Analysis of the influence of the level of adherence to the ABNT NBR ISO 9001 quality management system on the management of the maintenance of defibrillators within a public health facility of reference in the specialty of cardiology

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Abstract:
The occurrence of adverse events and technical complaints related to hospital medical equipment (HME) is considered one of the biggest problems in the health area internationally. In Brazil, these technologies are subject to health surveillance. Defibrillators are high-risk HME, which can cause harm to users or lead patients to death. The unavailability of this equipment in health care facilities (HCE) is critical; thus, managing the maintenance of this equipment is imperative for the safety and effectiveness of patient treatment. **Objective:** Therefore, this study aimed to analyze the influence of the adherence level of the ISO 9001 quality management system in the maintenance area on the maintenance management of defibrillators within a reference public health facility in the specialty of cardiology. **Methodology:** The method used was the case study and analysis of defibrillator maintenance from 2019 to 2020 and the performance of an internal audit in the HME maintenance area of the selected EAS against the requirements of the ABNT NBR ISO 9001 standard. **Results:** The equipment, when compared to each other, did not show equivalence related to the type of maintenance and the time interval defined for them, such as the high occurrence of sequential corrective maintenance, and, therefore, it can be concluded that preventive maintenance was not efficient for this equipment. The findings of the internal audit found that the establishment needs to establish and apply the improvements indicated by the ABNT NBR ISO 9001 standard.
Keywords: Defibrillators, cardiology, Hospital medical equipment, ISO 9001, maintenance.

Análise da influência do nível de adesão ao sistema de gestão da qualidade ABNT NBR ISO 9001 na gestão da manutenção de desfibriladores em um estabelecimento público de saúde de referência na especialidade de cardiologia

Resumo:
A ocorrência de eventos adversos e reclamações técnicas relacionadas a equipamentos médicos hospitalares (EMH) são consideradas um dos maiores problemas da área da saúde internacionalmente. No Brasil, essas tecnologias estão sujeitas à vigilância sanitária. Os desfibriladores são EMH de alto risco, podendo causar danos aos usuários ou levar os pacientes à morte. A indisponibilidade destes equipamentos nas unidades de saúde (EAS) é crítica; assim, gerenciar a manutenção desses

equipamentos é fundamental para a segurança e eficácia do tratamento do paciente. **Objetivo:** Portanto, este estudo teve como objetivo analisar a influência do nível de adesão do sistema de gestão da qualidade ISO 9001 da área de manutenção na gestão da manutenção de desfibriladores dentro de um EAS de referência na especialidade de cardiologia. **Metodologia:** O método utilizado foi o estudo de caso e análise da manutenção do desfibrilador, no período de 2019 a 2020, e a realização de auditoria interna na área de manutenção de ME do EAS selecionado frente aos requisitos da norma ABNT NBR ISO 9001. **Resultados:** Os equipamentos, quando comparados entre si, não apresentaram equivalência quanto ao tipo de manutenção e ao intervalo de tempo definido para eles, como a alta ocorrência de manutenções corretivas sequenciais e, portanto, pode-se concluir que a manutenção preventiva foi não é eficiente para estes equipamentos. As conclusões da auditoria interna constataram que o estabelecimento precisa estabelecer e aplicar as melhorias indicadas pela norma ABNT NBR ISO 9001.
Palavras-chave: Desfibriladores, cardiologia, equipamento médico hospitalar, ISO 9001, manutenção.

Análisis de la influencia del nivel de adherencia al sistema de gestión de calidad ABNT NBR ISO 9001 en la gestión del mantenimiento de desfibriladores en un establecimiento público de salud de referencia en la especialidad de cardiologia

Resumen:
La ocurrencia de eventos adversos y quejas técnicas relacionadas con los equipos médicos hospitalarios (EMH) son considerados uno de los mayores problemas en el área de la salud a nivel internacional. En Brasil, estas tecnologías están sujetas a vigilancia sanitaria. Los desfibriladores son EMH de alto riesgo, que pueden causar daños a los usuarios o provocar la muerte de los pacientes. La falta de disponibilidad de este equipo en los establecimientos publicos de salud (EAS) es crítica; por lo tanto, gestionar el mantenimiento de este equipo es imperativo para la seguridad y eficacia del tratamiento del paciente. **Objetivo:** Por tanto, este estudio tuvo como objetivo analizar la influencia del nivel de adherencia del sistema de gestión de calidad ISO 9001 en el área de mantenimiento en la gestión de mantenimiento de desfibriladores dentro de un EAS de referencia en la especialidad de cardiología. **Metodología:** El método utilizado fue el estudio de caso y análisis del mantenimiento de desfibriladores, de 2019 a 2020, y la realización de una auditoría interna en el área de mantenimiento EMH de la EAS seleccionada frente a los requisitos de la norma ABNT NBR ISO 9001. **Resultados:** Los equipos, al compararlos entre sí, no presentaron equivalencia relacionada con el tipo de mantenimiento y el intervalo de tiempo definido para los mismos, como la alta ocurrencia de mantenimiento correctivo secuencial y, por lo tanto, se puede concluir que el mantenimiento preventivo fue no eficiente para estos equipos. Los hallazgos de la auditoría interna encontraron que el establecimiento necesita establecer y aplicar las mejoras indicadas por la norma ABNT NBR ISO 9001.
Palabras clave: Desfibriladores, cardiologia, Equipo médico hospitalario, Norma ISO 9001, mantenimiento.

