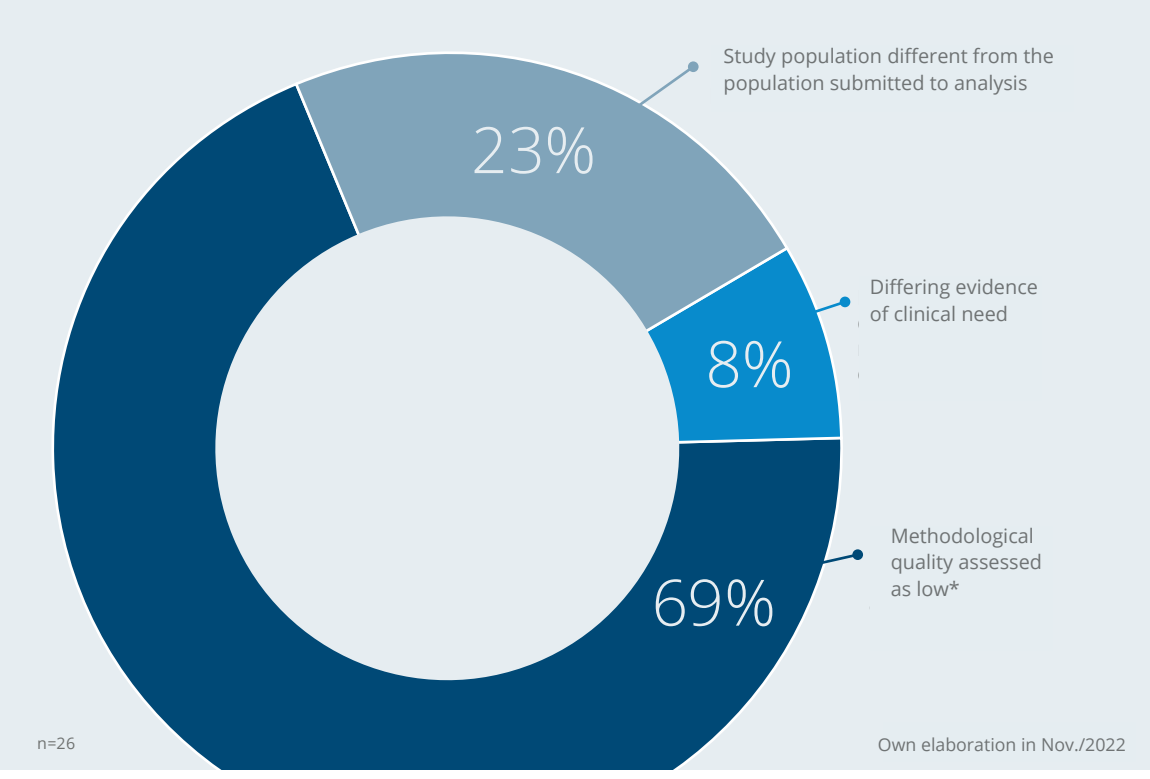
The Ministry of Health is the largest demander of CONITEC evaluations involving any medical device. The Ministry of Health also has the largest number of recommended submissions (71%). A common characteristic of the recommended submissions, especially in relation to diagnostic devices, is their connection with a SUS health/ pharmaceutical assistance program.

All procedures and medical devices analyzed within the scope of CONITEC and with a recommendation for incorporation have the common trait of classifying the available scientific evidence as “moderate”, regardless of the tool/instrument used for analysis.

Most of the procedures and medical devices analyzed within the scope of CONITEC with a negative response to their incorporation, present the classification of the available scientific evidence as “low”, regardless of the tool/instrument used for analysis.

Disagreement between the population studied in the clinical studies presented and the population submitted for analysis were addressed as the main reasons for non-recommendation by CONITEC. Figure 5 presents the reasons for the denials.

TABLE 1. References in the assessment of medical devices in the world.



Regarding the economic studies submitted to demonstrate the investment quality relationship, the classification of the available scientific evidence as low, regardless of the tool/instrument used for analysis, directly affects the interpretation of the results of the models used for analysis of cost-effectiveness of medical procedures and devices. Regardless of the model or result presented. The cost-effectiveness result was not used as a declared parameter to support the decision, whether for recommendation or non-recommendation.

As for the budget impact analyses, which demonstrate the amount of investment required for the incorporation of new procedures and medical devices, the decisions demonstrate a high budget impact in all 124 analyzes conducted, and the reasons for not recommending the investment were also based on the low quality of the scientific evidence. It is worth mentioning that the price that will be paid by the SUS for the new procedures and medical devices are available in the public domain.

When analyzing the number of evaluations of procedures related to medical devices, it may seem that little is produced in this area of evaluation. Access and adoption of health technologies in Brazil, in addition to the processes carried out by CONITEC and ANS, can still happen through legal demands, based on the constitutional right to health[19], as well as by individual decision of public hospitals through their Centers of Health Technology Assessment (NATS)[20], with funding coming from alternative funding sources to direct reimbursement from the SUS. In these cases, tracking of these individual decisions is not performed.

Supplementary health

In 2019, the National Supplementary Health Agency (ANS) determined an important change in the system for evaluating and incorporating new procedures into the list of mandatory coverage by health plans operating in Brazil. This change established more elaborate rules for the submission of proposals, including eliminating proposals that did not meet the established requirements at the time of entry.

Both the submitted processes and the analyzes by COSAUDE and the technical teams that evaluated the documents also become public, thus providing the opportunity for us to evaluate in more depth the flow and results of the submissions.

Out of a total of 671 submissions made to the ANS in 2019 (with the change in Law No. 14,307, of March 3, 2022[21], processes are now submitted in a continuous), only 231 (34%) completely completed the entire submission form.

After this first filtering of the process, a second analysis was conducted to verify the eligibility of the submitted proposals, where only 63 (27%) of the 231 proposals were considered to meet the eligibility criteria set forth in RN 439/2018. Figure 6 shows the reasons for ineligibility presented by the ANS[22]. The procedures considered eligible by the ANS went on to complete evaluation. Figure 7 shows a photograph of submissions to the ANS ROL with results published up to 2021.

FIGURE 6. Reasons for ineligibility - ANS List 2021.

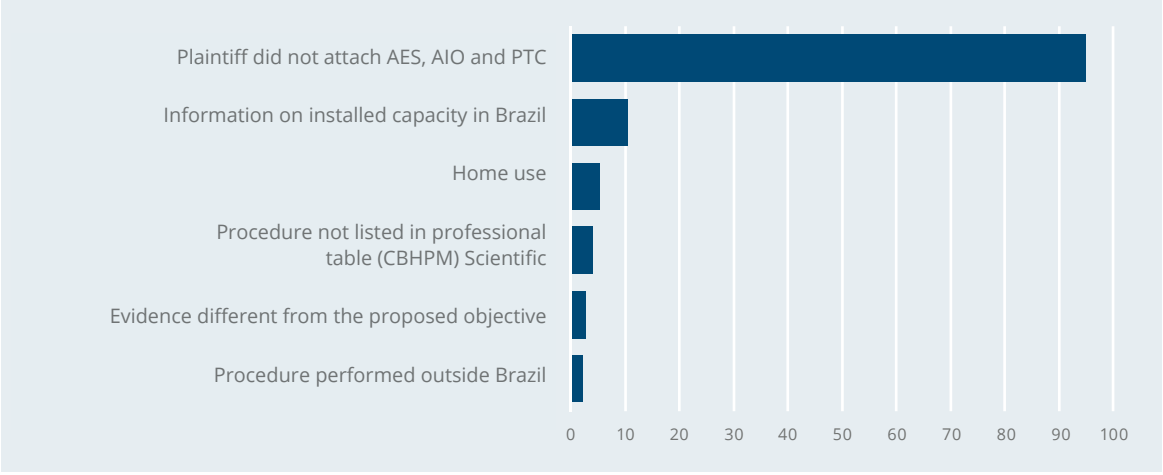
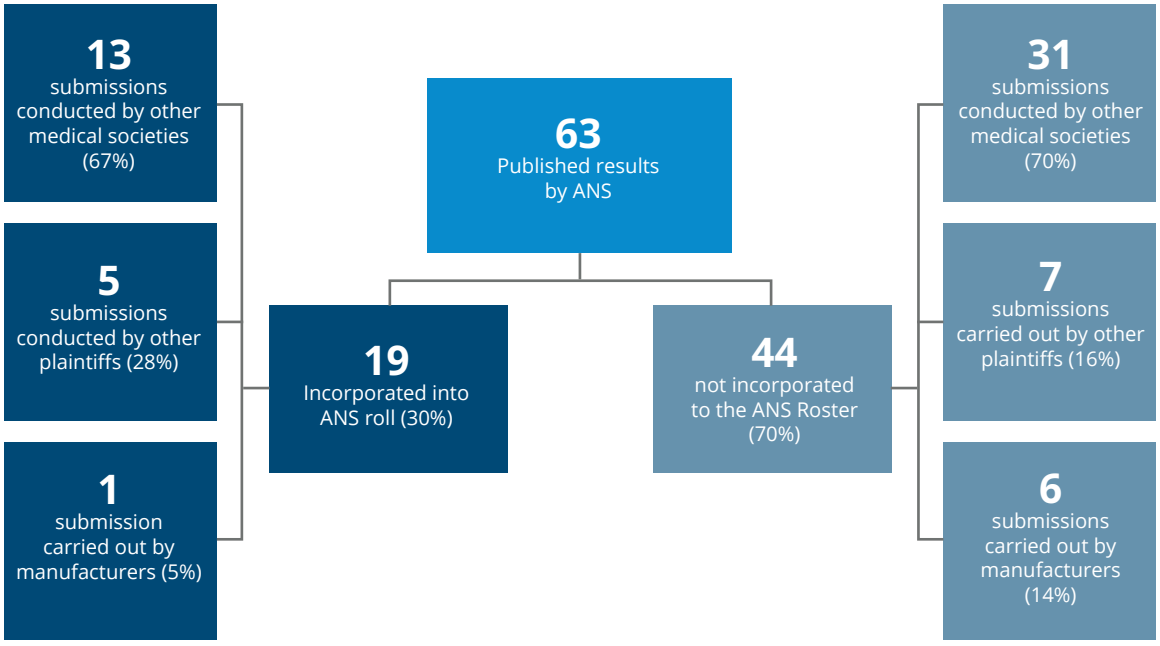


FIGURE 7. Profile of submissions with results published by ANS - Procedures, provisions (ROL 2020/2021).

