TRAINING AND QUALIFICATION OF NURSING PROFESSIONALS IN THE OPERATING ROOM TO CARE FOR PATIENTS INFECTED WITH SARS-CoV-2 IN EXTERNAL AREAS

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e are used to hearing that health professionals save lives, but today, amid the COVID-19 pandemic, we hear stories in which characters also get sick and lose their lives. There are an estimated 20,000 deaths of these professionals worldwide.¹ According to the nursing observatory of the Brazilian Federal Council of Nursing (Conselho Federal de Enfermagem - Cofen), Brazil is the world leader in the number of nursing professionals who died from COVID-19, totaling 454 by the first week of November.²

According to the International Council of Nurses,³ these numbers alert us to the inadequate conditions and performance structures for these professionals, as well as the lack of personal protective equipment (PPE), in addition to warning about a second wave of the pandemic being even more terrible without the presence of nursing professionals to care for patients.

In Brazil, a crisis management committee from Cofen⁴ and the Brazilian Medical Association⁵ are constantly observing the lack of PPE to ensure the safety of health professionals in the care of patients infected with SARS-CoV-2.

In this scenario of sustained uncertainty, we understand the need for nurses and nursing technicians working in the Surgery Center (SC) as an important workforce for the care of critical patients in the intensive care unit (ICU), considering their potential knowledge in monitoring, hemodynamics, and patient positioning.

In the pandemic period, surgical practice was directly affected by the suspension of elective procedures and the prioritization of urgent and emergency surgeries, aiming at reserving beds for patients in the ICU.

The roles of many team members have changed because of the lack of elective procedures. In many countries, perioperative professionals were relocated to contribute and do whatever was needed, such as temporary transfer to a different unit, assistance to colleagues in positioning the patient, and in wearing and taking off PPE.⁶

In Brazil, as well as in the world, the high demand for patients and care, in both public or private institutions, required the support of perioperative nursing for patients in need of critical care.

In catastrophe situations, a crisis management plan must be established. For COVID-19, besides allocating beds, equipment, and material resources, providing professionals to avoid the burden of care is a strategy of this crisis plan. According to the World Health Organization, personnel shortage, due to the combination of absence of professionals and the increased demand for services, must be anticipated and requires a plan to deal with it, such as reallocating or securing additional personnel.

As an SC manager, identifying the staff that had a profile/interest or previous experience in critical units was the first step to be taken. After that, the obligation of carrying out training, in partnership with continuing education, reviewing procedures/routines in the ICU – given the demand of the crisis, only one day could be made available – and, later, inserting these professionals in practice with follow-up by another professional in the field in the first days is required, until the moment that the perioperative nursing team had the same look at the critically ill patient as the intensive nursing team had.

In private hospitals, the migration of nursing technicians who were taking an undergraduate nursing course and showed interest because of the need to develop care skills for direct care to the patient was seen, as well as post-anesthesia care unit (PACU) nurses, with greater ability to assist patients and greater ease in the development of intensive care, and nurses in the room adequately supporting in surgical positioning.

At that time, the most important role was preparing professionals in case we had to, in contingency, use the AR room as an ICU. And our team should be prepared for this challenge.

As perioperative nurses, we have been experiencing a mixture of feelings, afflictions about the pandemic, fear of the unknown, possibility of becoming infected or of contaminating some family member when returning home, need to help as a mission of their profession, absence of patients in their sector, and uncertainty of the time it would all take. In addition, we were entering a new sector, a new routine, a new team, new assignments, and developing another perspective of the critically ill patient.

The experiences of this new perspective increased the skills of perioperative nurses to recognize the need for intraoperative interventions for better postoperative care, such as injury prevention, accommodation in the bed prepared for the patient's needs, the importance of family contact, analgesic comfort, correct positioning, support of vasoactive drugs and their concentrations, recognition of hemodynamic instability, and involvement in the multidisciplinary team as part of comprehensive care.

The qualities that made perioperative nurses so essential for healthcare, innovation, such as communication, flexibility, and adaptability were expanded during the response to COVID-19.6

Gradually, according to the demand and approval of elective surgeries, the team returned to the SC. The pandemic is still in force, and new learning and protocols related to the flow management of patients contaminated with coronavirus in the surgical environment are required. However, in November, after eight months of COVID-19 pandemic, a situation of greater control of the need for beds seems to be established, and the last members of the team return to the perioperative area full of histories, bonds, and skills.

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NOISE INTENSITY AND RAISING AWARENESS OF THE NURSING TEAM AT THE MATERIALS AND STERILIZATION CENTER

Intensidade de ruídos e conscientização da equipe de enfermagem no Centro de Materiais e Esterilização

Intensidad de ruido y conciencia del personal de enfermería del Centro de Materiales y Esterilización

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ABSTRACT: Objective: To identify the sound intensity, through decibels (dB), in the Materials and Sterilization Center (MSC) and to guide employees on the importance of ear protectors as personal protective equipment (PPE). **Method:** This is a descriptive and case report study. Sound Meter application was used to measure noise intensity in the MSC. Research was carried out in a large hospital in São Paulo City, for one week, in 2018. **Results:** The most intense noises were measured in the purge (93.0 dB), in the preparation area (92.3 dB), in sterilization areas at low temperature (91.6 dB), and steam sterilization (87.9 dB) different from the perception of collaborators. The team's awareness was based on the exposure of the measured results and discussion about the importance of PPE. **Conclusion:** There were more intense noises in the work areas with a higher number of machinery, and there was a divergence between the intensity of noise measured and that perceived by the professional. Reflective educational measures are needed to raise awareness about the importance of adhering to PPE. **Keywords:** Environmental hazards. Personal protective equipment. Hearing loss, noise induced. Perioperative nursing.

RESUMO: Objetivo: Identificar a intensidade sonora, por meio de decibéis (dB), no Centro de Material e Esterilização (CME) e orientar os colaboradores quanto à importância dos protetores auriculares como equipamento de proteção individual (EPI). **Método:** Trata-se de um estudo descritivo, do tipo relato de experiência. Utilizou-se o aplicativo Sound Meter para medir a intensidade de ruído no CME. A pesquisa foi realizada em hospital de grande porte de São Paulo, no período de uma semana, em 2018. **Resultados:** Os ruídos mais intensos foram mensurados no expurgo (93,0 dB), na área de preparo (92,3 dB), nas áreas de esterilização a baixa temperatura (91,6 dB) e a vapor (87,9 dB), diferentemente da percepção dos colaboradores. A conscientização da equipe deu-se por exposição dos resultados mensurados e discussão sobre importância do EPI. **Conclusão:** Verificaram-se ruídos mais intensos nas áreas de trabalho com maior número de maquinários, e houve divergência entre a intensidade do ruído mensurado e o percebido pelo profissional. Medidas educativas reflexivas são necessárias para a conscientização sobre a importância e adesão ao uso do EPI.

Palavras-chave: Riscos ambientais. Equipamento de proteção individual. Perda auditiva provocada por ruído. Enfermagem perioperatória.

RESUMEN: Objetivo: Identificar la intensidad sonora, mediante decibeles (dB), en el Centro de Material y Esterilización (CME) y orientar a los empleados sobre la importancia de los protectores auditivos como equipo de protección personal (EPP). **Método:** Se trata de un estudio descriptivo, del tipo informe de caso, La aplicación Sound Meter fue utilizada para medir la intensidad del ruido en el CME. La investigación se llevó a cabo en un gran hospital de São Paulo, durante una semana, en 2018. **Resultados:** Los ruidos más fuertes se midieron en la purga (93,0 dB), em el área de preparación (92,3 dB), en las áreas de esterilización a baja temperatura (91,6 dB) y vapor (87,9 dB), diferente a la percepción de los empleados. El equipo tomó conciencia al exponer los resultados medidos y discutir la importancia del EPI. **Conclusión:** Hubo ruido más intenso en las áreas de trabajo con mayor número de máquinas y hubo divergencia entre la intensidad del ruido medido y el percibido por el profesional. Las medidas educativas reflexivas son necesarias para sensibilizar sobre la importancia y adherencia al uso del EPI.

Palabras clave: Riesgos ambientales. Equipo de protección personal. Pérdida auditiva provocada por ruido. Enfermería perioperatoria.

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INTRODUCTION

Noise can cause a dull effect on hearing, interfere with people's personal and professional life, change their sensory perception, besides causing stress and irritability.¹

Noise is one of the most stressful factors in the workplace and can cause tinnitus and hearing loss. Tinnitus is characterized by an auditory sensation with no external stimulus, which appears in the form of whistles, beeps, hisses, among others. This sensation can be constant or intermittent, unilateral, or bilateral. Such injury can be classified by its duration; it can be chronic if it lasts for days; or acute, if the duration is short and lasts for a few seconds.²

Hearing loss is present in more than 360 million people worldwide. The most affected are older people, which can be due to the aging process itself or associated with other factors, whether genetic or environmental. A study carried out in Vila Velha City, Espírito Santo State, evaluated the epidemiological profile of 487 older and 303 young people, and found that, in both groups, speech disorders and tinnitus were some of the biggest complaints. Among participants, most presented damage due to exposure to noise, whose main symptom is tinnitus, present in more than 90% of cases.³

Noise-induced hearing loss (NIHL) is a damage caused by long-term exposure to noise and is defined as sensorineural hearing loss, usually bilateral, irreversible, and progressive with the time of exposure to noise.⁴

Among agents that damage hearing, noise is considered one of the aggressors that most contributes to the high rate of hearing impairment, causing sensorineural hearing loss.

The regulatory standard NR-15 establishes the limits of exposure to continuous noise, levels of 85 decibels (dB) as the maximum allowable daily exposure of eight hours, and 87 dB for six hours. The higher the dB index, the shorter the maximum exposure time.⁵

NR-15 establishes that not only exposure to extremely high thresholds and for a long period cause damage, but it portrays that ephemeral and exorbitant exposure can cause hearing damage, whether reversible or irreversible, given the trauma that leads to ear damage. In addition to the exposures, abrupt changes in acoustic levels can also cause damage. NIHL can be developed because of constant exposure to noise.⁵

Exposure time is directly proportional to injury. Thus, it is of utmost importance that the workplace has a favorable environment for employees to have adequate acoustic rest.⁴

NR-32 establishes basic guidelines for measures to protect the safety and health of health workers. Among these, there are essential supply of personal protective equipment (PPE) by the company, and its mandatory use by employees. Such equipment provides employees with greater security at the Materials and Sterilization Center (MSC), and the lack of its use exposes employees to occupational hazards, whether biological, ergonomic, or physical.⁶

The MSC is a unit with a high turnover of low, medium, and high complexity materials, and contains a variety of equipment. Such equipment must attend all stages of the process, especially automatic washers, compressed air jets, saturated steam autoclaves, and sterilization by hydrogen peroxide plasma, which, in turn, dissipate loud noises in the unit.

The unit shown in the study is one of the largest and most modern sterilization centers in Latin America, with numerous activities and very well divided. Employees working in this type of unit require constant training and responsibility in their actions. The MSC must provide materials for all units in the hospital; whether they are sterile or disinfected, both methods must be performed in an appropriate manner, always valuing quality for clients, that is, patients.

The occupational risk in this sector is quite significant, given the exposure to body fluids, present in materials in the process of arriving at the unit; sharps, erroneously left with other materials; in addition to the risks caused by the work environment itself.

Due to the work profile, the MSC is a critical area and predisposes employees to greater occupational risks. It is the institution's responsibility to provide continuing education and raising awareness of professionals about the risks to which they are exposed, besides adequate means of work. It is up to employees to engage to ensure work routines, as well as individual and collective protection carried out in an appropriate manner.⁷

Among the PPE used in the MSC, the present study highlights the use of hearing protection in environments in which noise pollution is high, above 85 dB, as established by NR-15. This level of sound pressure, associated with longer exposure times and frequency, can cause irreversible and more extensive damage. 1,8

In this context, allowing the sharing of measured noise levels with employees can help in understanding the importance of using PPE as a protective measure against hearing damage.

Even though PPE does not eliminate risks, it effectively reduces them. One way of spreading the institution' and its collaborators' responsibility is by exposing the problem, developing critical-reflective thinking with those involved.

During the experience of the first author as a resident nurse, employees were seen not to believe in the possibility of hearing damage or loss due to continuous exposure to noise from equipment in the areas that make up the MSC.

One of the problems in this context is not the product availability, since it is a low-cost material, but the support, which is offered without an analysis of the context of the work environment and a due clarification regarding resource use by employees.⁸

OBJECTIVE

To identify sound intensity, in dB, in the areas that make up the MSC and make employees aware of the importance of using hearing protectors.

METHOD

This is a descriptive-exploratory and field study, carried out at the MSC of a large, philanthropic hospital, located in São Paulo City. It was built based on theoretical grounds, ¹⁰ norms, resolutions, and monitoring of the work process in the sector.

In this MSC, inaugurated in August 2016, equipment with high production capacity and low operating cost was purchased, with the objective of improving logistics in relation to the supply of materials, as well as the work structure, focusing on health, and the safety of patients and employees.¹¹

This unit's employees maintain a work schedule of 6x1, with 6 or 8-hour shifts, which can be extended depending on the sector's demand and the absence of other employees.

The division of labor is carried out on weekly scales, thinking about their physical and mental health, because these activities are classified as light, moderate, and heavy scales, thus avoiding an exhaustive work sequence for employees.

Given the concern for collaborators' health, an initial discussion with nurses and nursing technicians of the unit was held about the perception of noise in their daily activity scales and the auditory discomfort as damaging to work, in addition to the probable reasons for not using ear protectors, since, despite being made available in the unit, there is no adhesion by employees. This was the problem that triggered interest to develop this study.

In the residency period in which the author worked at the MSC, the fact that employees did not use ear protectors, even though PPE was available, called attention; after all, the noise in the unit was quite uncomfortable most of the time. For better understanding the issue, conversations were held with employees individually so as not to influence opinions. In a standardized way, employees were asked about the reason for not using PPE and what they thought could be done to improve adherence. Most of the feedback regarding non-use of PPE was that employees had already become accustomed to the unit's noises; some said that they already felt their hearing was altered, so they did not give much importance to protection. On the other hand, others said that they did not believe that their exposure to the unit could cause any damage, or even hearing loss.

As for measures that would help improving adherence, most said that raising awareness of all employees on the subject is important, because most of them were not sure about the risk to which they were exposed. Another measure would be changing the ear protector model, as some found the one available in the unit to be uncomfortable and ineffective, preferring those of personal use, like headphones. Some employees believed headphones to be more effective because they drown out the sound better, besides being more comfortable.

Among the possibilities of the sector, the collection of data on dB was planned to obtain reliable measurements, so that it made employees aware of the work environment, providing the dimension of noise intensity to which they were exposed in most of their days, drawing a parallel with the damage shown in the literature on such exposure.

For the noise index, dB was collected using the Sound Meter application, available for Android and IOS, capable of evaluating the dB index within a given environment. Purge, preparation, autoclave sterilization, low temperature sterilization, and storage/distribution areas were measured.

Noise was collected at different times, from 7 a.m. to 7 p.m., which corresponds to the morning and afternoon work shifts, seeking each shift's highest peak noise.

Noise measurement locations were near washing machines in the purge, in instruments preparation areas, places close to the autoclave, areas of low temperature sterilization (hydrogen peroxide plasma), and in the distribution of materials to arsenals.

The locations selected for measurement were those mentioned by employees as having the most annoying noise. The value was measured for one minute per area, with or without the presence of a collaborator on the site, and the highest value reported by the application was used for comparison with the other areas. Measurement was performed and recorded in a specific spreadsheet for one week, in December 2018. The values provided by the Brazilian Ministry of Health were used as a basis for comparison.^{4,5}

The collected data were inserted in an Excel spreadsheet for later comparison with the maximum allowed noise exposure data, according to the Ministry of Health,^{4,5} considered the tolerable daily limit of 85 dB. A descriptive analysis of these data was carried out.

RESULTS

In discussions with employees in the sector, the areas of autoclave sterilization, low temperature sterilization, purge, preparation of instruments, and distribution were mentioned as those perceived with intense noise. Of these, the first three are work areas considered to be as heavy scales for noise intensity.

A total of 10 daily samples were collected, five in each shift, one for each daily scale. Despite scales division, some areas do not have structural division between one another, so noises end up merging in the sector, which made it difficult to accurately measure dB by scale.

With the application, reaching a dB value was possible, but measuring to how much this number falls with the use of ear protectors was not possible. The measured values are shown in Table 1.

The average of values with higher decibels in the morning corresponds to the preparation area (92.3 dB), followed by low temperature sterilization (91.6 dB), and autoclave (87.9 dB). In the morning, there is a greater number of surgical box screening to meet the daily demand and the beginning of sterilization processes.

In the afternoon, the areas with the highest average dB corresponded to the purge (93.0 dB), the preparation area (91.5 dB), and low temperature sterilization (91.0 dB). In the afternoon, there is a greater movement to finish surgical procedures and receive consigned materials, and the number of materials in the process of cleaning in the purge is high.

The perception of noise by employees differs in the classification of greater noise. When the autoclave sterilization

Table 1. Noise measurements in decibels (dB) by area and period of work at the Materials and Sterilization Center.

	12/12/2018	12/13/2018	12/14/2018	12/15/2018	12/17/2018	12/19/2018	12/26/2018	Average
Scale	Shift - Morning							
	dB	dB	dB	dB	dB	dB	dB	
Preparation	90.9*	91.5*	93.2*	95.6*	98.6*	90.3*	86.6*	92.3*
Autoclave	84.7	94.3*	83.9	89.6*	88.5*	85.8*	88.9*	87.9*
Low temperature	95.0*	86.8*	96.3*	94.8*	92.9*	85.2*	90.3*	91.6*
Distribution	83.8	83.9	84.9	82.3	82.3	82.2	80.0	82.7
Purge	93.7*	90.1*	84.6	85.0	85.7*	87.7*	83.9	87.2*
	Shift - Afternoon							
	dB	dB	dB	dB	dB	dB	dB	
Preparation	100.2*	92.1*	95.8*	85.0	89.3*	92.4*	85.9*	91.5*
Autoclave	90.0*	94.0*	93.2*	89.2*	87.9*	85.7*	88.3*	89.7*
Low temperature	96.8*	89.7*	89.3*	95.4*	90.3*	88.3*	87.6*	91.0*
Distribution	85.2*	85.0	83.6	85.8	85.5*	86.0*	84.3	85.0
Purge	95.2*	92.6*	98.1*	90.9*	92.3*	90.7*	91.6*	93.0*

^{*}Values above the Brazilian Ministry of Health recommendations

area mentioned by employees as the one with the highest noise perceptions, this area is below the highest levels measured in the preparation, purge, and low temperature sterilization areas when dB level is measured.

With the measured values, the awareness of the nursing team took place with an expository presentation of the measured values and employees' initial perception, demonstrating that the noise may not have been perceived by them. Emphasis was placed on the importance of using ear protectors as an essential PPE to protect hearing health. After showing the values, the group had time to discuss the use of PPE. Later, raising awareness was observed as not yet being effective for most employees to use ear protectors. This fact encourages the authors to create new action measures to improve the group's adherence.

