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Original Research Article

Implementing Clinical Engineering Departments in a Small Hospital: A 2017–2021 Regulatory Compliance and Organizational Analysis

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ABSTRACT

The integration of clinical engineering into healthcare systems is increasingly recognized as a key factor in improving regulatory compliance, equipment management, and patient safety. However, many hospitals in developing countries still lack formally established clinical engineering departments, leading to operational inefficiencies and safety risks. This longitudinal study evaluates the impact of implementing a clinical engineering department in a 10-bed secondary-level hospital between 2017 and 2021. Using a mixed-methods approach, regulatory compliance was assessed through two comprehensive audits conducted before and after the department's implementation, based on 423 standards derived from national regulations. Regulatory compliance increased from 54.61% in 2017 to 78.72% in 2021. A two-sample Z-test for proportions confirmed that this improvement was statistically significant ($Z = 7.44$, $p < 0.001$) with a 95% confidence interval of 17.95% to 30.27%, suggesting that the change was unlikely because of random variation. Although the same set of standards was evaluated in both audits, the 4-year interval and lack of item-level tracking justified the use of this approximation. An organizational analysis revealed that while the department contributed significantly to equipment oversight, process standardization, and regulatory compliance, its participation in high-level strategic decision-making remained limited. The dual role in both operational and strategic tasks posed ongoing challenges in prioritization and impact. Semi-structured interviews with clinical, administrative, and technical staff supported the quantitative findings. A total of 93% of participants were aware of the department, 87% understood its functions, and 86% rated its performance as "Good" or "Very Good". The majority also considered it essential or considerably necessary for hospital operations. Together, the quantitative and qualitative findings confirm that the creation of a clinical engineering department can significantly enhance hospital regulatory compliance, operational performance, and staff engagement with safety processes. These results provide a replicable model for healthcare institutions in similar contexts seeking to strengthen medical technology management and regulatory alignment.

Keywords—*Clinical engineering, Regulatory compliance, Medical equipment management, Patient safety, Longitudinal study, Healthcare quality.*

INTRODUCTION

Clinical engineering plays a fundamental role in the quality of hospital care, patient safety, and the optimization of both administrative and healthcare processes. Its importance has grown exponentially as medical technology has become an essential component for the proper functioning of healthcare institutions.[1] However, in developing countries, such as Mexico, the implementation of clinical engineering departments in hospitals faces major challenges because of the absence of standardized regulations, resource limitations, and a general lack of awareness about their impact on healthcare service delivery.[2]

In the context of the COVID-19 pandemic, the relevance of clinical engineering in Mexico became more evident than ever, demonstrating its critical role in medical technology management, the maintenance of essential equipment, and the implementation of strategies to optimize hospital resources.[3] The World Health Organization (WHO) has recognized that the presence of trained clinical engineers is key to ensuring effective investment in healthcare technology and achieving better patient care outcomes.[4] Furthermore, international studies have shown that the participation of clinical engineers in hospitals has a direct and positive impact on indicators of patient safety and efficiency of care.[5]

Despite the growing evidence on the benefits of clinical engineering, healthcare technology management in Mexico still faces structural and administrative barriers. Previous research has identified that many private hospitals lack formalized clinical engineering departments, leading to inefficient management of medical devices and posing a risk to the quality of care.[2] Moreover, the absence of clear regulations and standardized data on the operation of these departments has hindered their effective integration into the public sector.[6]

This longitudinal study builds upon prior research evaluating regulatory compliance with healthcare standards,[7] which analyzed compliance with Mexican Official Standards (Norma Oficial Mexicana, NOM) in infrastructure and equipment before the implementation of a clinical engineering department in a private hospital. In 2021, these standards were reevaluated, revealing significant improvements in regulatory compliance, which translated into safer and more efficient medical care. These findings reinforce the importance of clinical engineering as an essential component for the modernization of the healthcare sector in Mexico and other developing countries.

Recent literature confirms that regulatory frameworks, especially when aligned with accreditation programs or national standards, can significantly improve safety, process efficiency, and equipment reliability.[8] Studies have shown that hospital accreditation and standardized maintenance protocols not only reduce equipment downtime but also improve risk management, patient outcomes, and resource utilization.[9,10] In this regard, the presence of trained clinical engineers and the implementation of comprehensive medical device management systems, grounded in national and international standards, are considered fundamental to quality assurance in modern healthcare systems.[8]

This paper aims to provide evidence on the need to standardize healthcare technology management and promote the establishment of clinical engineering departments in hospitals as an effective strategy to improve the quality of care and patient safety.

MATERIALS AND METHODS

This longitudinal study employed a mixed-methods approach to evaluate the impact of establishing a clinical engineering department in a secondary-level hospital in a developing country, between 2017 and 2021. The hospital is a privately managed institution operating as a secondary-level facility with a capacity of 10 beds, serving a population of medium to low socioeconomic status. Before 2017, the absence of a formal clinical engineering department resulted in deficiencies in medical device management and regulatory compliance.