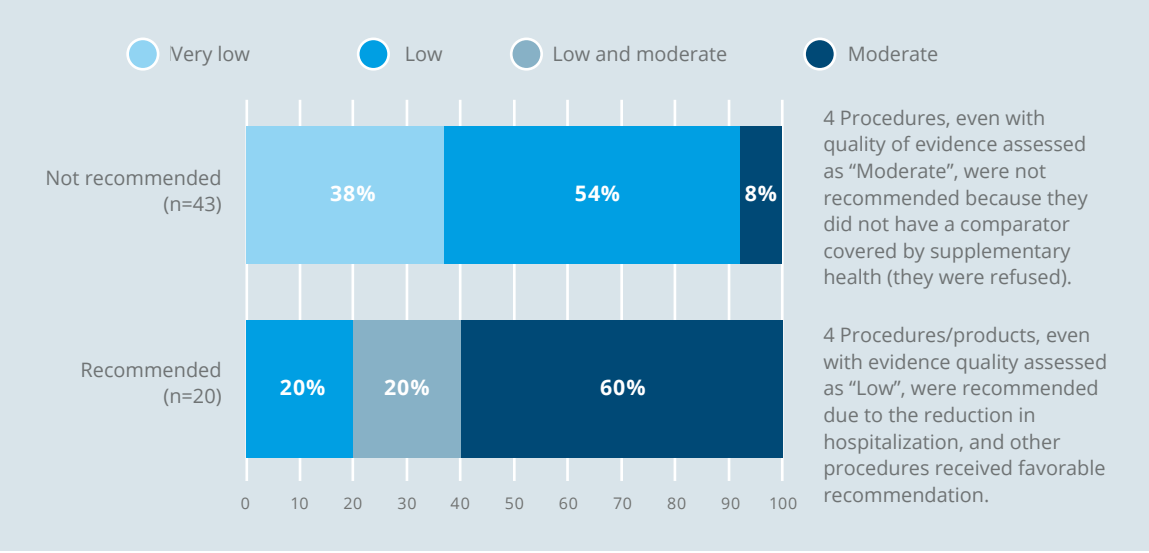


Own elaboration in Nov./2022

Medical Societies, as they are the users of medical devices in conducting procedures and diagnoses, are the largest group that demand ANS assessments involving a medical procedure/device. The evaluation of the methodological quality of the scientific evidence submitted to the ANS List also uses the tools/instruments presented in Table 1. In addition, depending on the type of evidence presented, the tool/instrument that best fits the qualification required for the analysis of the evidence is applied.

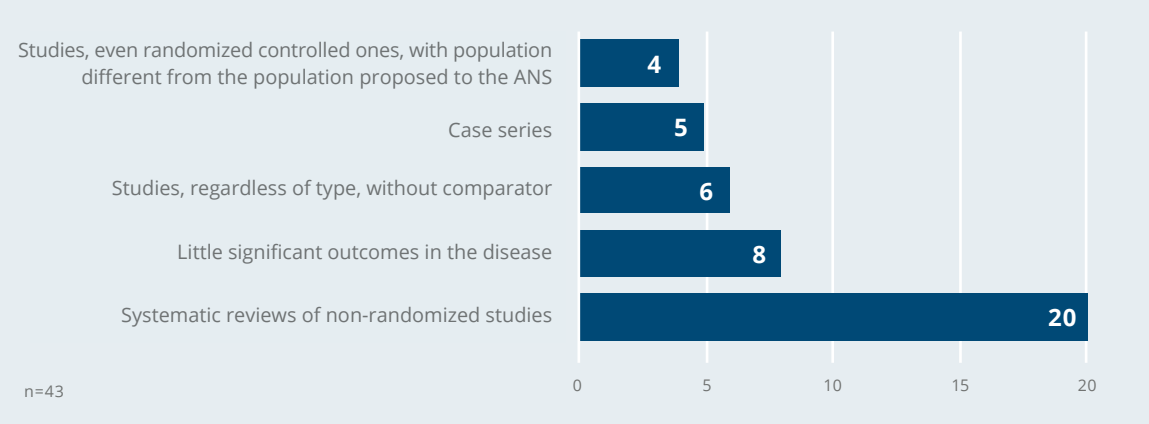
In the processes analyzed by the ANS, as well as at CONITEC, there is also a great discussion about the quantity and quality of clinical studies for medical devices, with 70% of the evaluated medical procedures/devices having the quality of the available evidence evaluated as “low” It is “very low”. Figure 8 presents a summary of the quality of evidence as stated in the analyzes published by the ANS.

FIGURE 8. Quality of evidence as stated in analyzes published by ANS (2020-2021).



The justifications for classifying the evidence presented as "low" and "very low" demonstrate a large concentration of procedures that, despite having systematic reviews, included non-randomized studies. Figure 9 presents an extract of what was considered "low" and "very low" evidence.

FIGURE 9. Justification for considering the evidence as "low" and "very low" (n=43).

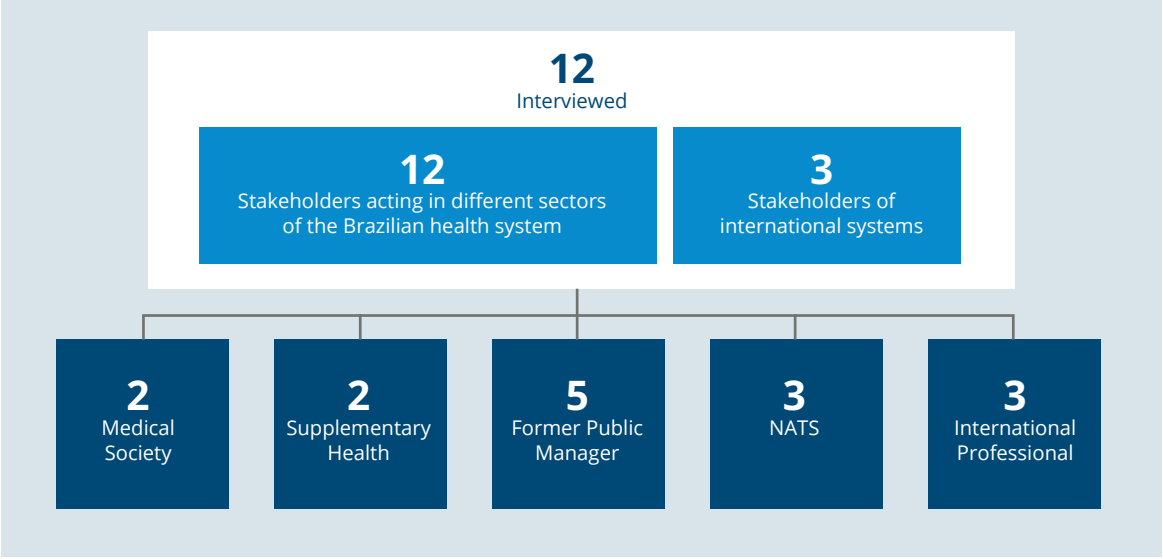


In the case of supplementary health, also when analyzing the number of evaluations of procedures related to medical devices, it may seem like a small number, but it is important to highlight that the ANS List represents the list of procedures with mandatory coverage by health plans, and coverage can still happen through legal demands as well as by individual decision of private hospitals and health plans. In these cases, the tracking of these individual decisions is not made available in the public domain.

Needs, visions and recommendations on the process of analysis of medical procedures and devices - opinion of the participants of the Brazilian health market

In order to expand the observational field of this study beyond secondary data, qualitative research was carried out with local and international specialists, active in the Brazilian health market for at least 15 years and with experience in the decision-making process and/or elaboration of analyzes from ATS to understanding and qualitative mapping of the needs, visions and recommendations for the discussion of a local process for the evaluation of medical procedures and devices.

FIGURE 10. Presents the profile of the experts interviewed.



The interviews were conducted between July 6 and 22, 2022 via ZOOM platform.

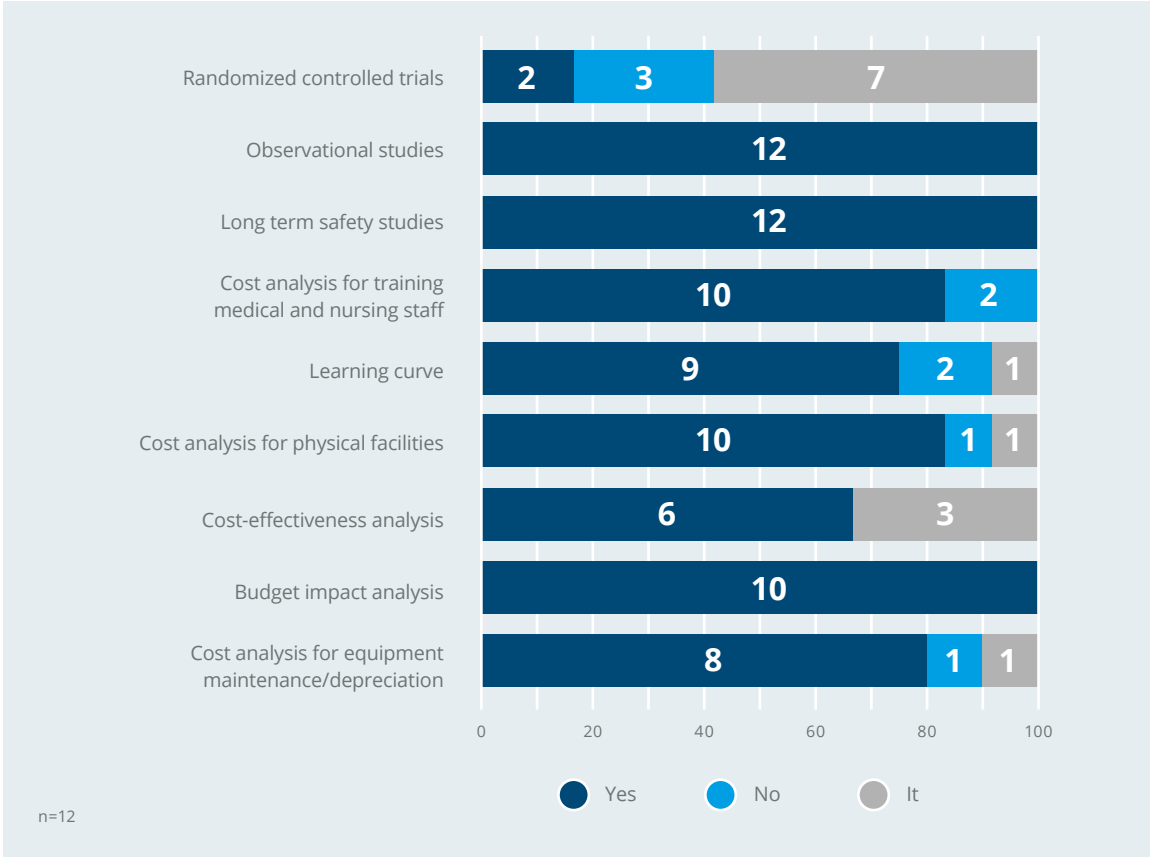
To obtain the answers of the interviewees, the research was structured in two stages.

Step 1
Individual interviews based on a semi-structured script

Step 2
Workshop for presentation of findings and validation of initial ABIMED proposals

As a result of the survey, three key points were analyzed and determined to be of significant importance by the participants.