DISCUSSION

The data in this study demonstrate high levels of noise to which employees are exposed in the MSC, when compared to the reference level of the Brazilian Ministry of Health, which shows that employees exposed to noise above 85 dB for certain periods can suffer hearing damage. The areas with the highest dB intensity correspond to those perceived by employees as having the highest intensity (autoclave sterilization, low temperature sterilization, and purge), but they differ in the classification of the highest noise level.

Such perception divergence may be related to the adaptation of employees to their work area, but it raises the question of employees maybe failing to wear ear protectors because they believe that the area in which they work has less noise intensity and, therefore, would not cause damage to their health. In fact, it is an area of greater intensity and can cause hearing damage according to the prolonged exposure time. A study showed that 25% of workers are exposed to noise-induced hearing loss.¹²

Regarding noise average, the only area with values according to the recommendation is the storage/distribution of materials, and this is due to the characteristic of the place in which storage of sterile material is carried out, without machinery, with reduced personnel flow. This is also the area perceived by employees as having the lowest noise intensity.

A similar study obtained strong and disturbing noises as results, evidenced in 97 and 96% of state and municipal

hospitals, respectively; noises came from machines and equipment. The areas of greatest intensity have a finding like those from the present study, which are preparation of instruments and sterilization at low temperature. Other studies have obtained a similar perception about the presence of noise in areas in which autoclaves are concentrated and in instruments preparation. 13,14

A study compared several damages to which MSC workers are exposed, and identified noise as one of the most prevalent, ranking third or present in 82.2% among all damage. In this study, employees reported using PPE, but after obtaining data, hearing protection was not mentioned among the most prevalent protective equipment used by employees.¹⁵

The lack of adherence to the use of hearing protection by employees and their perception of little importance in relation to the use of PPE are observed in the behavior of several employees working at the MSC.

In relation to poor PPE adherence and hearing damage, employees mentioned that the use of hearing protection causes some discomfort, drowns out verbal requests or bells, interfering with the sector's dynamics. Therefore, even though PPE minimizes the damage caused by noise, such equipment is little used by health professionals and requires different actions to raise awareness about its importance.

NIHL appears as the second most recurrent condition of the hearing system and is often perfectly feasible for prevention. The progression of damage stagnates when people are removed from the noise source.

A study, whose prevalence of NIHL in the participants was 30%, suggests that this pathology is more prevalent in people with advanced age and finds the prevalence before the longer time of exposure to noise. ¹⁶

The way in which workers perceive reality is often inadequate from the point of view of occupational safety. Thus, actions related to perception and risk propensity must be promoted so that employees are aware of health preservation as a priority.¹⁷

Each human being has a different sensitivity to noise, and having a dimension of the damage caused is only possible with consultation with a specialized professional, with proper anamnesis, inspection of the external auditory canal, audiometric examination, immittance test, which analyzes the functional integrity of the eardrum, and noise stimulus test, which checks for the presence of cochlear damage.¹

In a study carried out in São Paulo City, the effectiveness of noise attenuation was measured with the use of foam plug ear protectors, similar to what was found at the MSC headquarters of present research. The study was applied to 18 participants of both sexes, and the efficiency of the ear protector was measured with a noise dosimeter that contained two microphones, both strategically positioned in the same positions. With a microphone located in the external auditory canal, in the plug foam, and another near the shoulder, the authors simulated a normal work situation. Although the study reports differences among participants, which is also caused by the anatomical characteristics of each one, there was noise attenuation in all situations with the use of PPE. In all samples, the values of the microphone installed in the ear were lower when compared to those of the shoulder, thus showing the effectiveness and importance of wearing ear protectors, especially in situations in which the environment presents noise above the level recommended by the Brazilian Ministry of Health.18

Educational actions are effective when they encourage the reflection of workers, promote their autonomy, and encourage the adoption of protective measures for them and for others.¹⁷

Among research limitations, not being able to measure how much ear protectors decrease the chances of developing damage without the proper devices is one of them. However, what became clear was the extent to which employees are subject to affecting their physical and mental health if exposed to their work environment with no protection.

CONCLUSION

More intense noise was measured in work areas with a greater number of machinery, and there was a difference between the intensity of the measured noise and that perceived by the professionals. In the morning, the low temperature preparation and sterilization areas had the highest noise levels, with averages of 92.3 and 91.6 dB, respectively. In the afternoon, the purge and preparation areas had the highest noise levels, 93.0 and 91.5 dB, respectively.

Mere guidance on the importance of using PPE is not enough for conscious adherence. Therefore, other strategies, such as educational campaigns on hearing health, are required to raise awareness of MSC workers.

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ORIGINAL ARTICLE

IMPLEMENTATION AND DAILY USE OF THE SURGICAL SAFETY CHECKLIST IN HOSPITALS

Implementação e uso diário da lista de verificação de segurança cirúrgica em hospitais

Implementación y uso diario de la lista de control de seguridad quirúrgica en hospitales

Maria Fernanda do Prado Tostes¹, Cristina Maria Galvão²

ABSTRACT: Objective: To identify the implementation process and the daily use of the surgical safety checklist, according to the report of nurses who worked in the surgical center of hospitals. **Method:** Descriptive-exploratory study, with a sample of 77 nurses. Data collection took place over six months in 2016, with the application of an instrument prepared and submitted to face and content validation. In the data analysis, descriptive statistics was adopted. **Results:** The realization of an educational program was essential in the process of implementing the surgical safety checklist. The circulator nurse was responsible for checking the instrument daily in the operating room. Most nurses reported partial adherence to the use of the checklist by the surgical team; there was difference in adherence between the checking stages (sign in, time out, and sign out) and between professional categories. **Conclusion:** The knowledge produced offers subsidies for the implementation of the instrument and the use of strategies that can assist in daily clinical practice. **Keywords:** Checklist. World Health Organization. Patient safety. Perioperative nursing.

RESUMO: Objetivo: Identificar o processo de implementação e o uso diário da lista de verificação de segurança cirúrgica, segundo relato de enfermeiros que atuavam no centro cirúrgico de hospitais. **Método:** Estudo descritivo-exploratório, com amostra de 77 enfermeiros. A coleta de dados ocorreu durante seis meses, no ano de 2016, por meio da aplicação de instrumento elaborado e submetido à validação de face e conteúdo. Na análise dos dados, adotou-se a estatística descritiva. **Resultados:** A realização de programa educacional foi essencial no processo de implementação da lista de verificação de segurança cirúrgica. O circulante era o responsável pela checagem diária da ferramenta na sala cirúrgica. A maioria dos enfermeiros relatou adesão parcial no uso do *checklist* pela equipe cirúrgica; houve diferença de adesão entre as etapas de checagem (entrada, pausa e saída) e entre as categorias profissionais. **Conclusão:** O conhecimento produzido oferece subsídios para a implementação da ferramenta e o uso de estratégias que podem auxiliar no cotidiano da prática clínica.

Palavras-chave: Lista de checagem. Organização Mundial da Saúde. Segurança do paciente. Enfermagem perioperatória.

RESUMEN: Objetivo: Identificar el proceso de implementación y uso diario de la lista de verificación de seguridad quirúrgica, según el informe de enfermeras que laboraron en el centro quirúrgico de los hospitales. **Método:** Estudio descriptivo-exploratorio, con una muestra de 77 enfermeros. La recolección de datos se llevó a cabo durante seis meses, en 2016, mediante la aplicación de un instrumento elaborado y sometido a validación facial y de contenido. En el análisis de los datos se adoptó estadística descriptiva. **Resultados:** La realización de un programa educativo fue fundamental en el proceso de implementación de la lista de verificación de seguridad quirúrgica. El circulador se encargaba de revisar la herramienta diariamente en el quirófano. La mayoría de las enfermeras informaron un cumplimiento parcial del uso de la lista de verificación por parte del equipo quirúrgico; hubo una diferencia en la adherencia entre los pasos de verificación (entrada, pausa y salida) y entre categorías profesionales. **Conclusión:** El conocimiento producido ofrece subsidios para la implementación de la herramienta y el uso de estrategias que pueden ayudar en la práctica clínica diaria.

Palabras clave: Lista de verificación. Organización Mundial de la Salud. Seguridad del paciente. Enfermería perioperatoria.

INTRODUCTION

Since 2008, the Surgical Safety Checklist (*Lista de Verificação de Segurança Cirúrgica* - LVSC), developed by the World Health Organization (WHO), has been recommended to improve the safety of surgical patients. After 12 years of creating this instrument, teamwork, communication, and patient safety were aspects that were improved with its use in hospitals.

In the world context, with studies, experiences with the implementation of the LVSC were disseminated, and the results obtained indicated that the instrument was adapted and implemented in a different way among health services, with the need to integrate different strategies to improve surgical safety practices and achieve the benefits of using the checklist in different scenarios.^{3,4}

In hospitals, the implementation of LVSC consists of a complex and challenging process, as it requires surgical teams to change behaviors and learn new habits. ^{5,6} Furthermore, scholars of the problem claim that, many times, the way the instrument was put into practice resulted in incomplete or inconsistent execution. ⁴

In Brazil, the available scientific evidence covered knowledge, perception, and attitudes of the team, adherence and impact of the LVSC.^{7,8} However, the studies developed little explored the process of implementing the checklist.⁶⁻⁹

Furthermore, in a literature review, the authors highlighted that, in developing countries, such as Brazil, there is a shortage of studies regarding all aspects of the use of LVSC that need to be addressed. To continuously defend LVSC as a surgical safety measure applicable to the global population, research in these countries needs to be a priority. Implementation strategies should be investigated in the context of developing countries so that hospitals can evaluate the most appropriate approach to introduce its use in a more compatible way with the local reality, in order to promote the increased use of this instrument and benefit more patients.⁹

Considering the potential of the LVSC to improve the safety of surgical patients and the need to generate evidence that can contribute to the reduction of knowledge gaps, the present study was guided by the following research question: how did the process of implementation and the daily use of the LVSC in studied hospitals?

OBJECTIVE

To identify the implementation process and the daily use of the surgical safety checklist, according to the report of nurses who worked in the surgical center of hospitals.

METHOD

This is a descriptive-exploratory study, carried out in 16 hospitals that implemented the LVSC, in two main cities in Paraná State, of which 11 are in Londrina City and 5, in Maringá City. For the selection of hospitals, the National Registry of Health Establishments (Cadastro Nacional de Estabelecimentos de Saúde - CNES) of the Brazilian Ministry of Health (MS) was consulted.

The target population was nurses working in the surgical center (SC) unit of the selected hospitals, namely: coordinating nurse or assistant nurse. Nurses who did not exclusively worked in the sector were excluded, in addition to professionals who were covering someone's time off, vacation, or any type of leave.

The population was 81 nurses working in the SC, 58 in hospitals in Londrina City and 23, in Maringá City. From the total, after applying the selection criteria, four nurses were excluded: two professionals did not agree to participate in research, one was on a medical leave, and one, on maternity leave. Thus, the sample consisted of 77 nurses, 56 in Londrina and 21 in Maringá.

An instrument developed by the researchers was used for data collection, which was submitted to face and content validity by three nurses (judges), with teaching and/or research activities in perioperative nursing. The instrument included data on the characterization of nurses, the hospital and the SC, and on the implementation and daily use of the LVSC. Data collection took place over six months in 2016.

An electronic spreadsheet was created in Microsoft Excel for data storage, and the double entry technique was adopted. The Statistical Package Social Sciences (SPSS) software version 19.0 was used for data analysis. The variables investigated were described by absolute (No.) and relative (%) frequency, arithmetic mean, and standard deviation.

The study was approved by the Ethics Committee under opinion No. 164/2015, CAAE No. 48347115.9.0000.5393, and the nurses participated by reading and signing the Free and Informed Consent Form.

RESULTS

Of the 77 nurses, most (72; 93.5%) were female; the average age was 34.6 years (standard deviation=9.5); and the length of experience in the SC was 5.6 years (standard

deviation=6.2). The majority (46; 59.7%) of participants worked in a private hospital. The average time for implementing the checklist was 27.8 months. Table 1 presents data on the process of implementing the LVSC in the selected hospitals.

As to the LVSC format, "two or more formats" of the available instrument in the operating room (OR) corresponded to the highest percentage (35; 45.4%), covering the both printed and poster installed on the OR's wall (13; 16.9%), as well as printed and electronic (13; 16.9%), electronic and poster (3; 3.9%), and printed, electronic and poster (6; 7.8%).

For the implementation of the LVSC in hospitals, most participants (65; 84.4%) answered that there was an educational program, offered exclusively to the nursing team.

With regard to the definition of responsibility for conducting the daily LVSC check in the OR, the circulator nurse was the person who received the highest percentage (59; 76.6%) (Table 1). It should be noted that, in the data collection instrument, respondents could indicate one or more options.

Regarding the initiative to implement the LVSC in hospitals, the participants attributed the highest percentages to nurses, namely: 49 (63.6%) to the SC nurse, 48 (62.3%) to the SC coordinating nurse, and 38 (49.4%) to the nursing manager. Of the 77 nurses, 26 (33.8%) attributed the initiative to the anesthesiologist or head of the anesthesia service, 14 (18.2%) to the administrative diretor, and 12 (15.6%) to the surgeon or head of the surgery service. In the data collection instrument, nurses could indicate one or more options (data not shown in tables).

With regard to planning, the participants attributed the highest percentages to nurses, in the following distribution: 55 (71.4%) nurse from the SC, 44 (57.1%) coordinator nurse from the SC, and 33 (42.9%) nursing manager. Next, the anesthesiologist or head of the anesthesia service (25; 32.5%), the surgeon or head of the surgery service (12; 15.6%), the administrative director (6; 7.8%), and others professionals (9; 11.7%). In the data collection instrument, respondents could indicate one or more options (data not shown in tables).

Regarding the daily use of the LVSC by the surgical team, for most nurses (52; 67.5%), the surgical team partially adheres to the use of this instrument. And, for most participants (50; 64.9%), there was an increase in adherence to the use of the checklist by the surgical team as from its introduction in the health service (Table 2).

According to the nurses' opinion (n=44), 31 (70.5%) pointed out that the sign in was the stage to which the surgical team had the greatest adherence, and 16 nurses (36.4%) indicated the sign out as the stage with the least adherence (data not shown in Table 2).

For 64 nurses (83.1%), there was a difference in adherence to the use of the LVSC among the professional categories (Table 2), and the nursing team (48; 75.0%) had greater adherence; for only one participant (1.6%), the anesthesiologist was the category with the highest adherence. Regarding professionals with less adherence to the daily use of the checklist, 35 nurses (54.7%) reported surgeons, and 11 (17.2%), surgeons and anesthetists (data not shown in Table 2).

Most participants reported that the LVSC checking occurs verbally (56; 72.7%). However, only 27 (35.1%) stated that the complete surgical team is present, pays attention, and participates in the checking (Table 2).

Most nurses (57; 74.0%) answered that all items of the LVSC were checked in the OR, but 19 (24.7%) indicated the existence of items that were not checked (Table 2).

Regarding the items whose checking was neglected (n=19), four participants (21.0%) pointed out the items

Table 1. Characterization of the surgical safety checklist implementation process in hospitals, according to the nurses' report.

Variables	Nurses			
Variables	n=77	Percentage (%)		
Time of implementation (months)	27.8 (21.4)*	-		
Format of the LVSC				
Printed	34	44.2		
Electronic	06	7.8		
Board fixed in the operating room	02	2.6		
Two or more formats	35	45.5		
Educational program for the surgical team				
Yes	65	84.4		
No	12	15.6		
Responsible for the checking				
Surgeon	3	3.9		
Coordinator nurse	18	23.4		
Anesthetist	11	14.3		
Nurse of the surgical center	43	55.8		
Circulator nurse	59	76.6		
Others	15	19.5		

*Mean (SD=standard deviation); LVSC: surgical safety checklist.

belonging to sign in, among which: laterality marking (n=1), investigation on the use of medicines and previous surgeries (n=2), and difficult access to patients' airway (n=1). For five participants (26.3%), the items belonged to time out, namely: estimated length of surgery (n=1), anticipation of additional risk (n=1), all items belonging to time out (n=2), and issues/concerns with equipment (n=1). Five nurses (26.3%) also reported that the items belonged to sign out: all indicated the surgical count, and one (5.3%) highlighted the items that were duplicated in the LVSC or that did not apply to a particular surgery. Two participants (10.5%) pointed out the items related to two stages of the LVSC, namely: prediction of blood loss (sign in) and surgical count (sign out) (n=1), and questions related to equipment (time out) and surgical count (sign out) (n=1); two nurses (10.5%) did not inform the data.

Table 2. Characterization of adherence to daily use of the surgical safety checklist in hospitals, according to the nurses 'report.

Variables	Nurses			
Variables	n=77	Percentage (%)		
Adhesion of the surgical team to the use of the LVSC				
Total	21	27.3		
Partial	52	67.5		
No	04	5.2		
Increase in adherence since the	e implementat	tion of the LVSC		
Yes	50	64.9		
No	26	33.8		
Did not answer	01	1.3		
Difference in adherence between checking steps				
Yes	44	57.1		
No	33	42.9		
Difference in adherence to the LVSC among professionals				
Yes	64	83.1		
No	11	14.3		
Did not answer	02	2.6		
Verbal checking of the LVSC by the team				
Yes	56	72.7		
No	19	24.7		
Did not answer	02	2.6		
Complete surgical team present, paying attention and participating in the checking				
Yes	27	35.1		
No	50	64.9		
Existence of items of the LVSC that are not checked				
Yes	19	24.7		
No	57	74.0		
Did not answer	01	1.3		

LVSC: surgical safety checklist

DISCUSSION

In the present study, the results indicated the predominance of two LVSC formats available for use in the OR, the realization of an educational program for the nursing team, and the circulator nurse as the responsible for checking the instrument in the OR. Also in higher percentages, the results indicated that nurses were responsible for the initiative and planning of the LVSC implementation process. These results were corroborated with research data on how the LVSC implementation process took place in hospitals in Canada. ¹⁰

For the effective implementation of the LVSC, the process should be conducted by a multidisciplinary team. The recommendation is including representatives of each function (surgeon, anesthetist, nurse, circulator nurse, and instrumentalist) and people with the following characteristics: respected by peers, enthusiastic, committed and interested in initiatives to improve patient safety and who believe that communication and teamwork can be optimized. For recruitment purposes, surgeons and anesthetists, in particular, must have availability, exercise good influence, and have a positive image with their peers.⁵

In a similar investigation, the use of the printed format of the LVSC (73%) prevailed over the others.⁸ However, there is no evidence on which type of list format best supports the team's performance in checking.^{3,5}

Most nurses indicated that they carry out an educational program, only with the participation of the nursing team, prior to the introduction of the LVSC in the OR, with content centered on explanations of why and how to use the instrument. In addition, 12 nurses indicated that this strategy was not offered. In the literature, education, involving all professional categories, is agreed to be an essential and facilitating element in the implementation of the LVSC. 3,5,11 Given the diversity of educational strategies used, the involvement of only a few professional categories 3,11 or the absence of an educational process, education as a facilitator can become a barrier. 12

To better subsidize this fundamental and irreplaceable element, education is recommended as a more comprehensive process under the triad:

informal conversation with each member of the surgical team: the dialogue aims to connect each professional with the idea and purpose of the LVSC and, directly, request collaboration for using the instrument before the actual introduction into the OR;

- train each member of the surgical team before its actual use: the approach includes an explanation of how to do, demonstrate and give the surgical team an opportunity to practice checking exhaustively. For the feasibility of this step, team members can be trained individually, in groups, or all together;⁵
- continuous training and on-site guidance, for the introduction of the LVSC in the OR: team members need to be supported and oriented to improve performance in daily use.^{5,11}

With regard to the responsible for conducting the daily LVSC checking in the OR, the highest percentages indicated by participants were the circulator nurse in the room, followed by the SC nurse. In other studies, the results showed that the circulator nurse coordinated the LVSC⁸ checking process or that the responsibility for the checking the instrument was shared among the different professional categories. ^{12,13}

Based on the analysis of available evidence, a guide for more assertive implementation and sustainability of the LVSC was developed. In general, the following steps are necessary: the composition of a multidisciplinary team to plan and execute the implementation, with definition of roles, expectations, and processes; an implementation team who must know the historical aspects and objectives related to the checklist; the assessment of the work environment with on-the-spot observation of the teams' performance and the group's dynamics in the context of the OR and culture assessment; decision-making to introduce the LVSC, that is, deciding whether the time is right to introduce the instrument based on the preliminary assessments mentioned; the adaptation and testing of the LVSC, consideration of one of the key tasks of the implementation team, prior to the use of the instrument; the planning, which includes defining what the implementation team will do, how and when, to disseminate the use of the instrument with a list of tasks related to each action and preparation of a schedule. In this phase, individual conversations should be held, the use of the isntrument should be promoted, as well as education/training for the team and training, on-site supervision.5

Private conversations are considered the first stage of learning for the surgical team. It should be noted that there is no substitution for this conversation with each team member. At this point in the conversation, promoting the LVSC with creative strategies, conveying messages about it, presenting the efforts undertaken and the progress achieved so

far is recommended. The second stage of learning consists of training and disseminating the instrument, with the objective of explaining it and demonstrating how it should be used, and giving the team the opportunity to practice. Monitoring, feedback, support, and continued on-site training are considered the third part of the learning process for an effective use of the LVSC and sustainability over time. This step is performed by a coach, a team member recruited and previously trained for this function, with a view to improving the team's daily performance. Promoting continuous improvement with periodic reviews can help in the proper use of the checklist and assist teams in adapting to new conditions.5

In the present study, in relation to the daily use of the LVSC, the results showed that most nurses responded that the surgical team partially adheres to its use. Adherence is different between the checking stages, with greater adherence at the sign in and lesser at sign out. Among the professional categories, there was greater adherence by the nursing team and lesser by surgeons, and also the existence of LVSC items that are not checked; time out and sign out items were the most neglected.

