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Clinical engineering as a strategic component of hospital governance: implications for patient safety and technological risk management

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Abstract

Background: Hospitals increasingly operate as technology-intensive environments in which medical devices, digital platforms, and diagnostic systems constitute essential infrastructure for safe and effective care delivery. The traditional scope of clinical engineering, historically associated with equipment maintenance and technical support, has progressively expanded toward broader responsibilities involving technology governance, regulatory compliance, risk management, and strategic institutional planning. This study investigates how clinical engineering has been incorporated into hospital governance structures and examines the organizational implications associated with this integration. Methods: A systematic literature review was conducted according to PRISMA 2020 guidelines. Searches were performed in Scopus, Web of Science, PubMed/MEDLINE, Embase, SciELO, and the Virtual Health Library. The search period covered January 2000 to December 2025. Eligible studies included peer-reviewed publications addressing governance, management, or institutional roles of clinical engineering and medical technology management. A two-stage screening process was applied (title/abstract and full-text review). Methodological quality was assessed using CASP and Joanna Briggs Institute appraisal tools. Results: A total of 742 records were identified. After duplicate removal and eligibility screening, 25 studies were included in the qualitative synthesis. Three analytical domains emerged from the literature: integration of clinical engineering into executive governance structures; interaction with patient safety systems; and institutional accountability associated with medical technology management. Evidence suggests increasing recognition of clinical engineering as a governance-relevant function, although organizational models remain heterogeneous. Conclusions: Formal integration of clinical engineering into hospital governance contributes to improved technological traceability, enhanced patient safety practices, and stronger institutional accountability. However, standardized governance indicators and multicenter empirical validation remain limited. Future research should focus on developing comparative frameworks capable of evaluating technological governance maturity across healthcare systems.

Keywords: Clinical engineering; Hospital governance; Patient safety; Medical technology management; Healthcare technology governance; Medical device risk management

Background

The rapid expansion of advanced medical technologies has profoundly transformed the organizational structure of modern healthcare institutions. Contemporary hospitals depend on complex technological infrastructures including diagnostic imaging systems, infusion pumps, ventilators, digital information platforms, and interconnected

monitoring devices. These technologies constitute essential components of clinical care delivery and directly influence diagnostic accuracy, treatment effectiveness, and patient safety outcomes. [1,2]

Historically, clinical engineering departments were primarily responsible for preventive maintenance, equipment calibration, and technical support. Over time, however, the growing complexity of healthcare technologies, the increasing cost of medical devices, and the expansion of regulatory oversight have significantly broadened the scope of this professional field. Clinical engineering now encompasses technology lifecycle management, regulatory compliance, procurement support, risk assessment, and participation in institutional decision-making processes. [1,3] [4,5]

Within contemporary healthcare systems, governance structures increasingly emphasize transparency, accountability, and risk management. Hospitals must ensure that technological infrastructures operate safely and reliably while meeting regulatory requirements and accreditation standards. Failures in medical device management may result in adverse clinical events, legal liability, operational disruption, or financial losses for healthcare organizations. [6,9]

Despite the growing importance of medical technology governance, the scientific literature addressing the intersection between clinical engineering and hospital governance remains fragmented. Few studies provide structured analysis of how clinical engineering functions are incorporated into executive management structures or how such integration affects institutional performance and patient safety.

This study therefore aims to analyze the integration of clinical engineering into hospital governance structures and to explore the organizational implications associated with technological governance in healthcare institutions.

Methods

Study design This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement.

Data sources and search strategy

Electronic searches were conducted in the following databases: Scopus, Web of Science, PubMed/MEDLINE, Embase, SciELO, and the Virtual Health Library (BVS). The search covered publications from January 2000 to December 2025. A combination of keywords and Boolean operators was applied.

Example search strategy

("clinical engineering" OR "biomedical engineering management")

AND
("hospital governance" OR "healthcare governance")

AND
("patient safety" OR "medical device governance" OR "technology risk")

Eligibility criteria

Inclusion criteria:

• Studies addressing clinical engineering or medical technology management within governance or organizational contexts

• Studies linking medical technology management with patient safety or institutional risk management

• Peer-reviewed publications in English, Portuguese, or Spanish

Exclusion criteria:

• Studies focused exclusively on equipment maintenance

• Laboratory-based engineering studies

• Editorials or non-peer-reviewed materials

Study selection

All records were exported to reference management software and duplicates were removed. Titles and abstracts were independently screened according to predefined eligibility criteria. Full texts of potentially relevant articles were assessed to determine eligibility. Disagreements during the selection process were resolved through consensus. The study selection process followed the PRISMA 2020 guidelines and is summarized in Figure 1.