Regulatory Audits and Compliance Assessment

The analysis was based on two comprehensive audits, conducted in 2017 (pre-implementation) and 2021 (post-implementation), following the guidelines of the applicable Mexican Official Standards (NOMs) for hospital infrastructure and equipment (Table 1). A total of

423 regulatory standards were assessed, covering key aspects of medical equipment, infrastructure, safety, and hygiene in critical hospital areas. The selection of the 423 NOM items focused on infrastructure, equipment, and regulatory criteria that fall within the typical scope of clinical engineering responsibilities in hospitals. Standards were drawn from six Mexican Official Standards (NOMs) covering areas such as electrical safety, intensive care, emergency services, anesthesiology, and hazardous waste management. Emphasis was placed on items related to the physical environment, medical devices, and safety procedures, where clinical engineering interventions are most relevant. In addition, selected regulatory aspects were included to reflect areas where the department may influence institutional regulatory compliance.

On-site inspections of equipment and infrastructure were performed using checklists derived from the NOMs to evaluate the physical condition of devices and the adequacy of facilities. In addition, document reviews of records, logs, and service orders were conducted to assess the management and maintenance of medical devices.

The first regulatory audit was conducted in September 2017, prior to the establishment of the clinical engineering department. The department was formally implemented in June 2018, and the follow-up audit was conducted in February 2021, resulting in a total observation period of 3 years and 5 months between the baseline and the post-implementation assessment.

No major organizational changes occurred during the implementation of the clinical engineering department that could have influenced the audit results or staff perception. The hospital's leadership, governance structure, and departmental management remained stable throughout the observation period, ensuring continuity in operational processes.

To ensure methodological consistency across both time points, the audits conducted in 2017 and 2021 were carried out by the same evaluation team, using identical checklists and assessment procedures. The 423 regulatory standards assessed remained unchanged throughout the study period, as no modifications were introduced to the applicable national regulations. Both audits followed a standardized protocol involving documentary review, on-site inspections, and structured interviews. This consistency in evaluators, instruments, and regulatory criteria minimized the potential for measurement bias and ensured a reliable longitudinal comparison.

TABLE 1. List of Mexican Official Standards (NOM) used to evaluate regulatory compliance in hospital infrastructure, medical devices, and safety procedures relevant to clinical engineering.

Standard	Field of Study
NOM-001-SEDE-2012	Electrical Installations (use).
NOM-016-SSA3-2012	Establishes the minimum infrastructure and equipment requirements for hospitals and specialized medical consultation facilities.
NOM-025-SSA3-2013	For the organization and operation of intensive care units.
NOM-087-ECOL-SSA1-2002	Biological-infectious hazardous waste classification and handling specifications.
NOM-006-SSA3-2011	For the practice of anesthesiology.
NOM-027-SSA3-2013	Establishes the criteria for operation and care in emergency services of medical facilities.

Organizational Analysis

To complement the regulatory audits, a qualitative organizational analysis was performed to assess the impact of the clinical engineering department on hospital structure, roles, and operational processes. Three key aspects were evaluated:

1. Structure: The organizational hierarchy of the hospital was reviewed to determine the position and influence of the clinical engineering department in strategic and operational activities.

2. Responsibilities: The roles and delegated tasks of the clinical engineering department were analyzed, focusing on its contributions to infrastructure management, regulatory compliance, and interdepartmental collaboration.

3. Processes: The study examined how hospital workflows evolved following the implementation of the clinical engineering department, specifically improvements in medical device oversight, standardization of procedures, and staff training programs.

Semi-Structured Interviews

To further explore the perception of these changes, semi-structured interviews were conducted with clinical, technical, and administrative staff selected based on their involvement in hospital operations. These interviews examined staff perceptions regarding operational improvements, safety culture, and interactions with the clinical engineering department. The questions were designed to capture both individual experiences and broader perspectives on the department's contribution to hospital efficiency and patient safety.

A total of 15 hospital staff members participated in the interviews, which were conducted anonymously to promote candid responses. Participants were selected from all shifts, including weekends, to ensure extensive representation. The interviewees included clinical, technical, and administrative personnel, covering a wide range of services and time blocks.

Based on institutional records and operational estimates, the hospital operates with a total staff of approximately 40 members, including all departments. During the observation period, the clinical engineering department was composed of one full-time staff member and two interns. The sample of 15 interviewees includes all three technical staff members, two administrative staff, and a substantial portion of the clinical team.

Given the hospital's small size and the deliberate inclusion of all functional roles and operational shifts, the sample is considered sufficiently diverse and representative to support meaningful qualitative insights.

Study Design and Statistical Analysis

The study design is illustrated in Figure 1, which outlines the main stages of the investigation. The process began with an initial audit in 2017 to establish a baseline for regulatory compliance. Following the implementation of the clinical engineering department, key actions included the appointment of specialized staff, the creation of internal policies, and the adoption of management systems. In 2021, a final audit was conducted to evaluate the effectiveness of these interventions.