In a national study, the authors analyzed 375 medical records of surgical patients. The results showed adherence of 60% to the use of the LVSC, but only in 4% the form was completely filled in.⁸ In places in which the rates of adherence to the LVSC are high, the quality of filling and the reliability of the instrument's objectives are often compromised.¹¹

In the present study, most nurses responded that there was an increase in adherence since the beginning of the implementation of the LVSC in the health services surveyed. However, for 33.8% of the participants, there was no increase in adherence by the surgical team. Other studies have shown similar results, because the use of the checklist has not been sustained over time. ^{13,14}

As to the difference in adherence between the stages of the LVSC, data in the present study were similar to those identified in a national survey conducted in three hospitals in the Federal District. Adherence to the sign out stage was lower than the first two stages, mainly in relation to the item regarding problems with equipment and surgical counting. In cases in which surgical counting was performed, the procedure occurred after the patient left the OR.⁸

A possible explanation for low adherence to the last stage of the LVSC may be the departure of members of the OR surgical team before the end of the procedure.¹⁵

When an LVSC stage is omitted, without damage to the patient, the improper use is easily incorporated by the team;

in these circumstances, this instrument can be considered a weak security barrier. 16

In the literature, there is evidence to prove the different resistance in the use of the LVSC among the professional categories: supporting the instrument use tends to be greater by nurses and anesthesiologists than by surgeons.^{3,4} Generally, nurses are more used to the use of checklists as a structured component of clinical care, which can favor adherence by this category.¹⁷ In contrast, doctors believe that the formal use of the LVSC is redundant, because they already promulgate safety principles in clinical practice. Therefore, the sustained use of the LVSC can be discipline-specific and successful when doctors are actively engaged in the process.⁴

In this study, most nurses answered that, in the daily checking of the LVSC, the complete surgical team is not present, does not pay attention, and there is no active participation of team members. In view of these inadequacies, the use of the LVSC may have been understood as a mere exercise in pointing out items in these places, and not as a practice that favors the prevention of adverse events, improved communication and teamwork, that is, contradictory understanding to what is advocated by the WHO.

In a study carried out in five hospitals in England with a focus on observing the execution of the LVSC in ORs, the results were similar. In 40% of cases, team members were absent during their time out and sign out, and were unable to interrupt other activities in approximately 70% of cases. The most adequate performance occurred when surgeons conducted the checking: all members were present and interrupted other activities to comply with the items of the LVSC.¹⁵

In the health service, the fact that the LVSC is not performed reliably to the WHO recommendation should not be viewed with dismay, as it reveals the possibility for improving the implementation process. ¹⁸ In general, the implementation of behavioral interventions designed to qualify clinical practice is permeated with nuances of success or failure, given that the experience is rarely successful or unsuccessful in its entirety. The implementation of the LVSC may promote the qualification of the work process and teamwork in some contexts, but it fails or has limited success in others. Considering such premises in the implementation of this instrument is essential to list approaches that are more compatible with the institutions' realities.⁴

Checking the LVSC should not be limited to confirming the patient's identity, the operation and the surgical

site, the necessary instruments, fluids, blood products, and available equipment. It must also include the presentation of all team members, and the surgeon must inform about the critical stages of the surgery and resolve any concerns voiced by the anesthesia and nursing teams. ¹⁹ The lack of active participation by team members violates the guiding principles of the LVSC, since dialogue can improve surgical care and positively change the way members of the surgical team interact with each other and with patients. Therefore, these items should not be removed or neglected. ⁵

In a North American study, conducted in 2018, the authors described the experience of hospitals in implementing the LVSC from 2010 to 2017. From this process, three lessons were presented for hospital policy makers at the local, state, or national level:

- successful program must be planned to involve all stakeholders (doctors, nurses, nursing technicians, instrumentalists, among others);
- a variety of strategies must be offered (educational process that includes face-to-face meetings, online seminars, face-to-face training, and follow-up visits);
- implementation process that proposes changes in the conventional process will need time and resources.²⁰

In the context of safe surgery, participative nursing leadership, with communication between the team and the patient, with family members and with hospital managers, will contribute to promoting patient-centered care, in a continuous and safe way.²¹

Regarding the limitations, caution is recommended in generalizing the results listed, because the study was conducted in two municipalities in Paraná State. Data analysis was based on information reported by nurses working in the SC. Thus, relevant aspects of the LVSC implementation process may have been reported differently according to reality. For example, the reporting of data on adherence and other aspects of the LVSC use may have been more positive than, in fact, it occurs in practice, when the context is observed directly.

CONCLUSION

Regarding the main study conclusions, the LVSC was available in two formats for use in the OR; the educational program was a relevant strategy carried out, but offered predominantly to the nursing team, and checking the instrument, in most cases, involved only the circulator nurse. Nurses were primarily responsible for the initiative and for planning the implementation process of the checklist in question.

According to most nurses' opinion, adherence to the use of the instrument is partial, with differences between the checking steps, being higher at sign in and lower at sign out. Adherence to daily use of the LVSC is higher by the nursing team and lower by surgeons. And, among the checking stages, items of the time out and sign out were the most neglected.

As to the implications for perioperative nursing, the evidence generated offers subsidies for the knowledge of how the implementation of the LVSC occurred, its daily use and which strategies were adopted in this process in the Brazilian context. Therefore, such evidence contributes to reduce knowledge gaps and promote scientific advancement in this Nursing area. In addition, the knowledge produced helps to implement the instrument in services that do not yet use this practice, as well as to review those who have already adopted it in their daily activities. Therefore, the evidence generated leads to an increase in the quality of care provided and permanent promotion of surgical patient safety.

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ORIGINAL ARTICLE

PERCEPTION OF THE MULTIDISCIPLINARY TEAM CONCERNING HUMANIZED ASSISTANCE AT THE SURGICAL CENTER

Percepção da equipe multidisciplinar acerca da assistência humanizada no centro cirúrgico

Percepción del equipo multidisciplinar sobre la asistencia humanizada en el centro quirúrgico

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ABSTRACT: Objective: To understand the perceptions of professionals of the multidisciplinary team concerning humanization in the surgical center. Method: This is a qualitative study, with descriptive purposes, whose data collection took place in a regional public hospital of medium complexity, in Brasília, Federal District, from August to October 2019, with 18 professionals in the medical and nursing areas. An open and individual interview was conducted, composed of five guiding questions, analyzed through Bardin's content analysis. Results: The answers to each of the questions were categorized, considering that humanized assistance was perceived as the search for the patients' well-being, maintaining a relationship of empathy for others, and focusing on holistic care. Conclusion: Humanization involves aspects inherent in the condition of being human and, for its effectiveness, the involvement of the entire multidisciplinary team in patient care is necessary.

Keywords: Humanization of assistance. Surgicenters. Delivery of health care. Patient care team. Interdisciplinary communication.

RESUMO: Objetivo: Compreender as percepções dos profissionais da equipe multidisciplinar acerca da humanização no centro cirúrgico. Método: Estudo de abordagem qualitativa, com fins descritivos, cuja coleta de dados ocorreu em um hospital público regional de média complexidade, de Brasília, Distrito Federal, no período de agosto a outubro de 2019, com 18 profissionais das áreas médica e de enfermagem. Realizou-se entrevista aberta e de caráter individual composta de cinco perguntas norteadoras, examinadas por meio da análise de conteúdo de Bardin. Resultados: As respostas a cada uma das questões foram categorizadas, considerando-se que a assistência humanizada foi percebida como a busca pelo bem-estar dos pacientes, mantendo relação de empatia pelo próximo com enfoque no atendimento holístico. Conclusão: A humanização envolve aspectos inerentes à condição de ser humano, e, para sua efetivação, é necessário o envolvimento de toda a equipe multidisciplinar nos cuidados com os pacientes.

Palavras-chave: Humanização da assistência. Centros cirúrgicos. Assistência à saúde. Equipe de assistência ao paciente. Comunicação interdisciplinar.

RESUMEN: Objetivo: Comprender las percepciones de los profesionales del equipo multidisciplinar sobre la humanización en el quirófano. Método: Estudio de abordaje cualitativo, con fines descriptivos, cuya recolección de datos se realizó en un hospital público regional de mediana complejidad, en Brasilia, Distrito Federal, de agosto a octubre de 2019, con 18 profesionales de las áreas médica y de enfermería. Se implementó una entrevista abierta e individual, compuesta por cinco preguntas orientadoras, analizadas a través del análisis de contenido de Bardin. Resultados: Se categorizaron las respuestas a cada una de las preguntas, considerando que el cuidado humanizado se percibía como la búsqueda del bienestar de los pacientes, manteniendo una relación de empatía por los demás con un enfoque de cuidado integral. Conclusión: Se pudo entender que la humanización involucra aspectos inherentes a la condición del ser humano y que, para su efectividad, es necesario involucrar a todo el equipo multidisciplinario en el cuidado de los pacientes. Palabras clave: Humanización de la atención. Centros quirúrgicos. Prestación de atención de salud. Grupo de atención al paciente. Comunicación interdisciplinaria.

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INTRODUCTION

Humanization represents conducts aimed at suppressing the instincts and acting according to rationality and, therefore, being in conformity with moral values and benevolence toward others. In order to consolidate these measures within the scope of the qualification of healthcare services, in 2003, the National Humanization Policy (*Política Nacional de Humanização* – PNH) was formulated, which stipulates strategies that integrate good management and assistance, aiming at implementing the principles of the Brazilian Unified Health System (SUS) that promote humanization in the healthcare practice^{1,2}.

Humanization of assistance can be differently interpreted due to its subjective and individual configuration. From a legal point of view, it can be perceived as an inherent right to anyone. Technological advances are very important for providing care to patients assisted in the surgical center (SC); however, they can be complicating factors in the humanization process. Such circumstances are due to the increasing mechanization of assistance, which makes the need for humanizing the relationships between professionals and patients essential, but such situation is not auspicious for its effectiveness^{3,4}.

The SC corresponds to the hospital department aimed at performing anesthetic-surgical procedures and at post-anesthetic recovery. This place represents an intensified care environment that requires assistance from the multidisciplinary team focused on the specific needs of each patient. Hence, the activities undertaken in this place should be entrusted with systematic and thorough assistance, based on institutional standards, in order to condition the safety and well-being of patients and healthcare professionals^{5,6}.

The assignments focused on assistance in the SC need greater commitment from the professionals who work there, which is related to the patients' vulnerability, who are already languid, thus requiring humanized assistance based on communication and receptivity on the part of the team. Nevertheless, this situation becomes complex when observing that, under this scenario, the team feels overwhelmed by the excessive work demand on their activities, which generates greater tension and accountability^{7,8}.

Teamwork in healthcare services should provide the patients with better quality of care, aiming at their recovery and reintegration as soon as possible in their family and social environment. These exchanges of multiprofessional experiences, combined with effective communication and humanization of assistance, although presenting many challenges to be faced, ensure the patients an effective and quality treatment, allowing the rehabilitation of their health.

It is paramount to improve the knowledge of the surgical team on the humanization matter. A greater focus on this issue in undergraduate programs and institutions that provide healthcare services is of great relevance. Lectures, meetings, and congresses, combined with a greater commitment on the part of academics, professors, and healthcare professionals on the humanization process, would improve the quality of the care provided to patients, thus facilitating the understanding of their singularities, desires and feelings, that is, perceiving the patient as a "bio-psycho-socio-spiritual" being who needs attention, care, and affection ^{10,11}.

Taking this into consideration, the interest in understanding what is the perception of the multidisciplinary team of the SC regarding the provision of humanized assistance has aroused. This research may lead to a better understanding and reflection on humanization processes in the provision of care to surgical patients on the part of healthcare professionals of the team working in this sector, in addition to the possibility of adding future research as databases.

OBJECTIVE

To understand the perceptions of professionals of the multidisciplinary team, by their knowledge and practical experiences, regarding the implementation of humanization in the SC environment.

METHOD

This is a qualitative study, with descriptive purposes. Data collection took place in the SC of a regional public hospital of medium complexity, located in the Western health region, Ceilândia, in Brasília, Federal District – Brazil, from August to October 2019.

Data collection consisted in an individual interview, composed of five open and guiding questions:

- what does humanization mean to you?;
- in your opinion, what strategies can be used to humanize care at the SC?;
- in your opinion, what is the main difficulty in humanizing care at the SC?;
- how can your profession contribute to humanize care at the SC?;
- in your opinion, how should the multiprofessional team be hold accountable for humanized assistance?

A total of 18 professionals were interviewed, namely: five nurses, five nurse technicians, five surgeons, and three anesthesiologists. In the category of anesthesiologists, five professionals should participate in the interview; however, due to the unavailability of some of them at the time of the interview, only three participated in the research.

The inclusion criteria were: professionals belonging to the multidisciplinary team of the SC and who were present at the time of the interview.

The exclusion criteria were: professionals belonging to the multidisciplinary team of the SC who refused to participate in the research or who were working at the time of the interview.

Data processing was conducted by content analysis as proposed by Bardin. According to the author, this method employs a set of techniques that analyze the communication of subjects based on objective and systematic processes of description of the content of the messages. Thus, it provides an accurate observation about the messages and the understanding of the interviewees' behaviors, providing a better understanding of their perceptions^{12,13}.

The interviews were recorded and transcribed, followed by an extensive reading of the material, highlighting the main words and key ideas, which were categorically analyzed and structured.

The speeches were protected by the use of acronyms and numbers that indicate the category of the interviewees, aiming to preserve their anonymity. For the category of nurses, the acronym "NUR" was used; for nurse technicians, "NUR TEC"; for, surgeons, "SURG"; and for anesthesiologists, "ANEST," followed by the number corresponding to the order in which the interviews were conducted.

The research complies with the ethical-legal criteria established by Resolution No. 466 of 2012, of the National Health Council. The project was approved by the Research Ethics Committee of Instituto de Educação Superior de Brasília (CEP/IESB), under Certificate of Presentation for Ethical Consideration (CAAE) no.15040119.7.0000.8927, and by the Research Ethics Committee of Fundação de Ensino e Pesquisa em Ciências da Saúde (CEP/FEPECS), under CAAE no. 15040119.7.3001.5553.

Formalization of acceptance to participate in the research took place by signing the informed consent form, providing information on the research, and by signing the Authorization for Use of Image and Voice for Research Purposes.

RESULTS

The 18 interviewees who composed the sample of this study considered several points and perceptions about humanized assistance in the SC, as shown in the categorization of the five questions addressed in this research.

Question 1: Perception of the multidisciplinary team concerning the humanization concept

Categories: Well-being. Empathy. Holistic care.

When asked about what it would be like to humanize, the interviewees mentioned that it is offering well-being to patients, seeking to assist them in a dignified manner, making them feel welcomed and respected in order to provide a quality care: "Humanization is making the patients feel good, treating them as humanly as possible. Patients will feel better, safer" (NUR TEC 01); "For one, it is treating the patients well, seeking to know what they are feeling" (NUR TEC 05); "Humanization means humanizing the patients [...], providing them with the best quality" (NUR 04).

The interviewees also highlighted the importance of maintaining an empathic relationship for others, considering the anguish of the other and seeking to resolve doubts about what will be done: "For you to be humanized, you must put yourself in somebody's shoes" (NUR TEC 02); "Humanization is treating the patient as a member of my own family" (SURG 02); "It's putting yourself in somebody's place, and doing your best when explaining

everything to the other person, all the procedures that will be performed, in the best possible way" (NUR 02).

They also highlighted the provision of care with a holistic focus as very relevant, covering the integrality of patients treated at the SC: "Humanization means treating patients in an integral way, not only because of their illness" (SURG 03); "It means having this view of the patient as a whole, not only seeing them with the disease that needs to be operated" (NUR 01); "It is when we care for the patient, aiming not only to solve that health problem, but seeing them as a whole" (NUR 03); "Humanization within the surgical center is understanding the patients as a whole, including their fears" (ANEST 03).

Question 2. Strategies that can be adopted to humanize the assistance at the SC

Categories: Teamwork. Effective communication. As for this question, interviewees highlighted the need for teamwork as a strategy, in which everyone is important for fulfilling the humanization processes: "The strategies involve from the administration to the cleaning staff. Strategies concerning the conducts toward the patient" (NUR TEC 03); "I think that, if it is a multidisciplinary team, it should work together" (NUR 03).

They also pointed out that effective communication favors the provision of humanized assistance: "Communication between the teams [...] I think that's basically it. To establish a good relationship between the teams" (ANEST 02);

Team integration, as we often have isolated information [...]. The surgeon gives an information to the patient that is different from the anesthesiologist's, from the nursing staff's, precisely because we did not talk before, we did not discuss the case. So, a strategy would be the prior discussion of each individual case. I think these would be interesting strategies to make the assistance more humane for the patient (ANEST 03).

Question 3. Main difficulties in humanizing the assistance at the SC

Categories: Overabundance of patients. Few employees. Many assignments.

