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Original Research Article

The Role of Clinical Engineering in Management and Decision-Making in Brazilian Hospitals

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ABSTRACT

In an ever-changing hospital landscape, where technology intertwines with health care, clinical engineering emerges as a beacon to guide medical equipment management. But how do managers perceive the role of this crucial area? This study aims to unravel this question by exploring the views of 25 public and private hospitals across Brazil. Equipped with a carefully crafted online questionnaire, we embarked on an exploratory expedition, using Google Forms® as our map. Through the responses of 25 hospitals, we unraveled the structure and performance of clinical engineering, seeking to understand its relevance in hospital management. Following Donabedian's footsteps, we evaluated quality through three lenses: structure, processes, and outcomes. The responses revealed that clinical engineering plays a pivotal role in equipment management, the pursuit of accreditation seals, and strategic planning, proving its growing importance. In spite of the limited scope (only 25 out of over 7,100 Brazilian hospitals), the responses provided a glimpse into the evolution of clinical engineering. More than that, they revealed gaps that call for more in-depth research, opening up a range of possibilities for future studies. This study serves as a beacon for hospital managers, illuminating the path to structuring a robust and effective clinical engineering department. Clinical engineering is not limited to mere operation but rather stands as a strategic ally in the pursuit of excellence in health care. The results of this study indicate that, although clinical engineering is still largely viewed as an operational function, its role in the surveyed hospitals shows a clear movement toward greater strategic relevance. Managers increasingly recognize its value in cost management, investment decision-making, contract oversight, participation in institutional projects, and contributions to organizational strategy. When interpreted through the Donabedian model, the findings suggest that more structured departments—particularly those aligned with Health Technology Assessment HTA committees—tend to produce stronger organizational outcomes. In spite of variations in structure, hierarchy, and employment models, evidence shows that clinical engineering plays an expanding role in enhancing care effectiveness, optimizing the technology fleet, and promoting the sustainability of health care services. Overall, the study points to a gradual maturation of the field, in which strengthening its technical and managerial leadership becomes essential for continuous hospital improvement. Through continuous and in-depth research, we can further unlock the potential of this crucial area for the future of health.

Keywords—*Clinical engineering, Biomedical engineering, Hospital management, Hospital administration, Health technology.*

INTRODUCTION

Clinical engineering arises from the application of engineering principles to efficiently address clinical challenges, grounded in knowledge from various disciplines such as electrical engineering, mechanical engineering, and physiology. Its origins trace back to the need to enhance communication among health care professionals, hospital managers, and engineers. In addition to creating job opportunities for engineers, this field plays a crucial role in optimizing patient care, developing technological solutions for diagnosis and treatment, and creating research opportunities.[1] According to Porto and Marques, in the 1940s, the first maintenance course for military medical equipment emerged in the United States, coinciding with the development of various types of medical devices.[2] Taghipour emphasizes that the increase in the number of medical devices requires the implementation of a medical equipment management program in hospitals.[3] Not only did costs increase, whether related or not to these devices, but there was still concern about safety aspects in the use of these medical devices, following reports of serious patient events related to equipment maintenance issues or improper handling. This led the Food and Drug Administration (FDA) to establish stringent processes for evaluating the design and manufacturing of medical equipment. In the 1970s, the term "clinical engineer" was defined as the engineer who manages the installed base of medical equipment in a hospital.[2] Since the early 21st century, the image of the clinical engineer has remained the same, characterized by a stereotypical view:

What is the first image that comes to mind with the term "clinical engineer"? For many, it is that of a middle-aged man with higher education and advanced training who manages a department of technicians and support staff, with the primary role of repairing medical equipment. Typically, this department is in some basement of the hospital, near infrastructure equipment, or even the morgue. There is no apparent reason for this, but this is often the case.[1]

After more than 20 years, such a scenario persists. A similar setup is implemented in our clinical engineering department, with equivalent examples found in other hospitals. In Brazil, during the 1980s, there were hospitals with much deactivated equipment, beyond repair. As a result, hospitals created their own maintenance teams because of the difficulty in accessing training, manuals, and spare parts.[4] A significant milestone in the country was the founding of ABEClin in 2003 (Associação Brasileira de Engenharia Clínica, in Portuguese), the Brazilian Association of Clinical Engineering. It promotes courses and scientific events and raises awareness about the role of the clinical engineer in equipment management. Since the early 2000s, numerous specialization courses in clinical engineering have emerged, aimed at professionals working in hospitals managing the installed base of medical equipment. Currently, there are over 70 active courses available in either in-person or distance formats.[5] In which clinical engineering is considered a specialization, derived from a biomedical engineering undergraduate degree. Considering that clinical engineering operates differently across various hospitals, with diverse hierarchical structures and responsibilities, there is still no consensus on how its activities should be developed. Given this context, there remains a question of whether hospital managers are aware of the role of the clinical engineer and recognize the field as potentially capable of supporting them in the management of the installed range of medical equipment. Thus, the guiding question of this applied work is: What is the role of clinical engineering, according to the perception of hospital management leadership?

The scope of the bibliographic research was defined as the period from 2003 to 2023, based on the founding date of ABEClin on October 16, 2003, as noted on its website.

ABEClin was established as a nonprofit private legal entity with an unlimited duration. Its goals include encouraging, consolidating, integrating, and qualifying professionals working in the field of clinical engineering. Its founding marked a formal milestone for those working in clinical engineering.

The field research was exploratory, involving the distribution of a questionnaire to 127 private hospitals associated with ANAHP, the Brazilian National Association of Private Hospitals. In addition, 10 invited hospitals, both public and private, were included in the study.

The study was conducted over a 30-day period, from March 8 to April 8, 2024, with the aim of analyzing the

understanding of managers from various public and private hospitals about the role of clinical engineering in management and decision-making within high-complexity hospitals, ranging from medium to large size, across the country.

LITERATURE REVIEW

The History of Clinical Engineering

The origins of clinical engineering trace back to the 1940s in St. Louis, USA, when the armed forces initiated training programs for the maintenance of military medical equipment. The subsequent proliferation of medical technologies—such as ultrasound and computed tomography—triggered a significant increase in health care costs, directly and indirectly related to medical devices. In response, the U.S. FDA extended its regulatory scope to include medical equipment, initially applying the same approval protocols used for pharmaceuticals, which later proved inadequate.[4] The enactment of Public Law 94-295 in 1976 formally subjected medical devices to FDA approval, imposing obligations on manufacturers such as facility registration, product listing, compliance with good manufacturing practices, and reporting of adverse events.[6] Brazil followed a similar path with the establishment of the National Health Surveillance Agency (Anvisa) in 1999, adopting analogous regulatory principles.[7] This regulatory evolution fostered the emergence of a new professional field—biomedical and clinical engineering—dedicated to ensuring the safety, efficacy, and performance of medical technologies within health care environments. The 1970s introduced the term clinical engineer to describe engineers responsible for managing hospital equipment.[2] In Brazil, institutional recognition of the discipline began in the 1980s. According to clinical engineering in Brazil[8], a 1982 task force led by the National Council for Scientific and Technological Development (CNPq) identified major deficiencies in equipment acquisition, maintenance, training, and cost management. The evaluation and perspectives project further emphasized the need for specialized training to support technology management in health care services. A milestone of this period was the creation of the Biomedical Engineering Center at the State University of Campinas (Unicamp), which combined research, training, and technical advisory functions. However, until the early 1990s, clinical engineering services remained rare in Brazilian hospitals. The Ministry of Health's PROEQUIPO program addressed this gap by establishing nationwide training courses, which effectively defined the professional profile and competencies of clinical engineers. The creation of the ABEClin in 2003 represented the consolidation of the field, marking its maturity within the national health care context.[8] Further advancement occurred with the establishment of the Brazilian Hospital Services Company in 2011 (Law No. 12,550), aligned with the National Program for the Restructuring of Federal University Hospitals (REHUF).[9] EBSERH's standardized management framework, refined through pilot projects in six hospitals, culminated in the *Clinical Engineering Processes and Practices Handbook*, setting national benchmarks for equipment management and quality outcomes.[10]

Distinction Between Biomedical and Clinical Engineering

Although closely related, biomedical engineering and clinical engineering perform distinct roles. Biomedical engineering focuses on developing new materials, modeling physiological processes, and creating devices for diagnosis or rehabilitation. Clinical engineering, conversely, concentrates on managing the life cycle and operational performance of medical technologies through maintenance programs, risk management, contract control, forensic engineering, health technology assessment (HTA), human factors engineering, and point-of-care operations.[11] As Zhang defines, human factors engineering aims to design systems that adapt to human capabilities and limitations, ensuring usability and safety in health care technology applications.[12]