INTRODUCTION

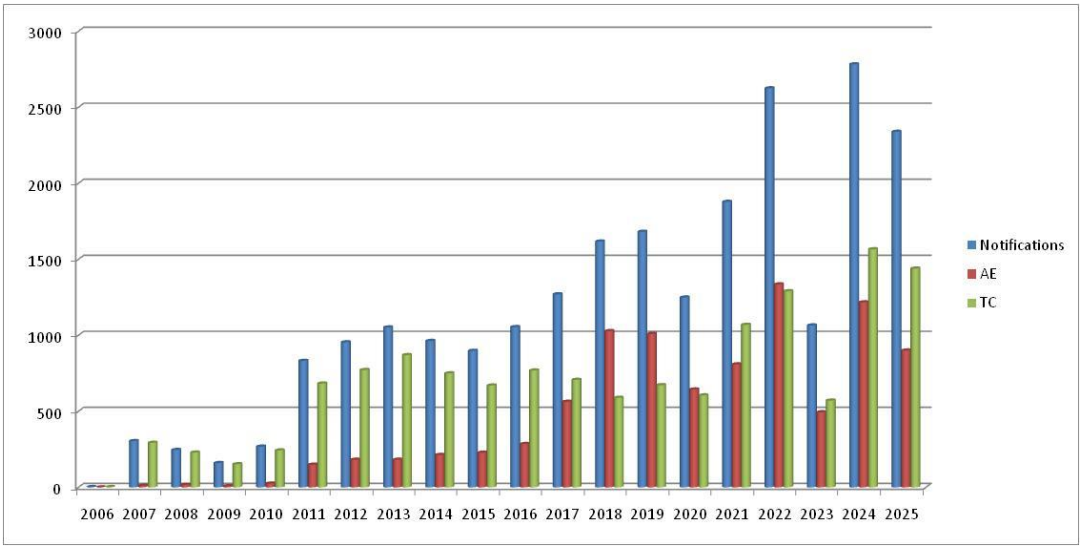
In Brazil, since the 1988 Federal Constitution, public health has been structured within the Unified Health System (SUS) (Ministry of Health, 2023). The SUS has several bodies and

institutions in its composition, including healthcare establishments (HCE) of different levels of complexity, public and private, which in turn make use of hospital medical equipment (HME) in the provision of health services to the population (Amorim *et al*, 2015).

Hospital Medical equipment (HME), also known as electromedical equipment, included in the category of health products, is essential for carrying out diagnoses, treatments, prevention, and rehabilitation in health (Blandford; Furniss; Vincent, 2014; Almeida; Silva, 2016; Flauzino *et al.* , 2022). Its use dates back to the 17th century, with the invention of the thermometer by Galileo, and to the 19th century, on the occasion of the invention of the stethoscope by Laennec and the discovery of x-rays by Roentgen and, additionally, the invention of the electrocardiograph in 1903 by Einthoven (Fries, 2005; Shanmugam; Chokkalingam; Bakthavachalam, 2020). Without these devices, the success of modern medicine would be less, and countless human lives would have been lost; however, the use of this equipment can cause different degrees of severity of adverse events for both patients and health professionals (Jacobson; Murray, 2007; Queiroz *et al*, 2017), especially when they malfunction (Kihiu; Maranga; Mutia, 2012).

According to its attributions, the National Health Surveillance Agency (ANVISA) is the federal agency responsible for monitoring adverse events (AE) and technical complaints (QT) of health products in the post-marketing phase (called technosurveillance). The Notifications in the Technovigilance Portal (Brazil, 2025) report a total of 10,014 adverse event (AE) notifications (40.55%) and 14,679 technical complaint (QT) notifications (59.45%) related to hospital medical equipment in the period from 2006 to 2025. Figure 1 illustrates the temporal evolution of notifications recorded by ANVISA pertaining to hospital medical equipment over the specified period. The figure demonstrates a consistent upward trend in the number of occurrences, culminating in a peak of 2,783 notifications in 2024. Notably, the notifications registered up to 2025 (2,339) correspond to approximately 84.04% of those reported in 2024.

Figure 1. Evolution of notifications of Adverse Events and Technical Complaints related to Medical Equipment.



Source: Elaborated from Brazil (2025).

Therefore, it is strategic to ensure better access, quality and use of medical products and health technologies (Pérez Hernández *et al*., 2021). According to Novaretti *et al* (2014), adverse events and incidents are relevant quality indicators, providing essential information for planning a safer health system. Nevertheless, QT and AE may be associated with the maintenance of HME within the AE.

As pointed out by Zamzam *et al* (2021), health institutions are faced with inadequate functioning and the unavailability of medical equipment, often due to deficiency in the management and maintenance of the state of the medical equipment by the person in charge. The work by Cardoso and Waqued (2019) points out that about 40% of HME in Brazilian public sector hospitals are underutilized or inoperative due, to problems related to maintenance of this equipment. In the study, the authors identified that 46% of the HME belonging to a public hospital in the Federal District were unusable or unserviceable, 90% of which comprised of defibrillators.

The importance of the effective maintenance of HME in public HCE has been discussed in the literature. For example, Ishida *et al* (2014) conducted a study with 356 Japanese hospitals consider that the underused of HME can lead to critical accidents, highlighting the

importance of proper maintenance. Vala *et al* (2018) postulate that small amount of medical equipment available for use in public hospitals located in developed countries leads to overuse of this equipment, resulting in failures and low availability, demonstrating the importance of implementing strategies aimed at ensuring good health management maintenance. The evaluation of maintenance effectiveness is fundamental for resource utilization optimization (Iadanza *et al*, 2019). In this sense, Zheng *et al* (2023) state that "good medical devices maintenance should be implemented by hospitals to minimize breakages or failures, ensuring that they are accessible and reliable when necessary".

Strategies to improve maintenance management of HME in proposed HCE focus, in general, on prioritizing maintenance (Hutagalung; Hasibuan, 2019; Hernández-López *et al*, 2020; Corciovă; Andriţoi; Luca, 2020); however, no studies were identified that address the relationship between the adoption of a quality management system (QMS) and the effectiveness of maintenance performed in HME. On the other hand, there are works that show the benefits of using quality tools and systems on companies that provide maintenance services (Lee; Lam, 1997; Mami *et al*, 2019; Sui Pheng; Wee, 2001; Liu *et al*, 2022).

