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Analysis of technology management in medical equipment in intensive care units: Challenges for coping with COVID-19

Análise do gerenciamento de tecnologias em equipamentos médico-assistenciais em unidades de terapia intensiva: desafios para o enfrentamento da COVID-19

Frederico Inácio e Silva[I,*]

Paula Cicília Faquim Rodrigues[II]

Ricardo Antonio Gonçalves Teixeira[III]

Ellen Synthia Fernandes de Oliveira[III]

ABSTRACT

Introduction: The pandemic caused by the SARS-CoV-2 coronavirus has brought a huge pressure on health systems, in particular the availability of beds, equipment and human resources in Intensive Care Units (ICU), which even before this scenario already had difficulties, especially in equipment management. Although more than 10 years have passed since the beginning of mandatory technology management in health services, its implementation in practice is still a challenge and a public health problem. **Objective:** To verify the implementation of the Medical Equipment Technology Management Plan in the ICUs of Goiânia, Goiás, an integral part of technology management. **Method:** As a basis, secondary data collected in a Guide prepared by the Sanitary Surveillance was used, applied in two moments during inspections in the ICU. The data were analyzed comparatively and the results presented through absolute and relative frequency and statistical analysis. **Results:** The levels of implementation of the Technology Management Plan found were 25.8% and 40.9% in the 1st and 2nd inspection, respectively. **Conclusions:** Investments in training and in a permanent education program can be a direction to improve the implementation of the plan and, consequently, an advance in the quality of the service offered to the user. Considering that Health Surveillance is an important catalyst for this change, this study provides important data for managers to prioritize actions and formulate public policies in Public Health that will serve to improve patient safety and, consequently, help in coping with COVID-19.

KEYWORDS: Biomedical Technology; Durable Medical Equipment; Patient Safety; Health Surveillance; Intensive Care Units

RESUMO

Introdução: A pandemia causada pelo coronavírus SARS-CoV-2 trouxe uma pressão descomunal sobre os sistemas de saúde, especialmente sobre a disponibilidade de leitos, equipamentos e recursos humanos das unidades de terapia intensiva (UTI), que mesmo antes desse cenário já apresentavam dificuldades, em especial na gestão de equipamentos. Embora se tenha passado mais de 10 anos do início da obrigatoriedade da gestão de tecnologias em serviços de saúde, a sua implementação na prática ainda é um desafio e um problema de saúde pública. **Objetivo:** Verificar a implantação do Plano de Gerenciamento de Tecnologias de equipamentos médico-assistenciais nas UTI de Goiânia, parte integrante da gestão de tecnologias. **Método:** Como base utilizou-se dados secundários coletados em um guia elaborado pela Vigilância Sanitária, aplicado em dois momentos durante as inspeções em UTI. Os dados foram analisados de forma comparativa e os resultados apresentados por meio de frequência absoluta, relativa e de análise estatística. **Resultados:** Os níveis de implantação do Plano de Gerenciamento de Tecnologias encontrados foram de 25,8% e 40,9% na 1ª e 2ª inspeção,

[I] Departamento de Vigilância Sanitária e Ambiental de Goiânia, Goiânia, GO, Brasil

[II] Superintendência de Vigilância em Saúde, Secretaria de Estado de Saúde de Goiás, Goiânia, GO, Brasil

[III] Instituto de Patologia Tropical e Saúde Pública (IPTSP), Universidade Federal de Goiás, Goiânia, GO, Brasil

* **E-mail:** fredericoinacio@gmail.com

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respectivamente. **Conclusões:** Investimentos em treinamento e em programa de educação permanente podem levar a uma melhoria na implantação do plano e, consequentemente, a um avanço na qualidade do serviço oferecido ao usuário. Considerando que a Vigilância Sanitária é um importante catalisador dessa mudança, este estudo traz dados importantes para os gestores priorizarem ações e formularem políticas públicas na Saúde Coletiva que servirão para melhorar a segurança dos pacientes e, por consequência, ajudar no enfrentamento da COVID-19.

PALAVRAS-CHAVE: Tecnologia Biomédica; Equipamentos Médicos Duráveis; Segurança do Paciente; Vigilância Sanitária; Unidades de Terapia Intensiva

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, named as COVID-19 (after coronavirus disease 2019), started with an outbreak in Wuhan, China[1], in December 2019, and was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020[2]. From then until June 2021, the disease had already been identified in 222 countries on five continents, with approximately 177.5 million reported cases and over 3.8 million deaths[3].

Despite the adoption of preventive measures like increased hygiene, widespread testing and social distancing, in many cases, COVID-19 progresses into more severe forms, which resulted in the collapse of various healthcare systems[2].

In this sense, this disease put enormous pressure on healthcare systems, especially on the availability of beds in intensive care units (ICUs)[4]. This is because the rapid rise in the number of cases of the novel coronavirus disease required countries to increase the number of available beds in ICU settings[2]. Moreover, respiratory diseases, cancer, cardiovascular diseases, hypertension and diabetes can increase its lethality[2].

A study in the Chinese city of Wuhan estimated that 24.9% of hospitalized patients diagnosed with COVID-19 became critically ill. Of these, 80.0% needed to be admitted to ICU beds[5], while data from an Italian study indicated that between 9.0% and 11.0% of patients admitted to ICUs in that country had COVID-19[4].

Additionally, patients undergoing treatment for COVID-19 admitted to ICUs made intensive use of devices like mechanical ventilators, multiparameter monitors and others for therapy and diagnosis[6]. These pieces of equipment are classified as medical devices (MDs) and are subject to technology management[7,8].

This class of equipment is widely used in ICUs, where continuous monitoring of vital signs (diagnosis) and even replacing an organ's function (therapy) need to be performed[7,9].