Education and Professional Training in Clinical Engineering

Biomedical engineering education, typically offered at the undergraduate level, integrates engineering principles with medical sciences to design and optimize health care technologies.[13] Training is regulated by the Ministry of Education (MEC) and the Regional Council of Engineering and Agronomy (CREA), with professional representation through the Brazilian Society of Biomedical Engineering, founded in 1975. Clinical engineering specialization, in

contrast, emphasizes the operational management of medical devices. While biomedical curricula prioritize technical and mathematical foundations, clinical engineering programs highlight managerial competencies alongside technical proficiency. For instance, an undergraduate curriculum (Federal University of São Paulo - UNIFESP) distributes its 64 courses across technical (71.9%), mathematical (14.1%), biological (6.3%), and administrative (7.8%) domains. A clinical engineering specialization (Einstein) allocates 53 courses as technical (50.9%), biological (9.4%), and administrative (39.6%), reflecting a stronger management orientation. As of April 2024, Brazil offers 71 clinical engineering specialization programs—93% in private institutions, 19.7% of which are nonprofit—and only 7% in public universities.[5] The oldest program was established in 2005 at the Federal University of Health Sciences of Porto Alegre. As can be observed in Figure 1, these programs are present in 19 states, with concentrations in Minas Gerais, São Paulo, Goiás, Santa Catarina, Paraná, Rio Grande do Sul, Rio de Janeiro, and Bahia, which together host 63% of the total. Course formats include 36.6% in-person and 63.4% distance learning, expanding access to qualified training nationwide. The evolution of clinical engineering, both globally and in Brazil, underscores its vital role in bridging technology and patient safety. Its trajectory reveals a continuous alignment between regulatory rigor, educational development, and the growing complexity of health care systems.

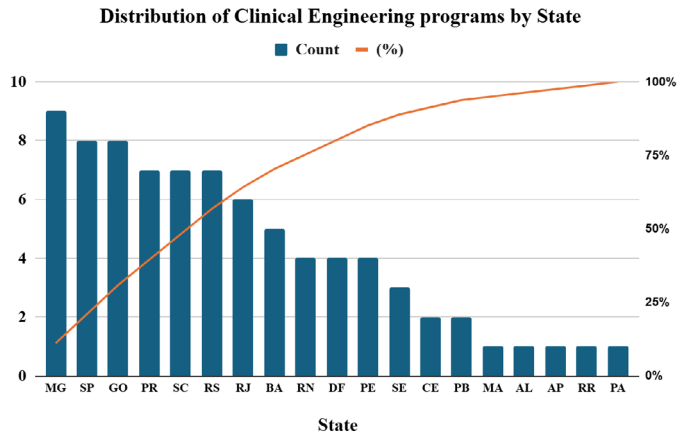

FIGURE 1. Specialization courses in clinical engineering in Brazil.
Note: Elaborated by the author based on the National Registry of Courses and Higher Education Institutions—e-MEC.[5]

Health Care Organization Accreditation Bodies

A study conducted in Canada revealed that pursuing accreditation can enhance hospital performance, although there is insufficient evidence to confirm that it directly improves care delivery or health outcomes. The main benefits identified include fostering teamwork, promoting continuous improvement programs, encouraging new leadership, strengthening professional relationships, and enhancing interaction among health care organizations. These initiatives demand continuous learning and investment, producing results over time; however, after about a decade, new strategies are often required to sustain motivation for ongoing improvement.[14] To ensure the quality and safety of health care services, accreditation plays a fundamental role, structured upon internationally recognized standards. Two leading global organizations in this field are the Joint Commission International (JCI) and Accreditation Canada International (ACI). JCI, a nonprofit institution, identifies and disseminates best practices in patient safety and quality, supporting health care organizations to enhance performance and outcomes. ACI operates through the Qmentum accreditation program, with a similar focus on quality advancement. In Brazil, the National Accreditation Organization(ONA) defines and manages national quality and safety standards for health care institutions.[15] ONA offers three accreditation levels (ONA 1, ONA 2, and ONA 3), and over 80% of accredited hospitals in the country hold ONA certification. This recognition extends internationally through its membership in the International Society for Quality in Health Care (ISQua), a nonprofit organization present in more than 70 countries across 6 continents National Accreditation Organization(ONA).[16] The JCI specifies in its Hospital Accreditation Standards manual that hospitals must "develop and implement a medical equipment management program throughout the organization".[17] This reinforces the need for structured and comprehensive equipment management, both as a quality requirement and an accreditation condition. Similarly, National Accreditation Organization(ONA), Accreditation manual details in Section 4.1 the entire technology management process, covering planning, operation, and deactivation of medical equipment—including that of third parties—to

ensure safe use.[15] Item 8 of Subsection 4.1 emphasizes the management of medical and hospital technology and mandates the implementation of technical training programs for clinical engineering teams, aligned with clinical applications and continuously evaluated for effectiveness. ONA currently recognizes nine qualification seals for clinical engineering services in Brazil, all held by private companies. As a result of these accreditation initiatives, health care institutions are required to establish comprehensive medical technology and facility management policies. These have expanded to include activities such as technology assessment, asset management, professional training, financial management, technical and managerial reporting, contract control, project development, technovigilance, quality tool application, root cause analysis, and participation in committees related to standardization, radiological protection, HTA, and patient safety. According to a JCI accreditation consultant, external certification for a 300–500-bed hospital costs approximately US$300,000, covering preparation, organization, and audit expenses, excluding structural adaptations. Each recertification, required every 3 years, costs about US$75,000. Since accreditation standards mandate the implementation of medical equipment management plans, it becomes essential to investigate whether hospitals without accreditation still maintain such programs. This raises an important question: Is there a correlation between the presence of clinical engineering departments and the absence of hospital accreditation?

The Relationship with the Hospital's Technology Park

In the complex environment of hospital management, the administration of medical equipment is crucial, as hospitals constantly seek innovation and new services to remain competitive. Within this context, clinical engineering applies structured management methods to medical devices, creating historical records and performance indicators that classify equipment according to clinical use.[18] Considering the life cycle of medical devices, acquisition cost alone provides a misleading basis for decision-making. The total cost of ownership (TCO) model offers a more comprehensive assessment, encompassing expenses such as acquisition, installation, energy consumption, maintenance, repairs, upgrades, and training. Frequently, the TCO far exceeds the initial purchase price, reinforcing its adequacy as an evaluation method.[19] According to Moraes et al.[20], the use of medical technologies can be optimized through multi-criteria decision aid (MCDA) tools, which identify process stakeholders, capture their contributions, and organize results into structured decision-making frameworks—highlighting the importance of multidisciplinary collaboration.

As established by Donabedian[21], the quality of care is defined by three dimensions:

- Structure, referring to the material, human, and organizational resources;
- Process, representing what occurs during care delivery; and
- Outcome, reflecting the effects of care on individuals or populations.

The relationship between care improvement and associated costs is not linear: after a certain point, process enhancement no longer translates into better clinical outcomes, even as costs continue to rise. Thus, the expansion of a hospital's technological park may increase expenses without proportionate clinical benefit. In this context, just as patient information is essential to assess care quality, historical data on medical equipment—spanning its entire lifecycle—are critical to evaluating the performance and efficiency of the installed technological park.

Resolutions and Norms Guiding Clinical Engineering Services

Resolution No. 473/2022 of the Federal Council of Engineering and Agronomy (CONFEA/CREA) establishes professional titles such as Biomedical Engineer (code 121-12-00), Health and Safety Engineer (421-02-00), and Occupational Safety Engineer (424-01-00). No specific title exists for the clinical engineer. According to Anvisa RDC 02, professionals responsible for medical technology management must possess higher education and registration with their professional council when applicable, though no further requirements are defined. In Brazil, clinical engineering training occurs mainly through postgraduate programs, open even to nonengineering professionals, and focused on management and administration rather than technical certification. Thus, CREA registration is not

required. The most common professional designations are specialist, master, or doctor in clinical engineering.[22] The regulation of the clinical engineering profession remains under discussion, with CONFEA/CREA currently recognizing only biomedical engineers. The literature attributes the responsibility for medical technology management to biomedical engineers[1,23], while laws and resolutions assign this function to clinical engineering services within health care institutions.