Thus, this article analyzes the influence of adherence level to ABNT NBR ISO 9001 Quality Management System in maintenance area on maintenance management of HME defibrillators, within the scope of reference HCE in cardiology area, in municipality from Rio de Janeiro, Brazil.

MAINTENANCE OF MEDICAL EQUIPMENT: DEFINITIONS.

For the World Health Organization (WHO), "an effective medical equipment maintenance program requires proper planning, management, and execution". Such steps are essential, as the definition of this program allows medical equipment to be "continuously reviewed and managed in financial, personnel and operational aspects to ensure that the program is maintained without interruption and that necessary improvements are made" (WHO, 2011). For this work, the following definitions are relevant:

a) Corrective maintenance (CM): process used to restore the physical integrity, safety and/or performance of a device after a failure. Thus, corrective maintenance and unscheduled maintenance are terms equivalent to the term repair.

b) Preventive Maintenance (PM): involves maintenance performed to prevent failures and extend the useful life of the device. PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (of filters, for example), replacing parts that wear out (such as bearings) or have a finite life span (such as piping). Procedures and intervals are commonly established by the manufacturer. In special cases, the user can change the frequency to accommodate local environmental conditions. Preventive maintenance is sometimes referred to as "planned maintenance" or "scheduled maintenance".

c) Repair: process used to restore the physical integrity, security and/or performance of a device after a failure.

d) Failure: condition of not meeting the intended performance or safety requirements and/or the condition of violation of physical integrity. A failure is corrected by repair and/or calibration.

e) Inspection refers to the scheduled activities required to ensure that medical equipment is operating correctly, including performance and safety inspections. This checkup typically occurs in conjunction with preventive maintenance, corrective maintenance, or calibration, but can also be completed as a standalone activity scheduled at specific intervals.

In view of these definitions, it can be understood that PM, when carried out with proper planning, reduces failure rates, that is, it minimizes the need for CM and extends the useful life of the equipment. On the other hand, CM does not allow for determining the time required to solve the problem or the time the equipment will be out of operation. Thus, the cost of correcting equipment is significantly higher when compared to the expenses of preventive interventions. Moreover, failures render the equipment inaccessible, hindering tasks and/or production, which impacts the organization's results and profits.

THE ABNT ISO 9001 AND THE MAINTENANCE ACTIVITY.

The ISO 9001:2015 standard – Quality Management Systems – Requirements – establishes a management system aimed at optimizing processes and developing products more quickly. The standard specifies the minimum requirements for a quality management system, in which the organization must demonstrate its ability to consistently provide products or services that meet customer and regulatory requirements; address customer satisfaction through the effective application of the system and development of processes for continual improvement and prevention of errors; and achieve, maintain, and improve both overall performance and capabilities (ABNT, 2015).

For these benefits to be achieved, organizations must determine and apply the criteria and methods of the standard, including those related to monitoring and measuring products and services, as well as performance indicators of service quality and results, in order to ensure the effective operation and control of their processes. It is important to emphasize that all the requirements of this standard are generic and intended to be applicable to all organizations, regardless of their type, size, or the products and services they provide. (ABNT, 2015).

In the context of maintenance activities, the quality of the records demonstrates whether the processes are being carried out effectively, allowing the reassessment of future services in ME. The study of the consistency and integrity of failure history records should provide sufficient detail to enable the determination of corrective and preventive maintenance.

The competence of personnel working in the activity is also a requirement of ISO 9001:2015. Thus, the standard specifies that "the necessary competence of the person(s) carrying out work under its control that affects the performance and effectiveness of the quality management system must be determined; ensure that these persons are competent, based on appropriate education, training or experience; where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken; and retain documented information appropriate as evidence of competence." (ABNT, 2015)

As the organization must evaluate the performance and effectiveness of the quality

management system, the HCE must retain appropriate documented information, such as evidence of the results of maintenance and equipment calibrations. Customers, who are the users of the equipment, must not suffer any type of damage when submitting to the procedures carried out, and it is based on historical records that the good performance of the equipment used can be attested.

It is important to highlight that the norm presents a logical approach by process. Applying the process approach to a quality management system provides:

a) understanding and consistency in meeting requirements;

b) consideration of processes in terms of added value;

c) achieving effective process performance;

d) the improvement of processes based on the evaluation of data and information" (ABNT, 2015).

Therefore, performance indicators should be used. Such quality indicators provide greater reliability of measurement, control and monitoring, as established by ISO 9001. Given this, it is even possible to evaluate the performance of the equipment.

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Thus, the quality management of a production process is responsible for establishing standards that meet the needs of customers. As a result, it ensures that the planned goals are completed, focusing on the improvement of products and services.

Good customer service encompasses everything from your reception at the establishment to your medical discharge. There are internal and external customer

satisfaction surveys that can be valuable indicators for continuous improvement. Requirement 9.1.2, "Customer satisfaction", guides that the organization must monitor the perception of customers based on the degree to which their needs and expectations were met, determining the methods to obtain, monitor and critically analyze this information.

That said, it is important to note that customer perceptions can be monitored in different ways. Examples include: customer surveys, customer feedback on delivered products or services, customer meetings, market share analysis, compliments, warranty claims, and distributor reports.

Monitoring in the form of indicators is very efficient because it demonstrates the degree of adherence of establishments to established processes. The indicators must be periodically analyzed and evaluated, according to the needs of each process, since they are valuable tools to understand whether the results achieved are consistent with the plan.

A systematic literature review was conducted to identify studies correlating ISO 9001 with defibrillator maintenance. To identify eligible studies, a systematic search strategy was performed in PubMed, ScienceDirect, Web of Science and Scopus using the following search string: ("maintenance") AND ("defibrillators") AND ("ISO 9001"), published in the last 10 years. No articles were found in the databases listed previously that met the search criteria.