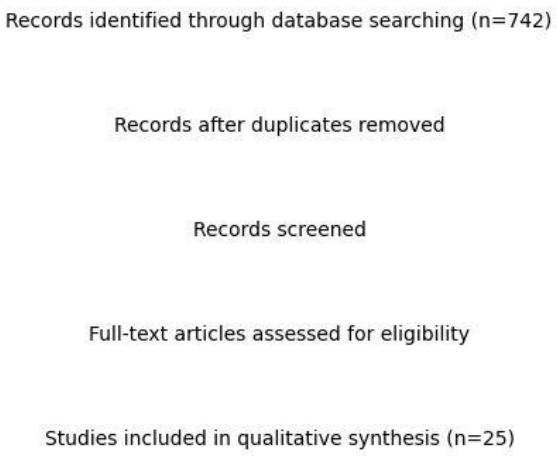

Figure 1. PRISMA flow diagram describing the identification, screening, eligibility, and inclusion of studies in the systematic review.

Quality appraisal

Methodological quality was evaluated using the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies and Joanna Briggs Institute appraisal tools for observational studies. Each article was assessed for methodological rigor, clarity of design, relevance to healthcare governance, and reporting transparency.

Data synthesis

Due to heterogeneity among study designs and outcomes, a qualitative thematic

synthesis approach was adopted. Analytical categories were identified through iterative comparison of study findings.

Results

Overview of included studies

The database search identified 742 records. After removing duplicates and applying eligibility criteria, 25 studies were included in the qualitative synthesis. The main characteristics of the included studies are summarized in Table 1.

Table 1. Characteristics of the studies included in the systematic review.

Author	Year	Country	Study Design	Governance Aspect	Main Findings
Dyro	2014	USA	Review	Technology management	Clinical engineering supports governance decisions
Iadanza	2019	Italy	Review	Technology lifecycle	Integration with hospital management
Fennigkoh	1989	USA	Observational	Equipment management	Framework for equipment control
WHO	2017	Global	Report	Health technology governance	Policy guidance for CE services
ECRI	2023	USA	Report	Technology hazards	Risk identification for medical devices
Kaplan	2009	USA	Review	Health IT governance	Organizational technology management
Carayon	2006	USA	Study	Patient safety systems	Human factors in healthcare systems
Kohn	2000	USA	Report	Patient safety	System-based safety framework
Vincent	2010	UK	Review	Safety governance	Risk and safety frameworks
Sorenson	2014	USA/EU	Policy study	Regulation	Medical device governance policy
IOM	2005	USA	Report	Medical device safety	Technology safety oversight
WHO Atlas	2017	Global	Survey	Technology infrastructure	Global distribution of devices

ISO	2019	International	Standard	Risk management	Medical device risk frameworks
JCI	2021	International	Standard	Hospital accreditation	Technology governance standards
Campbell	2016	UK	Observational	Clinical engineering roles	Strategic hospital integration
Wang	2018	China	Observational	Technology assessment	Hospital device governance
Silva	2020	Brazil	Case study	Equipment management	Integration with patient safety
Garcia	2017	Spain	Case study	Technology lifecycle	Strategic device planning
Lopez	2019	Mexico	Observational	Hospital governance	Engineering in decision committees
Singh	2021	India	Study	Risk management	Technology safety processes
Park	2018	South Korea	Observational	Hospital tech management	Governance alignment
Brown	2015	USA	Review	Biomedical engineering management	Strategic planning
Chen	2022	China	Observational	Technology governance	Engineering in hospital strategy
Rossi	2016	Italy	Case study	Technology procurement	Clinical engineering advisory role
Almeida	2023	Brazil	Study	Technology risk	Governance and compliance

Three principal analytical domains were identified:

Integration of clinical engineering into executive governance structures Several studies describe the incorporation of clinical engineering professionals into hospital committees responsible for technology management, procurement decisions, and strategic planning. Such participation allows technical expertise to inform institutional decision-making processes.

Interface with patient safety systems Clinical engineering departments frequently collaborate with patient safety and risk management programs. Responsibilities may

include investigation of device-related incidents, technology performance monitoring, and implementation of preventive maintenance strategies.