MATERIALS AND METHODS

This study was developed through a bibliographic review of academic publications and institutional reports from databases and organizations such as EBSCO, SciELO, Google Scholar, WHO, ANAHP, MEC, CNES, and SBEB, covering the period 2003–2023. The search terms included: "Clinical Engineering", "Tecnologias Médicas", "Health Technology", "Medical Technology", "Dispositivos Médicos", "Medical Devices", "Gestão Hospitalar", "Hospital Management", "Gestão Econômica", "Economic Management", "Tomada de Decisão", "Decision Making", "Orçamento Hospitalar", "Hospital Budget", "Gestão Baseada em Evidências", "Evidence-Based Management", "Administração Hospitalar", "Hospital Administration", "Resultado Financeiro", "Financial Results", "Engenharia Biomédica", "Biomedical Engineering", and "Engenharia Clínica".

Within EBSCO's Business Source Complete, Boolean searches produced:

- (ti:("health technology") AND TX:("management" AND "clinical engineering")) → 22 results;
- (ti:("hospital management") AND TX:("clinical engineering")) → 28 results;
- (ti:("evidence-based management") AND TX:("clinical engineering")) → 6 results.

Complementing the literature review, exploratory field research was conducted with hospitals affiliated with ANAHP, as well as comparable public and private institutions, to broaden representativeness. The ANAHP secretariat authorized and distributed the research invitation, including the Invitation Letter, Informed Consent Form, Microsoft Forms survey link, and Ethics Committee approval (document P.057.2024, CEPH/FGV). In addition to ANAHP's 127 member hospitals, other institutions were invited, including Charitable hospitals (Santas Casas), a military hospital, and philanthropic and public hospitals serving both SUS and private patients, ensuring diverse perspectives. The study followed exploratory research methodology, designed to provide familiarity with the investigated phenomenon and identify the most relevant analytical dimensions.[24] As Babbie[25] emphasizes, exploratory studies deepen understanding, test methodological feasibility, and guide future research focus. The field data, collected via Microsoft Forms, employed categorical and open-ended responses ("yes", "no", or keywords with commentary). The questionnaire was based on seminal works such as *Health & Citizenship: Hospital Equipment Maintenance Management (Saúde & Cidadania: Gerenciamento de Manutenção de Equipamentos Hospitalares)*[26], *Quality in Local Management of Health Services and Actions (Qualidade na Gestão Local de Serviços e Ações de Saúde)*[27], *Clinical Engineering Handbook*[1], and *Clinical Engineering*.[28] In spite of the robust design, technical issues prevented some hospitals from receiving the survey. The ANAHP secretariat reported that IT filters categorized the emails as spam, reducing response rates. The limited yet rich dataset revealed fragmented internal information systems, underscoring the absence of standardized mechanisms for managing and retrieving clinical engineering data across hospitals.

Preparation

For the hospitals associated with ANAHP, an initial contact was made through the association's secretariat, and research materials were sent to be distributed to the hospitals and their associated leaders via email. For the other invited hospitals, contact was first made through telephone calls and subsequently via email, attaching a request for authorization to conduct the research and sending the link to access the instrument.

Survey Implementation

For all respondents, an explanation of the project, the research objectives, and the confidentiality of the work were provided. Authorization documentation, the file containing the research questions, and the online response link were sent as attachments in each recipient's email. Responses were organized in an Excel spreadsheet, with data sorted

by theme and question. Typographical errors were corrected, and graphs were created. Responses with free text were analyzed, and data were categorized according to the theme addressed. The collected data were examined, grouping responses and checking relationships between the data and the research theme. Using Excel spreadsheets and calculation tools, the percentage of participation in constructing each response was calculated, and tables and graphs of the results were generated.

RESULTS

In the following section, in Figure 2 we present the aggregation of responses obtained through the field survey, compiled in an Excel spreadsheet. Based on the collected data, graphs were created for each research theme. Here are some key topics that emerged from the study:

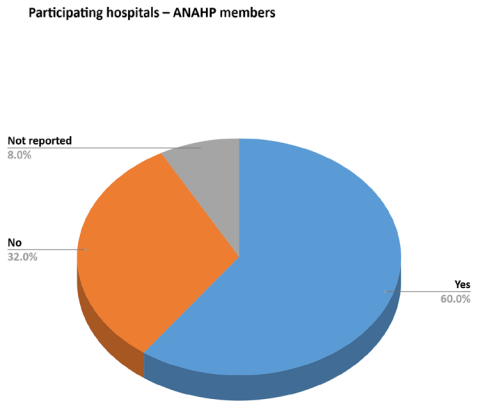

FIGURE 2. Hospitals that responded to the survey according to ANAHP affiliation.

The survey was designed to gather responses from professionals in leadership positions, consistent with the objectives of the study. As shown in Figure 3, participants reported a variety of roles. When considering both "director" and "superintendent" as executive-level positions, 14 hospitals—representing 56% of all respondents—provided answers from individuals in directive roles within their institutions. It is also noteworthy that two respondents chose not to disclose their positions.

The next analysis presents the distribution of participating hospitals across seven different states, with one hospital choosing not to report its location, as shown in Figure 4. Among the respondents, hospitals from São Paulo, Minas Gerais, and Paraná predominated, accounting for 80% of the sample, or 20 hospitals in total.

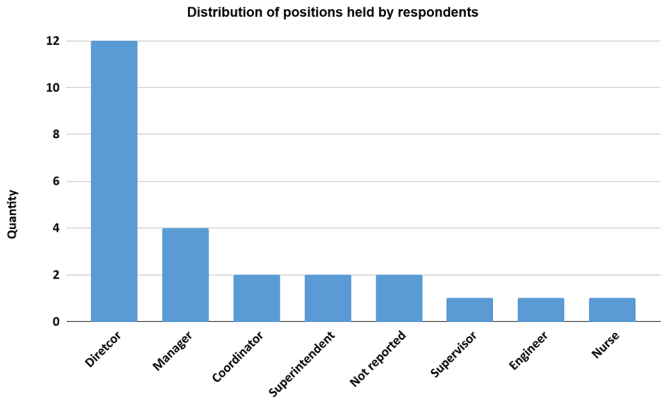

FIGURE 3. Positions of survey participants.

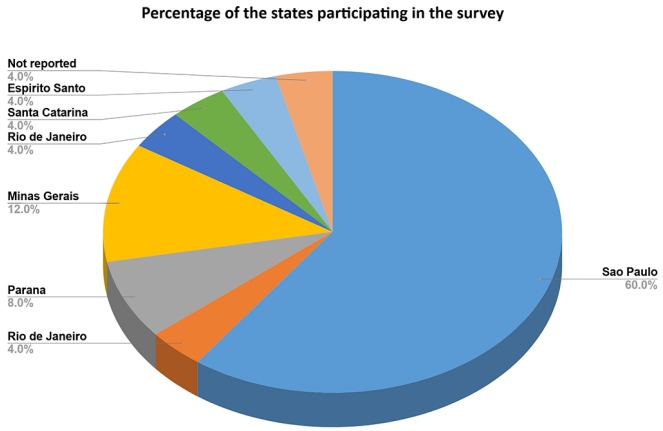

FIGURE 4. Distribution of survey participants by state.

Considering the national distribution of hospitals based on the National Registry of Health Establishments[29], 62.1% of listed hospitals are private and 37.9% are public. In our survey, 19 private hospitals participated, representing 76% of the total. This proportion is, to some extent, aligned with the public–private distribution reported by CNES. However, it is important to note that our sample does not possess sufficient statistical representativeness to confirm this correspondence conclusively, as shown in Figure 5.

Hospitals with more than 5,000 employees have bed capacities ranging from 340 to 2,950, as shown in Figure 6. Notably, one hospital in the sample, with nearly 3,000 beds, stands out significantly in size compared with the others.

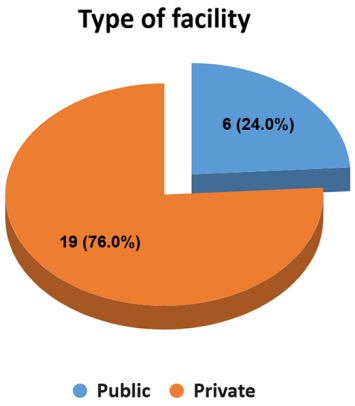

FIGURE 5. Hospitals that responded to the field survey, by type of facility.