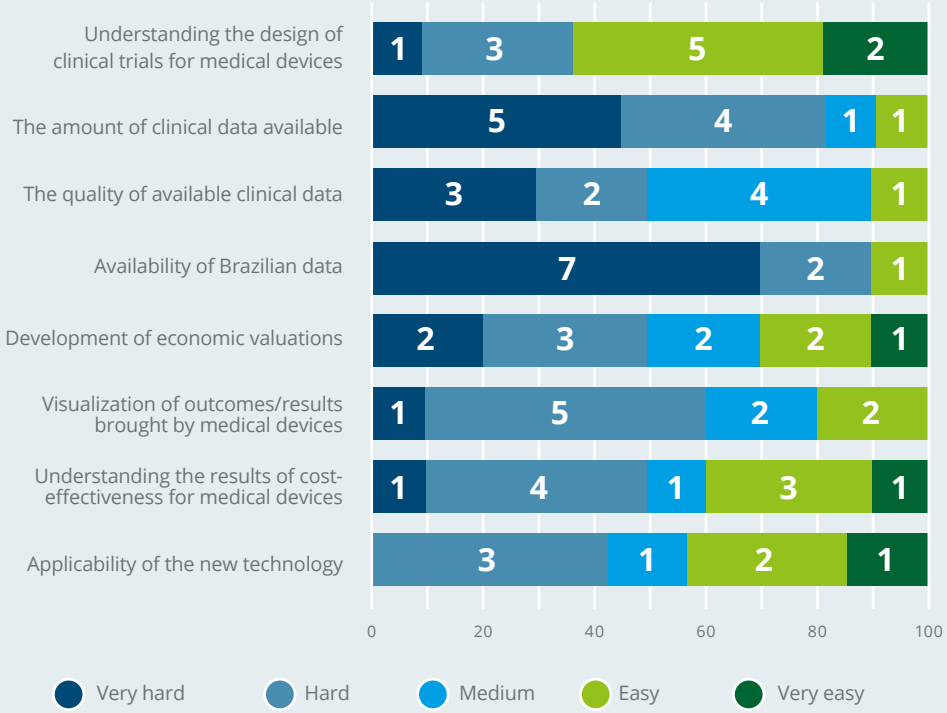
1. What a procedure and medical device must present to be evaluated



The item Randomized Studies is the one that opens the most room for discussions regarding the need for specific evaluations and when it is absolutely necessary. At the same time, there is a consensus on the pertinence of including Observational Studies, Long-Term Safety Studies, and Budget Impact Analysis.

Cost-effectiveness analyzes are considered necessary, but bring reservations as to how they should be performed for medical procedures and devices. It was agreed that the proper evaluation of procedures and medical devices should use a multi-criteria format, including additional or even differentiated information from what is done in the medication evaluation process.

2. Level of difficulty in the evaluation process for incorporating a procedure and medical device

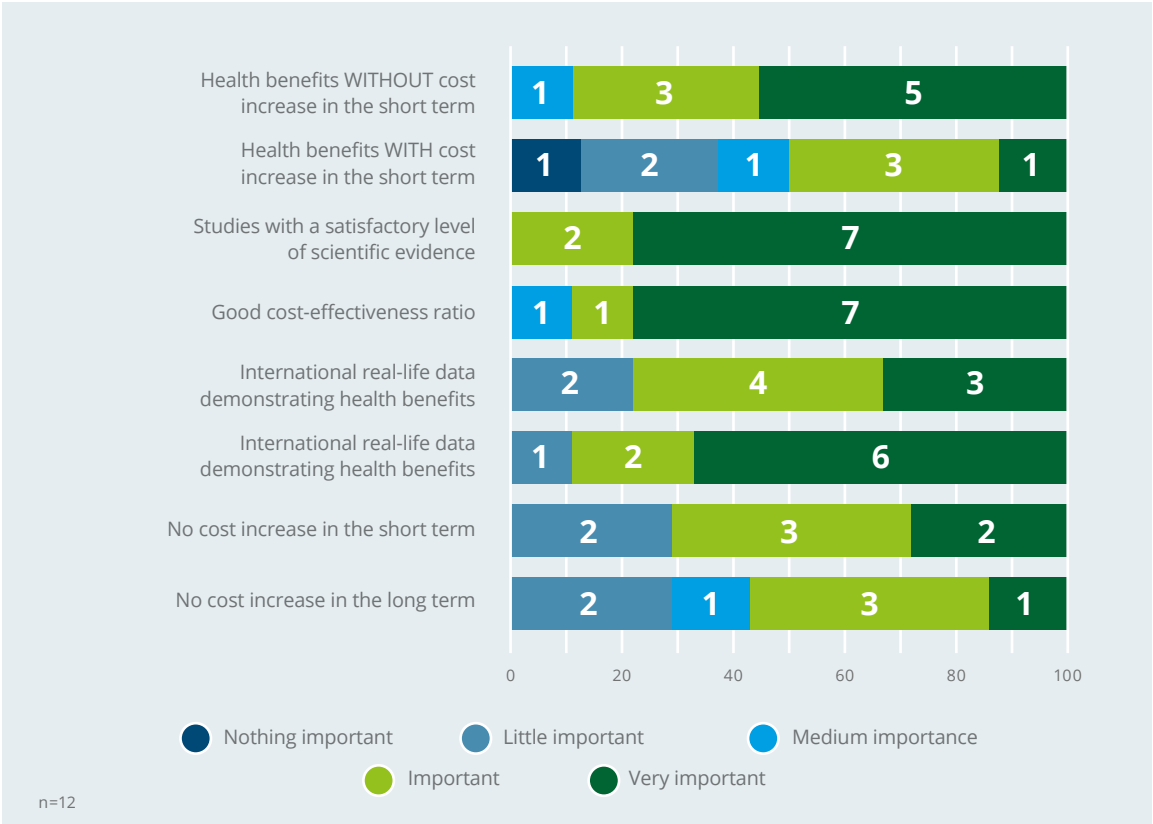


n=12

In general, a significant barrier to the evaluation process of a procedure and medical device refers to a significant difficulty in understanding the quality and quantity of the clinical data presented, which is directly related to the design of the studies.

The availability of local data on the results of the new technology in the Brazilian health environment has a special impact on decision-making processes.

3. Key factors for the incorporation of a medical device and procedure



All evaluated items were classified as important for the procedure. During the discussion process, the need to apply an analysis process was presented where various aspects inherent to the need to assess the future impact of the procedure and medical device need to be considered.

In this context, the concept of **(Value-Based Heath care – VBHC)** emerged spontaneously during the discussion, applied as an auxiliary form in the process of evaluating and incorporating a procedure and medical device.

Conducting this research brought about the need for a more in-depth and different look at procedures involving medical devices as something real and desired by market participants.

As an exercise in the search for solutions that were necessary and feasible, the interviewees were asked to determine the ideal scenario for the evaluation of procedures involving medical devices, being "appointed" as responsible for necessary changes and adjustments. As a result of this exercise, the participants elaborated the following proposals:

— Form multidisciplinary teams of specialists, where the evaluation does not pass only by a single technician (doctors, economists, methodologists, statisticians, information engineering, epidemiologists, clinical engineers, biomedical engineers, pharmacists, nurses, physiotherapists, among others) – **Cited as the main barrier**.

— Create legal mechanisms for meeting all parties involved in the process for dialog, discussion and development of the best methodologies, standardization and classification of devices;

— Develop a structure designed exclusively for procedures and devices within CONITEC, with a multidisciplinary and plenary evaluation team specific to devices;

— Reassess and adapt the criteria, guidelines, and processes for evaluating procedures and devices;

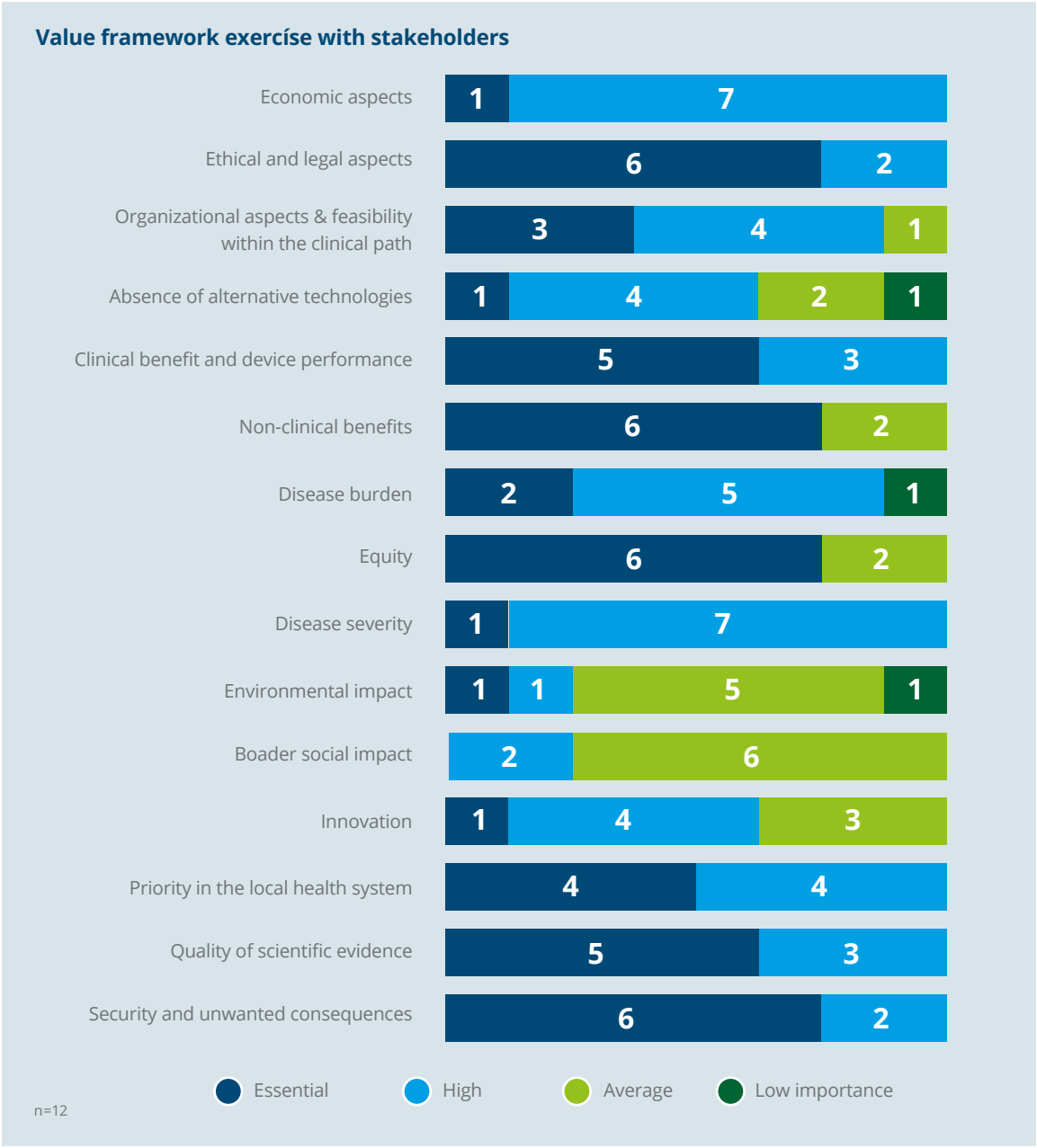
— Train / Recycle the knowledge of specialists/professionals involved in the evaluation of procedures and devices.