It is estimated that a patient undergoing an anesthetic procedure uses at least 12 medical devices, but this number can exceed a hundred different products—including medical devices and medications—depending on their health condition and length of stay[10].

The use of medical equipment, however, is not risk-free[11]. To promote the safe and effective use of medical equipment, there are regulations by Brazil's National Health Surveillance Agency (Anvisa) and standards by the Brazilian Association of Technical Standards (ABNT), including joint board resolution (RDC) n. January 10, 2010 by Anvisa, replaced in May 2021 by RDC (Anvisa) n. 63, of November 25, 2011 and ABNT NBR 15.943, respectively[7,8,12,13].

This normative framework encourages health establishments (HE) to manage these technologies by establishing a Technology Management Plan (TMP) with the objective of ensuring traceability, quality, efficacy, effectiveness, safety and, in some cases, the performance of health technologies used in the provision of health services[7]. TMPs must cover every management stage, from the planning phase to entrance into the HE to disposal, aiming at the protection of workers, patient safety, and conservation of public health and the environment[7].

The choice to conduct the study in an ICU was due to the combination of three factors: i) the complexity and importance of MDs for diagnosis and therapy; ii) their large-scale use in ICUs; and iii) the demand for intensive care that is highly dependent on technology.

An MD TMP is a tool for managing technology in an ICU, so knowing each stage of its implementation, its strengths and weaknesses and the before and after the specific inspection of the municipal health surveillance of Goiânia, as proposed in the methodology of this work, can guide managers and the health surveillance body itself in their actions and in proposing improvements to the quality of services provided in the ICU of the city of Goiânia in their most important dimension: patient safety.

In this scenario, the objective of this study was to present the level of implementation of an MD TMP in an ICU in the city of Goiânia, state of Goiás, considering that there are no studies of this nature on ICUs in Brazil.

It is expected that the results of this study can serve as a parameter for managers of ICU and health surveillance bodies of other Brazilian states and enable them to compare their realities of TMP implementation with the situation found in this study.

METHOD

This is a cross-sectional and descriptive study. The data were collected through a specific guide called "Assessment guide

for the implementation of the technology management plan in ICU medical devices", prepared by the team of tax auditors of the municipal health surveillance body of Goiânia. The guide was prepared based on Anvisa RDC n. 2/2010[7] and n. 63/2011[13] and ABNT NBR 15.943[8]. This instrument was used during the pilot project to assess the implementation of the MD TMP in an ICU in the city of Goiânia, where the study was conducted.

The municipality of Goiânia is the capital of the state of Goiás and is located in the Center-West region of Brazil. It has a population of 1,302,001 inhabitants, making it the 12th most populous city in Brazil according to the last census carried out by the Brazilian Institute of Geography and Statistics (IBGE) in 2010[14].

Data collection took place in two phases. In the first, an on-site inspection was performed in the ICUs of the municipality between December 19, 2017 and May 4, 2018, and each item of the guide was evaluated according to the following categories: "compliant", "non-compliant" or " not applicable". In addition to the fulfillment of the guide by the auditors, the inspected establishment was also required to correct the non-compliant items identified in the guide.

The second phase took place from June 19, 2018 to December 14, 2018, with a new inspection of the ICUs. Then, each item of the guide was reassessed according to the aforementioned categories, and so was the correction of the non-compliant items identified in the 1st inspection.

Inclusion criteria for this study were all ICUs in the city of Goiânia that were in operation and that were inspected in the two previously reported phases. When in the same hospital there were two or more ICUs with different managers, they were counted individually. The ICUs that, at the time of the inspection (1st or 2nd), were inactive and were not inspected by the municipal health surveillance team of Goiânia were excluded from this study. In all, 47 HEs met the inclusion criteria and were included in the study.

It was then requested from the department of health surveillance of Goiânia to consent to the use of data obtained from specific guides filed at the health surveillance of Goiânia. Therefore, secondary data were used.

The data provided in the guides were typed, structured and processed in a database. During the analysis process, information about the identification of the HEs and the contacted employees was erased to ensure the anonymity of the results.

Data analysis was performed using descriptive and inferential statistics with the SPSS statistical package, version 23. In addition to exposing the data from descriptive statistics, Student's T Test was used in the context of inferential analysis.

The data were presented in a way that ensures the anonymity of the participants, as well as that of the health institutions. This project was submitted to the Research Ethics Committee (CEP) of the Federal University of Goiás (UFG) and approved on September 25, 2018, under opinion n. 2.916.336.

For the presentation of the results, the assessment guide was divided into three main groups called: A – Before use; B – During use; and C – After use. Each large group was subdivided into groups, totaling 13 groups. Each group consisted of one or more sections of the guide, as shown in Figure 1.

To calculate the level of implementation of the TMP in each group, the values of the categories related to the implementation in each section were initially obtained. Then, the simple average was calculated between the values of the sections within the same group, in cases where the group contained more than one section. Finally, the results of the general level of TMP implementation were calculated by averaging the values in relation to the level of TMP implementation of the 13 groups.

In the presentation of the results about the sizing of the ICUs in the city of Goiânia, we decided to use the data related to the 2nd inspection because they were more recent.

RESULTS

Sizing the network of intensive care units

During the research period, 47 HEs that had at least one ICU were identified as *operating* in the city of Goiânia.