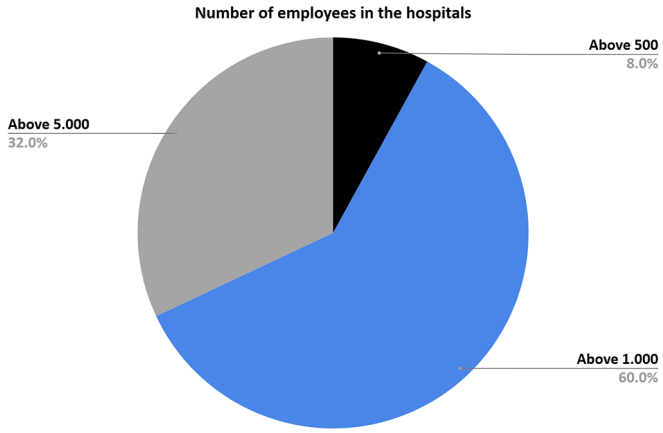

FIGURE 6. Number of employees reported by the hospitals in the survey.

The initial classification of hospitals by bed capacity was based on the combined total of general and critical-care beds reported by each institution. These totals were then grouped into three major categories, with medium- and large-sized hospitals predominating. Together, these two categories accounted for 72% of the sample, corresponding to 18 hospitals, as shown in Figure 7.

To classify hospitals according to the literature, the categorization based on hospital size proves to be the most effective. Chaves et al.[30] define hospital size by the number of beds as follows: small hospitals have up to 49 beds; medium hospitals range from 50 to 150 beds; and large hospitals have 151 to 500 beds.

An additional classification is provided by the Federal Council of Medicine (CFM)[31] in its 2023 *Manual de Procedimentos Administrativos para Pessoa Jurídica*, which

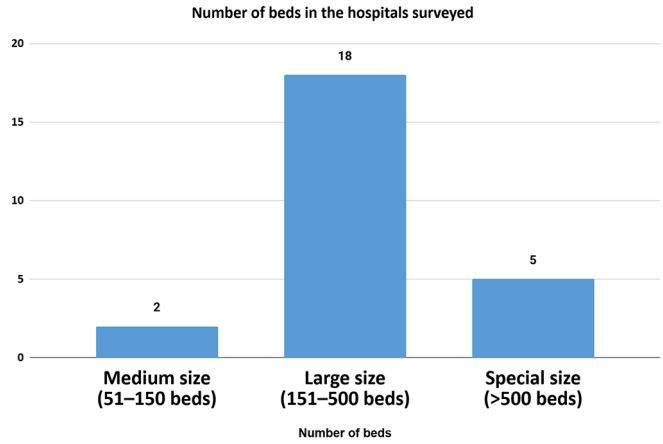

FIGURE 7. Number of beds reported by the hospitals in the survey.

categorizes hospitals as: Size 1, small hospitals with 5 to 50 beds; Size 2, hospitals with 51 to 150 beds; and Size 3, hospitals with more than 151 beds, noting that institutions with fewer than 5 beds are not registered as hospitals.

As shown in Figure 8, the survey sample was predominantly composed of large hospitals, which accounted for 88% of participants, or 22 institutions.

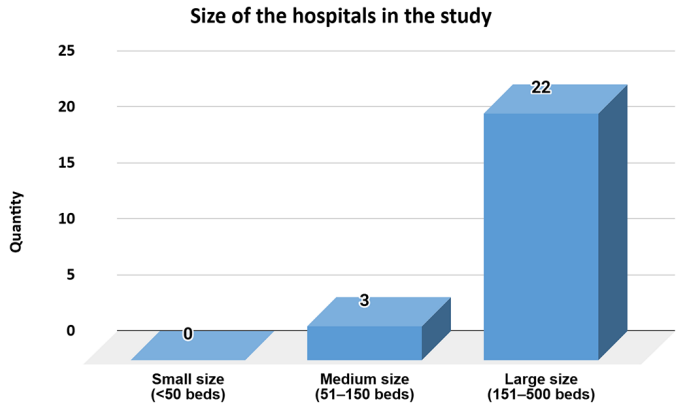

FIGURE 8. Distribution of hospitals by size.

Based on the data collected through the questionnaires, there is a clear predominance of hospitals operating with in-house clinical engineering teams, as illustrated in Figure 9. This distribution may reflect a sampling bias, given the participation of ANAHP-affiliated hospitals, as well as the limited number of survey responses.

When grouping responses that reported either fully in-house or mixed clinical engineering models, 23

hospitals—representing 92% of the sample—adopt these approaches. The mixed model allows for two interpretations: it may indicate the presence of professionals formally employed under the Brazilian Consolidation of Labor Laws (CLT), alongside externally contracted personnel by specialized service providers through technical support agreements.

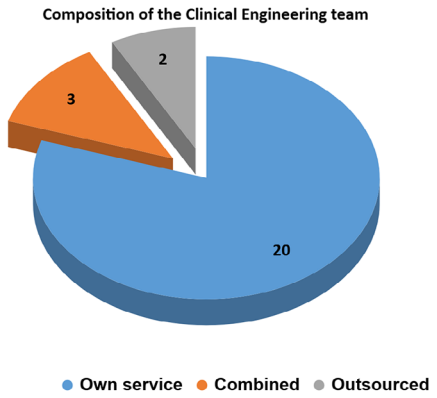

FIGURE 9. Types of clinical engineering composition in the research hospitals.

In addition, two hospitals reported fully outsourcing their clinical engineering services. This indicates that some institutions choose not to maintain an internal team, although no explanatory comments were provided to clarify the rationale behind this decision.

The following comments refer to the respondents' answers regarding the availability of in-house clinical engineering teams in their hospitals. Some statements suggest that, from the perspective of hospital managers, maintaining an internal team fosters greater engagement among clinical engineering staff. This perception is supported by remarks highlighting the team's participation and support in hospital operations. In contrast, comments about outsourced teams indicate a lower level of managerial involvement with contracted clinical engineering services.

Below are the verbatim comments gathered in the survey:

For in-house teams:

• "We provide 24/7 support and replace some activities on equipment that are usually performed by external service providers."

• "The team is highly participative in equipment maintenance processes and in identifying opportunities for process improvement."

• "The team truly embraces the institution's mission and strongly identifies with its purpose."

For outsourced teams:

• "The clinical engineering contract provides advisory support to the hospital in order to improve the service delivered by maintenance contractors."

• "We contract corrective and preventive maintenance services."

For mixed-model teams:

• "Management is handled by the hospital's team, and the technicians belong to a contracted company."

The participation of women in the workforce has increased significantly, particularly in the service sector.[32] In the hospitals surveyed—in spite of the small sample—the composition of clinical engineering teams remains predominantly male, as shown in Figure 10.

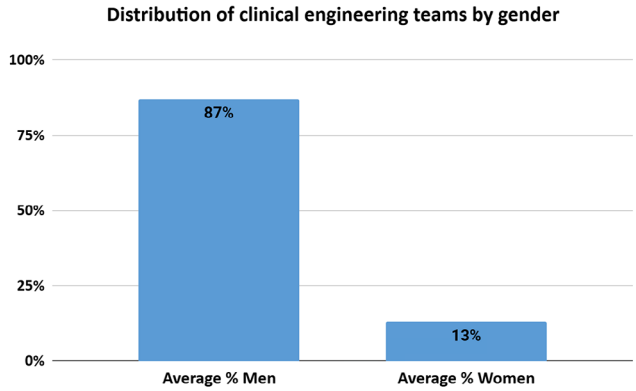

FIGURE 10. Distribution of clinical engineering teams by gender.

Chesler et al.[33] offer a contrasting view by showing a decline in the number of women graduating in biomedical engineering, even though it is the engineering field with the highest proportion of female students. The authors attribute this to challenges faced in male-dominated environments, influenced by "unconscious biases," as well as greater difficulty obtaining promotions, lower evaluations of their work, and the disproportionate burden of family-care responsibilities. They emphasize that "we simply need people with the best minds and skills, and many of them are women."

In this study, examining gender distribution in clinical engineering teams serves to better understand the context of participating hospitals. The analysis is exploratory and does not aim to define an ideal gender balance, but rather to complement the broader goals of the research.

Figure 11 shows a wide variety of positions cited as part of clinical engineering teams, totaling 138 roles. When grouped, the data reveal the main functions that compose these teams, with the mention of a purchaser as part of the department standing out as an unusual detail.

Another relevant observation is the presence of differing job titles for similar functions, such as "electronic technician" and "medical equipment technician." Among management roles, multiple hierarchical levels were identified, including leader, head, supervisor, coordinator, manager, executive manager, and director. Notably, two hospitals reported having only an engineer responsible for leading the clinical engineering department.