To assess the statistical significance of the observed improvements, we compared regulatory compliance rates between the 2017 and 2021 audits using a two-sample Z-test for proportions. Although both audits assessed the same set of 423 regulatory standards, they were conducted 4 years apart under distinct operational conditions and with separate data collection processes. Given

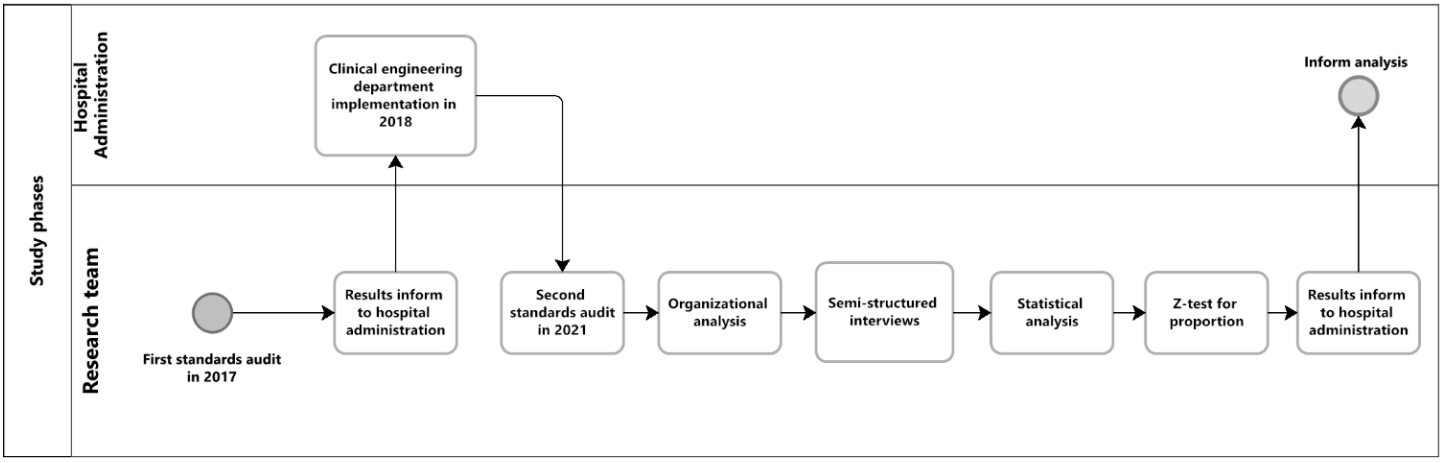

FIGURE 1. Study methodology outlining the main phases of the intervention, including baseline audit, implementation of the clinical engineering department, follow-up audit, and staff perception analysis.

the absence of item-level longitudinal tracking, the audits were treated as independent cross-sectional evaluations. We recognize that this method assumes independence and may slightly underestimate the standard error. A 95% confidence interval for the change in compliance proportion was also calculated. This methodology provides a model that can be replicated by other institutions facing similar challenges in medical technology management and regulatory compliance. The results offer empirical evidence on how the integration of clinical engineering contributes to enhancing hospital safety, operational efficiency, and regulatory alignment.

RESULTS

Normative Assessment

In the emergency department, regulatory compliance showed significant improvement between 2017 and 2021. During the initial evaluation in 2017, compliance was at 49%, while by 2021, it increased to 91%. This improvement was achieved through targeted interventions in critical infrastructure and processes, particularly regulatory compliance with key standards such as NOM-016-SSA3-2012 and NOM-025-SSA3-2013. These advancements are summarized in Table 2, which consolidates compliance data for the emergency department, intensive care unit (ICU), and the overall hospital level between 2017 and 2021

TABLE 2. Summary of regulatory compliance improvement in key hospital areas between 2017 and 2021.

Area/Level	2017 Compliance (%)	2021 Compliance (%)	Change (%)
Emergency Department	49	91	+ 42
Intensive Care Unit (ICU)	39	79	+ 40
General Hospital	54.61	78.72	+ 24.11

Note: The emergency department and ICU showed the most substantial gains, with increases of 42% and 40%, respectively. The overall hospital compliance improved by 24.11%, reflecting the impact of structured interventions in infrastructure, equipment management, and process standardization.

In the case of the ICU, the initial situation also presented significant deficiencies, with regulatory compliance at 39% in 2017. Following the implementation of corrective actions, including infrastructure improvements and strengthened operational protocols, compliance reached 79.27% in 2021. This progress highlights the importance of prioritizing standards related to critical infrastructure, particularly NOM-025-SSA3-2013. These values are included in Table 3, highlighting the ICU's significant improvement alongside other key hospital areas.

TABLE 3. Regulatory compliance with NOM-016-SSA3-2012 and NOM-025-SSA3-2013 in the intensive care unit.