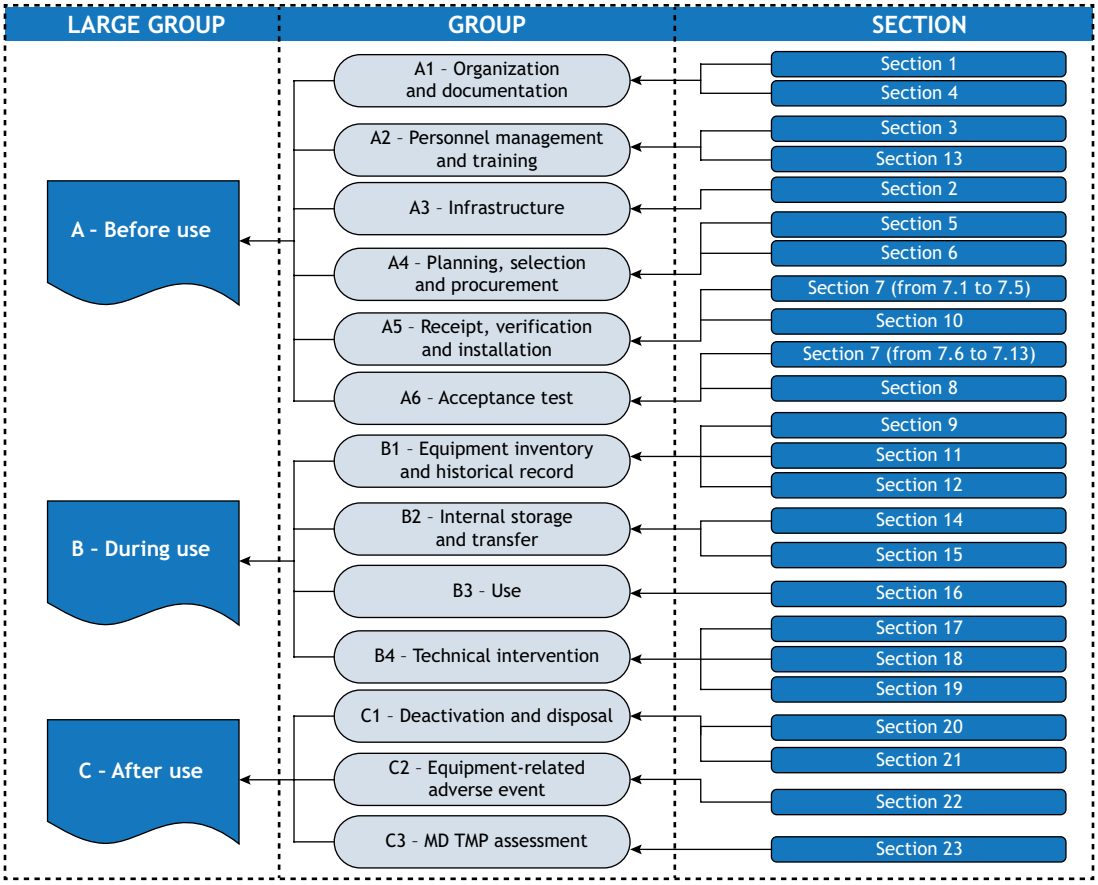
The 47 HEs offered a total of 907 ICU beds, distributed in the following amounts and proportion: 189 beds (20.8%) in neonatal ICUs (NN-ICUs); 72 beds (7.9%) in pediatric ICUs (P-ICUs), and 646 beds (71.2%) in adult ICUs (A-ICUs).

Six HEs (12.8%) were found to have only NN-ICU beds, one (2.1%) with a mixed ICU (ICU with P-ICU and NN-ICU beds in the same facility), 31 (66.0%) with A-ICUs, and nine (19.1%) with more than one type of ICU covered by the same TMP in the same HE.

Nine HEs with more than one type of ICU in their facilities were divided into: three units (33.3%) with NN-ICU and P-ICU; three units (33.3%) with NN-ICU and A-ICU; two units (22.2%) with P-ICU and A-ICU; and one unit (11.1%) with NN-ICU, P-ICU and A-ICU.

General level of implementation of the Technology Management Plan for medical devices

By analyzing all the items of the guide, we observed that the general level of implementation of TMPs was 25.8% in the 1st inspection and 40.9% in the 2nd inspection. Thus, there was an increase of 15.1 percentage points (p.p.), which is equivalent to an increase of 58.2% in the level of implementation of the TMPs. A statistically significant difference between the averages of the 13 groups ($t = -438.12$ and $p < 0.001$) was observed between the 1st and the 2nd inspection.



Source: Prepared by the authors, 2021.
TMP: Technology Management Plan; MD: Medical devices.

Figure 1. Flowchart of the composition of the Technology Management Plan groups.

The results regarding the level of implementation of the MD TMP in each group are shown in the Table.

a) Level of Implementation of the MD TMP in the groups of **Large Group A - Before use**

We observed that the group "A5 - Receipt, verification and installation" obtained the highest percentages of items in the "compliant" category in absolute numbers, both in the 1st and 2nd inspections, with 58.3% and 77.9% of compliance, respectively (Table).

The "A6 - Acceptance test" group, on the other hand, had the lowest percentage of compliant items in the two phases, 1st (10.6%) and 2nd (34.0%) inspections. However, it was the group that achieved the greatest progress between the two inspections when compared to the other groups belonging to the Large Groups (Table).

Within Large Group A, the group that made the least progress between the two inspections was "A2 - Personnel management and training", with an increase of +8.9 p.p. in compliance. Meanwhile, Groups A1, A2, A4, A5 and A6 showed a statistically significant difference between the averages of the two inspections at a confidence level of 95% (Table).

b) Level of Implementation of the MD TMP in the groups of **Large Group B - During use**

The Table shows that the Group "B1 - Inventory and historical record of the equipment" stood out because it has the highest absolute proportion of compliant items, with 31.7% and 51.9% of compliance in the 1st and 2nd inspections, respectively.