In Figure 12, we observe several hierarchical configurations within clinical engineering teams, based on the positions reported by each hospital. Leaner structures predominate, with one or two management levels, accounting for 16 hospitals that indicated this configuration.

An area of interest in the study was identifying the hospital directorate to which clinical engineering reports. The responses revealed a diverse set of reporting structures, with a predominance of administrative directorates—such as general administration, administrative, administrative and financial, operations, and financial—totaling 16 responses.

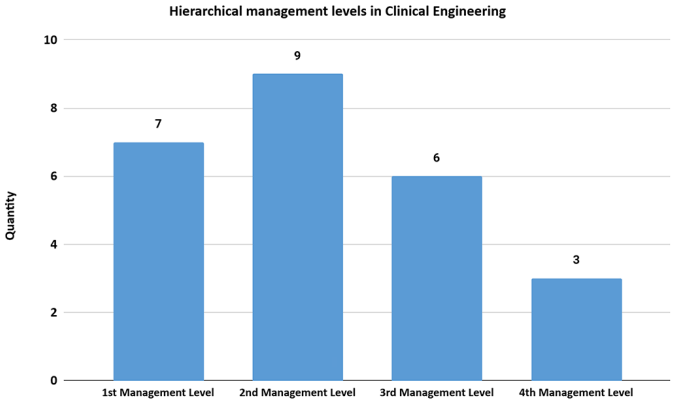

FIGURE 12. Grouping of hierarchical management levels of clinical engineering in the surveyed hospitals.

In addition, nine hospitals indicated reporting lines linked to technical directorates, including Infrastructure, Technical, Clinical Care, and Information Technology, as shown in Figure 13.

The placement of clinical engineering under the information technology directorate may be explained by the increasing integration of medical equipment into hospital networks, involving the transmission of images, data, and device-generated signals, as well as the growing

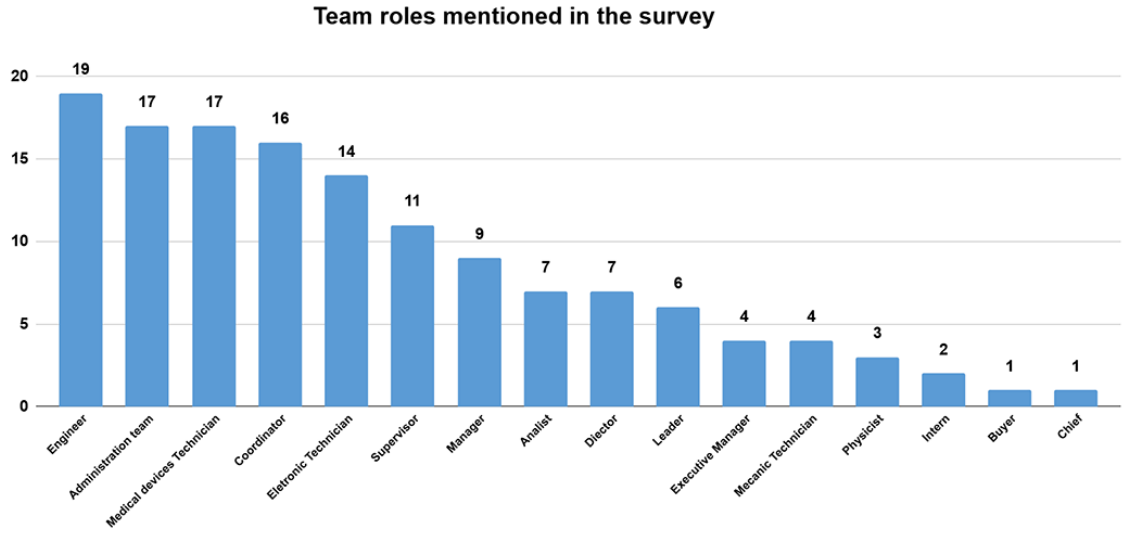

FIGURE 11. Types of positions cited that make up the clinical engineering team in the surveyed hospitals.

challenges related to safeguarding patient data. The presence of clinical engineering under the clinical care directorate also suggests a strong integration with care teams, aligning with Dyro's[1] interaction diagram, which identifies nursing as one of the key areas interfacing with clinical engineering.

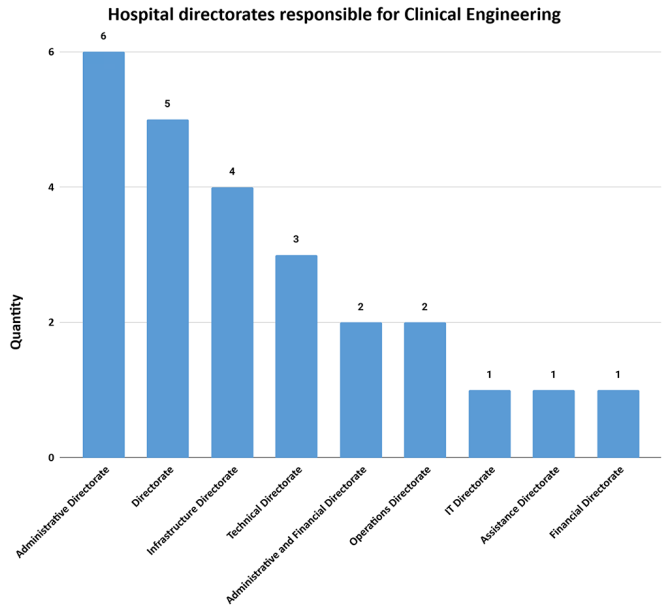

FIGURE 13. Directorates responsible for clinical engineering.

This study clearly demonstrates the diversity of areas to which clinical engineering reports within hospitals, as can be seen in Figure 14.

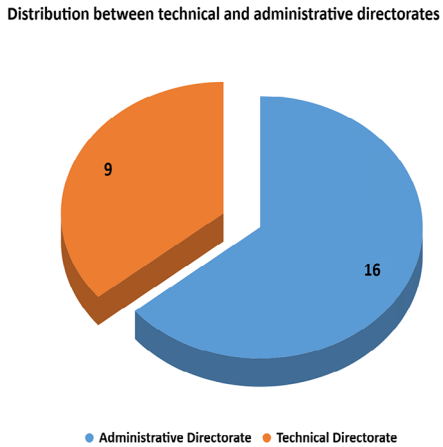

FIGURE 14. Grouping between technical and administrative directorates.

Among the open responses, several comments illustrate the diversity of reporting structures for clinical engineering, ranging from direct linkage to the corporate superintendency to matrix reporting through areas such as real estate or operational management.

The survey also examined the presence of HTA processes. HTA is essential for supporting evidence-based decisions regarding the incorporation and rational use of technologies.[27,34] In our sample, 15 hospitals reported having an HTA committee, as shown in Figure 15, a finding aligned with Francisco and Malik[27], who noted the limited influence of NATS on hospital decision-making. Likewise, Novaes and Soárez[35] observed low adherence to economic evaluation in national HTA bodies, with only a small proportion of CITEC and CONITEC studies incorporating such analyses.

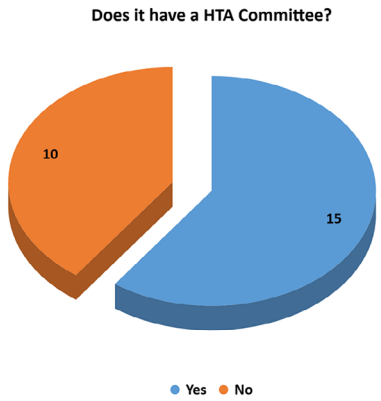

FIGURE 15. Hospitals and the HTA committee.

In spite of greater reported participation in HTA among the hospitals surveyed, these results do not confirm full institutional consolidation of HTA practices. As highlighted by Francisco and Malik[27], most hospitals still rely on simplified assessments rather than complete economic evaluations.

Open comments further illustrate this variability, referencing:

- alternative nomenclatures (e.g., "CITES");
- absence of formal committees, with decisions driven by internal prioritization and corporate budget review;
- committees still under development;

• collegial structures composed of clinical and administrative directors.

The open-ended responses suggest that HTA is still in a process of consolidation within hospitals, indicating that the full scope of HTA procedures is not yet clearly established or understood by many institutions. Among the 10 hospitals in our survey that reported not having HTA activities, 8 are private, as shown in Figure 16. These findings indicate that, regardless of whether hospitals are public or private, the presence of a formal HTA Committee is not yet a widespread reality.