As part of this same exercise, we propose the analysis of a local *"Value Framework"* to support the evaluation process of a medical procedure/device.

Value Frameworks represent tools and approaches that use clinical evidence, real-life data and data not published in traditional literature, along with patient-reported outcomes and economic modelling, where applicable, to measure the value of different healthcare technologies. For value structures to be meaningful, health professionals or decision-makers must evaluate the totality of the evidence in conjunction with other tools and resources[23].

During the exercise, the specialists were invited to participate in an exercise where they listed as: essential, high, medium and low importance a list of criteria originally published by Augustovski F et al.[24], which proposes a value framework *(Value Framework)* to be applied in Latin America, where a broad group of experts from the region was invited to participate in the formation of these criteria: academia, hospitals, patients, public and private health managers and specialists in ATS. Figure 11 presents the results obtained from the presentation of the list of criteria to Brazilian specialists.

FIGURE 11. Results of value framework exercise with local experts.



The following criteria were determined to be essential in the assessment for most participants:

— Ethical and legal aspects
— Clinical benefit and device performance
— Non-clinical benefits
— Equity
— Quality of scientific evidence
— Security and unwanted consequences

For a broader view of the results, we delineated two large groups (without statistical significance) from the profile of respondents to verify the potential difference in the view of those who decide and those who evaluate: “Manager Profile” and “Technical Profile.” Figure 12 and Figure 13 show these results.

FIGURE 12. Results of the value structure exercise - Manager Profile.

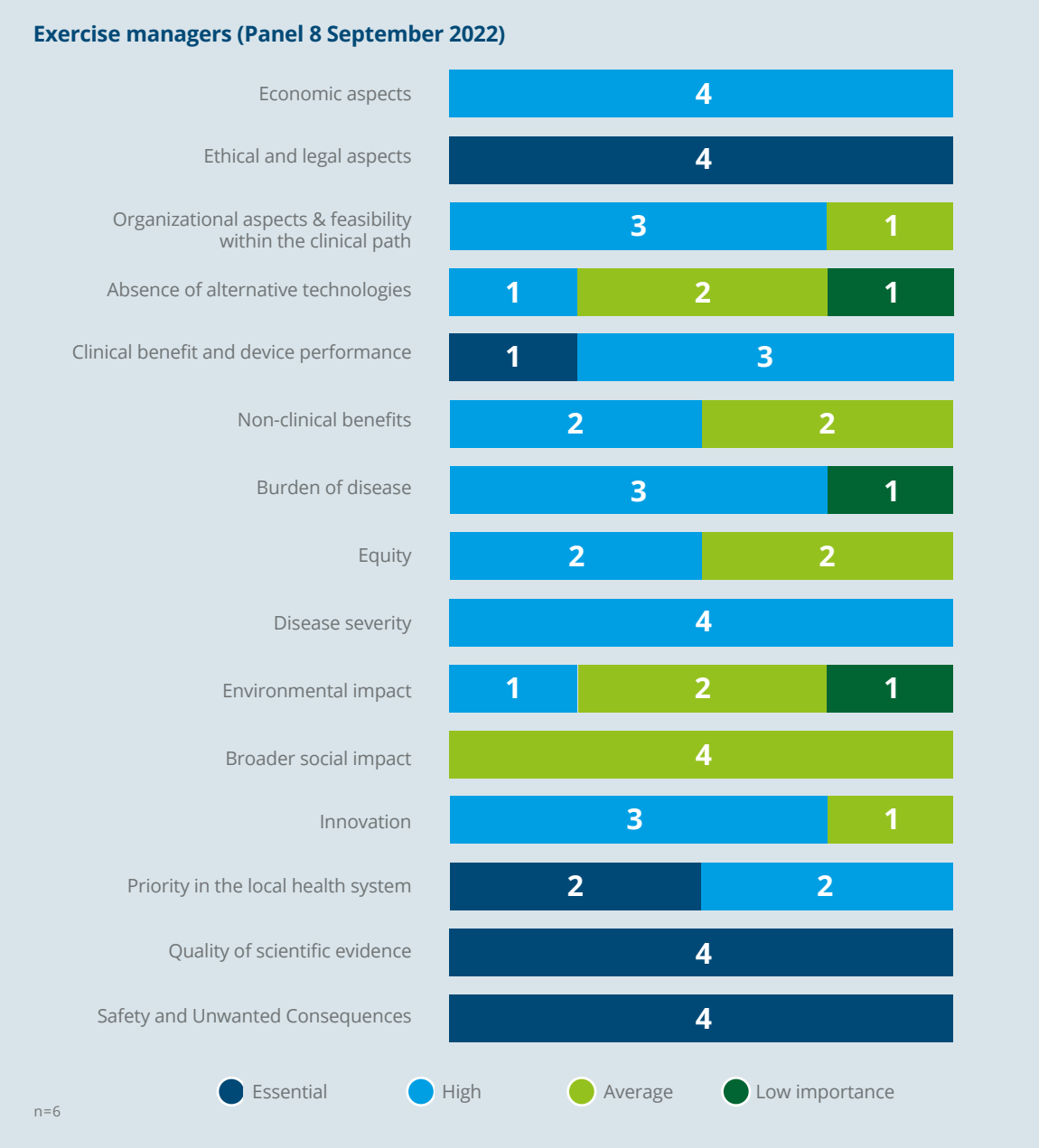
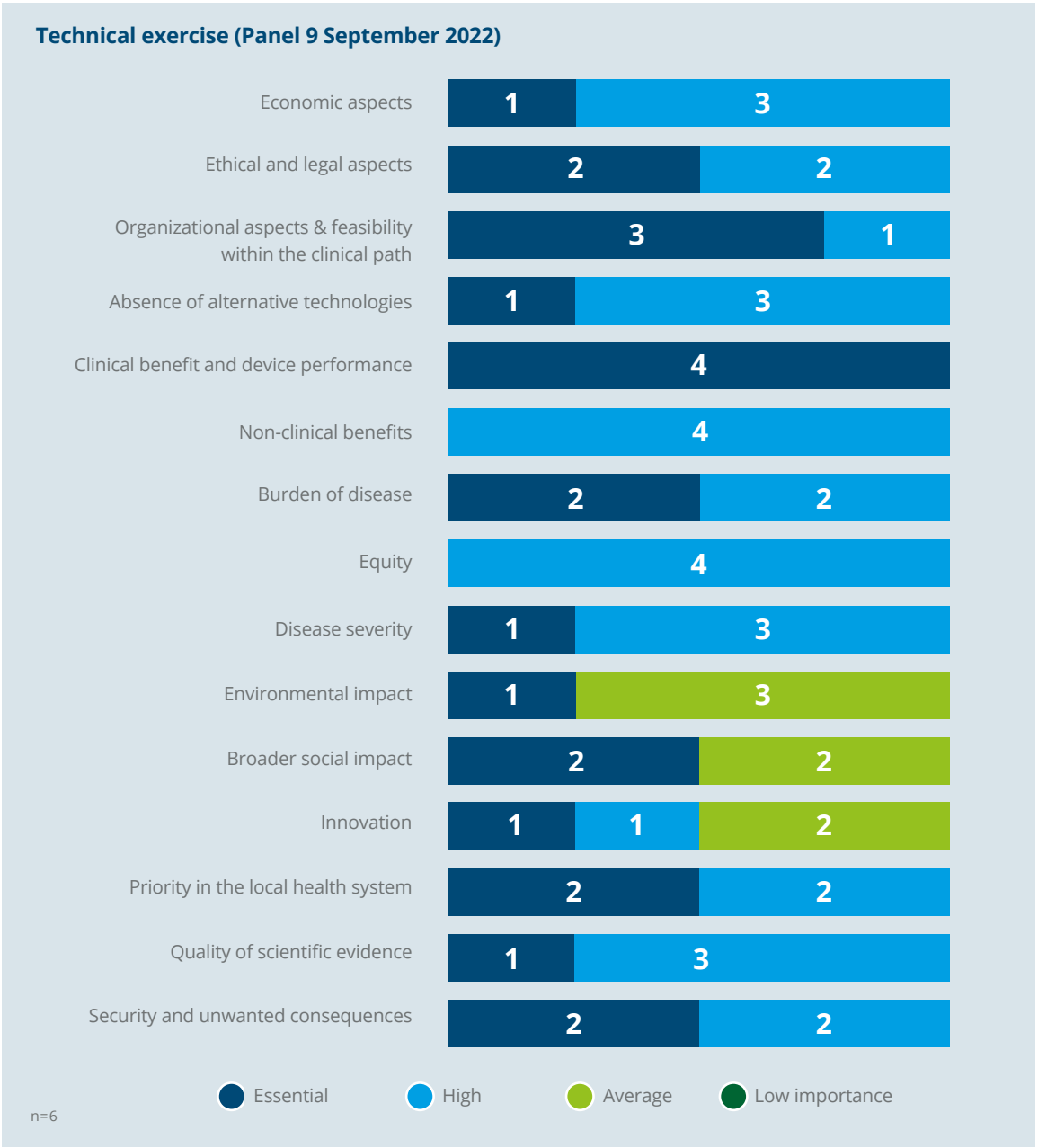


FIGURE 13. Results of the Value Structure Exercise – Technical Profile.



It is noted that when segmented by “technical profile” and “manager profile”, the degree of importance of some requirements changes significantly, that is, each group has different tendencies for the evaluation so that the “manager profile” transits between evaluations considered from essential to low, among the attributes presented, while the “technical profile” focuses on evaluating practically all attributes as essential to high importance, with only the attributes appearing: environmental impact, broader social impact and innovation with some mentions of medium importance.

This exercise shows us that technicians tend to be more demanding, as well as highlighting the need to equalize concepts, terms, and importance in a consensual manner between managers and technicians so that everyone “speaks the same language”, thus avoiding damage to evaluations. In this way, the development of a glossary/dictionaries of terms common to all would bring a huge gain to the dialogue between market participants.

How the evaluation process for medical procedures and devices is being defined around the world

The analysis of the current scenario of the evaluation process of medical procedures and devices demonstrates that in Brazil, as well as in the rest of the world, there is a latent need to define how an evaluation process of these health technologies will be built with the interaction between all the market participants.

The difficulties faced in the analysis of medical procedures and devices (when compared to the volume of medication evaluations) are not exclusive to the Brazilian health market, and different initiatives for dialogue and construction of technology evaluation processes, considering the peculiarities inherent to the procedures and medical devices, have emerged in recent years around the world.

In order to increase knowledge and understanding about the process for incorporating medical procedures/devices, a broad search was conducted in the literature and websites of international entities related to the subject. The most recent initiatives on the subject are described below.