The "B3 - Use" Group, on the other hand, obtained the lowest average values when compared to all other groups in the two inspection phases: 1st (4.2%) and 2nd (9.6%) inspections, respectively. It was also the group that achieved the least progress in absolute terms among the inspection averages of the entire study, with an increase of +5.4 p.p. (Table).

The group that made most progress between the two inspections of this Large Group B, in absolute terms, was "B4 - Technical intervention", with an increase of +22 p.p. between the averages of the 1st and 2nd inspections (Table).

On the other hand, Groups B1 and B4 showed a statistically significant difference between the averages of the two inspections ($p < 0.05$).

Table. Difference between the percentage of implementation of the Technology Management Plan for medical devices from the 1st to the 2nd inspection, by groups.

Variable	Variable	Percentage (1st inspection)[a]	Percentage (2nd inspection)[a]	Difference between the averages p.p.	t[b]	p-value
A - Before use	A1 - Organization and documentation	30.0	49.7	19.7	-3.40	**0.00**
	A2 - Personnel management and training	36.4	45.3	8.9	-1.96	**0.00**
	A3 - Infrastructure	43.2	63.6	20.4	-1.79	0.07
	A4 - Planning, selection and procurement	17.4	31.2	13.8	-2.18	**0.03**
	A5 - Receipt, verification and installation	58.3	77.9	19.6	-3.92	**0.00**
	A6 - Acceptance test	10.6	34.0	23.4	-3.55	**0.00**
B - During use	B1 - Equipment inventory and historical record	31.7	51.9	20.2	-3.18	**0,00**
	B2 - Internal storage and transfer	29.8	38.5	8.7	-1.60	0.11
	B3 - Use	4.2	9.6	5.4	-1.49	0.13
	B4 - Technical intervention	23.8	45.8	22	-3.06	**0.00**
C - After use	C1 - Deactivation and disposal	13.8	33.7	19.9	-3.42	**0.00**
	C2 - Equipment-related adverse event	27.1	33.0	5.9	-0.94	0.34
	C3 - MD TMP assessment	9.2	17.0	7.8	-1.27	0.20

Note: Values in bold denote a statistically significant difference between averages at a 95% confidence level.
[a] Denotes the percentage of compliant items at the time of the 1st or 2nd inspection; b Test statistic value with 92 degrees of freedom (N = 47 ICU); p.p.: percentage points; TMP: Technology Management Plan; MD: Medical devices.
Source: Prepared by the authors, 2021.

b) Level of Implementation of the MD TMP in the groups of **Large Group C - After use**

The results in which the highest absolute rates of compliance occurred, in the 1st inspection, can be seen in Group "C2 - Adverse event related to the equipment", with 27.1% of compliance. In the 2nd inspection, the Group "C1 - Deactivation and disposal" had the highest compliance rate in absolute terms, with 33.7%, and it was also the one with the largest difference between the averages in absolute terms from the 1st to the 2nd inspection, +19.9 p.p. increase (Table).

Group "C3 - MD TMP Assessment" achieved the lowest averages of this large group, with 9.2% (1st inspection) and 17.0% (2nd inspection), while Group "C2 - Equipment-related adverse events" made the least progress in absolute terms between the inspection averages of this Large Group C, with a difference of +5.9 p.p. between the 1st and 2nd inspections (Table).

The Table shows that there was a statistically significant difference between the averages of the two inspections at a confidence level of 95% in Group C1.

Figure 2 shows the test statistic values with 92 degrees of freedom (df) (N = 47 ICU). Groups A5 and A6 had the highest values of t (above 3.5), which represents the greatest changes between the 1st and 2nd inspections, in which the "compliant" items were accounted for according to the guide.