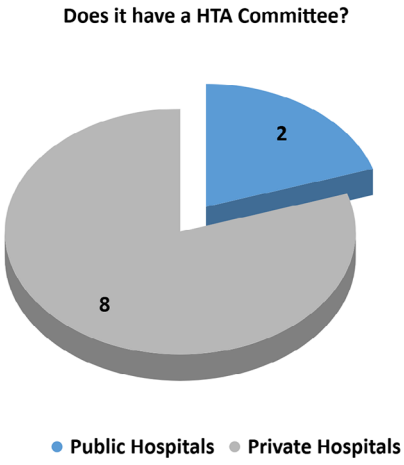

FIGURE 16. Hospitals without HTA Committee by type of facility.

One of the core responsibilities of clinical engineering is the maintenance of the installed fleet of medical equipment. Beyond maintenance activities, monitoring maintenance-related expenditures is essential to ensure alignment with the institution's budget. In some hospitals, however, the management of these expenses is assigned to other departments, which may indicate the absence of a dedicated clinical engineering manager or suggest a fully outsourced service model. In such cases, clinical engineering may focus solely on executing and documenting maintenance activities, while financial oversight is handled elsewhere.

Figure 17 shows that Clinical engineering predominates as the area responsible for managing maintenance expenses, with 20 hospitals reporting this arrangement. In five hospitals, this responsibility lies with other sectors—such as directors or superintendents—thereby positioning the clinical engineering team primarily as an operational executor rather than a financial manager.

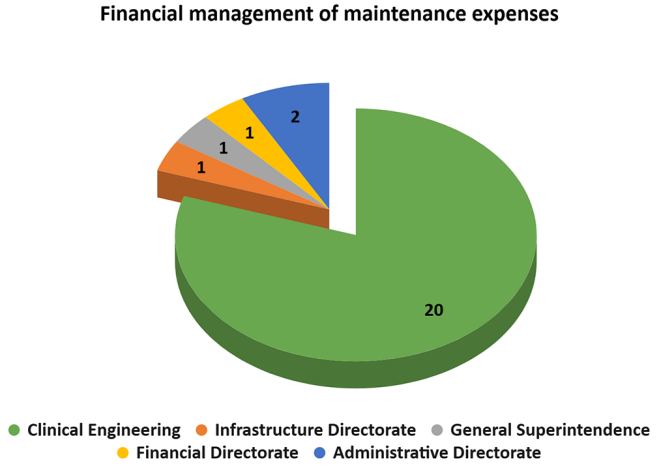

FIGURE 17. Areas that manage maintenance expenses.

Open-ended responses indicate that, in several hospitals, clinical engineering collaborates closely with finance in managing maintenance expenses. Examples include financial oversight by the infrastructure directorate, joint management with operations, support from financial units linked to the superintendency, and prioritization led by infrastructure.

In terms of contract management, responsibilities fall predominantly to technical areas—clinical engineering and the infrastructure directorate—which together account for 24 hospitals (see Figure 18). One hospital reported that contracts are managed by the contract directorate, consistent with its fully outsourced clinical engineering model.

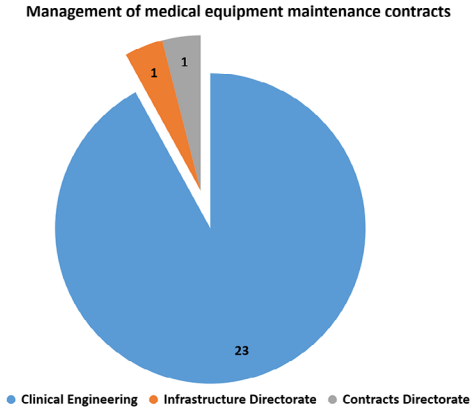

FIGURE 18. Management of maintenance contracts.

The open-ended responses suggest that clinical engineering often plays a supportive role in managing maintenance contracts, as illustrated in the comments below:

• "Responsibility lies with the hospital's infrastructure directorate, with support from clinical engineering."

• "Most contracts are corporate, with joint management for unit-specific needs. Contract execution, however, is primarily local."

• "Some contracts are managed corporately by the central unit."

One hospital reported not performing investment management. This institution is a public hospital with 612 beds, without an HTA department and with outsourced clinical engineering services. In such cases, investment decisions are typically led by the executive directorate, with clinical engineering acting as a supporting area (see Figure 19).

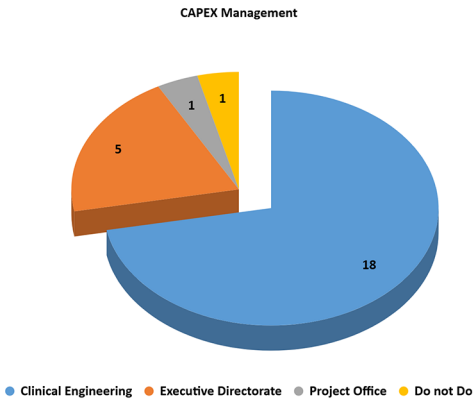

FIGURE 19. Areas that manage CAPEX (capital expenditure–capital expenses).

The open-ended responses for this question reinforce the perception that clinical engineering supports hospital leadership in evaluating and deciding on medical equipment acquisitions. Examples include:

• "Indicates replacement due to obsolescence and provides input on equipment purchases."

• "Responsibility lies with the infrastructure directorate, supported by clinical engineering and other hospital sectors."

• "Clinical engineering serves as an advisory body to the executive directorate for investment decisions in medical technologies."

Regarding budgeting, the responses show that clinical engineering plays a central role in preparing the budget for managing the hospital's medical equipment fleet. One hospital, however, reported that budget preparation is not the responsibility of clinical engineering because of its outsourced service model; in this case, financial planning is handled by a manager appointed by the hospital leadership (see Figure 20).

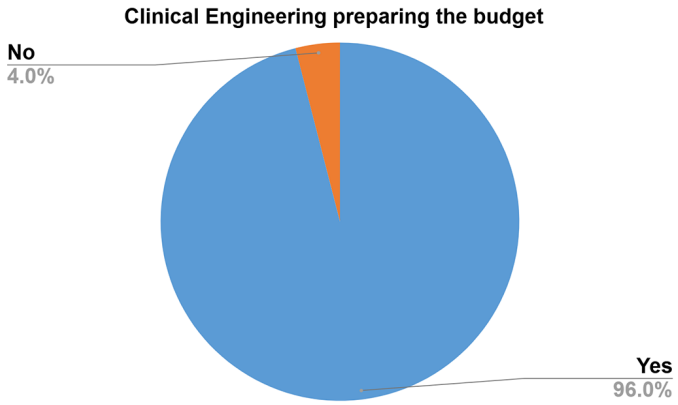

FIGURE 20. Clinical engineering and budget planning.

The open-ended responses reveal different degrees of involvement of clinical engineering in the budgeting process, as illustrated by the following remarks:

• "Through the infrastructure directorate."

• "Not only clinical engineering but also other business units through matrix management."

• "Yes. The total OPEX budget comes predetermined by the corporate office. It is then allocated across areas in agreement with the directorate and finance, with active participation in identifying needs and forecasting expenses. CAPEX also involves this participation."

• "Somewhat... clinical engineering prepares projections, but financial responsibility lies with finance."

• "Cost projections for general maintenance and fixed contracts are prepared."

Importantly, clinical engineering has a guaranteed seat in strategic meetings in 13 responses, suggesting that participation in strategic planning is considered essential in most hospitals. This finding aligns with the research question and indicates a relevant area for further exploration.

In Figure 21 we observed that in 12 responses, the participation of clinical engineering is occasional or occurs only when the need arises, indicating that it is not a permanent participant in strategic meetings.

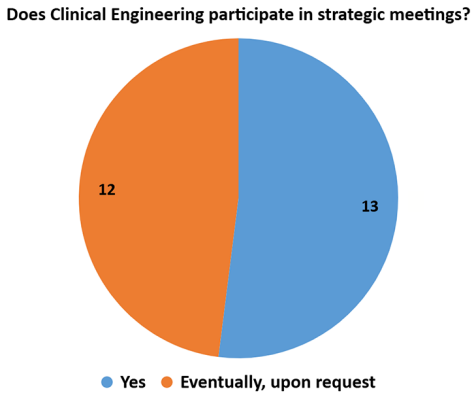

FIGURE 21. Participation of CE in strategic meetings.

Among the many open-ended responses, several deserve emphasis, as illustrated below:

• "There is participation in weekly meetings with the board, where results and strategic actions are reviewed. The area is represented by the Operations Manager, who requests direct involvement whenever decisions require Clinical Engineering support."