Standard	Evaluated Standards	Compliant	Non-compliant	Percentage
NOM-016-SSA3-2012	59	50	9	84.75%
NOM-025-SSA3-2013	23	15	8	65.22%
Total	82	65	17	79.27%

Note: Compliance improved to 84.75% and 65.22%, respectively, following the implementation of corrective actions in infrastructure, safety protocols, and medical device oversight. The combined compliance rate for both standards reached 79.27%.

At the general level, the hospital's regulatory compliance increased from 54.61% in 2017 to 78.72% in 2021, evaluating a total of 423 regulatory standards. This corresponds to an increase from 231 regulatory standards of compliance in 2017 to 333 regulatory standards of compliance in 2021, reflecting an absolute improvement of 102 items. This significant progress resulted from strategic interventions in the most critical areas, such as the emergency department and ICU, as well as the implementation of corrective measures related to standards like NOM-016-SSA3-2012 and NOM-025-SSA3-20. The overall evolution of regulatory compliance is also reflected in Table 2, providing a comparative overview of key improvements across hospital areas.

Furthermore, an analysis of noncompliances by type revealed that 63% of deficiencies were related to materials,

34% to infrastructure, and only 3% to processes. This breakdown allowed prioritization of areas with the greatest potential impact on hospital safety and operability. Details of this distribution are shown in Figure 2 (Breakdown of noncompliances by type).

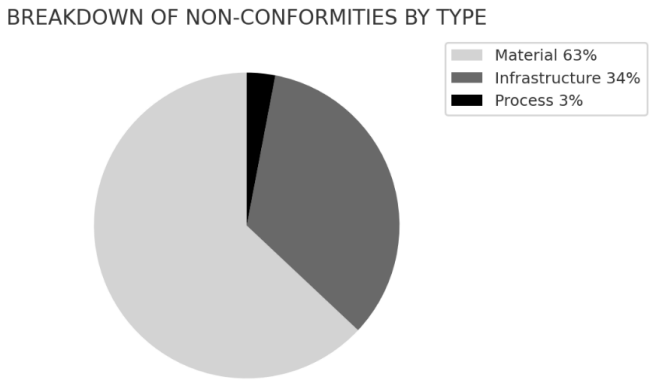

FIGURE 2. Distribution of noncompliances by type in the 2017 audit. Material-related issues represented 63%, infrastructure 34%, and process-related only 3%, guiding targeted corrective actions.

A Pareto analysis demonstrated that addressing deficiencies related to NOM-016-SSA3-2012 and NOM-027-SSA3-2013 would resolve over 80% of the identified noncompliances. This highlights the criticality of these standards in achieving overall regulatory adherence and improving hospital performance. The Pareto distribution is presented in Figure 3.

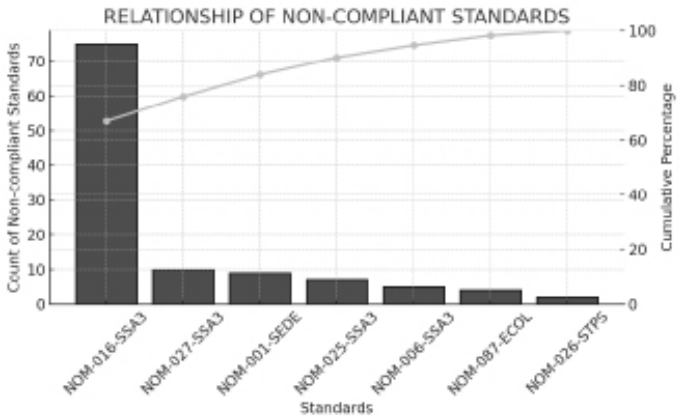

FIGURE 3. This chart illustrates the distribution of noncompliant standards, highlighting the most critical areas for improvement.

NOM-016-SSA3 accounts for the highest number of noncompliances, significantly impacting overall compliance. The cumulative percentage curve indicates that addressing the top three noncompliant standards—NOM-016-SSA3, NOM-027-SSA3, and NOM-001-SEDE—would resolve a majority of regulatory gaps.

Overall, the results demonstrate how the most critical areas, such as the emergency department and ICU, served as examples of the impact that implementing a clinical engineering department can have. These advancements contributed significantly to improving overall regulatory compliance and provided a roadmap that can be replicated by other institutions with similar characteristics.

Statistical Analysis: Impact of the Clinical Engineering Department on Regulatory Compliance

To determine whether the observed improvement in regulatory compliance was statistically significant, we conducted a two-sample Z-test for proportions. This test evaluated whether the difference in compliance between 2017 (prior to the implementation of the clinical engineering department) and 2021 (following its implementation) was due to chance or represented a meaningful improvement.

Hypothesis Formulation

Null hypothesis (H_0): There is no significant difference in regulatory compliance between 2017 and 2021 ($p_1 = p_2$).

Alternative hypothesis (H_a): There is a significant difference in regulatory compliance between 2017 and 2021 ($p_1 \neq p_2$).