There are already specific processes for the incorporation of medical procedures/devices

Medical devices, while effectively responding to the growing needs of the population in terms of treatment and diagnosis of diseases, need to go through evaluation and decision-making processes capable of considering a wide range of criteria, such as: value clinical, safety, potential and operational effectiveness, economic and organizational impact3, as well as bonuses and burdens for the end user[25].

The Health Technology Assessment (HTA) allows an effective approach to this complex decision-making process. The HTA, through the use of multicriteria decision analysis (MCDA) methods, can include a multitude of aspects of evaluation that are not necessarily linked to each other or even conflict with each other. Thus, in recent years, experiments with approaches that combine ATS and MCDA have been widely investigated for evaluating medical devices[25].

In August 2022, through decree 11,161[26], a restructuring of the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC) was determined. With the change, in addition to the Executive Secretariat, three committees were created: Medicines, Medical Devices and Procedures, and Clinical Protocols and Therapeutic Guidelines.

Especially in the case of medical devices, the creation of a specific subcommittee for Medical Devices and Procedures is undoubtedly a great advance for the evaluation of this type of health technology. Ordinance 4228/2002 determines that one of the attributions of this subcommittee is to contribute to the improvement of guides and guidelines for the evaluation of equipment and medical devices of the Ministry of Health. It will be of vital importance to create specific guidelines for the evaluation of health devices, since not evaluating medical devices specifically is something that is becoming a reality in other countries. The main and recent concrete actions around the world are described below.

European Union

The European Union, through regulation 2021/2282[27] of the European Parliament, is also seeking changes in the evaluation format of medical devices. The aim is to make it easier to assess the effects of new health technologies and their prices on health policies. **Launched in December 2021**, the document establishes the standardization of ATS Assessments for all bloc nations.

The new regulation, however, does not eliminate the need to submit an ATS at a national level for each country. ATS EU will provide information on the objective clinical aspects of the new technology. The national ATS will use the EU ATS as a base and add information such as budget impact and country-specific data.

The new rule will begin to be gradually applied from 2025 and will become definitive in 2028, being valid for devices classified in the highest risk classes. The choice of these risk classes in particular confirms the worldwide trend towards greater scrutiny for medical devices with a higher risk class and the use of risk classes for the evaluation of devices.

The document also determines that, as early as 2022, a coordination group will be established to create methodological guidelines for subgroups of each member nation that will also be established. The steering group will still be responsible for identifying emerging health technologies (technology horizon monitoring) and for stakeholder engagement.

MedTech Europe, in a position paper published in 2022[28], stated that medical devices impact all aspects of the operation of the health service and the availability of innovative devices is essential to improve patient outcomes.

To this end, MedTech Europe is committed to working closely with HTA agencies on the European continent to ensure that HTA is properly applied to medical devices. This is in order to promote fast patient access to effective, dependable, and safe technologies. MedTech Europe has listed some principles for this to happen:

— **Timing ATS:** The discussion between the manufacturer and the ATS agency should seek to identify the ideal time to perform the ATS, considering the need to inform adoption decisions with the availability of evidence. This is due to issues such as the learning curve for new devices.

— **Standards of Evidence and Patient Access:** Although randomized clinical trials are the most robust means of evaluating the efficacy comparatively, they still represent an artificial scenario and do not necessarily represent "real world" circumstances that are essential for cost-effectiveness analyses. HTA bodies should be pragmatic in considering other sources of evidence.

— **Transparency and Stakeholder Engagement:** The HTA process should be transparent and encourage the involvement of relevant stakeholders, including healthcare professionals, healthcare planners/payers, patients, and manufacturers at all stages of the process.

— **Impact of ATS on Innovation:** Policy-makers should consider the implications of HTA on the environment needed to promote innovation of medical devices. If the HTA introduces significant new challenges to market entry, there is a possibility that it could impact the innovation rate of the device industry which already faces several challenges.

Australia

The **Clinical Evidence Guidelines for Medical Devices** from the Australian Government Department of Health[29], published in June 2022, determines the rules for the evaluation of medical devices in that country. The document is in line with the structures proposed by the International Medical Device Regulators Forum (IMDRF), to which ANVISA is also a member, and with Australian legislation.

The Australian directive[29] defines 16 Essential Principles (six general and ten specific) that determine the requirements related to the safety and performance of devices. Table 3 presents these principles.

The document further states that evidence for devices with a higher risk profile should undergo more detailed scrutiny with a greater expectation of direct evidence and/or data from high-quality clinical investigation directly related to the expected level of evidence to the risk class. of the device. **The guideline further provides specific requirements for prosthetic joints, cardiac devices, implantable pulse generators, prosthetic coronary valves, and software**.

A factor of significant importance to our theme in this guideline is the treatment of devices with limited clinical data. This limitation, which most often occurs due to ethical issues that prevent devices from undergoing clinical tests in the same way as pharmacological medical devices (impossibility of double-blind testing, for example), must be justified in the evaluation request.

The document prepared by the Australian government also directly relates the expected level of evidence to the risk class of the device and lists **other data sources that can be part of the device analysis process medical: post-market data and real-life data**.

TABLE 3. Essential principles for determining assessment requirements.

GENERAL	
1	Use does not compromise health and safety
2	Design and construction must conform to safety principles
3	It should work the way the manufacturer intended
4	Must be designed and manufactured for long-term safety
5	Must not be adversely affected by transport or storage
6	The benefits must outweigh any undesirable effects
SPECIFIC	
7	Chemical, physical and biological properties
8	Microbial infection and contamination
9	Construction and environmental properties
10	Principles for medical devices with a measurement function
11	Radiation protection
12	Medical devices connected to or equipped with a power source
13	Information to be provided with a medical device
13 A	Implant-in-patient cards and patient information insert
14	Clinical evidence
15	Principles applicable only to in vitro diagnostics

Mexico

Mexico is another country that has exclusive guidelines for evaluating medical devices[30].

The existence of these guidelines is possibly connected to the fact that, according to the "Global atlas of medical devices 2022"[31] published by the World Organization (WHO), Mexico is the country with the largest number of biomedical/clinical engineers in Latin America, with 3,000 professionals. To get an idea of what this means in the professional context, the WHO publication presents the following numbers of professionals in the largest countries in the region:

— Argentina – 1,500
— Brazil – 600
— Chile – 650
— Colombia – 2,000
— Cuba – 550
— Mexico – 3,000

Among the rules determined in the document are the classification of devices according to type and risk class. Mexican guideline[30] even provides specific instructions on the points where medical devices and drugs differ.

The document also demonstrates the understanding that the existence of superior quality evidence, which proves the efficacy and effectiveness of medical devices, it is scarce. This, since carrying out randomized controlled studies and, consequently, the availability of systematic reviews and meta-analyses is difficult due to the following situations: carrying out blind studies is generally complex and sometimes unethical if it is a simulated procedure, randomization is also difficult, as patients are reluctant to participate in these studies due to concerns about being selected for an invasive surgical procedure as opposed to a minimally invasive procedure and the existence of learning curves associated with using the device.

The guideline also recognizes that some of the methodological quality tools (the same used in Brazil and described in Table 1) are not applicable to published documents, therefore, in order to carry out a correct critical reading, CENETEC determined a series of questions to have a better analysis of the methodological quality of the studies (which are listed in Table 9 of this report), considered as appropriate for the Mexican health system.

England

The *National Institute for Health and Care Excellence* (NICE) in England, considered one of the most prominent bodies in the assessment of health technologies, published in January 2022 a new manual for the assessment of health technologies. The document addresses some issues related to medical devices, such as the area of *digital health*, and also talks about the use of real-life data when it is not possible to conduct a randomized controlled trial[32].

However, a public consultation conducted by the institute itself showed that many stakeholders considered that the methods and proposals were heavily influenced by the evaluation of medicines by medical devices. This discussion is still open in England, but is undergoing, as highlighted by NICE itself, an adaptation process.

Institutional initiatives

The ISPOR device value assessment working group *(International Society for Pharmacoeconomics and Outcomes Research)* published a paper[7] in 2022 on generating evidence and appropriate methodologies that can be used to obtain appropriate and reliable evidence for effective value assessments of the devices, where it recommends questions to be answered to demonstrate the value of devices and inform pricing and reimbursement decisions. Table 4 presents this recommendation.

TABLE 4. Questions to answer to demonstrate the value of devices and inform pricing and reimbursement decisions.

Value assessment component	Questions
Identification of target indications	Which patient population could benefit most from the device?
Added clinical value	— How does the new device improve the performance or outcomes of the entire treatment pathway? — How does the new device fit into the entire treatment pathway? — Does the device replace another treatment? — What part of the treatment pathway will become obsolete once the device is on the market?
Economic value added	— How does the new device affect the costs of the course of treatment? — What are the average costs of the treatment route, including the new device? — How can the device improve healthcare delivery and reduce total staff time and/or allocated resources compared to the standard of care?
Prospective risk inventory	What is the device's potential security, financial, and legal risks?
Evaluation period	— What is a reasonable timeframe to improve a device's results or reduce its costs, given its life cycle and the state of medical practice? — Given that the user's ability to implement the device can improve with experience, how could the assessment better reflect the potential or expected learning curve? — What research designs and instruments are in place to generate relevant evidence?
Protocol for evidence generation and data collection	— Is a randomized controlled clinical trial necessary or feasible? If not, why didn't it work? — What are the relevant outcome measures? — What are the relevant comparators?
Value delivery requirements	— Under what circumstances can the new device add value? — How feasible and realistic are the preconditions for return on investment, infrastructure adjustments, operator training, logistics, accountability and other components of the assessment?
Price evaluation	How elastic is price relative to device market volume and scale?

Adapted from ISPOR[7]

Brazil

The method for evaluating procedures and medical devices in the country is a topic that has raised debates in recent years. The lack of a specific guideline, as well as a specific evaluation process for these health technologies, has been a problem for the parties interested in the subject.

It is possible to find a publication that addresses the topic of medical devices in the 2013 manual "Methodological guidelines for the preparation of studies for the evaluation of medical-assistance equipment". However, this document does not as a direct objective to guide the structuring of comparative evaluation processes between health technologies for submissions made to CONITEC. In fact, in addition to being limited only to the segment of medical-assistance equipment, not encompassing the other segments of medical devices, there are only instructions to evaluate the technology intrinsically.

Through the examples of other countries, we can see a strong tendency to change the way of evaluating medical devices.

At this point, it is important to highlight the differences between the two types of technologies. Unlike drugs, devices rarely have a systemic effect on the patient's body and offer analytical challenges that are also diverse. In view of this, the evaluation of medical devices should not be conducted using the same parameters and study designs that are required for drugs. Furthermore, even across devices, assessment cannot be performed in the same way. For example, the analysis of a new non-invasive diagnostic test can hardly be the same as that of an implant or even another diagnostic test that is invasive.

This difference between drugs and devices and even between the types of devices is already recognized by the National Health Surveillance Agency (ANVISA), which is part *International Medical Device Regulators Forum* (IMDRF).