• "Participation in discussions is carried out by the Director of Engineering."

• "This process is led by the Maintenance and Construction Management, which encompasses areas beyond Clinical Engineering."

The findings also show strong involvement of clinical engineering in project committees (see Figure 22). As a technical specialty, the area contributes to the implementation of new health care services by integrating medical equipment specifications with hospital infrastructure planning. Accordingly, 24 hospitals in the survey recognize the importance of including clinical engineering in project committees.

The study by Treib et al.[36], based on accreditation programs such as ONA, JCI, Accreditation Canada International (ACI) and Qmentum, shows that in spite of the growth in the number of certified hospitals, only 6.1% of the 6,424 hospitals registered in the CNES had accreditation as of

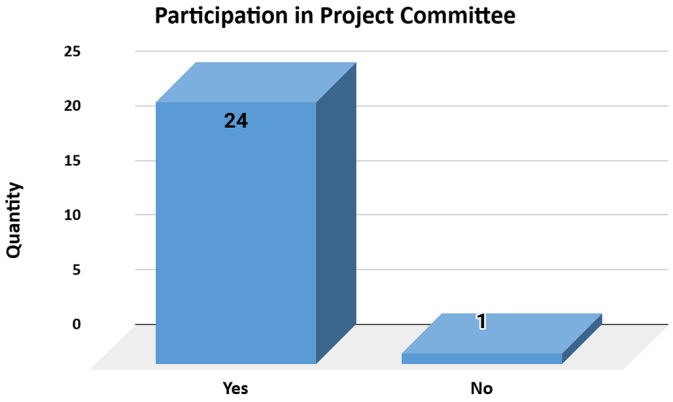

FIGURE 22. Participation in project committees.

September 2021. The authors conclude that accreditation in Brazil still exhibits an incipient level of adherence.

In our survey, three hospitals reported not having accreditation. Although most respondents indicated possessing some type of certification, the sample does not reflect the national scenario. The three hospitals without accreditation also reported not being ANAHP members; two of them are public institutions (one medium-sized and one large), and only one has a HTA committee (see Figure 23).

FIGURE 23. External evaluations.

The medium-sized hospital stated that clinical engineering does not participate in institutional strategy or budget planning, and that the service is outsourced. The analysis also identified one large private hospital without an HTA committee, suggesting that although accreditation is not necessarily linked to the type of management (public or private), some relationship may exist.

The absence of accreditation may indicate a lack of interest or insufficient resources to establish a clinical engineering team, a lower prioritization of technology assessment, or constraints related to human resources that hinder the formation of an HTA committee.

Of the 22 hospitals in the survey that reported having accreditation, many hold multiple certifications. We identified 42 mentions of different accreditation seals among these institutions, which may indicate that a quality-oriented culture fosters continuous improvement, or that obtaining multiple accreditations is being used as a marketing strategy to enhance competitiveness in the health care market (see Figure 24).

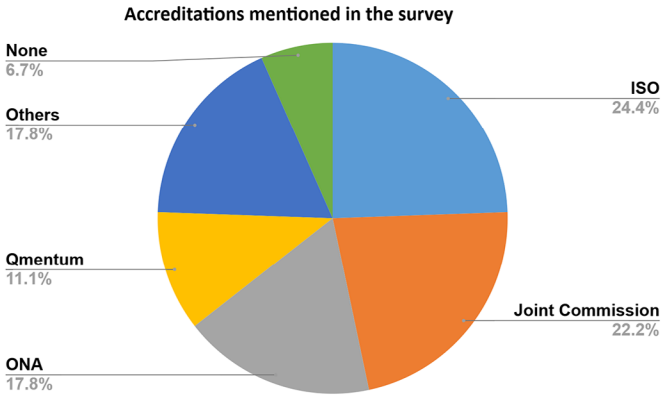

FIGURE 24. Mentions of accreditations.

Treib et al.[36] note that accreditation should promote a culture of quality and safety, driving positive changes in processes and the continuous improvement of health systems and services.

Finally, the perception of how clinical engineering is characterized shows overwhelmingly (see Figure 25) that it operates predominantly in an operational capacity, providing technical support for medical equipment. Moreover, as indicated by other responses in the survey, its involvement in strategic activities is less frequent and often occurs only when specifically requested.

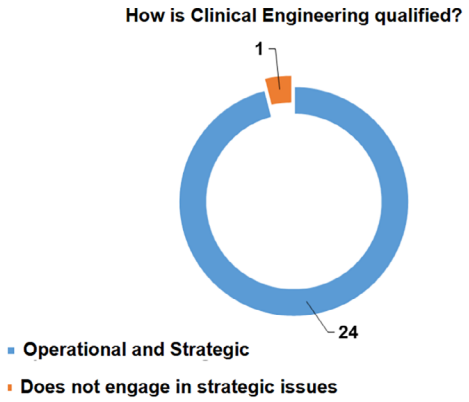

FIGURE 25. Qualification of clinical engineering.

DISCUSSION

Quality in Health Care in Clinical Engineering: An Approach Based on Donabedian

Donabedian[21] argues that the quality of technical performance is judged in comparison to the best practice, and that effectiveness is the extent to which expected outcomes are achieved. Therefore, the quality of technical care is proportional to its effectiveness, and it is necessary to have information on the cause-and-effect relationship between the attributes of structure, process, and outcome of care. To relate the research in this study to Donabedian's framework, we organized the responses according to the attributes mentioned: structure, process, and outcome. We highlighted the items with the absolute number of hospitals that responded to the categorical questions. We observed that most of the hospitals with accreditations have their own clinical engineering services, which predominantly include technology assessment processes (ATS). However, the depth of these assessments was not detailed. All the questions classified under the process attribute indicated a prevalence of clinical engineering in responses that converged on the understanding that, although clinical engineering is also cited as responsible for maintaining medical equipment, it is perceived as a department actively involved in managing expenses, maintenance contracts,

supporting investment decision-making, and participating in strategic discussions. Notably, its participation in the latter is often demand-driven rather than compulsory. Therefore, the study suggests that the role and actions of clinical engineering have gained significant traction within hospital management, aligning with the research question (Appendices 1 and 2).

Firstly, the number of hospitals that responded to the survey was small, with only 15 hospitals associated with ANAHP participating, representing 11.8% of the 127 hospitals in that group. The remaining 9 hospitals were from non-associated, public, and private institutions that accepted the invitation to participate. Thus, a total of 25 hospitals completed the survey.

The data collection period lasted 30 days, which limited the response time for the hospitals. Many managers missed the deadline and did not participate in the survey.

Many contacts with ANAHP hospitals were initiated by us through personal networks to raise awareness about the importance of the survey and ensure the delivery of the invitation emails, as there were reports that some hospitals did not receive the invitations because they were directed to spam folders.

Regarding the hospitals that received our invitation, some declined to participate because of various reasons, including concerns about compliance with the General Data Protection Law (LGPD), Law No. 13.709/2018 (https://www.gov.br/mds/pt-br/acesso-a-informacao/privacidade-e-protecao-de-dados/lgpd), or because the required information was stored in a central office with no access to specific data from the invited hospital. In addition, internal bureaucracy at some hospitals led to missed deadlines for response submission.

The survey yielded 28 responses within the 30-day period, from March 8 to April 8, 2024. However, 3 responses were duplicates from the same hospital, reducing the total to 25 hospitals, which is the basis for this study.

Two participants did not provide their name, job title, or the hospital's identification. Nevertheless, we considered all other responses from these hospitals in the survey because of their significant contribution to the study.

Two participants did not provide their name, job title, or the hospital's identification. Nevertheless, we considered all other responses from these hospitals in the survey because of their significant contribution to the study.

Despite the small sample size in this exploratory field research (25 participating hospitals), the recognition of clinical engineering by hospital managers was evident. Although the role and functions of clinical engineering were better understood, there were still discrepancies in the responses, indicating that gaps remain in the understanding of clinical engineering's role. This suggests that clinical engineering is recognized as a key player in managing medical equipment services and that it has a substantial role in hospital management. The sample provided valuable information for our research objective, revealing various organizational structures and the involvement of women in both management and technical roles, highlighting areas for further exploration and advancement. Despite the results, the research presents a significant field for study.