Statistical Test and Results

Using the total number of regulatory standards evaluated in both years ($n_1 = n_2 = 423$), the proportion of compliant standards was calculated:

$$2017: p_1 = \frac{231}{423} = 54.61\% \quad (1)$$

$$2021: p_1 = \frac{333}{423} = 78.72\% \quad (2)$$

A two-tailed Z-test for proportions was performed at a 95% confidence level, yielding the following results:

- Z-score = 7.44
- Critical value ($Z_{critical}$): ± 1.96
- p-value: 8.96×10^{-14}
- Confidence interval (95%) for the difference in proportions: 24.11% (95% CI: 17.95% to 30.27%)

Since the Z-score (7.44) exceeds the critical value (1.96) and the p-value is significantly lower than 0.05, we reject the null hypothesis. This indicates that the increase in regulatory compliance is statistically significant and unlikely to be because of random variation.

However, although the same set of standards was assessed in both audits, the lack of item-level tracking and the 4-year interval justified the use of an approximate method based on cross-sectional comparisons. This limitation is further discussed in the Discussion section.

Interpretation and Conclusion

The statistical analysis confirms that the implementation of the clinical engineering department had a measurable impact on regulatory compliance. The rate of compliance increased from 54.61% in 2017 to 78.72% in 2021, a difference of 24.11 percentage points. This change was found to be statistically significant ($Z = 7.44$, $p < 0.001$), with a 95% confidence interval ranging from 17.95% to 30.27%, indicating that the observed improvement is unlikely to be because of random variation.

Although the same set of regulatory standards was assessed in both audits, the absence of item-level tracking and the time gap between evaluations justified the use of a cross-sectional approximation. This finding aligns with improvements observed in critical areas, such as the emergency department and the ICU, further enhancing hospital regulatory performance and ensuring sustained improvement of quality.

Results of the Organizational Analysis

Organizational analysis was conducted through qualitative interviews with collaborators from the administration, clinical engineering, and hospital management areas. Key areas of inquiry included the organizational structure, departmental responsibilities, and the impact of new processes implemented by the clinical engineering department. The investigated aspects are summarized below:

Investigated Aspects

1**. Structure:** Reviewed current and previous organizational charts, departmental hierarchy, and participation in strategic activities such as acquisitions and decision-making.

2. Responsibilities: Analyzed the current and delegated responsibilities of the clinical engineering department.

3. Processes: Compared operational processes before and after the creation of the department, focusing on the changes implemented and interdepartmental impacts.

The analysis revealed the following findings:

1. Structural Challenges: The hospital lacks a formally defined and approved organizational chart. The clinical engineering department operates with dual roles, contributing to strategic functions such as technology evaluation and acquisitions, while simultaneously managing operational tasks like equipment repairs and supplier management. This duality often limits the department's ability to optimally focus on either strategic or operational tasks.

2. Limited Strategic Participation: Although the clinical engineering department is integral to specific decisions, such as technology acquisitions, its participation in high-level meetings is restricted. This limits its ability to influence broader hospital policies and initiatives.

3. Process Improvements: Before the creation of the department, different hospital areas managed equipment needs independently, leading to inconsistent approaches. The introduction of systematic routines, such as equipment verifications and staff training sessions, has standardized processes, improving equipment safety and operational efficiency.

A detailed representation of these findings is provided in Table 4, which illustrates the comparative roles of the department before and after its formal establishment.

This analysis underscores the critical need for institutional support to address structural and strategic gaps, enabling the department to maximize its contributions to hospital operations and patient safety.

Results of the Situational Analysis

The situational analysis was conducted to assess the level of knowledge and perception among hospital staff regarding the clinical engineering department. Key stakeholders from administration, technical staff, and clinical personnel were included to provide a comprehensive view of the department's relevance and performance in hospital operations.

Interviews were conducted anonymously with staff from all operational shifts, including weekends, to ensure a representative sample across the hospital. A total of 15 staff members, covering all technical staff, two administrative personnel, and a diverse portion of the clinical team participated. Based on staffing estimates, this sample represents approximately 40–50% of the total hospital workforce.

Interview questions focused on staff perception of equipment management, operational efficiency, and safety culture, including prompts such as: "What changes have you noticed in equipment availability?" or "How would you rate the department's support in your daily work?"

Awareness and Understanding

Most respondents (93%) were aware of the department's existence, and 87% understood its core functions. These results highlight a generally high level of visibility, though the gap between awareness and understanding suggests a potential opportunity to strengthen internal communication.

Perceived Contribution and Necessity

Participants broadly recognized the department's value, with 84% rating its contribution to workplace safety as "Significant" or "Considerable". Furthermore, 80% considered the clinical engineering department to be "Significantly" or "Considerably" necessary for hospital operations (Figure 4).

TABLE 4. Comparison of the clinical engineering department's role before (2017) and after (2021) its formal implementation.