The participants of this study mentioned the overabundance of patients, few employees, and many assignments as hindrances for the provision of humanized care: "This is

the greatest difficulty, because they stay for a short time and the assistance is limited. [...] There's lack of time [...] and we have few nurses. On duty hours, there's one nurse [...]. It is a lot of work for one person, and this also makes it very difficult" (NUR 01); "I believe it's the amount [of work], right? [...] many patients [...], little time, and the small number of employees so that you can provide the necessary care each patient deserves" (ANEST 01); "There's so many patients [...]. When there are many patients, we have a lot of work" (NUR TEC 01).

Question 4. Professional contribution to humanize assistance at the SC

Categories: Promoting guidance. Providing comfort.

When asked about the contribution of their profession to the humanization of assistance, the interviewees mentioned the promotion of guidance and provision of comfort to patients and their companions: "When patients have any doubts about the procedure, because they come here and they don't know what surgery they're going to do, what they'll undergo [...] [it is about] talking to the patients and ensure safety. I think it's up to paying attention" (NUR TEC 04); "Talking to the patient, right? [...] To perceive what are their anxieties, their anguish. I think this is our primary role" (SURG 01);

To better welcome the patients, comforting them, not just calming them down, right? Because they come [to the hospital] in fear of the environment, which they don't know well, they are already afraid of the surgical procedure, of everything. We must inform them what will be done in the best possible way (SURG 02).

Question 5. Accountability of humanized assistance for the multidisciplinary team

Categories: Individual task. Collective task. Management task.

Regarding this approach, the interviewees gave verbose replies: some said it was a collective task; others, and individual one; and they also mentioned that it is necessary for the management to request from the team to implement humanized practices: "Each one occupying their role can already be hold accountable" (NUR TEC 02);

I think it has to be a joint responsibility. I think everyone is a healthcare professional, everyone aims at something good; in my opinion, a unique good, not their own good, right? Everyone wants the patient to leave the hospital in the best possible way (SURG 03).

"I think that the head, the head of the team, both the nursing and the medical management, should have a service protocol" (NUR 03); "Responsibility must be delegated by the heads of teams and services in general, delegated and instituted by the higher ranks of the service" (ANEST 02).

DISCUSSION

Humanization has a great influence on the health-disease process and transcends the technical assistance provided to the patient. Humanizing means loving what you do, based on ethical and moral principles, prioritizing the human life, always seeking the well-being of those who need attention and assistance⁷. Accordingly, the interviewees of this research listed some points, such as the patients' well-being and empathy for others, in addition to providing care with a holistic approach, describing the characteristics that involve the complex act of providing humanistic care.

Undoubtedly, there is consensus among the speeches of members of the multidisciplinary team of the SC, participants of this study, on the fact that providing humanized assistance, among other perceptions, means providing comfort to the patient. In this regard, a study mentions that the humanistic relationship between the professional and the surgical patient is of vital importance for a good perioperative experience⁷. Another study describes that the dialogue and interaction between professionals and patients are paramount, making the horizontalization of human interactions feasible, giving dignity to subjects and the understanding of their feelings¹⁴.

Furthermore, by reconciling what has been previously mentioned about the provision of holistic care, which covers the integrality of the patients' physical, psychological, social, and spiritual foundations, it is possible to guarantee quality in the practical implementation of their right to health. Corroborating this perspective, a research contextualizes the importance of the universalization of health care, in such a way to provide care meeting all the patients'

demands, and that a separation of these elements can negatively interfere in the structuring of an effective therapeutic relationship¹⁵. Therefore, when treating patients with efficiency and affection, giving them attention, aiming at their well-being, it is possible to gain their trust and facilitate the provision of care, as patients feel welcomed and safe with the team assisting them. This humanized assistance is more than just being physically close to the patient. To do so, it is also necessary to be empathetic, seeking greater reflection on the wishes and needs of the others, making a self-reflection about your own pain, and understanding that all people are similar at physical, mental, and spiritual levels¹⁶.

The participants highlighted that the multidisciplinary work favors the provision of humanized assistance, considering that the interaction of knowledge of the most diverse health areas provides better therapeutic planning for those seeking care. And, for an effective and qualified combination of knowledge to occur, it is essential to have effective communication. Accordingly, a scientific study mentions that, through efficient dialogue, it is possible to have debates and improve ideas, to discuss opinions and to exchange information aiming at structuring a common objective, which is the provision of humanized assistance.

Other studies state that, in order to provide quality care and satisfactorily respond to the patients' needs, collective action, in addition to objective and clear communication, is paramount. Through teamwork, organization and division of tasks, performance of ordered actions, and by sharing opinions and ideas, it is possible to provide integrality and continuity of patient care, comprising the entire biopsychosocial context. Moreover, lapses in the relationship between interdisciplinary communication and teamwork can lead to irreversible health complications for the patients and, consequently, to the reduction of the efficiency of the provided care^{17,18}.

Therefore, the quality of humanized assistance at the SC, among other factors, depends on assertive communication and on good interpersonal relationships of professionals working in this sector. The importance of the exchange of knowledge between care teams is clear, considering that all are of great importance for providing care in the best possible way, aiming at quality and efficiency¹⁶.

Based on the question concerning difficulties encountered by professionals in providing humanized assistance at the SC, it was noteworthy to observe what the care teams perceive as difficulties in the sector that affect the effectiveness of humanized practices. All teams consistently

mentioned as difficulties the conjuncture that denotes the SC as an environment with a high flow of patients in transitory demand, in addition to the high demand for assignments to be performed and the small and disproportionate number of employees.

In line with the aforementioned notes, some authors consider that the lack of time of professionals working in the SC is a hindrance to the implementation of humanized assistance to patients. This problem may be due to the excess of performed procedures, with a short interval between them, the low number of employees, and the exorbitance of bureaucratic practices that take a long time from the work shift of the team, especially the nurse team, reducing and even preventing the direct affability toward each patient¹⁹.

Moreover, consolidating the relevance of the findings of this research about the difficulties to humanize, the same aforementioned authors point out that the disproportionate number of professionals, in comparison to the abundance of patients, makes the implementation of humanization unfeasible, resulting in the depersonalization of human relationships between the multidisciplinary team and the surgical patient, deteriorating the efficiency of the provided care¹⁹.

Within a thorough and comparative analysis of the speeches presented by the professional categories, a disparity of conceptions was perceived in relation to the task of the multidisciplinary team, considering that all teams deemed themselves as the main responsible for the fulfillment of humanized practices, thus disengaging themselves from the main characteristic of the correct performance of multidisciplinary practices, which is teamwork. Nevertheless, all teams showed consensus when stating that their profession can contribute by promoting guidance and comfort to patients and their companions, keeping them aware of all the processes inherent in the procedure in question.

In parallel with the aforementioned statements, research findings point out that guidance is seen as a fundamental part of the humanization process to support the patients and make them comfortable and confident in relation to the procedures that will be performed, and such is a constituent part of the assignments of each professional class. To do so, it is essential to establish a clear communication process in the professional-patient relationship, taking into consideration that establishing a good communication indicates the feeling patients will evoke during the experience¹¹.

As for how the multidisciplinary team should be hold accountable for humanized assistance, most professionals showed prolixity in the matter, a fact that constituted a series of repetitive conceptions about it. Some refer to accountability as a collective task and others, as an individual one, inherent in each professional. However, there was an interdisciplinary consonance related to self-imposition and demand regarding the implementation of humanized practices, which, according to some professionals, is a task to be performed by team managers.

All in all, it is evident that one of the primary processes of the SC flow is flawed, which is teamwork. A research shows that the basis of interpersonal development is communication, with which it is possible to influence attitudes, both positive and negative, in addition to constituting multiprofessional skills. Thus, by establishing an effective communication between the teams, it will be possible to compose a work dynamic favorable to the provision of humanized and quality care²⁰.

CONCLUSION

For the multidisciplinary team, humanized assistance involves aspects inherent in the condition of being human, such as providing well-being to others, being empathetic in relation to their anguish, and hospitable when dealing with their needs, understanding the individual as unique and irreplaceable. Some respondents understood that humanization requires teamwork, in addition to effective communication. Consonance and mutual cooperation are essential, considering that humanitarian care must be provided by everyone rather than just some of the professionals.

Other statements related work overload, insufficient professionals, lack of time, and overabundance of patients to complications that harm humanized care. It is worth mentioning that adequate conditions in the work environment are of great relevance to the quality of care. However, would it really be essential to adapt the statements previously mentioned to humanize the assistance at the SC? Should humanization not be an intrinsic premise of human beings?

It is evident that issues concerning the humanization terminology are wide and that, in this study alone, it is complex to detail and expose all the fields involved in this approach. Therefore, seeking a theoretical-practical deepening concerning what is expressed in this research can pave the way to new views, new questions, and new perspectives.

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NURSING CHALLENGES IN A TRANSPLANT UNIT IN THE FACE OF COVID-19

Desafios da enfermagem em uma unidade de transplantes ante a Covid-19

Retos de la enfermería en una unidad de trasplante frente a Covid-19

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ABSTRACT: Objective: To understand how nurses who work in a transplant unit perceive the challenges of their role in the face of COVID-19. **Method:** This is an exploratory, descriptive, qualitative study conducted through interviews in the transplant unit of a reference hospital in Ceará, Northeastern Brazil, between March and June 2020. Data were analyzed in the software Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires (IRAMUTEQ). Subsequently, we performed a correspondence factor analysis (CFA) and generated a word cloud, taking into account the evocations with higher frequency. **Results:** Fourteen nurses participated in the study, most of them women. The content analyzed was categorized into three classes: organization of the care flow for suspected cases, personal protection equipment in the COVID-19 pandemic context, emotional state in the face of the pandemic. **Conclusion:** We found that nurses are suffering due to fragilities related to the moment they are experiencing, as they are daily challenged to adapt to changes in their work routines. **Keywords:** Nursing. Coronavirus. Transplantation.

RESUMO: Objetivo: Conhecer a percepção dos enfermeiros que atuam em uma unidade de transplantes sobre os desafios de sua atuação ante a COVID-19. **Método:** Estudo descritivo e exploratório, com abordagem qualitativa, desenvolvido em uma unidade de transplantes de um hospital referência do Ceará, entre março e junho de 2020, por meio de entrevista. Os dados foram analisados pelo *software* Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires (IRAMUTEQ). Posteriormente, foi realizada a análise fatorial por correspondência (AFC) e gerada uma nuvem de palavras para a qual foram consideradas as evocações que apareceram com maior frequência. **Resultados:** Participaram do estudo 14 enfermeiros, a maioria do sexo feminino. O conteúdo analisado foi categorizado em três classes: organização do fluxo de atendimento de casos suspeitos, equipamento de proteção individual no contexto da pandemia da COVID-19, o emocional ante a pandemia. **Conclusão:** Constatou-se que os enfermeiros sofrem ante as fragilidades relacionadas ao momento vivenciado, pois estão sendo cotidianamente desafiados a se adaptarem às mudanças em suas rotinas de trabalho. **Palavras-chave:** Enfermagem. Coronavírus. Transplante.

RESUMEN: Objetivo: Conocer la percepción de los enfermeros que laboran en una unidad de trasplante sobre los desafíos de su desempeño ante el COVID-19. **Método:** Estudio descriptivo y exploratorio, con abordaje cualitativo, desarrollado en una unidad de trasplante de un hospital de referencia en Ceará, entre marzo y junio de 2020, mediante entrevista. Los datos fueron analizados por el *software* IRAMUTEQ (*Interface de R pour les Analyses Multimensionnelles de Textes et de Questionnaires*). Posteriormente, se realizó el Análisis Factorial por Correspondencia (AFC) y se generó un *Word Cloud* para el que se consideraron las evocaciones que aparecían con mayor frecuencia. **Resultados:** participaron del estudio 14 enfermeras, la mayoría mujeres. El contenido analizado se categorizó en tres clases: Organización del Flujo de Servicios de Casos Sospechosos, Equipo de Protección Personal en el Contexto de la Pandemia de COVID-19, La Emocional Frente a la Pandemia. **Conclusión:** Se encontró que los enfermeros padecen las debilidades relacionadas con el momento vivido, ya que diariamente se enfrentan al desafío de adaptarse a los cambios en sus rutinas laborales. **Palablas clave:** Enfermería. Coronavirus. Trasplante.

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INTRODUCTION

Currently, the coronavirus disease 2019 (COVID-19) is an infection with predominantly respiratory symptomatic characteristics firstly identified in Wuhan, China, in December 2019. This pathology is highly contagious. Despite the efforts to contain its transmission, the then epidemic spread to several other countries, and, on March 11, 2020, the World Health Organization (WHO) declared it a pandemic, when 118 thousand cases had been diagnosed in 114 countries¹.

Brazil was the first country to report a COVID-19 case in Latin America. From then until June 20, 1,067,579 cases were confirmed, and the disease caused 49,976 deaths. At present, Brazil is one of the countries with the highest incidence of COVID-19².

The pandemic has become a great challenge for health services due to the number of infected people and the demand for resources needed to face it, considering the diversity of materials and professionals involved. Among these professionals, nurses are at the front line of the care provided in different health scenarios³.

In this context, nurses represent the largest workforce for health systems and are crucial in the fight against COVID-19, given that these professionals plan, manage, evaluate, and provide care at all complexity levels^{3,4}. This fact shows that nurses are the professionals who spend more time in direct patient care.

With respect to the nurse's performance at all complexity levels and in several fields of activity, we highlight that these professionals provide specialized care for transplant patients as to the protection, promotion, and rehabilitation of the health of candidates, recipients, and their families⁵.

Nursing has been challenged to adapt and become more flexible in the face of these changes, having to develop new strategies to minimize the impacts caused by the pandemic on the care of transplant patients, who belong to a group at high risk for infection by the novel coronavirus (SARS-CoV-2), given their chronic immunosuppression and associated comorbidities. Thus, the facilities that serve this population needed to reorganize their care practices and try to mitigate the risk of infection among transplant patients⁶.

From this perspective, the present study is relevant, given the increasing number of individuals infected by COVID-19 and the limited knowledge regarding the perceived nursing care provided to transplant patients in the current pandemic context, considering that nursing professionals have the most direct contact with patients. Therefore, the investigation will provide support for transplant nursing care in the COVID-19 context.

OBJECTIVE

To understand how nurses who work in a transplant unit perceive the challenges of their role in the face of the COVID-19 pandemic.

METHOD

This is an exploratory, descriptive, qualitative study conducted in the transplant unit of a hospital reference in highly complex procedures; the unit has a postoperative intensive care unit (ICU) with 8 beds and a pre- and postoperative ward with 14 beds. This hospital performs kidney, liver, pancreas, and simultaneous pancreas-kidney transplants and is located in Fortaleza, Ceará State, Northeastern Brazil.

The study subjects were invited to participate in the research according to the following inclusion criteria: being a nurse and working in the transplant unit for over 12 months. We excluded professionals on sick leave or vacation. The sample size was determined by saturation, that is, when the statements had no new information. Thus, 14 nurses participated in the study.

We collected data from March to June 2020 through semi-structured individual interviews, developed and validated by the researchers of this study, comprising four guiding questions:

- "Regarding the transplant patient care flow, how do you perceive the ICU and the ward flow?";
- "What is your impression about the distribution of personal protection equipment (PPE) for the team?";
- "What feelings have you experienced in this pandemic?";
- "Considering the speed of management changes in the pandemic scenario, how have the instructions been given by the management?".

The validation of the instrument used for the interviews followed the guidelines by Souza et al.⁷, with qualitative and quantitative approaches as the method for validation with judges. The qualitative approach involved an evaluation by a group of experts composed of six health professionals with

specialist, master's, and Ph.D. degrees, and who had technical knowledge and practical experience in transplantations. The quantitative analysis was based on the calculation of the content validity index (CVI). As a result, we obtained an agreement rate of 0.97 among the judges.

The interviews took place in a private place without interruptions. The statements were exhaustively recorded and transcribed in an attempt to produce qualitative and quantitative indicators. The nurses were identified by the letter E, followed by Arabic numbers in the order of the interviews (E1, E2, E3...) to ensure their anonymity.

Data were analyzed in the software Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires (IRAMUTEQ). Classic lexicographic analyses were performed in IRAMUTEQ to understand the statistical data and quantify the evocations and forms⁸. We obtained the descending hierarchical classification (DHC) to evaluate the dendrogram data according to the generated classes, considering the words with $\chi^2 > 3.84$ (p<0.05).

Subsequently, we conducted a correspondence factor analysis (CFA). CFA is another way to visualize the content and relationships between classes, as it allows showing the proximity of words and classes through graphs based on DHC, taking into account their representations in the Cartesian plane. The interpretation involved distributing the words with greater frequency in the quadrants⁸. Lastly, we generated the word cloud, which unifies the words and distributes them graphically according to their frequency.

The study was submitted to the Research Ethics Committee (REC) of the Hospital Geral de Fortaleza, which evaluated the feasibility of the project and approved it under opinion no. 4,049,919. The study complied with all stages of the guidelines and standards for research involving human beings, according to Resolution no. 466/2012 of the National Health Council⁹. The nurses were asked to read and sign the Informed Consent Form (ICF).

RESULTS

The sample comprised 14 nurses on duty -11 women and 3 men; all worked in that transplant unit for over a year.

The general *corpus* consisted of 14 texts, divided into 81 text segments (TS), with the utilization of 69 TS (85.19%). A total of 2,808 occurrences (words, forms, or vocables) were identified, with 879 different words, of which 523 had

a single occurrence. The content analyzed was categorized into three classes:

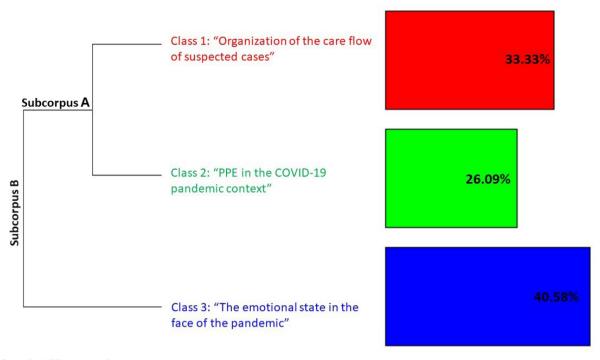
- class 1: "organization of the care flow of suspected cases", with 23 TS (33.33%);
- class 2: "PPE in the COVID-19 pandemic context", with 18 TS (26.09%);
- class 3: "the emotional state in the face of the pandemic", with 28 TS (40.58%) (Figure 1).

Aiming at better illustrating the words in their related classes in the textual *corpus*, we organized a class diagram with examples of words from each class assessed using the χ^2 test. This diagram demonstrates evocations that have a similar vocabulary and those with different vocabulary from other classes. Next, each class found in the DHC analysis will be presented, operationalized, and exemplified (Figure 2).

Class 1: "Organization of the care flow of suspected cases"

It comprises 33.33% (f=23 TS) of the total *corpus* analyzed. This class consists of words and roots in the interval between χ^2 =5.28 (fast) and χ^2 =16.59 (patient). It is composed of words such as "patient" (χ^2 =16.59), "flow" (χ^2 =16.27), "clean" (χ^2 =13.84), "ICU" (χ^2 =9.62), "correct" (χ^2 =8.49), "test" (χ^2 =7.39), "positive" (χ^2 =7.39), and "contaminate" (χ^2 =6.27).