FINAL CONSIDERATIONS

The research met its objectives, revealing a rich landscape of information about clinical engineering's role in supporting hospital managers. However, significant differences in the perception of this area's role suggest that a broader analysis could consolidate the data. There are still gaps in clinical engineering's operations, possibly because of a lack of awareness, resources, or qualified professionals. Therefore, it is necessary to expand the study to include more hospitals to better understand these disparities and strengthen clinical engineering in the country.

In Appendix 1, a key finding of this study is the strong indication that clinical engineering has significant potential to contribute to hospital management, working across multiple areas and reporting structures. This suggests that senior leadership is still developing a full understanding of how clinical engineering can support decision-making and operational performance. Professional organizations such as ABEClin and SBEB, along with scientific events and specialized training programs, play an essential role in strengthening and promoting the field in Brazil. Although the results show a generally positive trend, they are not unanimous, indicating that opportunities remain—particularly regarding the optimal placement of

clinical engineering within organizational structures. The analysis based on the Donabedian model shows that having a qualified team supported by structured processes leads to more strategic management of the medical equipment fleet. This contributes to reduced operational disruptions, cost efficiency, rapid repairs, precise technical support, critical analysis of expense-reduction opportunities, and evidence-based technology assessment. According to Donabedian, outcomes do not necessarily improve proportionally with higher investments, reinforcing that efficiency arises from best practices rather than elevated spending alone. Overall, these results highlight that effective clinical engineering enhances organizational performance and strengthens the department's credibility in achieving accreditation from recognized auditing bodies.

The work proved to be quite complex and challenging, given the country's dimensions. Even in a small-scale study, we encountered several difficulties, indicating that such tasks are neither simple nor quick. Hence, a good strategy would be to start with small niches of hospitals and then expand gradually to include more participants. While our research has already provided valuable information for analysis, a more detailed mapping could offer a clearer understanding of which management models in clinical engineering are prevalent in these institutions. By exploring how hospital managers perceive the role of clinical engineering and obtaining various perspectives according to the nature of the hospitals—whether public or private, small, medium, or large—we could achieve a more profound and refined understanding of the subject.

AUTHOR CONTRIBUTIONS

Conceptualization, M.D.B.; Methodology, M.D.B. and A.M.M.; Validation, M.D.B. and A.M.M.; Formal Analysis, M.D.B.; Investigation, M.D.B.; Resources, M.D.B.; Data Curation, M.D.B.; Writing—Original Draft Preparation, M.D.B.; Writing—Review & Editing, M.D.B. and A.M.M.; Visualization, M.D.B.; Supervision, A.M.M.; Project Administration, M.D.B.

All authors have read and agreed to the published version of the manuscript.

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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APPENDICES

Appendix 1. Distribution of questions in the Donabedian model.

Donabedian	Structure	Processes	Results
What type of organization is your hospital?	6 Publics (24%) **19 Privates (76%)**		
How many employees does your hospital have?	> 500 - 2 (8%) **> 1000 - 15 (60%)** > 5000 - 8 (32%)		
Size of the hospitals.	Small Sized - 0 Medium Sized - 3 (12%) **Large Sized - 16 (64%)** Special - 6 (24%)		
Does your hospital have a Clinical Engineering department? (The type of the contract does not matter here)	Yes - 25 (100%)		
If there is a Clinical Engineering department, what is the composition of the team?	**Own team - 20 (80%)** Outsourced - 2 (8%) Mixed - 3 (12%)		
Check all the positions/functions that make up the structure of Clinical Engineering	1 Managment level - 7 (28%) **2 Managment levels - 9 (36%)** 3 Managment levels - 6 (24%) 4 Managment levels - 3 (12%)		
The Clinical Engineering department at your hospital is under which board?	**Administrative - 16 (64%)** Technichal - 9 (36%)		
Do you have a Health Technology Assessment (HTA) Committee for medical technologies?		**Yes - 15 (60%)** No - 10 (40%) - **Public 8 (80%)** - Private 2 (20 %)	
Who manages the maintenance of medical technologies?		**Clinical Engineering - 25 (100%)**	
Who manages the financial expenses for the maintenance of medical technologies?		**Clinical Engineering - 20 (80%)** Administrative Directorate - 2 (8%) Infrastructure Directorate - 1 (4%) Financial Directorate - 1 (4%) General Superintendency - 1 (4%)	**Maintained Medical Equipment Park** **Specialized Team** **Strategic Planning** **Budget Management - Efficiency** **Accreditation Achievement**
Who manages the maintenance contracts for medical technologies?		**Clinical Engineering - 23 (92%)** Infrastructure Directorate - 1 (4%) Constracts Directorate - 1 (4%)	
Who manages the investments (Capex) for medical technologies?		**Clinical Engineering - 18 (72%)** Executive Directorate - 5 (20%) Project Office - 1 (4%) There is no managment - 1 (4%)	
Does the Clinical Engineering department play an active role in the preparation of your area's annual budget?		**Yes - 24 (96%)** No - 1 (4%)	
Does the Clinical Engineering department at your institution play an active role in the technical evaluation process and decision-making for purchasing medical technologies?		**Yes - 25 (100%)**	
Is the Clinical Engineering department involved in the hospital's planning discussions and decisions, regularly participating in strategic meetings?		**Yes - 13 (52%)** Eventually, upon request - 12 (48%)	
Is the Clinical Engineering department represented and actively involved in the hospital's Project Committees, contributing to the review and decision-making regarding technical initiatives and implementations?		**Yes - 24 (96%)** No - 1 (4%)	
Is the analysis of the Clinical Engineering department part of the decision-making process?		**Yes - 25 (100%)**	
Which external evaluation certificates does your institution hold?		**With certifications - 22 (88%)** Without certifications - 3 (12%)	
How do you qualify the Clinical Engineering department at your hospital?		**Operational and Strategic - 24 (96%)** Does not get involved with strategic issues - 1 (4%)	
Have you had the opportunity to visit the Clinical Engineering department at your institution to get to know its facilities, team, and operations?		**Yes - 25 (100%)**	

Appendix 2. Questionnaire–survey.

FGV

Name:		**Position:**	
Institution:		**City/State**	
Questionnaire – Survey			
1	How many general (non-critical care) beds does your hospital have?		
2	How many critical-care beds (ICU, step-down, UCG, UCO, cardiac units) does your hospital have?		
			Mark with an "x"
3	How many employees does your hospital have?	Fewer than 200	( )
		More than 200	( )
		More than 500	( )
		More than 1000	( )
		More than 5000	( )
4	How is your hospital classified in terms of organizational type?	Public	( )
		Private	( )
		Philanthropic	( )
		Other (specify):	Text:
5	Does your hospital have a Clinical Engineering service (regardless of the type of employment arrangement)?	Yes	( )
		No	( )
6	If your hospital has a Clinical Engineering service, what is the composition of the team?	In-house	( )
		Outsourced	( )
		Hybrid	( )
7	Which roles make up the structure of the Clinical Engineering department?	Director	( )
		Superintendent	( )
		Executive Manager	( )
		Manager	( )
		Coordinator	( )
		Supervisor	( )
		Team Leader	( )
		Engineer	( )
		Analyst	( )
		Physicist	( )
		Eletronics Technician	( )
		Mechanical Technician	( )
		Medical Equipment Technician	( )
		Administrative Staff	( )
		Others	Text:
8	Do you have an HTA Committee for medical technologies?	Yes	( )
		No	( )
9	Who is responsible for managing maintenance activities?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
10	Who is responsible for financial management?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
11	Who is responsible for managing medical technology contracts?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
12	Who is responsible for managing capital investments (CAPEX) in medical technologies?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
13	Is Clinical Engineering responsible for preparing the department's annual budget?	Yes	( )
		No	( )
14	Does Clinical Engineering participate in the processes of evaluating and purchasing technologies?	Yes	( )
		No	( )

15	Does Clinical Engineering participate in strategic meetings?	Yes	( )
		No	( )
16	Does Clinical Engineering participate in project committees?	Yes	( )
		No	( )
17	Is Clinical Engineering analysis part of the decision-making process?	Yes	( )
		No	( )
18	What is the gender distribution (%) in the Clinical Engineering department?	Men	( )
		Women	( )
		Others	( )
19	Which external evaluation certifications does your institution hold?	Joint Commission	( )
		ONA	( )
		PADI	( )
		CARF	( )
		ACR	( )
		Others	Text:
20	How do you perceive the Clinical Engineering department in your hospital?	It is purely operational	( )
		It is operational and strategic	( )
		It is solely strategic	( )
		It is not involved in strategic matters	( )
		I cannot say	( )
21	Have you visited your institution's Clinical Engineering department?	Yes	( )
		No	( )

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