Point of Analysis	Before Implementation (2017)	After Implementation (2021)
Structure	No defined or authorized organizational chart. Previous charts were unavailable, and the department lacked a clear position within the hospital. Its participation in strategic decisions was limited.	The clinical engineering department now has a mixed hierarchy, combining strategic and operational levels. It participates in technology evaluations and acquisitions, although its presence in management meetings remains limited.
Responsibilities	No formal assignment of responsibilities. Decisions regarding medical equipment were made in a dispersed manner across different areas without a defined responsible party.	The clinical engineering department now plays a key role in medical equipment management and contributes knowledge in infrastructure and regulations. It collaborates with other areas such as quality, administration, and IT.
Processes	Corrective maintenance was handled by various areas without a designated responsible party. There were no structured verification routines or training plans for the use of medical devices.	The clinical engineering department now supervises maintenance, provides medical equipment training, and ensures regulatory compliance, consolidating more structured and efficient processes.

Note: Key improvements include a defined organizational structure, clearer responsibilities, and more structured processes for the management of medical equipment and regulatory compliance.

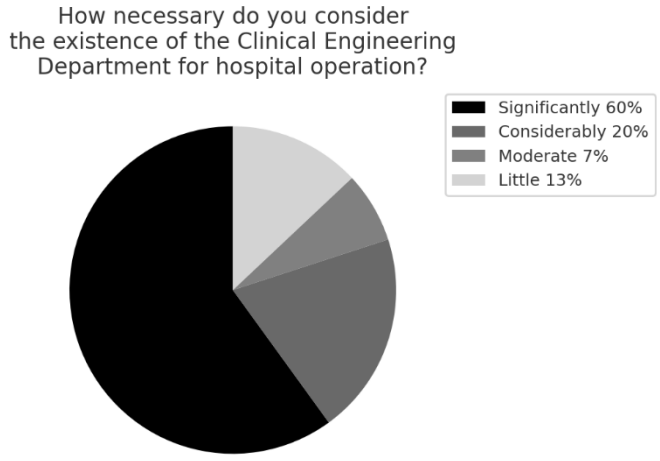

FIGURE 4. Perceived necessity of the clinical engineering department for hospital operations.

A total of 80% of respondents considered the department to be "Significantly" (60%) or "Considerably" (20%) necessary for the hospital's functioning, while only 7% selected "Moderate" and 13% "Little". These results highlight the strategic value attributed to the department by the hospital staff.

Staff Satisfaction

Satisfaction with the performance of the department was high: 86% rated it as "Very Good" or "Good", while only 14% rated it as "Fair" or "Poor". This overall positive perception reinforces the credibility of the department within the institution, though there is room for improvement in specific areas such as clinical training on equipment use.

Summary of Results

The full set of response distributions is summarized in Table 5, showing detailed percentages across each topic assessed.

TABLE 5. Summary of staff perceptions regarding the clinical engineering department.

Topic	Response Options	Result (%)
Awareness of CE Department existence	Yes/No	93% | 7%
Awareness of CE Department functions	Yes/No	87% | 13%
Contribution to workplace safety	Significant/ Considerable/ Moderate/ Low	50% | 34% | 8% | 8%
Necessity for hospital operations	Significant/ Considerable/ Moderate/ Low	60% | 20% | 7% | 13%
Evaluation of CE staff performance	Very Good/Good/ Fair/Poor	46% | 40% | 7% | 7%

Note: The table presents the response distributions for key dimensions evaluated in the situational analysis, including awareness, perceived contribution, institutional necessity, and performance evaluation. Percentages reflect the proportion of respondents selecting each option in a sample representing approximately 40–50% of the hospital workforce.

DISCUSSION

This methodology provides a model that can be replicated by other institutions facing similar challenges in medical technology management and regulatory compliance. The results offer empirical evidence on how the integration of clinical engineering contributes to enhancing hospital safety, operational efficiency, and regulatory alignment.

The findings of this study provide clear evidence of the positive impact that the implementation of a clinical engineering department has on regulatory compliance, operational efficiency, and staff perception in a secondary-level hospital in Mexico. The increase in regulatory compliance from 54.61% in 2017 to 78.72% in 2021 is a direct result of structured processes in medical technology management, infrastructure audits, and staff training.

The improvement in adherence to Mexican Official Standards (NOMs) is one of the key outcomes of this study.

The application of critical standards such as NOM-016-SSA3-2012 and NOM-025-SSA3-2013 has been fundamental in strengthening hospital safety. A deeper analysis of noncompliance issues showed that 63% of deficiencies were related to materials, 34% to infrastructure, and only 3% to processes, indicating that most problems can be addressed through investments in equipment and structural maintenance.

The observed improvement in regulatory compliance reflects a meaningful institutional change following the implementation of the clinical engineering department. While statistical analysis supports this interpretation, the absence of item-level tracking and the 4-year gap between assessments required treating both audits as independent observations. This approach, though limited, was methodologically justified as a cross-sectional approximation.