This class represents how nurses perceive the internal care flow and the diagnostic and therapeutic management of patients with suspected respiratory infection caused by COVID-19 in the unit context. The lack of action standardization to fight the pandemic is evident. The statements show the disruption of care and work process flows, thus increasing the risks to occupational and patient health: "There is no way to have an effective control to ensure a completely clean unit. We would need to have two types of flows: flow related to the patient [...] and flow related to the professional" (E2); "I see a totally inadequate flow because the patient who arrives at the ICU doesn't always come with a negative test [...], we don't have an adequate, coherent flow to follow, with a beginning, middle, and end" (E5); "Actually, the clinical ICU is not clean, only in theory, because several patients over the days tested positive for COVID, some were transferred there with just a negative rapid test, and, after a tomography, they received a clear and concise diagnosis" (E7).



Source: Software IRAMUTEQ, version: 0.7 alpha2.

Figure 1. Dendrogram of descending hierarchical classification (DHC).

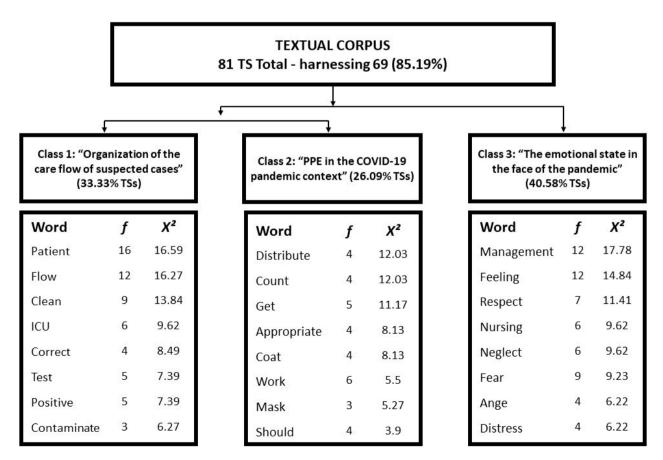


Figure 2. Organizational chart of classes based on interviews with nurses.

Class 2: "PPE in the COVID-19 pandemic context"

It comprises 26.09% (f=18 TS) of the total *corpus* analyzed. This class consists of words and roots in the interval between χ^2 =3.9 (should) and χ^2 =12.03 (distribute). It is composed of words such as "distribute" (χ^2 =12.03), "count" (χ^2 =12.03), "get" (χ^2 =11.17), "appropriate" (χ^2 =8.13), "coat" (χ^2 =8.13), "work" (χ^2 =5.5), "mask" (χ^2 =5.27), and "should" (χ^2 =3.9).

This class shows issues related to the distribution of PPE in the unit, which, in this case, is not considered a care unit for patients affected by COVID-19 by the competent bodies. The statements expose the persistent lack of this equipment, and, when it is supplied, the distribution is uneven, often without guaranteeing its effectiveness, and not always providing enough occupational safety and protection for the team: "PPE should be distributed like in the COVID area [...], but it is only partly provided when there is suspicion or confirmation" (E3); "PPE is only distributed to the COVID sector. Each shift is a struggle to get PPE and ensure a minimum of protection for us and the patients" (E4); "The coats are thin and far from being waterproof, and shoes are not provided by the service. We have to fight to get an N95 mask" (E9).

Class 3: "The emotional state in the face of the pandemic"

It comprises 40.58% (f=28 TS) of the total *corpus* analyzed. This class consists of words and roots in the interval between χ^2 =4.2 (pandemic) and χ^2 =17.78 (management). It is composed of words such as "management" (χ^2 =17.78), "feeling" (χ^2 =14.84), "respect" (χ^2 =11.41), "nursing" (χ^2 =9.62), "neglect" (χ^2 =9.62), "fear" (χ^2 =9.23), "anger" (χ^2 =6.22), and "distress" (χ^2 =6.22).

This class covers aspects related to the feelings experienced by the professionals in the pandemic. This situation has given rise to different emotional reactions, including fear, distress, loneliness, or anger, as reported in the statements: "Feelings of lack of respect, neglect, frustration, and fear. I have to keep working to be paid, so I give in" (E11); "Feelings of sadness, neglect, lack of respect, fear, I don't even know how to express my indignation. [...] Working in inadequate conditions" (E13).

We note that, when reporting their working relationship and interaction with the nursing management, most professionals feel unappreciated, as evidenced by their feelings of neglect and dissatisfaction: "In this pandemic, I felt a total neglect, a lack of care for us, zero respect, [...] the management keeps tabs on those who question and take a stand on the events" (E7); "The flow is absurdly inadequate. The sector is totally contaminated. We don't know who proposes such incoherent actions, but we regret that the management accepts them [...]; I feel a lack of respect for the professional" (E14).

Correspondence factor analysis

Based on the CFA, we could make text associations among the words, considering the frequency of incidence of words and classes, representing them on a Cartesian plane (Figure 3). We distributed and organized the words in quadrants based on frequency. This analysis allowed the distribution of textual elements in a two-dimensional space, according to the classes generated by the textual *corpus*⁸.

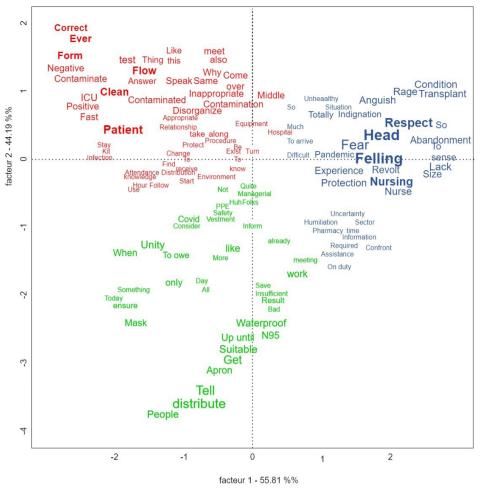
The upper left quadrant highlights "flow", "patient", "clean", and "ICU", referring to class 1. The opposite upper quadrant shows class 3, emphasizing the words "management", "feeling", "neglect", and "respect". In this regard, the predominant discourses relate to feelings and patient care flow. In contrast, the lower quadrants mostly involve class 2, with the words "get", "coat", and "mask" standing out.

Word cloud

Afterward, we analyzed the word cloud obtained through the participants' statements. The cloud shows that the most mentioned words were: "patient" (f=33), "PPE" (f=26), "flow" (f=23), "COVID" (f=21), "ICU" (f=14), "clean" (f=14), "work" (f=13), "distribution" (f=12), "unit" (f=12), and "sector" (f=10) (Figure 4).

DISCUSSION

Among other health professionals, nurses are directly involved in tackling the COVID-19 pandemic. These professionals were abruptly subjected to changes in the health service routine and confronted with overcrowded units and scarce equipment, maximizing the risk of coronavirus infection. In this context, working conditions and organization must be widely discussed^{10,11}.



Source: Software IRAMUTEQ, version: 0.7 alpha2.

Figure 3. Correspondence factor analysis.



Source: Software IRAMUTEQ, version: 0.7 alpha2.

Figure 4. Word cloud.

This study revealed the nurses' dissatisfaction with the internal care flow when they reported the disorganization of care and work process flows. Understanding that services must have operational and routine plans that can warn for suspected or confirmed cases of infection by the novel coronavirus is crucial¹².

Organizational measures should be developed in the context of each health service to ensure working conditions that minimize the spread of the virus¹⁰. Managers of these services have the role of elaborating action plans, with recommendations and construction of protocols that can change over time. Also, management and health professionals must provide technical updates based on scientific evidence¹³.

From this perspective, the purpose of PPE becomes critical in the chain of actions to protect health professionals in the current pandemic, preventing or minimizing the risk of COVID-19 infection¹³. However, the statements of the study participants reveal intense workloads dedicated to bedside

care, a shortage of appropriate PPE in health services, and no guarantee of the effectiveness of this equipment when provided¹⁰. These data differ from the recommendation of the Brazilian labor legislation in the Regulatory Standard for Work Safety and Health in Health Services (NR32), which indicates that employers must provide their employees with sufficient PPE to ensure the safe performance of their activities, in addition to offering continuous training and guaranteeing their protection whenever the exposure conditions change¹⁴.

Given the shortage of PPE, we also note the vulnerability of these professionals concerning emotional issues, evidenced primarily by the feeling of fear reported by nurses in this study. The fragility of professionals who are on the front line becomes inevitable since they deal with several feelings, including: fear of contracting and transmitting the virus, impotence, stress, and uncertainty about the disease and the treatment¹⁵.

Fear is understood as a natural reaction of human beings when confronted with a real and imminent threat. In this context, a rational action is necessary to deal with the issue so that protective measures can be taken. Nonetheless, situations like the current pandemic produce a constant feeling of fear, which may occasionally lead to different levels of anxiety¹⁶.

Another aspect that deserves attention is the lack of appreciation of these professionals by the nursing management, as reported by most interviewees. Nursing management must assume its leadership role, meeting the many demands created by the pandemic with the involvement of other segments of the health service, in addition to promoting the continuous training of the team to ensure the health of these professionals¹⁷.

In this scenario, based on the CFA, the Y-axis, precisely located in the upper quadrants, shows topics about the care flow and feelings experienced during the pandemic. Managers should be responsible for the changes in the care flow of patients, companions, and professionals, as well as for preserving and ensuring the health of these professionals¹⁷. Yet, studies report that professionals directly exposed to the

risk of contamination present anxiety, irritability, and exhaustion, among other negative feelings¹⁸. The X-axis addresses matters related to access to PPE. This access has become a constant concern, given the PPE shortage in various health facilities in Brazil and worldwide¹⁹.

Considering the many aspects exposed, the strengthening of interdisciplinarity and the effective communication between teams become more important than ever because, besides care and administrative activities, the professionals need to welcome, comfort, and support patients who are already coping with several battles and currently face this terrifying pandemic¹⁷. The word cloud showed a high frequency of the word patient, emphasizing the importance of providing quality care for them.

As study limitations, we can mention the summarized statements given by the nurses, since the interviews occurred mostly during their work routine, and the participants might have been conscious of the duration of the interview. Moreover, research on the theme is scarce, preventing the comparison of results with similar studies.

CONCLUSION

The development of the current study allowed understanding how nurses who work in a transplant unit perceive the changes in their role during the COVID-19 pandemic. We found that nurses are suffering due to fragilities related to the moment they, just as other health professionals, are experiencing, as they are daily challenged to adapt to changes in their work routines in the care of transplant patients.

We must review this situation and develop strategies to ensure safe nursing care, promoting continuous and dynamic reorganization of flows of patient admission to the unit, with the participation of the team and improvement in working conditions. Then, reducing harmful effects on the health of these professionals and their patients in the current pandemic will be possible.

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ORIGINAL ARTICLE

ELABORATION OF THE ASSESSMENT SCALE OF PATIENT KNOWLEDGE ABOUT CARDIAC SURGERY

Elaboração da escala de avaliação do conhecimento de pacientes acerca da cirurgia cardíaca

Elaboración de la escala de evaluación del conocimiento del paciente sobre cirugía cardíaca

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ABSTRACT: Objective: To develop and perform the face and content validation of the Assessment Scale of Patient Knowledge about Cardiac surgery (Escala de Avaliação do Conhecimento de Pacientes acerca da Cirurgia Cardíaca - EACCC). Method: This is a methodological, quantitative study, in which 30 nurses considered experts according to the criteria proposed by Fehring participated. Results: The respondents were mostly women (24; 80.0%), with an average training time of 5.5±10.43 years and experience time approximately to the training (5.0±10.78). There was no suggestion to change the way to evaluate the responses in each item and score them, with changes being made to the wording or content of items, as suggested. Conclusion: The final version remained with the same number of items as the first version. In general, in the assessment of judges, the scale proved to be useful for achieving its objective, being ready for clinical validation.

Keywords: Validation study. Psychometrics. Thoracic surgery. Knowledge. Cardiovascular nursing.

RESUMO: Objetivo: Elaborar e realizar a validação de face e conteúdo da Escala de Avaliação do Conhecimento de Pacientes acerca da Cirurgia Cardíaca (EACCC). Método: Trata-se de um estudo metodológico, quantitativo, em que participaram 30 enfermeiros considerados expertos pelos critérios propostos por Fehring. Resultados: Os respondentes eram em sua maioria mulheres (24; 80,0%), com tempo médio de formação de 5,5±10,43 anos e tempo de experiência aproximado ao de formação (5,0±10,78). Não houve sugestão para alteração na forma de avaliar as respostas em cada item e pontuá-las, sendo realizadas alterações para a redação ou o conteúdo de itens, conforme sugestões. Conclusão: A versão final permaneceu com a mesma quantidade de itens da versão primeira. De forma geral, na avaliação dos juízes, a escala apresentou-se útil para o alcance do seu objetivo, estando pronta para a validação clínica.

Palavras-chave: Estudo de validação. Psicometria. Cirurgia torácica. Conhecimento. Enfermagem cardiovascular.

RESUMEN: Objetivo: Elaborar y realizar la validación de rostro y contenido de la Escala de Evaluación del Conocimiento de los Pacientes sobre Cirugía Cardíaca (EECCC). Método: Se trata de un estudio metodológico, cuantitativo, en el que participaron 30 enfermeras consideradas expertas según los criterios propuestos por Fehring. Resultados: Los encuestados fueron mayoritariamente mujeres (24; 80,0%), con un tiempo medio de formación de 5,5±10,43 años y un tiempo de experiencia similar al de la formación (5,0±10,78). No se sugirió cambiar la forma de evaluar las respuestas en cada ítem y calificarlas, con cambios en la redacción o el contenido de los ítems, como se sugirió. Conclusión: La versión final se mantuvo con el mismo número de ítems que la primera versión. En general, en la evaluación de los jueces, la Escala resultó útil para alcanzar su objetivo, estando lista para la validación clínica. Palabras clave: Estudio de validación. Psicometría. Cirugía torácica. Conocimiento. Enfermería cardiovascular.

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INTRODUCTION

The preoperative period is dedicated to the process of preparing the patient, in addition to being the moment related to the educational process of providing information about surgical procedures and the care to be performed. Such guidelines range from the preparation for the surgical act to the care provided during the preoperative period, including the changes in life that may arise.

The prospect of undergoing surgery is commonly perceived by individuals as an event related to disability and/or alteration of body image, which can be a cause of stress and anguish, sensations related to questions about the anesthetic-surgical procedure and the uncertainty of the diagnostic result.² Preoperative stress and anxiety are thus directly related to patients' lack of knowledge and, indirectly, to the failure to take advantage of preoperative moments which the multidisciplinary team could offer them.³ Anxiety symptoms are related to a higher level of postoperative pain and negatively impact the results of surgery. This is also valid in the long term, in the postoperative period, which could be minimized with education strategies and interventions focused on the socioemotional issues involved.³⁻⁷

The waiting for cardiac surgery usually generates psychological and physiological repercussions because the heart is an organ that has great symbology for people, being idealized as the center of emotions, life, and body. In addition, it can also trigger decreased capacity for tissue recovery and slow immune response, contributing to a greater predisposition to infections. 5.6

In order to implement health education, the multidisciplinary team must seek to understand the learning needs of patients and have the scientific evidence needed to organize care and guide the educational process. Health education can be understood, in this context, as a social practice that promotes reflection and critical awareness, with an emphasis on a dialogical and organizing process of working with people, and not just a merely instructional act. §

For making the practice of health education more effective and efficient in the preoperative period of cardiac surgery, thinking of strategies with language accessible to the target audience is important, with educational and interactive actions between professionals and their patients. Preoperative guidance and visits are of utmost importance.^{7,8} When patient have such knowledge, preventing complications in the postoperative period is feasible, in addition

to allowing them to feel less anxious and accept better the guidelines they receive, meeting their psychological needs and contributing to a rapid improvement after surgery.⁹

Developing strategies for assessing the learning needs of patients about the procedure they will undergo is also necessary. To better plan how to intervene, professionals must have resources that provide them with security and allow them to optimize their time with more focused actions and directly evaluate the effect of these on the patient's education.

A validated instrument that would make it possible to assess patients' knowledge about the perioperative of cardiac surgery would serve a dual purpose: as a guide to check, objectively, the dimension of patients' learning needs, guiding a reflection on which aspects need a better approach; and, at the same time, to consider patients' progress after an educational intervention. For the measurement of effectiveness of educational interventions, this instrument could be applied, for example, before and after surgery, or only after it, whenever it would be possible to establish a goal of the minimum score to be achieved.

Therefore, research emphasizes the relevance of improving instruments for evaluating nursing care, especially health education strategies.

OBJECTIVE

To develop and perform the face and content validation of the Assessment Scale of Patient Knowledge about Cardiac surgery (*Escala de Avaliação do Conhecimento de Pacientes* acerca da Cirurgia Cardíaca - EACCC).

METHOD

This is a methodological, quantitative study. Methodological research investigates, organizes, and analyzes data to build, validate, and evaluate research instruments and techniques focused on the development of specific data collection tools for improving their reliability and validity.⁹

Data collection took place between May and October 2018. The invited nurses, according to the criteria described below, worked in three university hospitals in the Northeast of Brazil (Recife, Pernambuco's State Capital), who perform heart surgeries.

Research was conducted in two stages. In the first stage, the authors prepared the first version of the EACCC. For the scale proposition, contents taught, the most frequent doubts and the authors' experience with the theme were used. In turn, the content used to guide patients, performed in the hospital, was developed by a broad literature review, in addition to the experience of professionals and hospital protocols.

For surveying patients' doubts and learning needs, a previous investigation was carried out with 50 patients admitted to the specialized hospital, who were awaiting surgery. Care was taken not to interview patients who had already undergone any educational intervention to seek out the most primary doubts, that is, those doubts that had not been addressed by any other professional.¹⁰

At the end of this first stage, the initial version of the scale was elaborated with 18 items to be filled out by nurses during interviews with patients. After the interviews, the scale must be completed for each item evaluated, considering that:

- patients do not have knowledge about the question when there is no answer on their part or when they are completely wrong;
- patients partially have knowledge about the question when they do not use the terms correctly or do not know details, but know the main thing about the care to which the item refers;
- patients have knowledge about the question when they respond with their own words correctly regarding the main aspects related to the care to which the item refers.

The scale score is counted as follows: 0 point for each item that patients do not have knowledge about the question; 1 point for each item that patients partially have knowledge about the question; and 2 points for each item patients have knowledge about the question. The total score of the first version ranged from 0 to 36 points, the highest

score corresponding to a better knowledge of severe cardiac patients about cardiac surgery to which they could be submitted.

The second step for face or appearance, and content validation was carried out with the evaluation of the agreement by judge-nurses. After the evaluations returned, there was agreement between the evaluators' considerations about each item proposed on the scale and the scale itself.

Nurses were invited in person or by email to participate, filling out a collection instrument to assess the first version of the scale. One month was given from contact to conclusion; when it did not occur, a second contact was made to give fifteen more days as deadline.