METHODOLOGY

The present work is classified as applied research in relation to its method, using previous knowledge about ISO 9001 quality management system for practical and immediate application aimed at solving specific problems in maintenance of defibrillators in public HCE. The adopted approach was quantitative-qualitative, exploratory and descriptive, aims to describe the characteristics of defibrillator maintenance and the establishment of relationships between the maintenance of this equipments and ISO 9001.

The research was conducted in a public administration HCE located in the city of Rio de Janeiro, classified by the Ministry of Health as a reference in the specialty of adult and

pediatric cardiology. According to the website of the National Registry of Health Establishments, the HCE performs medium- and high-complexity outpatient and hospital procedures, in addition to carrying out activities related to teaching and research. Regarding equipment, it currently has 28 defibrillators in use. The research was developed based on the following steps:

a) survey of historical records of maintenance of defibrillator equipment used in the HCE, from 2019 to 2020;

b) analysis and interpretation of data from maintenance records, provided by HCE;

c) carrying out an internal audit in the sector responsible for maintaining the HME, based on the requirements of the ABNT NBR ISO 9001:2015 standard.

Data related to defibrillator maintenance were collected directly from the HCE maintenance area, covering the period from 2019 to 2020. The equipment data represent a sample that can be classified as non-probabilistic, selected based on accessibility and typicality, in which the analyzed elements are considered representative of the target population. The maintenance records refer to defibrillators located in the surgical center, hemodynamics unit, and pediatric intensive therapy unit (pediatric ITU) of the HCE, totaling nine defibrillators, three in each sector, in continuous use. All are from the same manufacturer and of the same model. Finally, the objective of the internal audit was to correlate defibrillator maintenance with the requirements of the standard.

To comply with ethical issues, the project was submitted and approved by the Human Research Ethics Committee (REC), under CAAE: 58847722.7.3001.5265). Data collection, internal audit and interviews were carried out between the months of January/2021 to May/2022, in compliance with the guidelines of CNS Resolution No. 580 of March 22, 2018.

RESULTS

The maintenance process begins with requests for defibrillator maintenance made by the EAS sectors to the maintenance department, thus reflecting a reactive approach by this department. Maintenance requests are recorded in an Excel control spreadsheet, which contains the following information: the requesting sector and the person responsible for the request; the asset number and the manufacturer of the defective equipment; the opening and closing dates of the maintenance service order (OS); the type of OS (calibration, preventive maintenance, or corrective maintenance); the serial number, model, and brand of the equipment; the sector and location of the equipment; and the prioritization of the service (emergencies). However, there is no information about the type of defect that triggered the maintenance request. Based on the information contained in the spreadsheet, the equipment is forwarded to the technical specialists, who then begin the maintenance activities.

Based on the opening and closing dates of the service orders recorded in the maintenance control spreadsheet, the frequency of maintenance performed on the defibrillator equipment was determined, as well as the sequence in which these maintenances occurred. The equipment was analyzed considering the time interval between maintenance activities. Since the HCE does not have maintenance data from the time of asset acquisition, nor the acquisition date itself, for calculation purposes the date of the first recorded maintenance occurrence in the spreadsheet was adopted as zero. Table 1 presents the list of defibrillators included in the HCE maintenance department's spreadsheet and selected for the study.

Table 1 – EAS Defibrillators analyzed in this study.

Sector	Model	Manufacturer	Serial number	Patrimonial number
Surgery Center	R series	Zoll	T08D101013	6681
Surgery Center	M series	Zoll	T08B09707	965
Surgery Center	R series	Zoll	AF10K013181	8405
Hemodynamics	R series	Zoll	AF10K012923	8925
Hemodynamics	R series	Zoll	AF10L013352	8923
Hemodynamics	R series	Zoll	AF10L013444	8401
Pediatric ITU	R series	Zoll	AF10L013292	751
Pediatric ITU	R series	Zoll	AF10L013406	9455
Pediatric ITU	Pace Maker	Zoll	Not disponible	738

Source: Authors.

Considering that maintenance activities follow a Student's *t* distribution, it is possible to determine the interval in which the population mean of maintenance for the selected equipment falls, through Equation 1. The results calculated for the confidence intervals of the population data, together with the coefficients of variation of the sample data, are shown in Table 2. These intervals were calculated using the following equation:

$$\bar{X} \pm t_{\alpha/2} \frac{s}{\sqrt{n}}$$

Where:

$\bar{X}$: sample average of maintenance intervals (days).

s : sample standard deviation of maintenance intervals (days).

n : sample size.

$t_{\alpha/2}$: t-statistic for □□ level of significance and n-1 degrees of freedom.

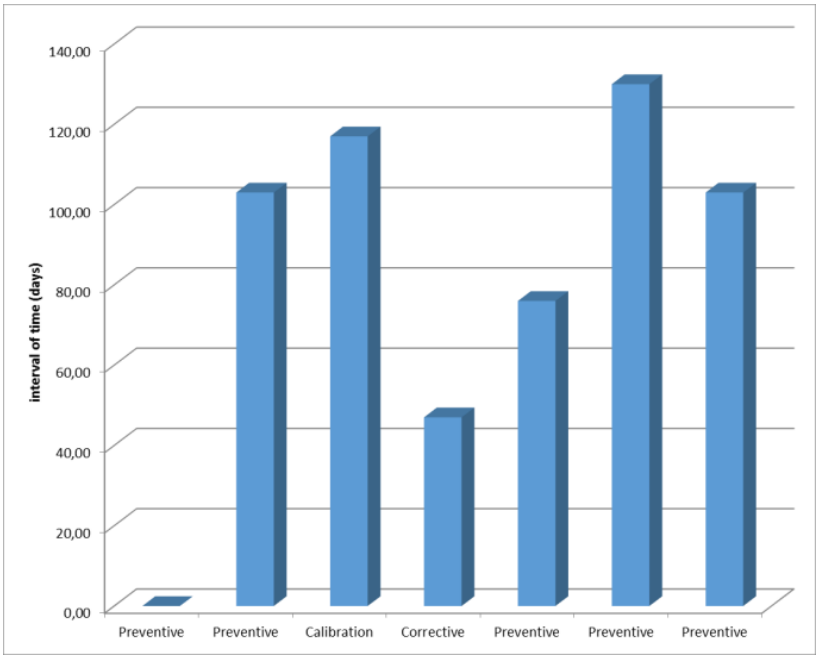
Table 2 – Statistics of maintenance intervals for defribrillators in study.