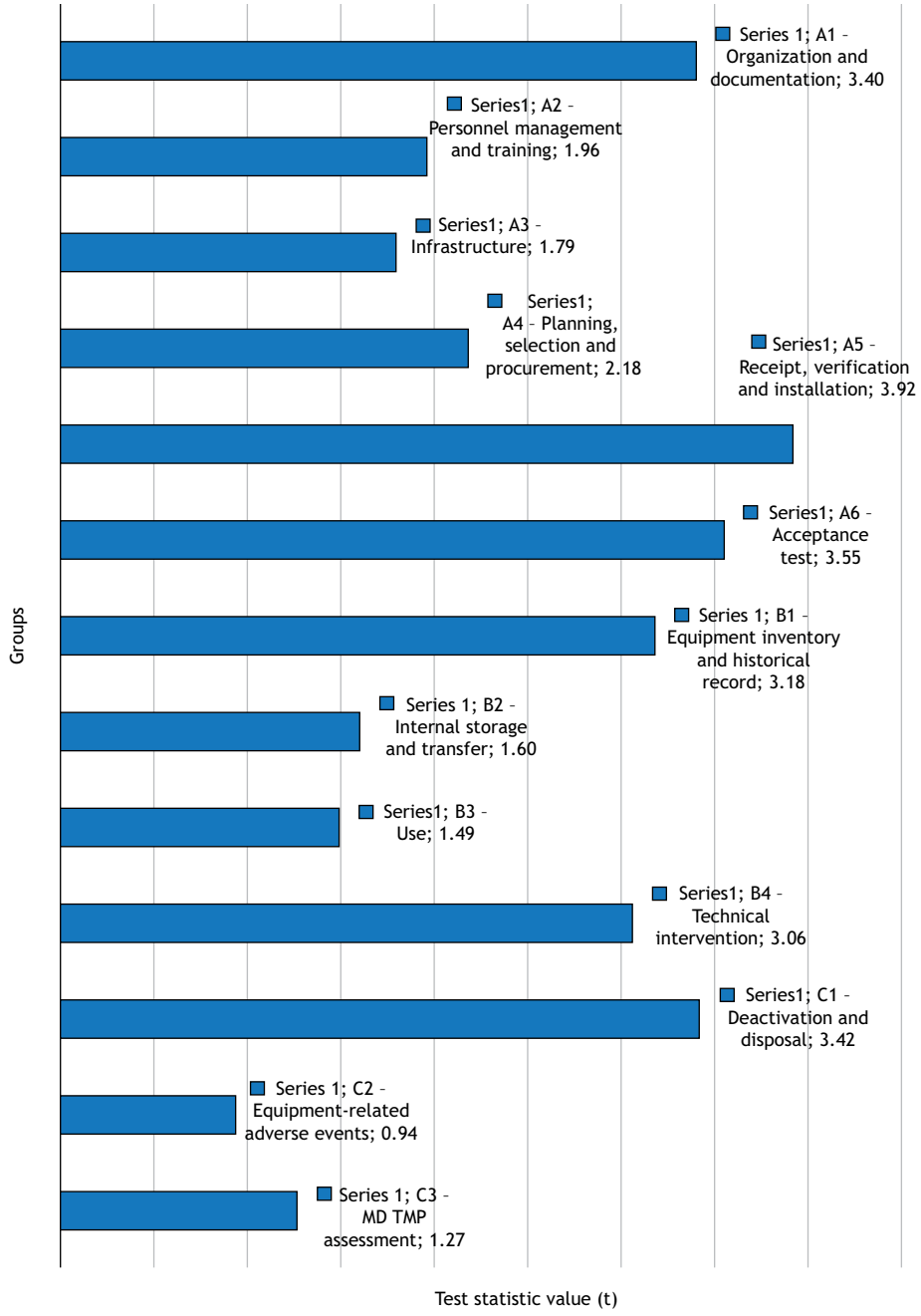
Among the lowest values of t, that is, those in which the inspection of the municipal health and environmental surveillance body of Goiânia caused fewer changes, the following stand out: i) in Large Group A - Before use, Groups A2 and A3 with values of t of 1.96 and 1.79, respectively; ii) in Large Group B - During use, Groups B2 and B3 (t = 1.6 and 1.49, respectively) and iii) in Large Group C - After use, Groups C2 and C3 were the ones with the lowest t values, 0.94 and 1.27, respectively. In all these groups there was no statistically significant difference, considering a confidence level of 95% (Figure 2).

Of the 13 study groups, eight (61.5%) have shown a statistically significant difference between the averages of the 1st and 2nd inspections ($p < 0.05$).

DISCUSSION

The spread of COVID-19 has tested the resilience of healthcare systems and required quick and effective responses from national and local governments. Anticipating problems, identifying weaknesses and estimating needs are decisive steps to enable coordinated responses that can face the disease. In a generalized context of uncertainty, these efforts become more difficult, but even more necessary[15].

According to the WHO, data from China in 2020 suggested that although the majority of people with COVID-19 had a mild (40%) or moderate (40%) illness, about 15% of those infected had severe illness and required oxygen therapy, and 5% were seriously ill and required treatment in ICUs[16]. However, depending on how fast the virus spreads in the population, healthcare systems may be under strong pressure from the additional demand



Source: Prepared by the authors, 2021.
Note: Value of t in module.

Figure 2. Test statistic value (t) between the 1st and 2nd inspection, separated by group.

generated by COVID-19[17]. In this sense, analyzing the situation of the ICU network available to the population in a given territory is essential.

Sizing the network of Intensive Care Units

According to Cotrim Junior and Cabral[18], there are regional inequalities in the distribution/allocation of ICU beds in Brazil, both in the public system (SUS) and in private institutions. The Southeast region concentrates (51.9%) of the ICU beds, while the North (5.2%) and Center-West (8.5%) regions do not reach 10.0% of the total beds. Additionally, the authors observed a leap in the number of ICU beds in the country, from 46,045 in December 2019 (pre-pandemic moment) to 60,265 (post-pandemic) in April 2020[18]. That is, in approximately four months, there was an increase of 14,220 beds, which represents a total increase of 23.5%, which is quite significant[18].

Regarding the spatial distribution of care coverage rates, it is worth noting that, according to Moreira[2], in relation to the total

number of ICUs, Brazil had 29,891 units, of which 14,094 were SUS ICUs and 15,797 were private ICUs. According to Noronha et al.[17], Brazil has 270,880 general beds (clinical and surgical) and 34,464 adult ICU beds, of which 66.0% and 48.0% are available for the SUS, respectively. Also according to the authors[17], the macro-regions with the lowest supply of beds are mostly in the North and Northeast of the country. On the other hand, Goiás is among the 30 macro-regions with the highest supply, with 30.3 beds per 10,000 inhabitants[17]. According to the recommendations of the WHO and the Ministry of Health, the ideal ratio of ICU beds is one to three beds for every 10,000 inhabitants[19], of which the SUS has an average of 1.4 beds for every 10,000, versus 4.9 of the private system[19].

Considering the population size of the city of Goiânia according to the IBGE Census (2010)[14] and the survey of the study regarding the number of ICU beds in the city, this study found that the city has 6.96 ICU beds for every 10,000 inhabitants. However, in a scenario in which 10.0% of the population is infected by the coronavirus in a period of 6 months, the estimated shortage of ICU beds would be 40,770[15]. This number is higher than the number of ICU beds existing today across the country, in the public or private sector[15].

In this scenario, with the news that field hospitals were being set up, the creation of beds and attempts to reopen or make unused public beds available, an expansion of these beds occurred throughout the country, segmenting the results by geographic region[18]. However, it is still important to consider that many of the new SUS beds created to face the COVID-19 pandemic are not permanent assets of the public system, since they are located in field hospitals, known to be temporary[18].