Digital health strategy in Brazil

The Digital Health Strategy for Brazil for 2028 (ESD28) seeks to systematize and consolidate the work carried out over the last decade, materialized in several documents and, in particular, in the National Policy on Information and Health Informatics - PNIIS, published in 2015 and under review in 2020, in the e-Health Strategy for Brazil (BRASIL, 2017) and in the Plan of Action, Monitoring and Evaluation of Digital Health for Brazil (PAM&A 2019-2023), approved in 2019 and published in 2020. The Digital Health Strategy is based on three axes:

1. MS Actions for SUS – This axis recognizes and values the Conecta SUS Program and its initiatives as essential actions for the Digital Health Vision to be achieved.

2. Definition of Guidelines for Collaboration – This axis recognizes and values the need to expand and consolidate the governance and organizational resources t hat will sustain the Digital Health Strategy.

3. Implementation of the Collaboration Space – This axis aims at the implementation of the Digital Health Strategy Collaboration Space as a space conceptual, virtual, distributed, logical and physical that enables collaboration between all actors in Digital Health, with clear definitions of expectations, roles, and responsibilities. The proposed collaboration is not exclusively technological and seeks to include models, services, methods, and knowledge that are enabled or become more efficient through the use of Digital Health.

The ESD28 considers the participation of all players in the health chain, and the possibilities for active participation by industry and the technology sector in the ESD28 are already determined, with varying degrees of intensity and commitment, and may occur through combined actions between the different actors. Table 5 summarizes the five types of participation expectations.

The set of actors relevant to Digital Health is diverse and broad, as it ranges from the user of health services – the centre of the ESD28 – to the payers of health services and regulatory agencies, with the industry and technology sector considered part of these relevant actors, and the ESD28 determines the type of expected participation, together with other relevant actors. Table 6 presents the expected contribution of the industry and technology sector together with other actors.

[c] Industry and technology sector - Public or private institutions that function as suppliers of inputs, medical devices, services or technologies for health care service providers, managers or payers of the health system.

It should be noted that ABIMED is interested and open to working together with the Ministry of Health, both in this digital health implementation process and in the implementation of any initiative involving medical devices manufactured by its associates.

TABLE 5. Types of participation expectations in the EDS28.

SPONSORSHIP	Institutional support or through financial, technological, and human resources, for structuring mechanisms and solutions that help initiative leaders in the distinct phases of their projects. Those with a sponsorship role are expected to be able to support or allocate resources for support at different times when deemed appropriate, and sponsors are not responsible for being responsible for delivery of results or the achievement of goals set for projects under the authority of leadership.
ENGAGE	The actors to be engaged are those who need to be informed of the decisions, guidelines, and practical actions of the initiatives under the management of the leadership that can impact their daily lives. Those to be engaged are expected to be able to absorb leadership reports and assume a collaborative role of informing leaders about the impacts brought by their actions, aiming to reach a fair outcome that considers the needs of all those involved.
CONTRIBUTE	The contribution function is a key element so that actors with notorious knowledge and previous experience in different initiatives can disseminate their knowledge to the leadership or to the strategic partners involved. Those who contribute are expected to undertake to be consulted and to assume a proactive stance to help in the process of co-creating solutions, developing suggestions for improvements and surveying directions for initiatives brought by leaders.
PARTNERSHIPS	The actors with the function of forming partnerships must be able to dedicate human and financial resources and respond to the governance structure established by the leadership, being subject both to the direct execution of activities and to playing a role in the development and implementation of partnerships for execution activities necessary to achieve leadership objectives. Those in charge of composing partnerships are expected to have both institutional involvement and accountability for achieving the goals set by the leadership for the partnerships signed.
LEAD	Assume responsibility for organizing governance capable of coordinating the allocation of human and financial resources and the execution of activities to achieve the objectives set for each delivery. It is expected of those with role of leadership that develop strategies and action plans for the execution – directly or indirectly – of the activities necessary to achieve the foreseen objectives, which establish partnerships and seek sponsorship and contribution, in addition to engaging the actors impacted by their initiatives. Leaders are accountable for deliverables, so they must continually monitor, evaluate, and improve solutions to ensure expectations are met.

Adapted from: EDS28.

TABLE 6. Expected contribution from Industry and technology sector, together with other actors, according to ESD28.

ENGAGE
— Institutionalization of the digital health strategy
— Digital health strategy leadership and governance
— Legislation and regulation for digital health
— Digital health strategy funding

CONTRIBUTE
— Promotion of telehealth and digital services
— Train professionals in health informatics
— Interoperability with external systems
— Promote assistance contact support
— Develop health surveillance initiatives
— Implement electronic prescription services
— Implement regulatory services
— Explore health value models
— Formalize and consolidate the monitoring and evaluation governance instances of CONECTE SUS
— Formalize and consolidate the monitoring and evaluation processes of CONECTE SUS

Adapted from: EDS28.

PARTNERSHIPS
— Establish regulation of innovation and interconnectivity environments
— Computerization of health facilities in the country
— User engagement
— Information platforms for citizens and users
— Valuing human capital in digital health
— Promote interoperability between levels of care
— Promote interoperability with pharmacy services
— Implement outpatient regulation services
— Strengthen the health terminology repository
— Develop standards for health information
— Develop initiatives in IOT, big data and secondary use of data
— Deploy the health data lake
— Support the incorporation of innovations
— Use translational search features

LEAD
Establish mechanisms for private financing

In all contexts analyzed, understanding the design of studies and scientific data from medical devices is the key to breaking the paradigm of evaluations

In many cases, the economic evaluation of medical devices is not conducted before they enter the market, but is carried out in the post-marketing phase, which would be equivalent to carrying out the economic study of a drug based on a phase IV study[33]. The possibility of conducting a cost-effectiveness study from the entrance of the medical device is substantial and can be used to demonstrate the economic value and impact of the medical device.

Safeguarding this use of data after entering the market to have a better accuracy and veracity of the results, from the methodological point of view, economic and budgetary impact studies can be conducted within the same methodologies used for pharmaceutical medical devices[33], adding for the total cost of ownership (price of purchase, operation, training, maintenance, replacement) of medical-hospital equipment.

Considering that the development of economic models and budget impact analysis are closely linked to the availability and quality of scientific evidence, understanding how the development of clinical evidence of medical devices works is a key factor for the necessary adaptation to the evaluation process of these technologies in health. Thus, the international guidelines[29,30] within the context of this purposeful document, strongly focus on the discussion of issues related to the peculiarities of clinical data of medical devices and how their understanding is the factor that modifies the entire process of evaluating health technologies.

Below we present the findings within these guidelines[29,30] which can be considered as the most didactic in their form of presentation to exemplify this understanding of the differences.

Medical devices and drugs are different

The Mexican guideline[30], in line with the base publication of ISPOR33 on the evaluation of medical devices, presents in a highly organized way the differences in the design of clinical studies for drugs and devices, as shown in Table 7.

TABLE 7. Differences in clinical trial design for drugs and devices[30]

MEDICINES	DEVICES
PHASE I CLINICAL STUDIES — Focus on drug safety and tolerability — Tests on healthy volunteers (20-100 subjects) — Studies to confirm dose and major adverse events	**PILOT STUDY** — Testing in small populations of sick individuals (10-30 individuals) — Focused on preliminary determination of safety and performance
PHASE II CLINICAL STUDIES — Focused on safety and effectiveness — Testing in small populations of sick individuals (50-200 individuals) — Studies to confirm dose and major adverse events	**PIVOT STUDY** — Testing in larger populations of sick individuals (150-300 individuals) — Focused on determining efficacy and adverse events
PHASE III CLINICAL STUDIES — Focused on safety and effectiveness — Testing in large populations of sick individuals (100-1000 individuals) — Studies to determine drug interactions and minor adverse events	**POST-ORDER STUDIES** — Focused on collecting long-term data and adverse event data
PHASE IV CLINICAL STUDIES — Post-marketing studies — Data collection and long-term adverse effects under real-life conditions	

The Mexican guideline[30] also in line with the principles advocated by ISPOR33 goes even further in this differentiation, and throughout the document it bluntly defines ten fundamental differences between drugs and devices. Table 8 presents the collection of differences presented throughout the guideline.

TABLE 8. Differences in the process of evaluating drugs and devices.[30]

Classification according to risk	
MEDICINES	**DEVICES**
Medications are not classified according to the risk offered. There are different modalities such as: orphan drug, generic drug, vaccine, and new molecule.	The classification depends on the health risk that its use implies and the invasiveness to the organism.

Clinical use	
MEDICINES	**DEVICES**
Clinical use is preventive or therapeutic (curative or palliative).	Clinical use is preventive, diagnostic, therapeutic, rehabilitative or combinations thereof.

Description of the technology	
MEDICINES	**DEVICES**
Clinical use is preventive or therapeutic (curative or palliative).	The description of the device is different from the drugs, because to describe them it is necessary to mention the following points: indication of use (what is its purpose?); operating principle (how does it work?); elements or parts that constitute it; accessories; consumables and spare parts as appropriate; likewise, depending on its nature, characteristics such as: sterility, special storage needs and whether the device is disposable or single-use, among others, must be mentioned.

Principles of operation or function	
MEDICINES	**DEVICES**
For the correct description of drugs, it is necessary to consult their pharmacodynamics (mechanism of action) and pharmacokinetics (absorption, metabolism, and elimination).	— It happens by physical means, techniques, procedures, or algorithms in order to generate an action or reaction in the human body and can be aided (for example, by some medicine) to achieve its purpose. In general, a medical device is designed for the benefit of the patient, however, its scope should not be limited to it, and may provide an advantage to the user (doctors, nurses, caregivers, or family members) or even improve a process of the Health System. — With regard to operation and handling, this aspect is not taken into account in medicines, while in medical devices their operation depends on the medical professional for their use in patients, a situation that implies prior training in use and/ or application since the efficiency is directly related to the operator and performance depends on it. — In general, there is scientific evidence on all these aspects and, as in the operating principles, a query should be made in the databases of scientific articles.

TABLE 8. (continued) Differences in the process of evaluating drugs and devices.[30]

Classification according to risk	
MEDICINES	**DEVICES**
Here, special storage and guard conditions are considered.	Depending on their nature and complexity, some medical devices require special installations (electrical, hydro sanitary, medical gases, steam, mechanics, IT, shielding, etc.).

Training	
MEDICINES	**DEVICES**
This aspect does not apply to medications since their administration is fully indicated in the package leaflet. the prescription of highly specialized drugs is restricted to specific specialties and scientific information is permanently updated.	For the use of a medical device, the health professional must be continuously trained for its use to be safe and efficient. Some of this training is audited by the corresponding authority and is sometimes an essential requirement for the service to function within the health care unit. This point is so relevant that even the effectiveness and efficiency of the use of medical devices improve with experience.

Maintenance and Calibration	
MEDICINES	**DEVICES**
These aspects do not apply to medicines.	Within the devices, medical equipment requires specific and periodic maintenance and calibration for each type of equipment, in order to guarantee optimal and safe conditions of use for both the patient and the operator. They vary in complexity and periodicity depending on the type of equipment.