Patrimonial number	Average sample (days)	Standard deviation (days)	Confidence interval for populacional average (days)	Coefficient of variation (%)
6681	96	30	[64 , 127]	31,25
965	115	12	[102 , 128]	10,44
8405	97	66	[42 , 152]	60,04
8925	59	58	[23 , 104]	98,31
8923	84	55	[37 ,135]	65,48
8401	49	57	[20 , 61]	116,32
751	82	42	[44 , 120]	51,22
9455	59	41	[29 , 88]	69,49
738	48	41	[21 , 74]	85,42

Source: Authors.

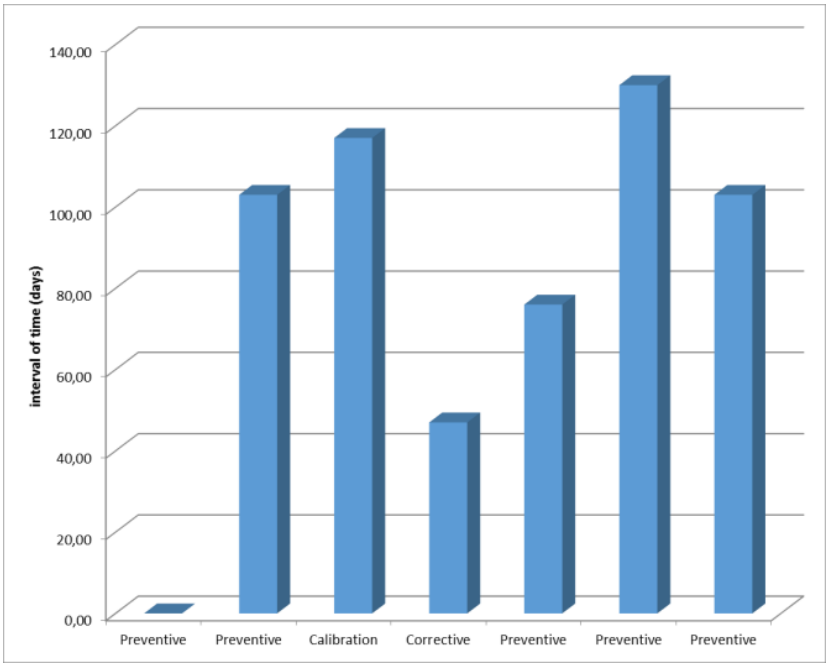
Figure 2 shows the sequence of maintenance performed on the equipment with asset number 6681. It can be observed that only one corrective maintenance (CM) was performed on this equipment, highlighting the effectiveness of preventive maintenance. The same conclusion applies to the maintenance carried out on the equipment registered under number 965, as shown in Figure 3. Both pieces of equipment are currently in use at the HCE Surgical Center.

Figure 2. Maintenance sequence for equipment with patrimonial number 6681.



Source: Authors.

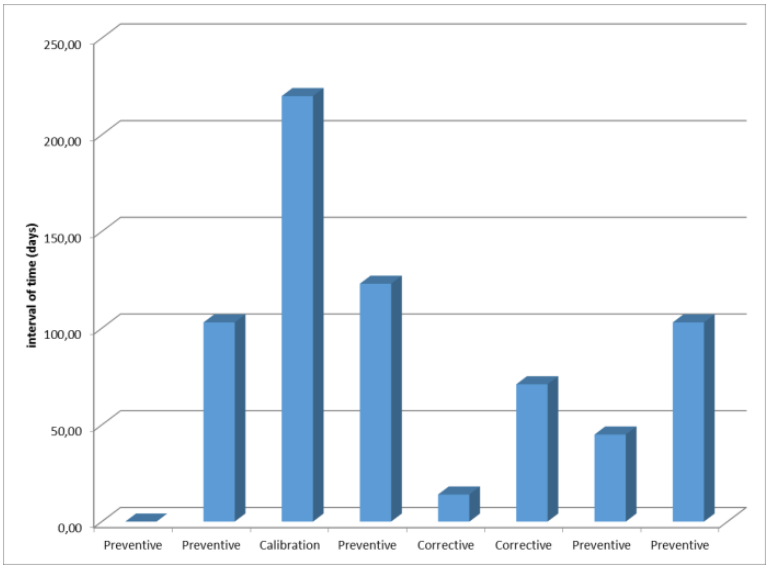
Figure 3. Maintenance sequence for equipment with patrimonial number 965.



Source: Authors.