Legal accountability and technological risk mitigation Healthcare institutions increasingly recognize that inadequate management of medical technologies may expose organizations to legal and regulatory consequences. Structured technology governance frameworks therefore contribute to risk mitigation and compliance with accreditation standards.

Discussion

The findings of this review suggest that clinical engineering is progressively evolving from a technical support function toward a strategic institutional role. As hospitals adopt increasingly sophisticated technological infrastructures, governance mechanisms must ensure that medical devices are effectively integrated into clinical workflows and patient safety systems.

Participation of clinical engineering professionals in governance committees represents an important organizational mechanism through which technical expertise informs decision-making processes. This integration supports more informed procurement decisions, facilitates lifecycle management of medical technologies, and enables proactive identification of technological risks.

Technological governance has also become closely linked to patient safety initiatives. Device failures, configuration errors, and inadequate maintenance practices represent recognized contributors to adverse events. The involvement of clinical engineering departments in safety committees allows healthcare organizations to strengthen surveillance mechanisms and implement preventive risk management strategies. [8,10]

Another important dimension concerns regulatory compliance and accreditation requirements. International frameworks such as ISO 14971 and Joint Commission standards emphasize structured risk management practices related to medical devices. Clinical engineering departments frequently serve as institutional interfaces between regulatory requirements and operational implementation. [11,14,15]

The maturity model proposed in this study describes progressive levels of integration between clinical engineering and hospital governance (Figure 2).

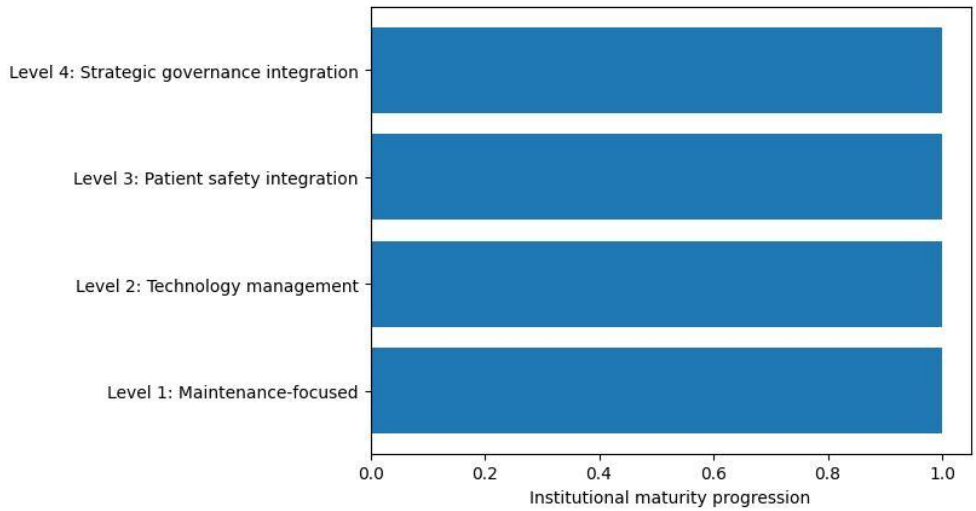

Figure 2. Institutional maturity model illustrating the progressive integration of clinical engineering functions into hospital governance structures.

At early stages, departments focus primarily on maintenance functions. Intermediate stages involve broader technology management responsibilities and collaboration with safety programs. At advanced stages, clinical engineering becomes integrated into executive decision-making structures and contributes to strategic technology planning. Recognizing clinical engineering as a governance function rather than solely a technical service may therefore strengthen institutional capacity to manage technological risks and improve patient safety outcomes.

Limitations

This study presents several limitations. First, methodological heterogeneity among included studies limits direct comparison of findings. Second, the number of multicenter empirical investigations examining governance structures remains limited. Third, most studies rely on qualitative methodologies, which may restrict generalizability. Publication bias may also influence the available literature, as unsuccessful governance models are less frequently reported.

Conclusions

Clinical engineering demonstrates substantial potential to function as a structural component of hospital governance systems. When integrated into executive and clinical decision-making structures, clinical engineering contributes to improved technological traceability, enhanced patient safety practices, and stronger institutional accountability. Future research should prioritize multicenter studies capable of evaluating governance models across diverse healthcare systems and developing standardized indicators to measure institutional maturity in medical technology governance.

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Ethics declaration

Not applicable. This study is a literature review based on previously published data.

Competing interests

The author declares no competing interests.

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