Sanitary Registry	
MEDICINES	**DEVICES**
Authorization for registration is based on the result of the evaluation, which consists of two opinions: one chemical and one clinical. There are different modalities such as: new molecule, generic, vaccine and orphan. Requirements vary by modality. An example of the type of information requested is pharmaceutical development, bioavailability and/or bioequivalence studies, preclinical studies (pharmacodynamics, pharmacokinetics, toxicological) and clinical studies (Phase I, II, III).	The registration authorization is given based on the evaluation result, which consists of a single opinion; Obtaining the Sanitary Registration is subject to meeting requirements that are very different from those requested for medicines (e.g. user manual, compliance with electrical tests, biocompatibility, toxicity, pyrogens, assembly, electromagnetism, certificate of analysis of the finished medical device) and which may vary or be more stringent depending on the risk rating of the device.

TABLE 8. (continued) Differences in the process of evaluating drugs and devices.[30]

Comparators	
MEDICINES	**DEVICES**
The drug is often compared to another drug in the same family, or with similar therapeutic action, or a placebo.	In some cases, there is not enough information to allow the definition of an adequate comparator. In the case of devices, we must consider that the comparator will not necessarily be another medical device, it could be a drug, a medical or surgical intervention and the possibility of comparison with a placebo.

Clinical evidence	
MEDICINES	**DEVICES**
In this case, the evidence of efficacy and effectiveness is based on randomized controlled trials, systematic reviews, and meta-analyses, among others.	The existence of good quality evidence proving efficacy and effectiveness is scarce, as the performance of randomized controlled studies and, consequently, the availability of systematic reviews and meta-analyses is hampered due to the following situations: — Conducting blinded studies is often complex and sometimes unethical if it is a sham procedure. — Randomization is also difficult. Patients are reluctant to participate in these studies because of concerns about being selected for an invasive surgical procedure as opposed to a minimally invasive procedure. — Existence of learning curves associated with the use of the device, especially those intended for surgery, due to the fact that instead of demonstrating the differences between the procedures themselves, the difference between experience with the old surgical procedure and inexperience is demonstrated with the new process.

Evaluation of clinical data goes beyond published data

Having quality data on devices and using quality tools are inherent factors in the evaluation process, but it must be recognized that it is not possible to conduct randomized controlled trials for each and every device, due to the following reasons:

— Conducting blinded studies is often complex and sometimes unethical if it is for the evaluation of a sham procedure.

— Patients are reluctant to participate in randomized trials because of concerns about being selected for an invasive surgical procedure as opposed to a minimally invasive procedure.

— Existence of a learning curve associated with the use of the device.

For a critical reading of the scientific data available to evaluate the device, CENETEC formulated questions for a better analysis of the quality and pertinence of the data presented based on the principles presented in this document (Table 7 and Table 8) differentiating the peculiarities of the analysis of medical devices. Table 9 presents the formulated questions.

TABLE 9. Analysis of the quality and relevance of the data presented.

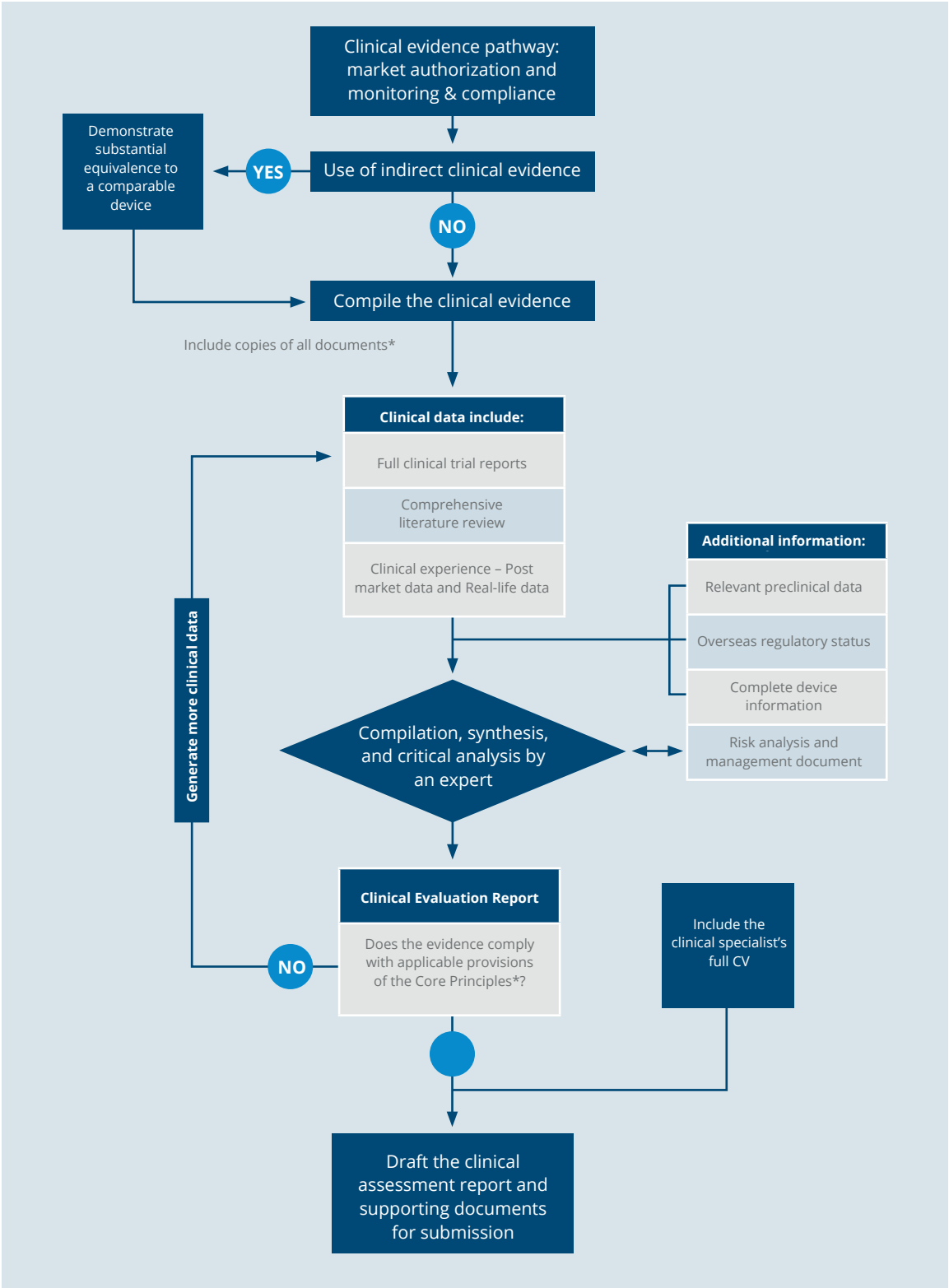
GENERAL QUESTIONS
Does the title of the scientific article clearly indicate the proposed health or technology issue in the applicant's PICO question?
Are the objectives of the study clearly indicated (comparison, health problem to be solved, etc.)?
Is the type of study design indicated?
METHODOLOGY
Is the place and country where the study was conducted indicated?
Is the study period indicated?
Has the total number of patients to be treated been included, specifying their characteristics, as well as the inclusion and exclusion criteria?
Is monitoring of research subjects specified? Is this follow-up adequate to the natural history of the disease?
The characteristics of the device and comparator used in the study are explicitly presented (device vs. reference standard)
Was the data collection process, and statistical analysis (sensitivity, specificity, relative risk) among others included?
RESULTS
Is the synthesis of the results described?
Are the results clearly defined?
Are results presented in terms of measures of effect or association?
DISCUSSIONS
Does it present a summary of the main aspects found in the study?
Are the limitations of the study described?
CONCLUSIONS
In the clinical study, are the conclusions of the authors duly indicated (in some cases they only indicate the discussions)?
OTHER ASPECTS
Have potential conflicts of interest been informed?

The Australian guideline[29], published in 2022, also recognizes these differences between drugs and devices and presents a flow for the construction of a clinical evaluation report. Figure 14 shows this flow and the materials needed for its composition.

An especially important factor in this flow is the inclusion of a clinical specialist in the analysis process. Australian guideline[29] states that all clinical data in the clinical evaluation report must be critically evaluated by a competent clinical specialist, who must reach an informed conclusion about the benefit-risk profile of the device under evaluation and provide his endorsement and/or signature in writing. The review requires consideration of all relevant clinical evidence about the device, including less favourable evidence as well. The manufacturer must show due diligence to ensure that all relevant clinical evidence is identified and discussed.

A competent clinical specialist is generally someone with relevant medical qualifications and direct clinical experience using the device or device type in a clinical setting. For a new high-risk device, it is expected that the clinical specialist has current or recent clinical experience with the device type (preferably within the last two years). For a low-risk device that is not normally used by a physician, another healthcare professional who uses the device or similar devices in a clinical setting may be considered an appropriate clinical specialist. In order for the evaluator to determine if an appropriate clinical specialist has been chosen, the complete curriculum of this expert should be included with any convergence of interests or potential conflict with the manufacturer or sponsor noted therein.

FIGURE 14. Construction flow - Device clinical evaluation report.

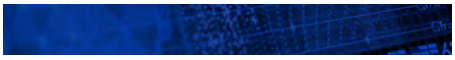


* Essential principles - see Table 3

The evaluation process of a medical procedure/device in Brazil is evolving and ABIMED is ready to contribute

The challenges for conducting a complete evaluation of a procedure related to a medical device are concentrated in the organizational and regulatory spheres, in the composition of protocols and in the dialogue between market practitioners: government, industry, medical society and patients.

From the results obtained in the analysis of secondary data, points listed by the study participants and the study of international experiences on the subject, ABIMED presents its proposals for contribution to the evaluation process of medical procedures and devices.



Development of the structural proposal for the collaborative development of a multicriteria evaluation for medical and diagnostics devices in Brazil

The compilation of local and international movements on the subject presented in this document, aims to motivate the creation of a specific guideline, which accommodates all the peculiarities necessary for the evaluation of procedures and medical devices.

Based on the analysis of all the guidelines, good practice guides and recommendations for the evaluation of devices presented and discussed throughout the present study, **ABIMED presents as an annexe to this document its Structural Proposal for the collaborative development of a multicriteria evaluation for devices doctors and diagnoses in Brazil, based on the findings and sources of the present study, is willing to participate actively in the process of elaboration of HTA technical guidelines for devices** that, in a democratic way, must also count on all other interested parties such as: patient associations, managers, civil society and any others that wish to express themselves.

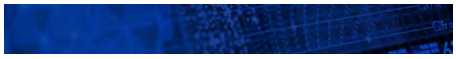
Within this structural proposal for evaluating medical procedures a nd devices, the following key points common to all currently available international processes need to be considered:

— Standardization of differences between drugs and devices.

— Establishment of a clinical evaluation process where the peculiarities related to clinical studies of devices are considered, including the use of real-life data and post-market data in the decision-making process.