A Pareto analysis further demonstrated that addressing deficiencies in just three key standards (NOM-016-SSA3, NOM-027-SSA3, and NOM-001-SEDE) would resolve over 80% of the identified regulatory compliance issues, highlighting the importance of a strategic approach in prioritizing regulatory efforts.

Beyond regulatory compliance, the creation of the clinical engineering department has driven significant organizational changes. The standardization of procedures and the introduction of periodic equipment verifications have strengthened patient safety and operational efficiency. However, structural challenges remain, particularly regarding the department's integration into high-level hospital decision-making.

Despite its critical role in medical technology management, the clinical engineering department continues to operate under a hybrid model, balancing both operational and strategic responsibilities. This dual role may limit its ability to influence high-level decisions and maximize its potential impact on the quality of hospital service.

The semi-structured interviews reflect a high level of acceptance and recognition of the department among hospital staff. A total of 93% of respondents acknowledged the department's existence, 87% understood its functions, while 84% considered it essential or significantly necessary. This level of recognition suggests that the work of the department has generated a tangible impact on organizational culture and the perception of hospital safety. However, the results also revealed areas for improvement. Fourteen percent of respondents perceived the department's performance as "fair" or "poor", suggesting that certain aspects, particularly in training and communication with clinical and administrative staff, require further optimization.

Although the findings are encouraging, the applicability of this model to other types of healthcare institutions requires further consideration. While the results of this study are promising, they must be interpreted within the context of a small, secondary-level hospital with a capacity of 10 beds. The operational dynamics, staffing patterns, and regulatory oversight in such a facility differ significantly from those in larger hospitals with higher patient volume, broader departmental structures, and more complex governance systems. However, the structured methodology used for implementing the clinical engineering department—focusing on regulatory alignment, equipment management, and process standardization—offers a foundation that can be replicated and adapted to institutions of greater scale. Future multisite studies, particularly those involving tertiary care hospitals and diverse healthcare systems, would provide valuable comparative data to validate and refine the model presented in this study.

It is also important to consider the broader healthcare context in which this study was conducted. Between 2019 and 2021, the COVID-19 pandemic introduced unprecedented changes in hospital operations, resource allocation, and regulatory enforcement. These changes may have influenced the results observed in the post-implementation audit, particularly in critical departments such as the ICU and emergency room, which were directly impacted by the pandemic. While the observed improvement in regulatory compliance can largely be attributed to the establishment of the clinical engineering department, it is possible that heightened regulatory scrutiny, emergency preparedness protocols, and resource mobilization related to COVID-19 contributed in part to this progress. However, the absence of a parallel audit in a comparable

hospital without a clinical engineering department limits the ability to isolate these external influences. Future studies incorporating multicenter comparisons could help clarify the independent effect of clinical engineering interventions under varying external conditions.

Despite these positive results, this study has certain limitations. The analysis was conducted in a single secondary-level hospital, which may limit the generalization of the findings to other healthcare settings. In addition, although the same 423 standards were evaluated in both audits, they were assessed independently without item-level tracking. This limits the ability to apply paired-data statistical tests such as McNemar's test, which could have provided a more precise estimation of the intervention's effect. Future research should consider structured item-by-item longitudinal tracking to enable the use of paired analyses and strengthen the causal attribution of observed improvements. Furthermore, while the study included both quantitative and qualitative methods, future research could benefit from a longer follow-up period to assess the sustainability of the implemented improvements.

The implementation of a clinical engineering department has proven to be an effective strategy for enhancing regulatory compliance, optimizing processes, and strengthening hospital safety. The statistical validation and confidence interval analysis confirm that the impact of the intervention is both meaningful and statistically significant. To maximize its long-term contribution, it is essential to promote the department's integration into hospital governance and ensure its consolidation as a strategic actor within the organizational structure. This study provides a transferable model that may inform future initiatives aimed at strengthening healthcare systems in Mexico and other developing regions.

CONCLUSIONS

This study provides strong empirical evidence that the implementation of a clinical engineering department in a secondary-level hospital in Mexico significantly improves regulatory compliance, operational efficiency, and staff perception of hospital safety. The increase in compliance with Mexican Official Standards (NOMs) from 54.61% in 2017 to 78.72% in 2021 demonstrates the effectiveness of structured interventions in medical technology management, infrastructure standardization, and staff training.

These findings reinforce the effectiveness of the intervention and its direct impact on regulatory performance. Although both audits assessed the same set of standards, they were conducted under different operational conditions and without item-level tracking, warranting the use of a cross-sectional approach. Future studies should apply paired-data statistical methods—such as McNemar's test—supported by longitudinal tracking, to strengthen the attribution of observed improvements.

Beyond compliance metrics, the study highlights the positive impact of the department on hospital workflows and organizational structure. The standardization of medical equipment management and verification processes contributed to a safer and more efficient hospital environment. However, despite these improvements, the department's limited participation in strategic decision-making remains a challenge that could hinder its long-term effectiveness.