Judges were selected according to their Lattes curriculum, following the criterion proposed by Fehring (1994) for the selection of experts, explained in Chart 1, adapted for the Nursing area within Cardiology.^{11,12}

From a total of 14 possible points for the curricula evaluation, experts who considered at least 4 points were considered experts qualified to participate as judges. The sample of nurses was estimated between 25 and 50, according to the Fehring method for validation by experts.¹²

The data were tabulated in the Microsoft Excel program and analyzed using SPSS version 20.0, of public domain. For data analysis, the resources of descriptive statistics (absolute and relative frequencies, means and standard deviations) and the content validity index (CVI) were used, which measures the agreement of judges regarding the representativeness of the items, in relation to the content under study.

The CVI was calculated by dividing the number of judges who assessed the item as being clear and objective, with a relevant presence, and which makes it possible to reach the scale's objective by the total of judges (evaluation per item), resulting in the proportion of judges who judged the valid item. The level of agreement considered as acceptable for the scale was 80%. A fourth item was proposed as

Chart 1. Adaptation of the expert scoring system to Fehring's content validation model (1994).

Master in Nursing	4
Master in Nursing with dissertation on Cardiac Nursing	1
Research with publication in the field of Cardiac Nursing	2
Article published in the field of Cardiac Nursing	2
Doctorate in Nursing or related areas	2
Clinical practice of at least one year in the field of Cardiac Nursing	1
Specialization certificate in the areas of Cardiac Nursing, Surgical Clinic, or Adult Health	2
Highest score	14

a Likert type, in which judges had to assign a value from 1 to 5 for the item's relevance for scale. The calculation of the CVI of this item considered as positive those responses that scored with 4 and 5, that is, with the greatest relevance. To calculate the instrument's general CVI, the sum of all CVIs calculated separately was performed, dividing it by the number of items. 9,12,13

The CVI result varies from 0 to 1, demonstrating the agreement between judges from 0 to 100%. An index of ≥0.80 was defined and acceptable (80% agreement between the judges), considered both for the evaluation of each item and for the general evaluation of the instrument.^{9,12,13}

Both the first and the final versions were evaluated by two professionals qualified in reviewing the Portuguese language. Research was prepared based on the precepts of Resolution No. 466/2012, and evaluated and approved by the institution's Research Ethics Committee (Opinion No. 2.434.581, CAAE 56496116.5.0000.5192).

RESULTS

A total of 45 nurses was invited to participate, who had a score higher than 4 after previous analysis of their Lattes curricula to be considered experts. Of these, 30 responded to the survey after the deadline, with an average score of 7.0±1.26 points, ranging from 4 to 12 points.

Most respondents were women (24 / 80.0%), with an average training time of 5.5 ± 10.43 years and experience time like that of training (5.0 ± 10.78) . The time of experience varied between 4 and 28 years, and all worked in care provision.

As for academic training, 18 (60.0%) held a master's degree in Nursing, and 27 (90.0%) had a specialization in Cardiology, Surgical Clinic, or related areas in adult health. Only 2 (6.67%) held a doctor's degree; 66.67% (20) had published articles in journals in the field of Cardiac Nursing; 56.67% participated or used to participate in research in the area; and 76.67% (23) had care experience in this area. The remaining 23.3% (7) had experience in surgical clinic, including the pre and postoperative periods.

The evaluation of the items by the IVC revealed that they were mostly valid for the evaluated criteria. Those that were not valid, that is, did not reach CVI≥0.85, are described below in Table 1:

as for clarity and objectivity (CVI = 0.87): items
 3 (describe this type of surgery), 7 (necessary

- trichotomy), 9 (position for the patient who has cardiac surgery to sleep in the hospital);
- as for the relevant presence to evaluate information/ care (CVI = 0.94): items 3 (describe this type of surgery), 4 (what is fasting);
- as for the value of enabling the achievement of the scale objective (CVI = 0.94): items 3 (describe this type of surgery), 4 (what is fasting);
- As for the relevance to the general objective (CVI = 0.88): items 3 (describe this type of surgery), 4 (what is fasting).

Then, nurses answered questions for the general assessment of the scale, considering it easy to read and understand for nurse practitioners (26 / 86.7%), which makes it possible to assess the knowledge of patients in the preoperative period about cardiac surgery to which they are eligible (26 / 86.7%). Of the respondents, 40.0% (12) stated that more questions should be added, and 60.0% (18)

Table 1. Content validity of each item on the Assessment Scale of Patient Knowledge about Cardiac surgery (*Escala de Avaliação do Conhecimento de Pacientes acerca da Cirurgia Cardíaca* - EACCC) - 1st version.

LACCC) - 1 Version.					
ltem	Clarity and objectivity	Relevant presence	Enables reaching the scale objective	Relevance to the overall objective	
1	0.87	0.97	1.00	0.87	
2	0.93	1.00	1.00	0.97	
3	0.70	0.67	0.70	0.57	
4	0.97	0.77	0.77	0.63	
5	0.97	1.00	1.00	1.00	
6	0.90	0.87	0.87	0.80	
7	0.63	0.93	0.93	0.77	
8	0.87	1.00	1.00	0.97	
9	0.73	1.00	0.97	0.90	
10	0.87	0.97	0.97	0.93	
11	0.90	1.00	1.00	1.00	
12	0.90	1.00	0.97	0.93	
13	0.87	0.97	0.97	0.90	
14	0.93	0.90	0.90	0.87	
15	0.93	1.00	1.00	1.00	
16	0.87	1.00	1.00	1.00	
17	0.87	1.00	1.00	1.00	
18	0.97	0.87	0.77	0.77	

Table 2. General assessment of the scale by the judge-nurses.

Questions	Ye	es	No		Partially	
questions	N	%	N	%	N	%
Is the scale easy to read and understand for nurse practitioners?	26.0	86.7	0.0	0.0	4.0	13.3
Does it make it possible to assess the knowledge of patients in the preoperative period about the cardiac surgery to which they are eligible?	26.0	86.7	0.0	0.0	4.0	13.3
Any questions that you think should be added to the instrument?	12.0	40.0	18.0	60.0	0.0	0.0
Any questions that you think are unnecessary considering the totality of the instrument and its proposed objective?	18.0	60.0	12.0	40.0	0.0	0.0
Is there consistency between the proposed items and the patients' need for knowledge about cardiac surgery, in a way that indicates learning needs and health education opportunities?	29.0	96.7	0.0	0.0	1.0	3.3

stated that there were unnecessary questions, considering the totality of the instrument and its proposed objective. Finally, a question was asked in order to ratify and explore the previous ones and, for this, 29 (96.7%) judges assessed that there was consistency between the proposed items and the need for knowledge on the part of patients about cardiac surgery (Table 2).

There was no suggestion to change the way to evaluate the responses in each item and score them. Considering the CVI and the response to the items that the nurses found unnecessary on the scale, items 3 (describing this type of surgery) and 4 (what is fasting) were removed in the final version. After removing these items, the CVI of the four aspects evaluated was high (CVI≥0.85). Based on the nurses' suggestions, the following items were included: the bath routine in the immediate preoperative period (6 suggestions), the presence of tubes, drains, tubes, etc. upon awakening in the postoperative period (8 suggestions).

The final version thus remained with the same number of items as the first version, being evaluated in the same way.

DISCUSSION

The construction and validation of scales, which aim at assessing the knowledge of patients, is essential for means to be sought to provide better knowledge about their disease. 13,14

Although there is no strong evidence for this, a survey found that patients who were not proficient in the language in which they received guidance had higher rates of infection and hospital stay, reinforcing the importance of adapting language to the population and patients in health education strategies.¹⁵ This publication reinforces the need to

carry out face and content validation so that the resources developed are effective in healthcare practice.

Despite this relevance, steps to validate nursing instruments, protocols, or diagnoses are still difficult to perform due to the difficulty in finding professionals who can be considered experts, as well as making those found as respondents and evaluators. ¹² In this work, despite the fact that most of the invited nurses had been linked to the same institution at some point during their training (former residents, graduate students, members of research groups), only two thirds responded to the invitation to participate.

The evaluation scales, when used by well-educated professionals about their applicability, allow them to identify changes in the patients' clinical condition and can, with these instruments, propose intervention measures to provide better quality of care to individuals.¹⁶

Assessment instruments are devices that can be used in educational proposals in the health field and that aim to make it possible to measure the efficiency of the teaching and learning process, in order to propose changes in behavior related to the disease. ^{14,16} The changes made by the evaluation of judges, with the replacement of two items for others that had not been contemplated, allowed the instrument in its version to be better tuned to meet these purposes.

The educational actions propose the formation of a set of actions that aim to provide knowledge to patients, their family members and caregivers about a certain issue related to their health status, thus favoring the organization and changes related to their care.¹⁶

Studies show that adherence to the rehabilitation process is associated with the fact that patients are aware of the procedure that they will undergo and their recovery process. ¹⁶⁻²⁰ Nursing interventions in the preoperative period,

with special emphasis on educational interventions, are essential for patients to become responsible, with the team, for their recovery and self-care process, and may even impact clinical variables that indicate surgery success. 16-20

As a study limitation, at this stage, a more refined result could be achieved if nurses from other regions of the country were included, who contributed with regional aspects of language and other realities of surgical care in cardiology.

CONCLUSION

The first version required few adjustments, with only two items removed and replaced by two others. In general, in the judges' assessment, the EACCC proved to be useful for achieving its objective, having been designed to be applied by nurses to patients in the preoperative period of cardiac surgery. This version of the scale must also be validated with patients to assess reliability, applicability, and factor structure, and after this stage of elaboration and validation (face and content by judges), it is ready to be used (Appendix 1).

We suggest the scale in clinical validation with patients to be constantly improved to assess its psychometric properties by checking the possibility of grouping the items into domains and possible cutoff points in which the presented knowledge is classified (for example, as sufficient or insufficient knowledge).

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Appendix 1. Assessment Scale of Patient Knowledge about Cardiac surgery (*Escala de Avaliação do Conhecimento de Pacientes acerca da Cirurgia Cardíaca* - EACCC).

Scale use:

After the interviews with patients, for each item evaluated, the scale must be filled in considering that:

- patients do not have knowledge about the question when there is no answer on their part or when they are completely wrong;
- patients partially have knowledge about the question when they do not use the terms correctly or do not know details, but they know the main thing about the care to which the item refers;
- patients have knowledge about the question when they respond with their own words correctly about the main aspects related to the
 care to which the item refers.

About the cardiac surgery to which he/she is candidate, the patient knows:	Does not know	Partially knows	Knows
1. The type of surgery to be performed.			
2. The reason for performing this surgery.			
3. The bath routine in the immediate preoperative period.			
4. How long it is necessary to fast before surgery.			
5. The reason for the fast.			
6. The necessary trichotomy.			
7. If he/she can cough and care for their cough after surgery.			
8. The position for the patient who undergoes cardiac surgery needed to sleep in the hospital.			
9. That he/she will wake up in an intensive care unit (ICU).			
10. The presence of tubes, drains, probes, etc. upon awakening in the postoperative period.			
11. The care he/she should have with food and diet after surgery.			
12. The possibility of returning to daily life activities performed before surgery.			
13. The possibility of returning to physical activities.			
14. If exhausting physical effort can be made, such as picking up heavy objects after discharge.			
15. The possibility of normal sexual life after discharge.			
16. Care for the surgical wound after discharge.			
17. Signs of infection of the surgical wound.			
18. You he/she can smoke after surgery.			

Result analysis:

The scale score will be given as follows:

- 0 point for each item that the patient does not have knowledge about the question;
- 1 point for each item that the patient have partial knowledge about the question;
- 2 points for each item that the patient have knowledge about the question.

The total score will vary from 0 to 36 points, the highest score being related to a better knowledge of the severe cardiac patient about the cardiac surgery to which he/she may be submitted.

QUALITY INDICATOR: INTRAOPERATIVE AND POSTOPERATIVE MORTALITY RATE

Indicador de qualidade: taxa de mortalidade intraoperatória e pós-operatória

Indicador de calidad: tasa de mortalidad intraoperatoria y postoperatoria

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ABSTRACT: Objective: To identify and characterize the quality indicator of intraoperative and postoperative mortality rate. Method: This is a retrospective, quantitative, descriptive, cross-sectional study with variable correlation, based on 18,337 medical records and conducted from January to December 2017. The methods used were descriptive and inferential statistics, with analysis of probability issues of a population according to sample data. Results: In the study period, 18,337 patients underwent surgery, with a mortality rate of 1.75% in the intraoperative period and 1.76% in the first seven postoperative days. Among them, 191 (58.95%) were men, and 32.71% were classified as American Society of Anesthesiologists class III; 80.24% of urgent surgeries, considered clean, had a mean duration of up to 120 minutes. Conclusion: The mortality rate found in the facility is in accordance with the values described by the Commitment to Hospital Quality. The following variables showed a significant correlation: operative time (up to 120 minutes) and urgent surgery; and surgical contamination (clean) and death period (up to seven days). Keywords: Death. Intraoperative period. Postoperative period. Hospitals, teaching.

RESUMO: Objetivo: Identificar e caracterizar o indicador de qualidade de taxa de mortalidade intraoperatória e pós-operatória. Método: Estudo retrospectivo, quantitativo, com delineamento descritivo, transversal e correlação entre variáveis, realizado de janeiro a dezembro de 2017 em 18.337 prontuários. Foram utilizados métodos de estatística descritiva e inferencial, analisando-se questões de probabilidade de uma população com base nos dados da amostra. Resultados: No período estudado, houve 18.337 pacientes com taxa de mortalidade intraoperatória de 1,75%, e a referente aos sete primeiros dias de pós-operatório foi de 1,76%. Destes, 191 (58,95%) eram do sexo masculino, 32,71% dos pacientes foram classificados como American Society of Anesthesiologists III, e 80,24% das cirurgias de caráter de urgência, classificadas como limpas, tiveram tempo médio de duração de até 120 minutos. Conclusão: A taxa de mortalidade encontrada na instituição está em conformidade com os valores descritos pelo Compromisso com a Qualidade Hospitalar. Houve correlação significativa entre as variáveis: tempo de cirurgia (até 120 minutos) e caráter de urgência; e classificação da cirurgia (limpa) e período de morte (até sete dias). Palavras-chave: Morte. Período intraoperatório. Período pós-operatório. Hospitais de ensino.

RESUMEN: Objetivo: Identificar el indicador de calidad de las tasas de mortalidad intraoperatoria y posoperatoria. Método: Estudio retrospectivo, cuantitativo, con diseño descriptivo, transversal y correlación entre variables, realizado de enero a diciembre de 2017 en 18.337 registros. Se utilizaron métodos de estadística descriptiva e inferencial, analizando la probabilidad de una población a partir de los datos muestrales. Resultados: Durante el período de estudio, hubo 18.337 pacientes, con una tasa de mortalidad intraoperatoria del 1,75%, y la de los primeros siete días postoperatorios del 1,76%. De estos, 191 (58,95%) eran hombres, 32,71% de los pacientes fueron clasificados como American Society of Anesthesiologists III, 80,24% de las cirugías urgentes, clasificadas como limpias, tuvieron una duración media de hasta 120 minutos. Conclusión: La tasa de mortalidad encontrada en la Institución está de acuerdo con los valores descritos por el Compromiso con la Calidad Hospitalaria. Hubo una correlación significativa entre las variables: tiempo de cirugía (hasta 120 minutos) y urgencia; clasificación de cirugía (limpia) y período de muerte (hasta 7 días). Palabras clave: Muerte. Periodo intraoperatorio. Periodo posoperatorio. Hospitales de enseñanza.

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INTRODUCTION

Hospital mortality rate has been used as a quality indicator, seeking to identify the care provided in some procedures in which death is not a rare event¹. Operative death is defined as the death of a patient during or up to seven days after the anesthesia-surgical procedure².

Patient safety has become a global concern since 2000, when the United States Institute of Medicine published the report *To err is human: building a safer health system*, showing that approximately 98 thousand people die annually due to medical errors³. In the surgical context, safe care is a challenge. Estimates indicate that 234 million surgeries are performed worldwide per year, with a death incidence ranging from 2 to 7 million. However, half of these deaths could be avoided⁴.

In order to raise professional awareness and political responsibility to ensure health care safety, the World Alliance for Patient Safety launched the campaign Safe Surgery Saves Lives, aimed at reducing the morbidity and mortality rate resulting from surgical procedures. This is the fourth global goal of the World Health Organization, focused on increasing the quality of health services. The campaign comprises four items: surgical site infection prevention, safe anesthesia, safe surgical teams, and measurement of surgical services⁵.

With the intent of guiding the service toward health care quality and safety, some organizations, such as the Joint Commission on Accreditation of Healthcare Organizations, have presented programs to provide health care to the patient and decrease the number of incidents in prevention environments⁶.

The Ministry of Health, through the Brazilian Health Regulatory Agency, has launched six operational protocols that address the relationships between drug therapy, risk of falls, hand hygiene, prevention of pressure ulcers, patient identification, and safety during surgical procedures. Considering that patient safety means reducing the risk of unnecessary damage associated with health care to a minimum acceptable level, recognizing the incidents that occur in the surgical center (SC) is crucial.

Quality of care – not only in the SC – is mainly connected to non-compliance control. The operative death of a patient within the first 24 hours after the anesthesia-surgical procedure is considered a severe non-compliance⁹. Thus, we can note that this quality indicator only involves the absolute number of intraoperative deaths. Hence the importance of this study, as it discusses the operative mortality rate as an indicator of the care provided in the perioperative period.

OBJECTIVE

To identify and characterize the quality indicator of intraoperative and postoperative mortality rate.

METHOD

This is a retrospective, quantitative, descriptive, cross-sectional study with variable correlation. The research was conducted in a teaching hospital with extra capacity (708 beds) located in São José do Rio Preto, São Paulo State, Southeastern Brazil. The facility provides care to 2 million inhabitants, patients of the public and private health systems, from 102 municipalities in the Rio Preto Regional Health Division. The SC has 25 operating rooms, receiving, on average, 18,337 patients submitted to surgeries per year, of whom 10,642 (58.03%) are covered by the public health system and 7,695 (41.96%) by private health insurance providers.

Data were collected in the SC between July and August 2018, and included patients submitted to elective, urgent, and emergency surgeries who died in the intraoperative period and up to seven days after the anesthesia-surgical procedure from January to December 2017. The exclusion criteria were patients younger than 14 years, those who underwent surgery in the minor procedure room and the internal children hospital, which is part of the facility and organ procurement complex, individuals submitted to ophthalmic and obstetric surgeries, and with American Society of Anesthesiologists (ASA) class VI.

The information was gathered using the hospital database, with data provided by the billing and SC department managers. This collection involved reviewing the (online) medical records of 18,337 patients operated on between January 1 and December 31, 2017 — 324 records corresponded to patients who died in the intraoperative period or up to seven days after the procedure. Patients who died were characterized as to: gender, age, medical specialty, type of surgery (elective and urgent), surgical contamination (clean, contaminated, clean-contaminated, and dirty-infected), operative time (surgical complexity), and ASA physical status.

We calculated the operative mortality rate using the Commitment to Hospital Quality (*Compromisso com a Qualidade Hospitalar* – CQH) formula — the ratio between the number of operative deaths divided by the number of surgeries performed multiplied by 100².

The methods used were descriptive and inferential statistics, with analysis of probability issues of a population according to sample data. In certain situations, given the necessity and to improve the understanding, we employed the following methods: mean, median, Kolmogorov-Smirnov test, Poisson regression, Mann-Whitney test, Spearman's correlation, significance level, and standard error. The correlations verified were: type of surgery and gender; type of surgery and medical specialty; type of surgery and age; type of surgery and surgical contamination; type of surgery and ASA; type of surgery and operative time (in minutes); death after surgery (days) and surgical contamination; ASA and surgical contamination; ASA and sender.