— Use of Value Based Health Care (VBHC) criteria, with the adoption of a value structure where a multi-criteria evaluation process is adopted.

At the same time, ABIMED will conduct a broad action with its associates so that the internal teams are qualified for this new reality proposed here, as well as in raising awareness and action in the availability of assertive and complete information on the efficiency and safety of the technologies they manufacture. and what is their value within the procedures / processes where they are included.



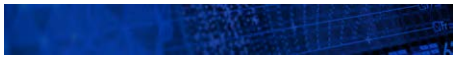
Expansion of specific structure and plenary for the discussion of procedures and medical devices or diagnoses

Considering all the different needs that the evaluation of medical devices requires, having a focused team and structure appears to be the best way to meet this need.

Due to the recent change, promoted by Decree 11,161/2022 and Ordinance 4,228/2022, which already determined the creation of a specific subcommittee, this new organization by CONITEC represents an important moment for the future of the Brazilian health system and a milestone for the evaluation of medical procedures and devices, opening the opportunity to finally establish a specific guideline for the evaluation of this type of technology.

For the change already envisaged by the Ministry of Health through Decree 11,161/22 to be fully implemented, the newly created Committee on Medical Devices and Procedures needs to have within its structure a multidisciplinary team that has authentic experience with the analysis of devices.

Additionally, ABIMED and its associates believe that the participation of medical device manufacturers in CONITEC is of fundamental importance since those who can best explain, provide additional data and answer for these new technologies are those who manufacture them and request their participation. formally in the evaluation process, not only as applicants for the evaluation, but as part of the committee. This process would bring an enormous gain in the speed and quality of the assessments, allowing the incorporation of technologies that really bring real value to Brazilian patients. Along the same line, ABIMED and its associates also request your formal participation in the evaluation process within the ANS.

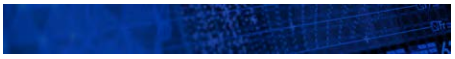


Fostering the composition and training of multidisciplinary teams of evaluators of medical procedures and devices, with technical fluency and look 360º

In order for more people interested and involved in the evaluation of procedures and medical devices, ABIMED will offer the market a **distance education program** (EAD), to provide basic education on the subject. The distance learning program is under development and will be made publicly available.

O **Distance Learning Program** brings basic-theme classes to assess medical procedures and devices, with a target audience of doctors, health managers, payment sources, technicians, members of commissions, members of the Congress, graduates e postgraduates of health-related engineering, by means of their professionals associations (SBEB, Abeclin, SBIS) and the industry itself.

Brazil has very high-level professionals in numerous key areas for the evaluation of medical procedures and devices. These professionals will be invited to the best universities in the country to collaborate in the formation and composition of the instructors of the Distance Learning Program, thus bringing practical and already experienced aspects in conducting the evaluations in a complete and efficient way, as well as participating in the promotion of the dialogue between market actors.



Increase and intensification of dialog between actors and institutions that conduct HTA in Brazil

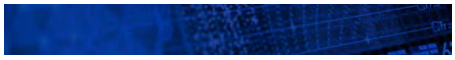
By sharing data, technical opinions and using the expertise of professionals who deal daily with medical devices, we believe we can significantly contribute to a new evaluation method.

In addition to a work agenda to be proposed to other market participants, ABIMED proposes to be the organizer of an annual immersion meeting to promote the interaction of interested parties, thus allowing the exchange of knowledge and unique perspectives of each actor on the subject.

As an activity of constant preparation and review of the process, a multi-disciplinary work group, thus making this a living and evolving process along with the Brazilian health system, will be supported by ABIMED so that this annual immersion promotes:

— Exchange of experiences
— Case study workshops
— Construction of technical documents in the area
— Fine adjustment of doubts and clarifications outside the negotiation environment, promoting a qualified discussion with a lower degree of conflict of interest.

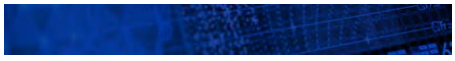
The main objective is to increase the interaction between the parties and leave the meetings with solutions and a positive agenda for all involved.



Shorten the learning curve time, generating local experience

Since the vast majority of devices are associated with a procedure and these procedures are performed by human beings, it is expected that with the repetition and empirical knowledge involved these people gain experience with the device in question and get better results.

Knowing that this learning curve has a direct impact on the outcomes related to the procedures and needs to be promoted in the local market, **ABIMED will carry out educational work with its associates to generate interest and incentive for the development of real-life studies and generation of local experience**, and thus shorten the distance between new technologies and the local market, mainly patients.



Actively participate in building the digital health process in Brazil

The third axis of the **Digital Health Strategy for Brazil for 2028** (ESD28), deals with the Implementation of the Collaboration Space of the Digital Health Strategy as a conceptual, virtual, distributed, logical and physical space that enables collaboration between all actors in Digital Health, with clear definitions of expectations, roles and responsibilities.

Considering that the collaboration proposed at ESD28 is not exclusively technological and seeks to include models, services, methods and knowledge that are made viable or become more efficient through the use of Digital Health, ABIMED and its associates are available to interact actively, through a r**egular agenda with the Ministry of Health, actively participating in discussions, especially in the ESD28 items "Innovation Ecosystem", "Value-based health" and "Evaluation and incorporation of new technologies", composing a working group** to present proposals and experiences already lived, both in other jurisdictions and in the private health market in Brazil, which may meet the plan in the ESD28 and, mainly, meet the health needs of the Brazilian population.

Final considerations

The process of developing new solutions in medical devices is intense and increasingly seeks to improve the health and longevity of human beings.

The evaluation of medical devices is a subject under discussion in different countries and continental regions, and there is already a consensus on the need to create a process that is, at the same time, guided by good practices in the evaluation of health technologies as well as the specificities of the medical devices presented throughout the document.

The technology assessment process in Brazil is a reality and is part of the decision-making process, whether in the SUS or within the scope of health plans. The retrospective analysis of the evaluations carried out by CONITEC and COSAÚDE demonstrated the need for parameterization of concepts in relation to the process of analysis of medical devices and the opportunity to open a dialogue between the market participants for the construction of an evaluation process consistent with the particularities and specificities of medical devices as well as with its real impact on the health system, bringing value to the patient who starts to receive more efficient and modern health care.

Although each country presents unique characteristics in relation to its health system and social values, this analysis demonstrated the existence of common factors that permeate the currently existing proposals for the evaluation of medical devices.

Globally impact institutions such as EMA, ISPOR and MedTech Europe, which recognize the acute need for this adequacy, have presented their proposals as described in the study and are holding meetings based on the theme and encouraging the realization of this type of focused analysis. Also considering the technological evolution focused on bringing real improvements, the digital health revolution is a factor of great spectrum and impact, being of absolute necessity for the rapid implementation of the Health Strategy for Brazil for 2028 (ESD28), so that Brazilians are benefited and have more access to health care.

ABIMED believes that through joint and democratic work, dialogue channels will be promoted more solidly, preparing guidelines for good methodological practices, exchanging knowledge, meeting overlapping expectations in assessments and, raising the quality of processes in order to offer the best solutions for the health of Brazilians, expanding the possibilities of receiving efficient and innovative health care.

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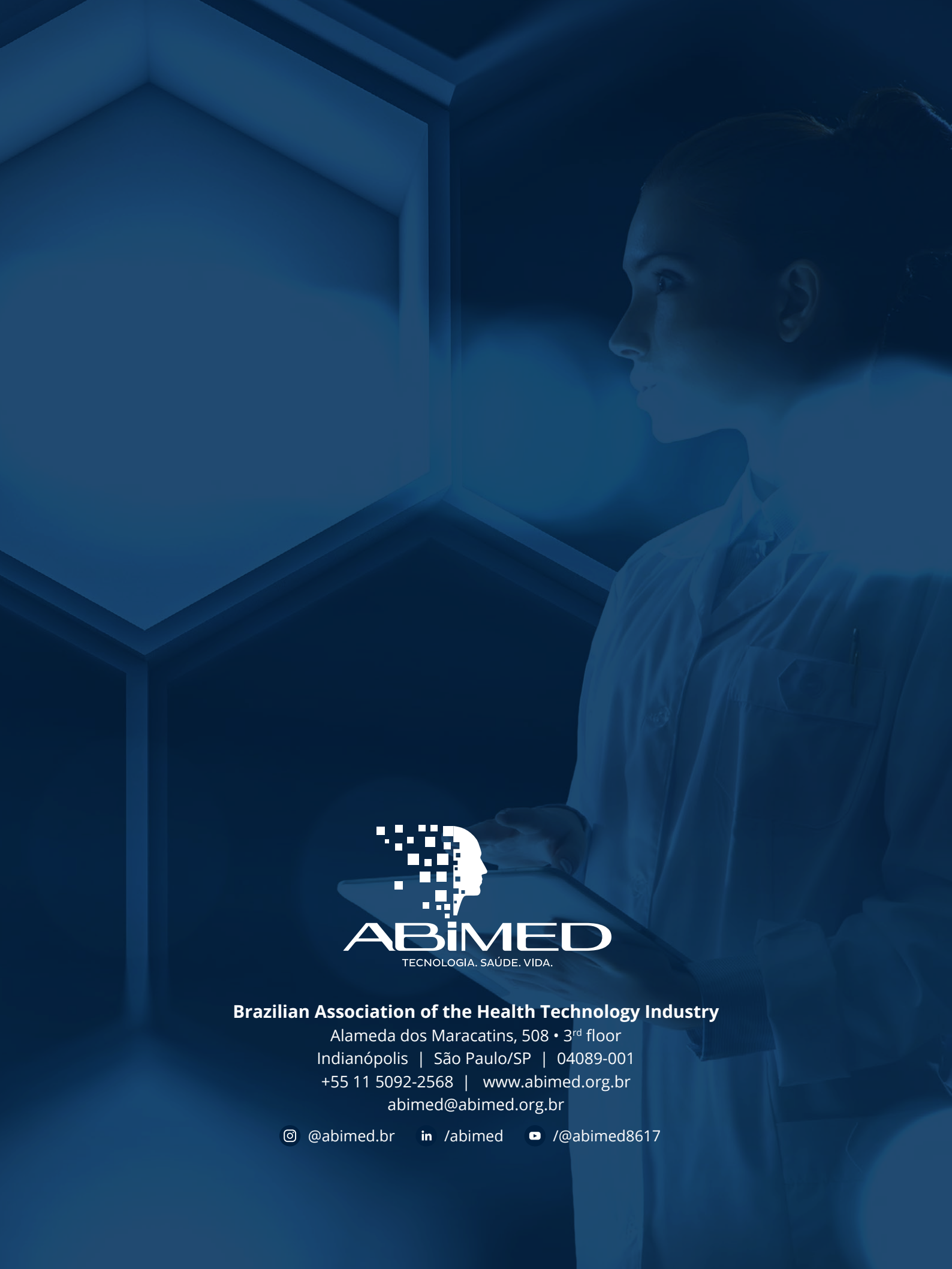

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