Level of implementation of Technology Management Plans

As a general result of the 1st inspection of the implementation of MD TMPs, we verified slightly more than a quarter of what would be considered adequate according to the guide based on the legislation then in force and the specific NBR[7,8,13]. These data demonstrate that the ICUs we assessed were not adequately prepared during the pre-COVID-19 pandemic period. Nevertheless, after the request for compliance by the municipal health and environmental surveillance team of Goiânia in the 1st inspection, there was a significant improvement in items of the guide that was applied again in a 2nd inspection.

The data of this study emphasize the importance of the actions performed by health surveillance to enable the greater protection of the population's health, prevent potential damage, injuries or risks and improve the safety of ICU patients in the municipality[20]. However, the data also show that we still have a long way to come to adapt ICU equipment to effectively fight the COVID-19 pandemic and provide other treatments that require intensive care.

In a study that evaluated risks in hemotherapy services in Brazil using an assessment method based on inspection guides applied by the health surveillance bodies of states and municipalities in Brazil, in 2011 and 2012, Silva Júnior and Rattner[21] reported that, of the 64 assessed items, 62 showed some improvement in their compliance index, and all ten items that made up the category "Materials and devices" showed some progress from one inspection to the other, which is consistent with the findings of this study.

It is also in line with what was described in the study by Groseclose and Buckeridge[22], who described the key role health surveillance plays in the modern practice of public health by collecting and analyzing data and information to assess and characterize the burden and distribution of adverse events, prioritizing actions, monitoring the impact of control measures and identifying emerging health conditions that can have a significant impact on the health of the population. This reinforces the relevance of the topic proposed in this study in knowing the management of technologies in HEs and the monitoring of the implementation of MD TMPs.

This study also demonstrated that health surveillance actions carried out with planning, methodology, clear objectives and adequate tools (guides) can be effective to promote changes in specific situations. However, our data reveal there is much room for improvement in the implementation of MD TMPs in the ICUs of the municipality in question, since, even after the 2nd inspection, more than half of the items of the guide were still considered non-compliant with the legislation.

Furthermore, the comparison of the progress of each group between inspections and the final percentage of implementation of each group provides important data, both for the municipal health surveillance body of Goiânia and for the healthcare services, on which areas of their MD TMP need more attention. We found no statistically significant difference (CI = 95%) in groups A3, B2, B3, C2 and C3, while groups A4, A6, B2, B3, C1, C2 and C3 presented absolute results below the average of MD TMP implementation in the 2nd inspection. In this sense, we suggest that the planning of actions by the municipal health surveillance body of Goiânia can be based on data like these to guide future inspections in HEs.

Groups of the Technology Management Plan for medical devices

When analyzing what groups had the highest percentages of compliant items, we observed that they were those in which the evidence used to conclude whether or not an item was compliant with the guide was related to bureaucratic aspects like procedures, verification sheets, registration of equipment and related to physical conditions of the setting. Groups A3 – Infrastructure, A5 – Receipt, verification and installation and B1 – Inventory and historical record stood out.

On the other hand, the groups in which the assessed evidence was linked to the execution of actions like training for the use of equipment (Group B3), design and assessment of indicators to verify the effectiveness of the MD TMP (Group C3) and the assessment of equipment-related adverse events (Group C2) had the lowest percentages of compliant items in both inspections.

These results showed something we already expected: after inspection, the HEs that had not yet implemented a technology management service or that were in an initial and incipient process of implementing it chose to remedy the most accessible non-compliant items first, precisely the documentary issues that require small changes in physical structure. Correcting these non-compliant items requires less time, money and culture change in HEs.

In our assessment, this shows the importance of health surveillance work to encourage these HEs to go further and make progress in complex issues that require the engagement of several HE areas and employees, including promoting a continuing education program and a patient safety culture, with the consequent awareness of the importance of reporting adverse events, their evaluation and the actions taken to prevent their recurrence.

Observing the results of the groups separately, in the Large Group "Before use", the negative highlight was Group A2 (Personnel management and training), in which the difference between the 1st and 2nd inspection represented the second worst result of the survey, ahead only of Group C2 – Equipment-related adverse event.

This result attracts even more attention because the actions assessed in Group A2 are important for the improvement of the others, like: i) the identification of adverse events (Group C2), which requires a team with expertise in the equipment and its potential risks, aware of the importance of event reporting for improving patient safety and service quality; and ii) the use of equipment (Group B3) which, as the title itself reveals, is expected to have a professional who is trained in the use of all equipment handled in the daily care of patients and who participates in a continuing education program, with a formal record of these training programs, including the evaluation of their effectiveness[7,8].

A study carried out by Reis et al.[23] found that successful patient safety strategies depend on investment in continuing and permanent education initiatives, in addition to involving from top management to leading employees in health processes. Since the implementation of MD TMPs in ICUs is a tool to increase patient safety, by analogy it can be inferred that the training of the people involved in each stage of the TMP is key to offering safe and quality care to patients when these MDs are used.

In the same sense, in the Large Group "During use", the worst results, both in the 1st and 2nd inspection, were verified in the use of equipment (Group B3), a worrying fact when we consider that the main cause of adverse events related to equipment is related to misuse[24]. Incorrect use may be associated with failure in other stages of MD management, like poor training of employees who use the equipment, inappropriate equipment for its intended use (failure in the planning and selection process of equipment, Group A4) and even equipment manufacturing errors, like those related to design and button spacing; the intuitiveness of the equipment design, reverting to default mode without warning, overcrowded graphical interface, and transparency of operations[25].