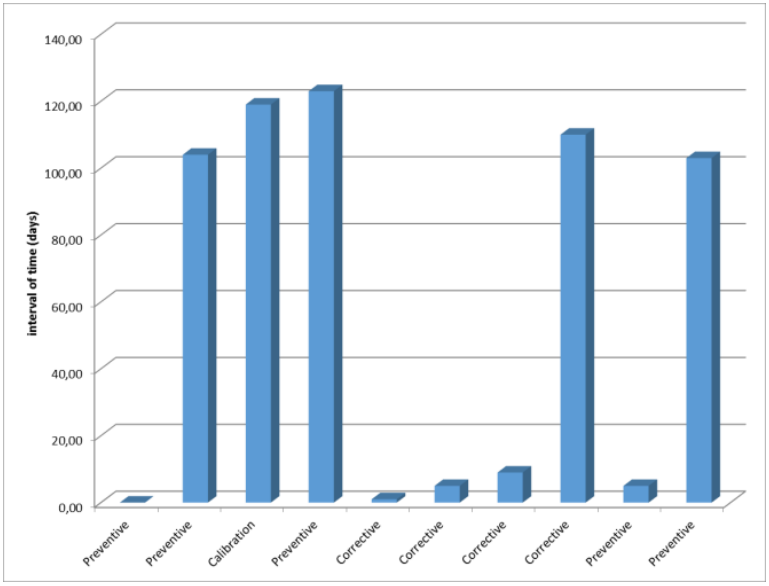
Figures 4 and 5 show the sequence of maintenance performed on the equipment with asset numbers 8405 (Surgical Center) and 8925 (Hemodynamics). The occurrence of two consecutive corrective maintenance (CM) actions may indicate a potential issue with the effectiveness of preventive maintenance for these pieces of equipment. For the Surgical Center equipment, a corrective maintenance was carried out 14 days after the second preventive maintenance, followed by another corrective maintenance 71 days later. For the Hemodynamics equipment, there is a sequence of four corrective maintenance actions following preventive maintenance within a short period, which may be related to inefficiencies in both preventive and corrective maintenance.

Figure 4.: Maintenance sequence for equipment with patrimonial number 8405.



Source: Authors.

Figure 5. Maintenance sequence for equipment with patrimonial number 8925.

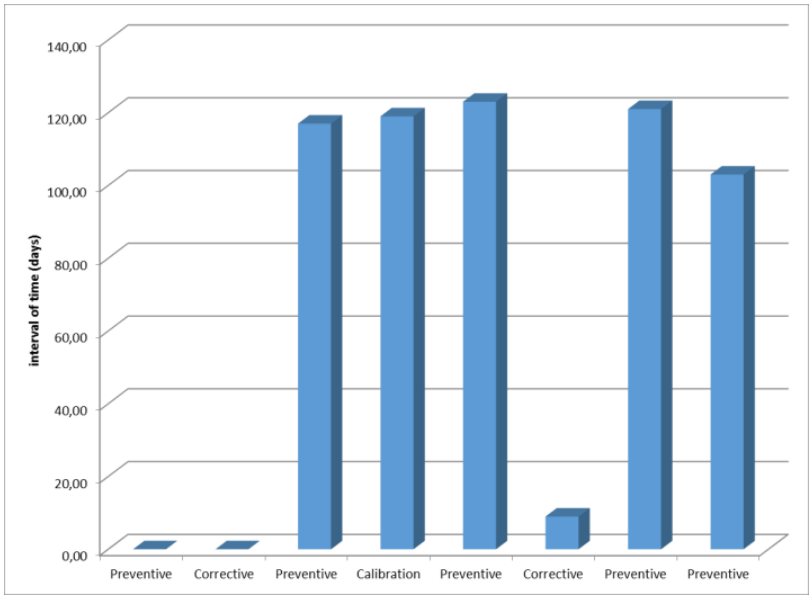


Source: Authors.

The maintenance sequences for the other two pieces of equipment in the Hemodynamics sector of the HCE are shown in Figures 6 and 7. An unusual pattern of maintenance can be observed on the equipment with asset number 8401, characterized by a

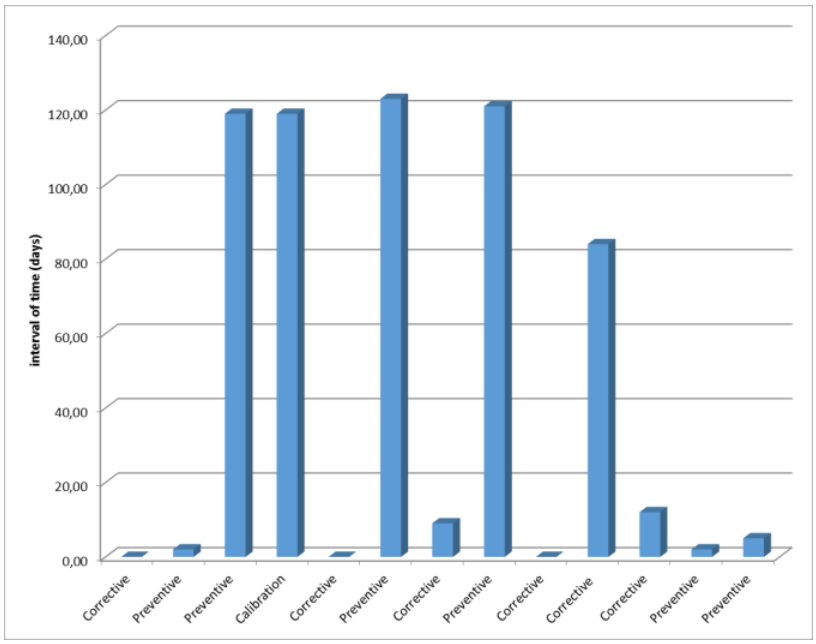
predominance of corrective maintenance, which most likely indicates ineffective preventive maintenance.

Figure 6. Maintenance sequence for equipment with patrimonial number 8923.



Source: Authors.