Staff perception of the clinical engineering department was overwhelmingly positive, with 93% of the hospital personnel acknowledging its role and 86% rating its performance as "Good" or "Very Good". However, the study also identified areas for further optimization, particularly in training programs and internal communication strategies to ensure a deeper understanding of the functions and contributions of the department.

The findings suggest that the successful integration of clinical engineering into hospital systems can serve as a model that can be replicated by other healthcare institutions facing similar challenges in regulatory compliance and medical equipment management. However, for long-term sustainability, hospitals must ensure institutional support, continuous staff training, and periodic evaluations to maintain compliance and drive continuous improvement.

Although this study presents a compelling case for the role of clinical engineering in hospital optimization, it is not without limitations. The research was conducted in a single hospital, which may limit the generalizability of

its findings. In addition, the lack of paired data prevents the use of more precise statistical methods that account for dependency across time points. Future research could benefit from broader sampling, item-level tracking, and longer follow-up periods to further validate and expand upon these results.

In conclusion, the integration of a clinical engineering department significantly enhances hospital compliance, operational processes, and safety perceptions. To fully capitalize on its benefits, hospital administrations must ensure strategic inclusion of clinical engineers in decision-making processes, adequate resource allocation, and long-term institutional commitment. These measures will be crucial for consolidating the department's role as a fundamental pillar in hospital quality and patient safety in Mexico and beyond.

AUTHOR CONTRIBUTIONS

Conceptualization, G.C.E. and R.P.L.A.; **Methodology,** G.C.E.; **Validation**, G.C.E., R.P.L.A., and V.G.A.; **Formal Analysis,** G.C.E.; **Investigation**, G.C.E. and R.P.L.A.; **Resources**, V.G.A.; **Data Curation**, G.C.E.; **Writing – Original Draft Preparation**, G.C.E.; **Writing – Review & Editing**, R.P.L.A. and V.G.A.; **Visualization**, R.P.L.A.; **Supervision**, G.C.E.; **Project Administration**, G.C.E.

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DATA AVAILABILITY STATEMENT

Because of ethical and institutional restrictions, the datasets generated during this study are not publicly available.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest related to this study.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study did not involve human subjects, animals, or identifiable personal data. Ethical approval was not required.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

REFERENCES

1. Judd, T. and David, Y. The growing role of clinical engineering: Merging technology at the point of care. *Glob Clin Eng J.* 2022;5(1):29–32. https://doi.org/10.31354/globalce.v5i1.146.
2. Fernández Avilés, L.E. Decodifying healthcare technology management (HTM) in Mexican private hospitals. *IFMBE Proceedings*. 2017.
3. Bello, M. COVID-19 highlights importance of biomedical engineers. Mexico Business News 2020. Available online: https://mexicobusiness.news/health/news/covid-19-highlights-importance-biomedical-engineers.
4. World Health Organization. *Human resources for medical devices, the role of biomedical engineers (WHO Medical Device Technical Series)*. Geneva: WHO; 2017. Available online: https://www.who.int/publications/i/item/9789241565479.
5. David, Y. and Judd, T. Evidence-based impact by clinical engineers on global patient outcomes. *Health Technol*. 2020;10:517–35. https://doi.org/10.1007/s12553-019-00345-0.
6. Ayala, R. and Orencio, E. Identification of health technology management departments in Mexico's state health services. *Glob Clin Eng J*. 2019;2:17–21. https://doi.org/10.31354/globalce.v1i2.51.
7. Cabrera Jaramillo, L., Rosas Pacheco, L.A., González Campos, E., et al. "Evaluación Normativa de Equipamiento e Infraestructura en hospitales en la ciudad de León, México: Estudio de caso," presented at the IV Congreso Internacional

de Ingeniería Clínica, Medellín, Col., 2019. Available online: https://www.researchgate.net/publication/339541172_Evaluacion_normativa_de_equipamiento_e_infraestructura_en_hospitales_en_la_ciudad_de_Leon_Mexico_Estudio_de_caso.

8. Arab-Zozani, M., Imani, A., Doshmangir, L., et al. Assessment of medical equipment maintenance management: proposed checklist using Iranian experience. *BioMed Eng OnLine*. 2021;20(1):49. https://doi.org/10.1186/s12938-021-00885-5.
9. Abdurabuh, A., Hamid, M.D., Che Hassan, C.R., et al. Evaluating the Impact of Hospital Accreditation on Patient Safety Culture in Saudi Arabia Healthcare Facilities. *J Multidiscip Healthc*. 2024;17:5021–5033. https://doi.org/10.2147/JMDH.S480496.
10. Hussein, M., Pavlova, M., Ghalwash, M., et al. The impact of hospital accreditation on the quality of healthcare: a systematic literature review. *BMC Health Serv Res*. 2021;21(1):1057. https://doi.org/10.1186/s12913-021-07097-6.