The variables underwent inferential statistical analysis, whose method was based on the result of the normality test of the variable. The methods chosen to analyze the result variation between the groups investigated intended, in short, to verify their relationships, standardizing one of the variables as dependent and the other as independent, in order to conduct a predictive analysis between them. Results with p<0.05 characterized significance among the groups studied. All tests considered a 5% alpha error and a 95% reliability.

Data were collected by the first researcher, after approval by the Research Ethics Committee of the facility studied, under opinion No. 2,775.232.

RESULTS

In the study period (between January and December 2017), 18,337 patients underwent anesthesia-surgical procedures, ranging from 1,389 (7.57%) in April to 1,740 (9.48%) in August. The operative mortality rate was 1.76% per year, ranging from 1.15 to 2.25%, and the median was 1.75%, as shown in Table 1.

The sample characterization (Table 2) indicated a predominance of male patients (58.95%) and urgent surgeries (59.23%). The most representative age group was 61 to 80 years (45.37%) – in this case, urgent surgeries were the most prevalent (46.15%) –, and patients aged up to 20 years had the lowest incidence (0.93%).

As to the profile built based on medical specialties, we found higher numbers in general surgery (50%), with predominance of urgent procedures (54.23%), and lower incidence in endoscopy (0.62%), particularly elective surgeries (3.13%).

Concerning surgical contamination, clean procedures showed prevalence in the sample, totaling 46.91%.

Among them, urgent surgeries were the most frequent (43.08%). Clean-contaminated surgeries accounted for 27.47% of the procedures performed, and, out of them, urgent surgeries were also the most expressive (28.85%).

About the ASA classification, Table 3 reveals that 32.71% of patients who died up to seven days after the procedure were considered ASA III and underwent elective surgeries, followed by ASA IV patients submitted to urgent surgeries with 24.38%. These variables showed a significant relationship, with p=0.036.

A total of 43.83% of patients died in procedures performed in up to 120 minutes. In procedures with this duration, urgent surgeries were the most representative (49.23%). Next, the duration of 121 to 240 minutes presented 37.35% of deaths, among which urgent surgeries were also the most prevalent (37.31%). We found a significant correlation between these variables, with p=0.000.

Regarding surgical contamination and death period, the deaths ranged from 15 on the seventh day to 77 on the first day, as described in Table 4. Clean surgeries presented the highest percentage of deaths (152 patients/46.9%). When analyzing the day of death associated with surgical contamination, contaminated surgeries with death on the first day were more expressive (28 patients). The analysis of correlation of these variables showed a significant association, with p=0.040.

Table 1. Surgeries performed, operative deaths, and operative mortality rate from January to December 2017.

Month	Surgeries performed	Operative death	Operative mortality rate		
	n	n	%		
January	1,614	26	1.61		
February	1,441	30	2.08		
March	1,544	26	1.68		
April	1,389	25	1.80		
May	1,593	36	2.25		
June	1,517	18	1.18		
July	1,702	29	1.70		
August	1,740	20	1.15		
September	1,548	31	2.00		
October	1,422	25	1.75		
November	1,422	28	1.96		
December	1,405	30	2.13		
Total	18,337	324	1.76		

Table 2. Characterization of patients in the intraoperative period and seven days after the procedure, according to the type of surgery.

	Ele	Elective		gent	Total		
Gender	n	%	n	%	n	%	
Male	37	57.81	154	59.23	191	58.95	
Female	27	42.19	102	39.23	129	39.81	
No information	0	0	4	1.54	4	1.23	
Total	64	100	260	100	324	100	
Age (years)							
≤20	1	1.56	2	0.77	3	0.93	
21 to 40	3	4.69	26	10	29	8.95	
41 to 60	24	37.50	70	26.92	94	29.01	
61 to 80	27	42.19	120	46.15	147	45.37	
>80	9	14.06	42	16.15	51	15.74	
Total	64	100	260	100	324	100	
Specialty							
General surgery	21	32.81	141	54.23	162	50	
Neurosurgery	13	20.31	53	20.38	66	20.37	
Vascular surgery	4	6.25	19	7.31	23	7.10	
Orthopedics/traumatology	8	12.50	12	4.62	20	6.17	
Cardiovascular surgery	10	15.63	7	2.69	17	5.25	
Urology	2	3.13	10	3.85	12	3.70	
Thoracic surgery	3	4.69	7	2.69	10	3.09	
Colorectal	0	0.00	7	2.69	7	2.16	
Head and neck	1	1.56	4	1.54	5	1.54	
Endoscopy	2	3.13	0	0	2	0.62	
Total	64	100	260	100	324	100	
Contamination							
Clean	40	62.50	112	43.08	152	46.91	
Clean-contaminated	14	21.88	75	28.85	89	27.47	
Contaminated	8	12.50	57	21.92	65	20.06	
Dirty-infected	1	1.56	15	5.77	16	4.94	
No information	1	1.56	1	0.38	2	0.62	
Total	64	100	260	100	324	100	

Table 3. Distribution of the American Society of Anesthesiologists (ASA) classification and operative time according to the type of surgery.

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Information	Elec	:tive	Urg	jent	Total		
ASA	n	%	n	%	n	%	
ASA I	2	3.13	6	2.31	8	2.47	
ASA II	21	32.81	43	16.54	64	19.75	
ASA III	22	34.37	84	32.30	106	32.71	
ASA IV	14	21.87	65	25	79	24.38	
ASA V	3	4.68	12	4.61	15	4.62	
No information	2	3.13	50	19.23	51	15.74	
Total	64	100	260	100	324	100	
Operative time (minutes)							
≤120	14	21.88	128	49.23	142	43.83	
121 to 240	24	37.50	97	37.31	121	37.35	
241 to 360	16	25	24	9.23	40	12.35	
361 to 480	7	10.94	10	3.85	17	5.25	
>480	3	4.69	1	0.38	4	1.23	
Total	64	100	260	100	324	100	

Days	Contar	Contaminated		Dirty-infected		Clean		Clean- contaminated		No information		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	
0	11	16.92	2	12.50	39	25.66	13	14.61	0	0	65	20.06	
1	28	43.08	4	25.00	25	16.45	18	20.22	2	100	77	23.77	
2	6	9.23	5	31.25	20	13.16	21	23.60	0	0	52	16.05	
3	7	10.77	1	6.25	20	13.16	12	13.48	0	0	40	12.35	
4	5	7.69	1	6.25	13	8.55	12	13.48	0	0	31	9.57	
5	1	1.54	2	12.50	12	7.89	4	4.49	0	0	19	5.86	
6	2	3.08	1	6.25	16	10.53	6	6.74	0	0	25	7.72	
7	5	7.69	0	0	7	4.61	3	3.37	0	0	15	4.63	
Total	65	100	16	100	152	100	89	100	2	100	324	100	

Table 4. Distribution of operative deaths according to the day of death and surgical contamination.

DISCUSSION

The present study identified an indicator of operative mortality rate with a median of 1.75%. In the 2017 CQH Program, including records of 49 general hospitals, the same indicator had a median of 0.12%, ranging from 0.05 to $4.96\%^2$.

A study conducted in the hospital complex Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP), from 2007 to 2011, showed an operative mortality rate ranging from 1 to 2.3%¹⁰. A case-control study carried out in a public hospital in Santa Catarina presented a rate of 9.8%¹¹.

In a systematic literature review, the authors revealed that operative mortality rates are higher in Brazil and other developing countries compared to developed countries¹².

A prospective cohort study of 187 patients conducted in Porto Alegre found that 48% of patients who died were men¹³. These data are in line with the present research, which also detected a male predominance (58.95%). In contrast, 2 studies on deaths of patients submitted to orthopedic surgeries identified a predominance of women, with 76.9¹⁴ and 72.3%¹⁵, disagreeing with the results of the current study.

In 2010, a study performed in a database of French hospitals verified the derivation and validation of the Preoperative Score to Predict Postoperative Mortality, showing that the risk of hospital mortality was 3.46% after major orthopedic surgeries and 1.09% after vascular surgeries¹⁶. The above data differ from those of the current study, whose highest rates corresponded to general surgery (50%) and neurosurgery (20.37%). In this context, research conducted in a large

public hospital of Rio Grande do Sul, in 2017, presented similar data to those of the present investigation, with the most frequent cause of death being neurosurgery (44.3%), followed by general surgery (33.3%)¹⁷.

With respect to age group, operative death was predominant in older adults aged 61 to 80 years; however, we found no correlation between the variables age and death caused by surgeries. A study on operative deaths carried out in a public hospital in the inland of São Paulo showed that the prevalent age was 72 to 79 years¹⁸. In contrast, another research indicated that age was not an independent risk factor¹⁹, corroborating the results presented in this study.

A systematic literature review evidenced that most perioperative deaths occur in patients classified as ASA III or over and in urgent surgeries.

Research on mortality rate performed in the HCFMUSP found that the high complexity of the population treated in this facility reached 57.09%; these patients also showed the same classification − ASA≥III¹¹. The above data corroborate the results of the current study, which presented a significance level for these variables. A study conducted for three years (2008 to 2010) in a teaching hospital in Edmonton, Canada, revealed that most patients aged 80 years or older submitted to emergency general surgery had functional impairment, with prevalence of ASA III patients. In addition, over 60% of them showed good long-term survival²⁰.

Recent research reported that an elective surgery with duration exceeding 130 minutes is an independent risk factor for complications, as well as length of stay²¹. Thus, these data corroborate the findings of the current study, statistically

correlating the type of surgical procedure and operative time. We stress the importance of preceptors following the residents, an item highlighted in the literature by the *New South Wales Health Emergency Surgery Guidelines* as one of the main goals when redesigning the services, since it leads to a decrease in operative time, weakening a variable that affects the operative mortality rate²¹.

A study performed in eight hospitals in several countries (Canada, India, Jordan, Philippines, New Zealand, Tanzania, England, and the United States) identified the need for monitoring all patients in all stages they undergo while in the SC. The research showed that the values of all indices analyzed decreased, including mortality rate – from 1.5 to 0.8% –, representing a 55% reduction in postoperative mortality rate²².

The present study identified a higher mortality rate in clean surgeries up to 24 hours after the procedure, with statistical association. However, a prospective study that compared clinical results before and after the implementation of the ACERTO Project²³, which consists of a set of routines to accelerate the recovery of patients submitted to abdominal surgeries, revealed a mortality prevalence in surgeries classified as clean-contaminated, but with no statistical significance. These results disagree with those obtained in the present study.

This study has limitations, such as the scarcity of current national and international research related to the topic investigated and the presentation of data associated with mortality and the incidence of reoperations. Improving outcomes depends essentially on some factors, such as: recognizing the patient regarding their ASA classification, which considers the

physical status of the individual; seeking to reduce the operative time, which will allow the patient to be less exposed/susceptible to complications; and following routines and protocols that provide the best care to surgical patients, regardless of their potential for contamination. This study showed high mortality rate in surgeries considered clean, differing from national and international research.

Providing safe care to patients in all surgical stages is a challenge for all health care facilities that aim at reducing the morbidity and mortality caused by anesthesia-surgical procedures⁴.

CONCLUSION

Analysis of the information of 18,337 patients allowed us to calculate the operative mortality rate, which amounted to 1.75% in the facility studied, an incidence in agreement with the values described by the CQH. Regarding the patient profile, the findings showed a predominance of men, age group of 61 to 80 years, ASA III class, urgent surgeries, general surgery medical specialty, clean surgeries, and mean operative time of up to 120 minutes.

The topic addressed in this study is highly relevant given the scarcity of literature about it. This research allowed us to map the rate and characterization of operative mortality. These data may contribute to the situational diagnosis and the elaboration of strategies aimed at reducing this rate in the target population, improving the quality of care provided by the nursing staff and perioperative team as a whole.

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| ORIGINAL ARTICLE |

PROFILE AND LENGTH OF STAY OF INTENSIVE CARE PATIENTS ADMITTED TO THE POST-ANESTHESIA CARE UNIT

Perfil e tempo de permanência de pacientes intensivos assistidos na recuperação pós-anestésica

Perfil y estancia de pacientes intensivos asistidos en la recuperación postanestésica

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ABSTRACT: Objective: To identify the frequency, profile, and length of stay of intensive care patients admitted to the post-anesthesia care unit (PACU). **Method:** This is a retrospective cross-sectional study based on PACU admission records of a public hospital in Rio Grande do Sul, Southern Brazil, between July 2012 and June 2017. **Results:** In the study period, 22,333 patients were admitted to the PACU; 717 (3.2%) of them were intensive care patients due to the unavailability of beds in the intensive care unit. Among them, 67.6% were women, 61.2% were adults, and 61.5% were individuals submitted to neurosurgery. The mean length of stay in the unit was 10.7 hours, and 4.1% of patients died. **Conclusion:** The stay of intensive care patients in the PACU requires adapting the physical and operational structure of the unit, particularly in aspects related to the care team, including the number of personnel and the technical training necessary to ensure the quality of care.

KEYWORDS: Recovery room. Anesthesia recovery period. Postanesthesia nursing. Perioperative nursing. Critical care. **RESUMO: Objetivo:** Identificar a frequência, o perfil e o tempo de permanência de pacientes intensivos admitidos na sala de recuperação pós-anestésica (SRPA). **Método:** Estudo transversal e retrospectivo, realizado com base em registros de admissões na SRPA de um hospital público no Rio Grande do Sul, entre julho de 2012 e julho de 2017. **Resultados:** No período estudado, admitiram-se no setor 22.333 pacientes, sendo 717 (3,2%) pacientes intensivos por indisponibilidade de leito na unidade de terapia intensiva. Destes, 67,6% eram do sexo feminino, 61,2% em idade adulta, submetidos à neurocirurgia (61,5%). O tempo de permanência médio no setor foi de 10,7 horas, e 4,1% dos pacientes foram a óbito. **Conclusão:** A permanência de pacientes intensivos na SRPA requer adequação do setor em sua estrutura física e operacional, especialmente no que diz respeito à equipe assistencial tanto em quantidade de pessoal quanto em capacitação técnica necessária para assegurar uma assistência de qualidade.

Palavras-chave: Sala de recuperação. Período de recuperação da anestesia. Enfermagem em pós-anestésico. Enfermagem perioperatória. Cuidados críticos.

RESUMEN: Objetivo: Identificar la frecuencia, perfil y tiempo de estancia de los pacientes de cuidados intensivos ingresados en la Sala de Recuperación Posanestésica (SRPA). **Método:** Estudio transversal y retrospectivo, realizado a partir de los registros de ingreso en la UCPA de un hospital público de Rio Grande do Sul, entre julio de 2012 y julio de 2017. **Resultados:** En el período estudiado ingresaron al sector 22.333 pacientes, 717 (3,2%) pacientes de cuidados intensivos por indisponibilidad de camas en la Unidad de Cuidados Intensivos. De estos, el 67,6% eran mujeres, el 61,2% adultos, sometidos a neurocirugía (61,5%). La estancia media en el sector fue de 10,7 horas y falleció el 4,1% de los pacientes. **Conclusión:** La permanencia de los pacientes de cuidados intensivos en la SRPA requiere la adecuación del sector en su estructura física y operativa, especialmente en lo que se refiere al equipo asistencial, tanto en el número de personal como en la formación técnica necesaria para asegurar una atención de calidad.

Palabras clave: Sala de recuperación. Periodo de recuperación de la anestesia. Enfermería posanestésica. Enfermería perioperatoria. Cuidados críticos.

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INTRODUCTION

The post-anesthesia care unit (PACU) is designed to provide immediate care to patients under the effect of different types of anesthesia and surgery. To this end, the nursing team should be adequate and trained to provide this service, as sometimes highly complex care is necessary^{1,2}.

In this unit, the nurse ensures care until the patient has their vital signs stable, returns to full awareness, and recovers their protective reflexes, taking into account the surgical procedure and the type of anesthesia administered, in addition to inherent individual risks related to their clinical history³. However, the PACU has been currently used for intensive care patients after surgical procedures as a backup of the intensive care unit (ICU), since the high demand of critical patients is inversely proportional to the number of intensive care beds available. Other hospital departments have assumed this care while the patient waits for an ICU bed, causing them to stay hours or even days in the unit⁴.

PACU primarily provides assistance to patients requiring intermediate and semi-intensive care. Therefore, admitting and assisting critical patients demands a deeper reflection on how to ensure care with a clinical approach, considering not only the recovery from effects of the anesthesia-surgical procedure but also integrated care so as to provide a service suitable to the complexity of these patients⁵.

Bearing in mind that nursing care must be preceded by planning, knowing the profile and length of stay of intensive care patients in the PACU is paramount to understand its supply and demand and prepare the unit for both the physical and material resources and the workforce required, including ICU specialist nurses in its staff to ensure the quality of care for patients while they wait for an ICU bed^{4,6}.

OBJECTIVE

To identify the frequency, profile, and length of stay of intensive care patients admitted to the PACU.

METHOD

This is a retrospective cross-sectional study based on data collected in December 2017, whose information source was the records of intensive care patients admitted to the PACU

in a five-year period (July 2012 to June 2017). Data were collected in a 264-bed public hospital, a reference in the care for multiple-trauma patients in Rio Grande do Sul, Southern Brazil.

The hospital unit has six operating rooms (OR) in the main surgical center (SC) and one OR in the outpatient SC. On average, 525 surgeries are performed per month in the specialties of neurosurgery, traumatology, plastic surgery, vascular surgery, and oral and maxillofacial surgery. The PACU has 12 active beds and receives non-critical patients in the immediate postoperative (IPO) period, as well as intensive care patients who are waiting for an ICU bed.

The study variables analyzed were sex, age, surgical specialty, length of stay in the unit, and destination. Data were organized in an Excel spreadsheet and assessed by descriptive statistics and analysis of variance (ANOVA), considering p<0.05 as statistically significant.

Data were collected after approval from the Research Ethics Committee (REC) of the facility under study, under CAAE 78636917.8.0000.553, via Plataforma Brasil, according to recommendations of the National Health Council Resolution No. 466 from December 12, 2012⁷.

RESULTS

From July 2012 to June 2017, 22,333 patients were admitted to the PACU. Among them, 717 (3.2%) were intensive care patients who should have been admitted to the ICU immediately after the anesthesia-surgical procedure but who were admitted to the PACU due to the unavailability of ICU beds.

Table 1 presents the total number of patients and intensive care patients admitted to the PACU, according to month/year of admission, and Figure 1 shows the percentage of admissions of intensive care patients to the unit along the years.

Still on frequency, 2016 had the highest number of admissions (14.7 patients/month), and October presented the highest incidence of admissions over the years (17.8% of patients/month/year).

Table 2 reveals the main data regarding the profile of critical patients admitted to the PACU.

The length of stay of intensive care patients in PACU beds ranged from 30 minutes to 237 hours, with a mean stay of 10.7 hours. Table 3 shows the mean length of stay per month/year. We found an increasing trend in the mean

Table 1. Total patients and intensive care patients admitted to the post-anesthesia care unit per month/year (2012–2017).