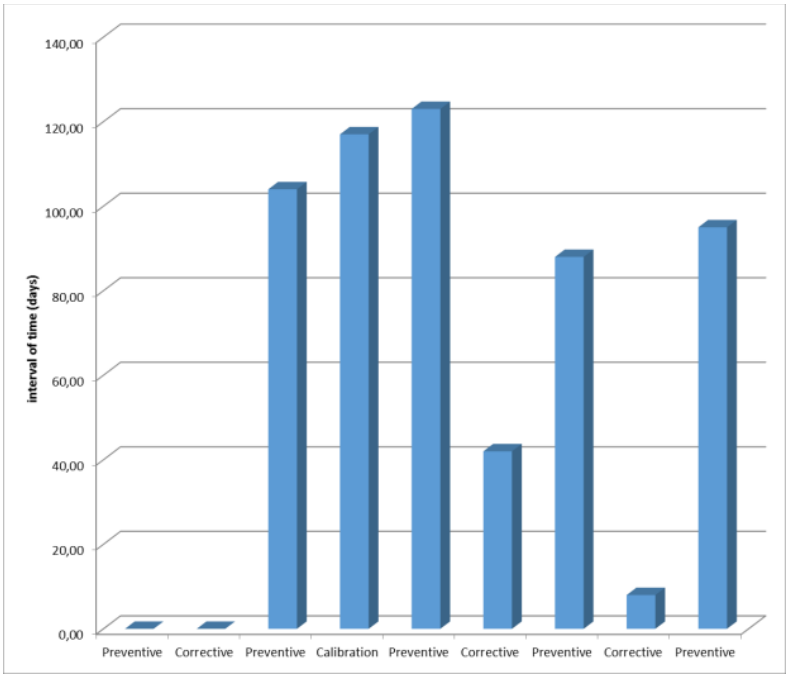
Figure 7: Maintenance sequence for equipment with patrimonial number 8401.



Source: Authors.

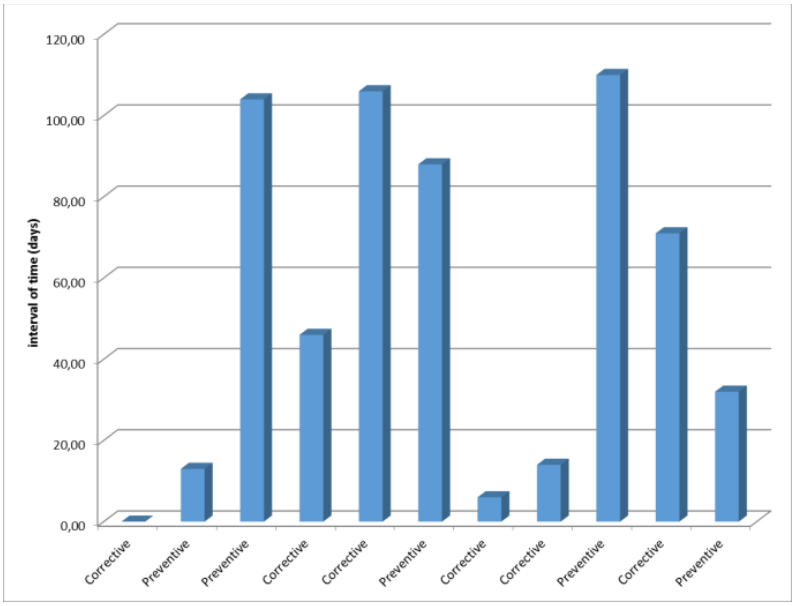
The sequences of maintenance on the equipment located in the Pediatric ITU are illustrated in figures 8, 9 and 10. It is possible to verify that sequence of maintenance suggests that the PM performed are not being effective.

Figure 8: Maintenance sequence for equipment with patrimonial number 751.



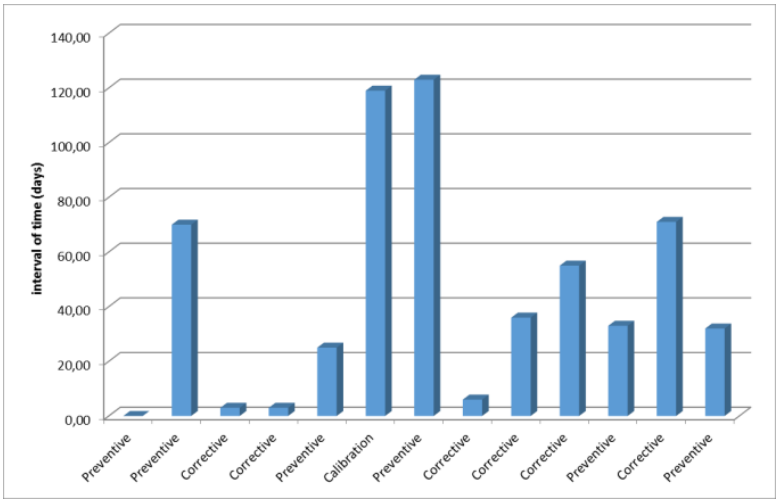
Source: Authors.

Figure 9: Maintenance sequence for equipment with patrimonial number 9455.



Source: Authors.

Figure 10: Maintenance sequence for equipment with patrimonial number 738.



Source: Authors.

DISCUSSION

The Pediatric ITU was the sector with the highest number of equipment showing consecutive corrective maintenance, indicating that this equipment was often unavailable for use, particularly in the Hemodynamics sector and, to a lesser extent, the Surgical Center. During an internal audit of the Maintenance Sector, no objective evidence was found of action plans to mitigate the risks associated with this unavailability and the occurrence of defects during use, which could affect both patients and staff. Similarly, no complaints regarding this equipment were identified that could help investigate the probable causes and types of equipment failures, despite the complexity of the patients treated in these sectors.