In the Large Group "After use", Group C2 – Equipment-related adverse event was the least sensitive to the work of the municipal health surveillance body of Goiânia. This is an important topic to be addressed (definition of actions) by regulators and healthcare services themselves. According to Ribeiro et al.[11], the concern with the safety of equipment in Brazil is recent and strategies to prevent adverse events related to its use are still incipient. The adoption of checklists for checking equipment and the formal training of all users are reported by Soltner[26] as strategies to prevent the occurrence of errors in the use of equipment and, consequently, improve patient safety.

In this context, team training associated with a non-punitive patient safety culture is also important to, first, encourage the reporting of near misses, errors and adverse events related to the use of MDs; second, once the risks arising from the use of MDs are known, barriers and protocols can be established to prevent the occurrence of new events; and, third, with the reporting of these events in the Health Surveillance Notification System (Notivisa), to promote the construction of an effective techno-surveillance network that provides material for regulatory bodies to take action at the national level. The human factor in the use of equipment has been observed as the most relevant to explain the occurrence of adverse events in inpatients[26,27], which confirms the need to pay special attention to equipment operators to provide services with greater safety and better quality.

According to Mattox[25], the first step to reduce equipment-related risks is knowing and recognizing the errors and adverse events with which the equipment is involved. The second step is reporting the events, overcoming the user/operator feeling of guilt, because when an equipment-related event occurs, it is natural that, at first, users blame themselves for it[25]. It is necessary to overcome this stage of blaming and start reporting the events, including with information about the setting that is usually used as an excuse for what happened, like lack of ambient lighting, fatigue, noise pollution and confusing equipment interface, which are essential to understanding events and preventing their recurrence[25]. The third step would be to reject inappropriate equipment. Before any equipment is purchased, the technical team should be consulted to assess the suitability of that equipment for the intended use and the potential risks arising from the use of that technology[25]. Nursing teams are in a vantage point within HEs to assess these questions, and including these teams in planning and equipment selection committees is important to reduce the risks arising from the use of equipment[25].

Therefore, we suggest that other studies explore the possibility of correlation indicated in this study, in which the weaknesses presented in staff training contribute to problems related to the use of MDs and the lack of identification of equipment-related adverse events.

A study correlating with the COVID-19 disease pandemic listed the challenges for ICU preparation based on the experience of Asian countries to face the complex scenario created by COVID-19. The study highlighted that it is not only necessary to increase the number of beds available, but also to equip them with appropriate devices, especially mechanical ventilators, in addition to the need to train workers[5].

From that perspective, the pandemic is a milestone in the technological revolution in the sector, as it imposed the need for new strategies and preparation of services in the face of a critical epidemiological and health reality[28]. That is, although the COVID-19 pandemic is a critical and unwanted situation, it is understood that the experiences of this period can provide opportunities for the improvement of processes and flows in the use of health technologies[28].

CONCLUSIONS

This study presented an overview of the implementation of MD TMPs in ICUs in the city of Goiânia. However, since the items in the guide used by the municipal health and environmental surveillance body of Goiânia for data collection are not weighted according to health risk, it is not possible to conclude - based only the number of compliant items - that there was an improvement in the safety of patients treated in the assessed HEs, although this is an indication. It was also not possible to compare the level of implementation of MD TMPs with other municipalities or states due to the lack of published studies on this topic, which also reinforces the importance of this work, which is the pioneer in this approach.

The interconnection between the assessed MD TMP groups and the literature suggest that continuing education initiatives for the professionals involved in the process can improve implementation levels, but the methodology of this study does not allow us to make this inference. Further studies are suggested, including studies with qualitative methodologies to investigate these correlations.

Even before the beginning of the COVID-19 pandemic, healthcare managers, professionals and service users were already concerned with the risks arising from the use of these technologies. Therefore, in the midst of the greatest health crisis in recent times, there is an urgent need to effectively implement TMPs in ICUs to improve the quality of care and patient safety.

Although not a limitation of the study, the ecological design does not enable us to draw individual-level inferences. Another important factor is the cross-sectional nature of this study, which does not enable us to formulate causal hypotheses. However, the objective was not to establish causal relationships, but association and assistive prognosis. Spatial knowledge of the occurrences of mortality and intensive care coverage can reveal places where interventions are necessary and help the country prevent the massive spread of COVID-19 from causing the collapse of the SUS[2].

REFERENCES

1. Lu H, Stratton CW, Tang Y. Outbreak of pneumonia of unknown etiology in Wuhan, China: the mystery and the miracle. J Med Virol. 2020;92(4):401-2. https://doi.org/10.1002/jmv.25678
2. Moreira RS. COVID-19: unidades de terapia intensiva, ventiladores mecânicos e perfis latentes de mortalidade associados à letalidade no Brasil. Cad Saúde Pública. 2020;36(5):1-12. https://doi.org/10.1590/0102-311X00080020
3. Worldometer. COVID-19 coronavirus pandemic. 16 jun 2021[acesso 16 jun 2021]. Disponível em: https://www.worldometers.info/coronavirus/
4. Remuzzi A, Remuzzi G. COVID-19 and Italy: what next? Lancet. 2020;395(10231):1225-8. https://doi.org/10.1016/s0140-6736(20)30627-9
5. Zhang G, Hu C, Luo L, Fang F, Chen Y, Li J et al. Clinical features and short-term outcomes of 221 patients with COVID-19 in Wuhan, China. J Clin Virol. 2020;127:1-7. https://doi.org/10.1016/j.jcv.2020.104364
6. Phua J, Weng L, Ling L, Egi M, Lim C-M, Divatia JV et al. Intensive care management of coronavirus disease 2019 (COVID-19): challenges and recommendations. Lancet Resp Med. 2020;8(5):506-17. https://doi.org/10.1016/s2213-2600(20)30161-2
7. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 2, de 25 de janeiro de 2010. Dispõe sobre o gerenciamento de tecnologias em saúde em estabelecimentos de saúde. Diário Oficial União. 26 jan 2010.
8. Associação Brasileira de Normas Técnicas – ABNT. NBR 15943: diretrizes para um programa de gerenciamento de equipamentos de infraestrutura de serviços de saúde e de equipamentos para a saúde. Rio de Janeiro: Associação Brasileira de Normas Técnicas; 2011.
9. Kelly FE, Fong K, Hirsch N, Nolan JP. Intensive care medicine is 60 years old: the history and future of the intensive care unit. Clin Med (Lond). 2014;14(4):376-9. https://doi.org/10.7861/clinmedicine.14-4-376
10. Galgon RE. Understanding medical device regulation. Curr Op Anaesth. 2016;29(6):703-10. https://doi.org/10.1097/aco.0000000000000391
11. Ribeiro GSR, Silva RC, Ferreira MA, Silva GR. Slips, lapses and mistakes in the use of equipment by nurses in an intensive care unit. Rev Esc Enferm USP. 2016;50(3):419-26. https://doi.org/10.1590/s0080-623420160000400007
12. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 509, de 27 de maio de 2021. Dispõe sobre o gerenciamento de tecnologias em saúde em estabelecimentos de saúde. Diário Oficial União. 31 maio 2021.

13. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 63, de 25 de novembro de 2011. Dispõe sobre os requisitos de boas práticas de funcionamento para os serviços de saúde. Diário Oficial União. 26 nov 2011.
14. Instituto Brasileiro de Geografia e Estatística – IBGE. Censo brasileiro de 2010. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2011.
15. Rache B, Rocha R, Nunes L, Spinola P, Massuda A. Para além do custeio: necessidades de investimento em leitos de UTI no SUS sob diferentes cenários da COVID-19. São Paulo: Instituto de Estudos para Políticas de Saúde; 2020.
16. World Health Organization – WHO. Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020. Geneva: World Health Organization; 2020.
17. Noronha KVMS, Guedes GR, Turra CM, Andrade MV, Botega L, Nogueira D et al. Pandemia por COVID-19 no Brasil: análise da demanda e da oferta de leitos hospitalares e equipamentos de ventilação assistida segundo diferentes cenários. Cad Saúde Pública. 2020;36(6):1-17. https://doi.org/10.1590/0102-311X00115320
18. Cotrim Junior DF, Cabral LMS. Crescimento dos leitos de UTI no país durante a pandemia de COVID-19: desigualdades entre o público x privado e iniquidades regionais. Physis. 2020;30(3):1-11. https://doi.org/10.1590/S0103-73312020300317
19. Associação de Medicina Intensiva Brasileira – AMIB. AMIB apresenta dados atualizados sobre leitos de UTI no Brasil. São Paulo: Associação de Medicina Intensiva Brasileira; 2020[acesso 2 maio 2020]. Disponível em: https://www.amib.org.br/fileadmin/user_upload/amib/2020/abril/28/dados_uti_amib.pdf
20. Seta MHD, Oliveira CVS, Pepe VLE. Proteção à saúde no Brasil: o sistema nacional de vigilância sanitária. Cienc Saúde Coletiva. 2017;22(10):3225-34. https://doi.org/10.1590/1413-812320172210.16672017
21. Silva Júnior JB, Rattner D. A vigilância sanitária no controle de riscos potenciais em serviços de hemoterapia no Brasil. Saúde Debate. 2016;40(109):136-53. https://doi.org/10.1590/0103-1104201610911
22. Groseclose SL, Buckeridge DL. Public health surveillance systems: recent advances in their use and evaluation. Ann Rev Public Health. 2017;38:57-79. https://doi.org/10.1146/annurev-publhealth-031816-044348
23. Reis GAX, Oliveira JLC, Ferreira AMD, Vituri DW, Marcon SS, Matsuda LM. Dificuldades para implantar estratégias de segurança do paciente: perspectivas de enfermeiros gestores. Rev Gaúcha Enferm. 2019(esp);1-7. https://doi.org/10.1590/1983-1447.2019.20180366
24. Alfonso Marín LP, Salazar López C, Franco Herrera AL. Incidencia de eventos adversos asociados a dispositivos médicos en una institución de salud em Colombia. Rev Ing Biomed. 2010;4(8):71-84.
25. Mattox E. Medical devices and patient safety. Crit Care Nur. 2012;32(4):60-8. https://doi.org/10.4037/ccn2012925
26. Beydon L, Ledenmat PY, Soltner C, Lebreton F, Hardin V, Benhamou D et al. Adverse events with medical devices in anesthesia and intensive care unit patients recorded in the french safety database in 2005–2006. Anesthesiology. 2010;112(2):364-72. https://doi.org/10.1097/ALN.0b013e3181ca2e55
27. Ribeiro GSR, Silva RC, Ferreira MA. Tecnologias na terapia intensiva: causas dos eventos adversos e implicações para a enfermagem. Rev Bras Enferm. 2016;69(5):972-80. https://doi.org/10.1590/0034-7167.2016690505
28. Celuppi IC, Lima GS, Rossi E, Wazlawick RS, Dalmarco EM. Uma análise sobre o desenvolvimento de tecnologias digitais em saúde para o enfrentamento da COVID-19 no Brasil e no mundo. Cad Saúde Pública. 2021;37(3):1-11. https://doi.org/10.1590/0102-311X00243220

Authors' Contribution

Silva FI, Rodrigues PCF, Teixeira RAG, Oliveira ESF – Conception, planning (study design), acquisition, analysis, interpretation of data and writing of the manuscript. All authors approved the final draft of the manuscript.

Disclosures

The authors report that there is no potential conflict of interest with peers and institutions, nor political or financial conflicts in this study.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.