The high recurrence of defects in equipment, even after preventive maintenance, can be considered a recurring nonconformity in service provision, thereby demonstrating a lack of adherence to the risk-based approach emphasized in the ABNT NBR ISO 9001 standard. From the perspective of this standard, it is necessary to identify the root causes that led to the recurrence of both preventive and corrective maintenance, such as equipment failures, required adjustments, user misuse, lack of planning, among others. However, no complaints

regarding consecutive corrective actions or records of nonconformity reports were identified. Additionally, it was observed that:

a) The maintenance area does not define how maintenance results are evaluated. Requirement 6.2.2.e of ABNT NBR ISO 9001 states that, when planning how to achieve its quality objectives, the organization must determine how results will be evaluated, which should be relevant to the conformity of products and services (6.2.1.d). Therefore, since results are not evaluated, preventive maintenance may not be performed with the necessary scope.

b) The maintenance area does not define, provide, or maintain the necessary infrastructure for process operation or for ensuring product and service conformity with respect to equipment, including materials, machines, tools, etc., as required by 7.1.3 of the standard. In other words, the maintenance area does not adequately determine what is necessary to carry out equipment diagnostics or maintenance control, meaning that preventive maintenance is not comprehensive. This infrastructure could be developed based on theoretical knowledge of the equipment and practical knowledge derived from the most frequently observed failures.

c) The maintenance area does not satisfactorily meet requirement 7.1.5.2. That is, it does not check or calibrate the measuring equipment used for defibrillator maintenance; fails to identify such equipment to determine its status; does not safeguard it against adjustments, damage, or deterioration that could invalidate calibration and subsequent measurement results; or does not determine whether the validity of previous measurements was affected when equipment was found unsuitable for its intended purpose.

d) The maintenance area defines personnel competence based on education, training, or appropriate experience. However, records of refresher or specific training for defibrillator maintenance were not verified. Consequently, personnel performing maintenance exhibit a skills gap, affecting their ability to correctly execute the service in accordance with requirement 7.2.

e) The maintenance area does not adequately determine service requirements based on applicable statutory and regulatory requirements, as specified in 8.2.2. Likewise, there was

no evidence of critical analysis of requirements related to provided services, as required by 8.2.3.

f) The maintenance area does not implement service provision under controlled conditions, in accordance with requirement 8.5. Therefore, documented information on the use of adequate monitoring and measurement resources may be insufficient. Additionally, according to 8.5.2, the maintenance area does not fully utilize appropriate means to identify outputs to ensure service compliance.

g) The maintenance area does not implement planned arrangements at appropriate stages to verify that service requirements have been met. Service release control is conducted via a computerized system, and maintenance data are stored therein. The requirements demonstrating compliance with acceptance criteria were not clearly highlighted, as per 8.6.

h) The maintenance area does not ensure that outputs failing to meet requirements are identified and controlled to prevent unintended use or delivery, according to 8.7 and 8.7.2.

It was also observed that the process approach principle of ABNT NBR ISO 9001 is not adopted by HCE, as the results obtained are not standardized. Consequently, monitoring and measurement controls, or control points, are not consistently applied. Therefore, it is necessary to consider adopting risk control measures to reduce these failures. According to the standard, this approach enables the organization to manage interrelationships and interdependencies between system processes, enhancing overall performance. In this context, no records were found for nonconformities, customer complaints, quality indicators, rework, or process interactions.

FINAL CONSIDERATIONS

This study enabled an analysis of the influence of the ABNT NBR ISO 9001 quality management system (QMS) on defibrillator maintenance services in a public HCE specializing in cardiology. The research concluded that the adoption of the QMS has the potential to

positively impact this service, reducing the recurrence of failures and consequently increasing the availability of critical life-support equipment in the EAS.

The high values observed for the standard deviation of the intervals between maintenance activities indicate a large dispersion of the data, as reflected in the coefficients of variation. This result may be attributed to the absence of, or failure to follow, a scheduled maintenance sequence.

Defibrillators should be available 100% of the time in specific sectors of the HCE. However, a high number of corrective maintenance activities were observed during 2019 and 2020, and only some of the studied equipment followed the expected maintenance sequence. The occurrence of corrective maintenance (CM) within very short intervals may indicate that preventive maintenance (PM) is not effective, either due to service deficiencies or the age of the equipment. Nevertheless, the EAS property sector does not have data to assess the impact of defibrillator age on maintenance. Likewise, the EAS does not monitor the frequency of device usage.

Corrective maintenance is the result of failures that were not prevented through preventive maintenance. CM is sometimes based on the assumption that failure is acceptable — when it does not significantly affect safety or the environment — or that preventing failure is not cost-effective or feasible. From a quality management perspective, failures requiring corrective actions must be analyzed, and a risk assessment should be conducted to identify the potential impacts of such corrective measures.

The sampling adopted for defibrillator maintenance was non-probabilistic due to the lack of population data from the HCE maintenance area, which makes it impossible to generalize the results. However, given the high criticality and risk associated with hospital medical equipment (HME), it is strongly recommended that these results be considered by both the HCE and government bodies when establishing criteria and requirements for HME maintenance management. The higher incidence of maintenance problems in defibrillators used by the Pediatric ITU of the HCE, which provides specialized care to critically ill children, may cause irreparable harm to patients who rely on the proper functioning of this equipment for survival. This could exacerbate their illness or result in preventable deaths, in addition to causing significant impact on the EAS medical team and the institution itself.

The originality of this study lies in use of ABNT NBR ISO 9001 to analyze defibrillator maintenance. As a suggestion for future work, studies regarding the reanalysis of the status of defibrillators in HCE that have a maintenance area where ABNT NBR ISO 9001 on the maintenance management of defibrillators has been implemented. Another suggestion is repeat this study in private HCE with or without ABNT NBR ISO 9001 implemented in the maintenance area.

AUTHOR CONTRIBUTIONS

Suiane Moraes Machado: Responsible for data collection and analysis, as well as for the initial drafting of the manuscript. All authors reviewed and approved the final version submitted, taking full responsibility for the content and the results presented..

Ricardo Kropf Santos Fermam: Responsible for the methodological design of the study. Contributed to scientific writing, critical content review, and adaptation of the manuscript to the journal's editorial guidelines. All authors reviewed and approved the final version submitted, taking full responsibility for the content and the results presented.

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