Month	2012		2012 2013		20	2014 2015		15	2016		2017	
Month	TA	TI	TA	TI	TA	TI	TA	TI	TA	TI	TA	TI
Jan.	-	-	397	9	353	5	369	5	349	13	398	11
Feb.	-	-	373	11	315	3	311	8	340	9	314	15
Mar.	-	-	381	16	303	5	425	8	424	22	420	24
Apr.	-	-	426	7	303	5	378	13	352	20	303	9
May	-	-	470	18	358	5	381	15	388	14	418	8
Jun.	-	-	359	14	370	8	371	18	386	16	389	9
Jul.	377	03	381	24	403	6	401	23	334	9	-	-
Aug.	418	09	399	13	356	11	394	10	404	8	-	-
Sep.	354	12	353	4	315	11	396	18	335	17	-	-
Oct.	413	13	374	18	362	13	375	18	345	27	-	-
Nov.	380	12	360	8	320	7	386	24	350	13	-	-
Dec.	380	9	369	6	386	10	398	9	391	9	-	-
Total	2,322	58	4,642	148	4,144	89	4,585	169	4,398	177	2,242	76

TA: total admissions; TI: total of intensive care patients.

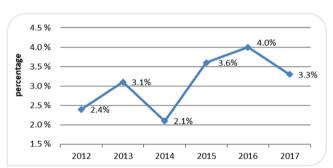


Figure 1. Percentage of admissions of intensive care patients to the post-anesthesia care unit per year (2012–2017).

length of stay during the study period, with no significant difference (p=0.510).

Concerning the patients' destination, 687 (95.8%) were transferred to the ICU when a bed became available, while 30 (4.1%) patients died in the PACU.

DISCUSSION

The deficit in ICU beds is considered a reality in the Brazilian scenario, corroborating the findings of this research, which presents a significant number of admissions of critically ill

Table 2. Characterization of the sample of intensive care patients in the post-anesthesia care unit, according to sex, age, and surgical specialty (n=717).

Variable	N	%		
Sex				
Female	485	67.6		
Male	232	32.4		
Age group (years)				
4–11 (children)	6	0.8		
12–18 (adolescents)	40	5.6		
19–59 (adults)	439	61.2		
60–97 (older adults)	232	32.4		
Surgical specialty				
Neurosurgery	441	61.5		
General surgery	168	23.4		
Orthopedic surgery	65	9.1		
Vascular surgery	21	2.9		
Plastic surgery	11	1.5		
Oral and maxillofacial	9	1.3		
Major burn surgery	2	0.3		
Total	717	100.0		

Table 3. Mean length of stay (in hours) of intensive care patients in the post-anesthesia care unit per year (2012-2017).

Month	2012	2013	2014	2015	2016	2017
January	-	11.4	5.8	11.8	8.3	11.4
February	-	15.8	8.6	6.7	5.4	17.1
March	-	13.0	11.4	7.7	18.9	15.0
April	-	8.2	15.6	16.8	11.2	14.6
May	-	10.5	6.0	9.0	14.2	21.2
June	-	10.0	5.6	14.1	18.6	8.3
July	7.6	13.2	20.8	15.0	14.3	-
August	10.2	15.0	8.1	15.6	5.1	-
September	11.0	7.5	27.5	12.2	17.5	-
October	11.7	8.2	21.3	18.1	24.5	-
November	8.2	14.6	15.5	12.0	10.6	-
December	10.0	8.8	5.6	13.2	16.7	-
Annual mean	9.8	11.4	12.7	12.7	13.8	14.6
Mean length of stay: 10						

patients to the PACU, with similar averages over the months and years studied, evidencing that this is not an isolated event^{5,8}.

Regarding the patient profile, this study showed a prevalence of biologically female individuals, differing from national data, which indicate that the male sex is more affected by external causes and more prone to intensive care hospitalization⁹⁻¹². According to data from the Mortality Information System (*Sistema de Informação de Mortalidade* – SIM) and demographic data from the Technology Department of the public health system (*Departamento de Informática do Sistema Único de Saúde* – Datasus), women are more vulnerable to deaths caused by traffic accidents and violence¹³.

As to the age group of patients, most of them were adults, a life stage with a higher incidence of accidents and situations related to urban violence, attributed in special to the aggressive and risk behavior of men, who are almost five times more likely to die early, that is, for each woman, approximately five men die in Brazil¹³.

Older adults comprise the second critical group most admitted to the PACU due to the aging process associated with chronic degenerative diseases and to domestic accidents, such as falls. The care given to the older surgical patients should be different from that provided to other age groups, especially when it comes to issues related to changes caused by the aging process and by the presence of associated diseases that may lead to functional impairment, increasing the vulnerability to postoperative complications¹⁴.

Neurosurgery was the specialty responsible for most hospitalizations of intensive care patients in the PACU in this study. This finding is justified by the fact that the neurosurgery service of the facility investigated is considered a state reference in high complexity procedures, with 45% of the patients admitted to the hospital. In addition to performing an average of 900 surgeries per year, it has the differential of maintaining a relationship with other specialized services, providing comprehensive care that involves 25 neurosurgeons and other professionals of the multidisciplinary team¹⁵.

The length of stay of intensive care patients showed great variation, corroborating the findings of another study conducted in the state of São Paulo, which presented an even higher variation: between 3 and 384 hours, with a mean stay of 41.4 hours², a value also superior to the mean stay identified in this research and much higher than the mean length of stay of patients in the IPO period or who require non-intensive care, which is only 1.8 hours⁸.

When comparing care with the length of stay in hours, we found that intensive care patients have a significantly higher mean length of stay and require more complex care than patients in other categories⁴.

Thus, the admission and stay of severe patients in the PACU negatively affect the team, since the intensive care patient, in addition to presenting functional instability of organic systems, leading to situations of imminent emergency and constant attention that are common for patients in the IPO period, also requires multiple invasive procedures¹⁶, producing a high level of stress in the team that works in the PACU^{2,4,8}.

Critical patients in backup beds need procedures that are not part of the PACU routine, which is characterized by low-or moderate-complexity care. These procedures include the administration of enteral diets and drugs by infusion pump, bed bath, prevention of pressure ulcers, and change in position, which are carried out by a team of nursing technicians, while the nurse provides highly complex care, such as catheterization, placement of the arterial line, large dressings for surgical wounds, among others^{2,8}.

In this scenario, personnel distribution must transcend merely mathematical issues and be planned from a qualitative perspective. Thus, we stress the need for a flexible systematization of care¹⁷, mainly because the presence of critical patients is not constant, and the length of stay varies, preventing the nurse from creating a fixed scale. We also emphasize the importance of having a nurse in the PACU at all times, which is not always a reality in many Brazilian facilities⁸.

In this regard, the Brazilian Association of Surgical Center, Anesthesia Recovery, and Sterile Processing Department Nurses (Associação Brasileira de Enfermeiros em Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização – SOBECC) recommends that PACU have one nursing technician for every three patients and an attending nurse for every eight beds of patients not dependent on respirators or three to four critical patients¹⁸.

When critical patients stay in the PACU, they directly impact the unit routine, demanding an appropriate number of workers available for care, as well as the technical qualification of such professionals. Some nursing professionals have reported feeling unprepared to assist critical patients and required adequate training for the work and the handling of specific equipment. In addition, PACU might not have an adequate physical environment to receive patients in isolation, for instance, and/or lack ICU-specific material resources and equipment, impacting the quality of care provided⁸.

We can also mention the lack of or delay in care by members of the multidisciplinary team, such as occupational therapists, physical therapists, and an intensivist monitoring the patient 24h/day. The difficulties may be aggravated by the presence of relatives during visiting hours, increasing the circulation of people in the unit⁸.

Concerning the destination of severe patients, the vast majority was transferred to the ICU, but part of them died

in the PACU, an atypical situation in the daily routine of the unit. Death in the PACU has two negative aspects: first, the emotional shock in workers engaged in saving lives, which can produce feelings of failure^{19,20}, and second, technical and operational issues. Procedures such as preparing the body, filling forms, transferring the body to a proper location, and contacting the family to communicate the death demand staff time, leaving other patients in the IPO period unassisted⁴.

This study presents limitations since it was developed in a specific region of Brazil. Therefore, we emphasize the importance of new studies on the theme in different regions of the country, where the use of the PACU as an ICU backup has become routine, in order to know the strategies used by these facilities to adapt the environment, the material and technological resources, and the nursing and multidisciplinary team for the safe and humanized care for critical patients.

CONCLUSION

In this study, 717 critical patients were admitted to the PACU over a 5-year period, with greater frequency in October of each year and in 2016 as a whole. The patients were mostly women, adults, and individuals submitted to neurosurgery. The mean length of stay of patients in the PACU was 10.7 hours.

These results indicate the PACU as an alternative to admit and assist intensive care patients after surgical procedures when ICU beds are unavailable, even though the unit is not primarily designed for this type of care.

The care for critical patients differs from the routine experienced in the PACU, which focuses on postoperative complications with high bed turnover. The unit also lacks structural conditions to ensure the privacy of patients in situations such as death.

This type of care, albeit sporadic, requires adjusting the physical environment of the unit, the amount and proper operation of materials and equipment, and the sufficient number of nursing professionals, as well as their adequate technical qualification, in addition to the constant presence of a nurse and an intensivist to provide support in any situation.

The long length of stay of intensive care patients is a constant reality in the facility investigated and has become common in other Brazilian contexts, showing that these institutions need to reorganize their care and administration without overworking the professionals involved in the service or harming the patients under their care.

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REVIEW ARTICLE

REUSE OF SINGLE USE MEDICAL DEVICES AND IMPLICATIONS FOR PATIENTY SAFETY

Reúso de dispositivos médicos de uso único e implicações para a segurança do paciente

Reutilización de dispositivos médicos de uso individual e implicaciones para la seguridad del paciente

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ABSTRACT: Objective: to describe aspects of the reuse of single-use medical devices and implications for patient safety. **Method:** academic essay, using integrative review data and author's expertise. **Results:** the reuse of single-use products is a worldwide reality and causes regulatory, technical, economic, ethical and patient safety debates, denoting several interests of the different actors involved: State, manufacturers, health services, academia, professionals and users. Although there is a theoretical risk, data do not identify a causal relationship between adverse events and reuse of these products. There are arguments for and against and are involved: risks and benefits, distributive and social justice. The label of these products represents a critical node and fomenting element of the dilemmas that permeate this practice. **Conclusion:** There is consensus that the reuse of a medical product should have the same safety standard, regardless of whether labeled as single-use or multipurpose. Some so-called single-use products can be safely reused, but this practice requires organo-structural conditions of health services, as well as expertise, adoption of protocols and supervision of these activities. Keywords: Medical device. Risk-taking. Patient safety.

RESUMO: Objetivo: Descrever aspectos do reúso dos dispositivos médicos de uso único e as implicações dessa prática para a segurança do paciente. **Método:** Ensaio acadêmico, utilizando dados de revisão integrativa e expertise da autora. **Resultados:** O reúso de produtos de uso único é realidade mundial e ocasiona debates regulatórios, técnicos, econômicos, éticos e de segurança do paciente, denotando diversos interesses dos distintos atores envolvidos: Estado, fabricantes, serviços de saúde, academia, profissionais e usuários. Embora haja risco teórico, dados não identificam relação causal entre evento adverso e reúso desses produtos. Existem argumentos a favor e contra que compreendem riscos e benefícios e justiça distributiva e social. O rótulo desses produtos representa nó crítico e elemento fomentador dos dilemas que permeiam essa prática. **Conclusão:** Há consenso de que o reúso de um produto médico deve ter o mesmo padrão de segurança, independentemente se rotulado como de uso único ou de multiuso. Alguns produtos ditos de uso único podem ser seguramente reusados, mas essa prática requer condições organoestruturais dos serviços de saúde, além de expertise, adoção de protocolos e supervisão dessas atividades. Palavras-chave: Dispositivos médicos. Exposição ao risco. Segurança do paciente.

RESUMEN: Objetivo: Describir aspectos de la reutilización de dispositivos médicos de un solo uso e implicaciones para la seguridad del paciente. Método: ensayo académico, utilizando datos de revisión integradores y la experiencia del autor. Resultados: La reutilización de productos de un solo uso es una realidad mundial y provoca debates regulatorios, técnicos, económicos, éticos y de seguridad del paciente, que denotan diversos intereses de los diferentes actores involucrados: Estado, fabricantes, servicios de salud, academia, profesionales y usuarios. Aunque existe un riesgo teórico, los datos no identifican una relación causal entre el evento adverso y la reutilización de estos productos. Hay argumentos a favor y en contra y están involucrados: riesgos y beneficios, justicia distributiva y social. La etiqueta de estos productos representa un nodo crítico y un elemento que fomenta los dilemas que impregnan esta práctica. Conclusión: Existe un consenso de que la reutilización de un producto médico debe tener el mismo estándar de seguridad, independientemente de si está etiquetado como de uso único o multipropósito. Algunos de los llamados productos de un solo uso pueden reutilizarse de manera segura, pero esta práctica requiere condiciones organoestructurales para los servicios de salud, además de experiencia, adopción de protocolos y supervisión de estas actividades. Palabras clave: Dispositivos médicos. Asunción de riesgos. Seguridad del paciente.

INTRODUCTION

Medical devices represent a significant portion of the hard technologies used in healthcare services, and are used to diagnose, treat, or prevent diseases. These devices, widely used in all healthcare fields, are defined by manufacturers as reusable or single-use items. Reusable devices are considered to be durable goods, and their reuse requires reprocessing, which is a multistep process that consists in converting a contaminated product into a ready-to-use device¹.

Single-use products are designed to be used only once, with a single patient. These products emerged with the advent of the plastics industry and gained popularity due to, among other reasons, the growth of infections caused by the human immunodeficiency virus. As a result, many healthcare products, which were initially manufactured as reusable, started being manufactured with low-cost plastic polymers, being disposable after a single use, which brought great economic benefit to manufacturers¹.

Regardless of the manufacturer's label, the practice of reusing single-use products is a worldwide reality, which began in the 1970s. Since then, there have been reports on the reuse of such products in several countries worldwide, even in developed nations, especially in those where reprocessing is forbidden^{2,3}. This trend has intensified several debates and considerations on patient safety, informed consent, technical, economic, environmental, legal, and ethical issues, and regulatory aspects for manufacturers and those who perform reprocessing, denoting different interests on the part of the political actors involved: State, manufacturers of goods, healthcare services, academia, healthcare professionals, trade associations, and users⁴⁻⁹.

There are many arguments that advocate for and against the reuse of single-use products^{1,4}. According to the favorable ones, the positive impacts on costs and the environment are justified, since they reduce the volume of waste generated from health care. Critics of reuse argue that these products are not designed for multiple uses and that reuse may pose a risk of transmitting infections and endotoxins, lack of functional reliability, loss of product integrity, or bioincompatibility⁴⁻¹⁰.

Although the reprocessing and reuse of single-use products pose a theoretical risk to health, clinical evidence show that certain products can be safely reprocessed. Nevertheless, this does not mean that the reprocessing of these products is always safe^{11,12}.

Accordingly, this study aims to answer the following guiding question: Is the reuse of single-use medical devices harmful to the safety of patients using these products?

OBJECTIVE

To describe historical and current aspects about the reuse of single-use products and the implications of this practice for the safety of the patient using these materials, in order to contribute to the analysis of emblematic issues related to the reuse of these devices.

METHOD

This is an academic essay conducted with the use of data from an integrative literature review, a method that allows the synthesis of results from studies with different methodologies, with no harm to the epistemological affiliation of these results. The study consists of five steps: problem formulation, data collection, data analysis, synthesis, and dissemination of results¹³.

The studies were obtained from the Virtual Health Library (VHL) portal, which includes searches in the following databases: Latin American and Caribbean Health Sciences Literature (LILACS), Spanish Bibliography Index of Health Sciences (IBECS), National Library of Medicine/NLM (MEDLINE), The Cochrane Library, Scientific Electronic Library Online, National Library of Medicine/NLM (PubMed), and Web of Science.

The used health sciences descriptors were: reprocessing single use medical device, reuse single use medical device, risk of reuse single use medical device, risk of reuse single use medical device, with the assistance of the Boolean operator "AND."

The inclusion criteria were: articles written in English, Spanish, and Portuguese, which addressed the topics of risk, reprocessing, and reuse of single-use products, with no restriction on publication time. The exclusion criteria were: articles on reuse and reprocessing of products in hemodialysis services and in dental services, and those published in other languages.

The data search was done online, from October to December 2017, obtaining 870 articles. After reading the title and the abstract, according to the established criteria, 827 articles were excluded and 20 were selected, among which some were cited in the references of the selected articles, composing the total of studies included in this study.

After selection, articles were read and analyzed using a data collection instrument that included: authors' names, title of the article, references, objectives, materials and methods, results, and conclusion.

In this study, the term "medical device" is used as a synonym for healthcare product, equipment, material, and medical commodity, in accordance with the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária do Brasil* – ANVISA). The terms "reprocessing" or "product processing" are also interchangeably used, despite considerations about the differences between them.

RESULTS AND DISCUSSION

Reuse of single-use products and implications for patient safety

The practice of reprocessing and reusing single-use products has been essentially studied from an ethical point of view ("should it be done?") and from a technical point of view ("how should it be done?")³. In this sense, there are many publications whose authors suggest safety and efficacy in the reuse of disposable products, especially in the field of cardiac intervention procedures; however, these studies vary in methodology and quality, which makes it difficult to reach consensus on the reuse of these products. Furthermore, information on adverse events related to medical products is often voluntary and, therefore, is underreported and may not represent all cases^{2,5,8,11,12,14}.

In 1990, the Food and Drug Administration (FDA), of the United States of America (USA) undertook a study on the safety of the reuse of single-use products and concluded that the pattern of adverse events of patients exposed to the reuse of these products does not depend on being single-use or multipurpose^{2,5,11}. In 2008, the United States Government Accountability Office (GAO) stated that there is no causal relationship between injuries and deaths of patients and the reuse of single-use products¹¹.

Thus, there is not enough data, neither from the FDA, nor from other studies, on the safety of reprocessed single-use products when compared with original ones^{8,11,15,16}. For such a comparison, it would be necessary to identify the types of products and adverse events, the control number of the original single-use products informed by the manufacturer and of the service when it is reprocessed, the number

of times each single-use product has been reused, and the rate of adverse events associated with the original product¹¹. The FDA has analyzed data on adverse events related to reprocessed single-use products, and has not identified a causal association between the adverse events and reprocessed single-use products¹¹.

Some international organizations have taken a stand on the reuse of single-use products.

The US Center for Disease Control and Prevention (CDC) take a positive position on the reuse of single-use products, and states that these products are not harmful if properly cleaned and sterilized⁵.

The European Medical Technology Industry Association opposes the reuse of single-use products, and states that patient safety is threatened when these products are reused due to the risk of cross-infection transmission, inability to clean these devices, presence of waste, alteration of material's components, mechanical failure, among other arguments¹⁵⁻¹⁷.

The European Association of Medical Devices Reprocessors (EAMDR) convoked member states to analyze how European regulations are implementing the reuse of these products, and states that the "high quality of product reprocessing in all member states can only be guaranteed if performed regardless of the label chosen by the manufacturer" ¹⁵⁻¹⁸, a statement that prioritizes the quality of the process, regardless of the product, whether single-use or not.

For the Joint Commission International (JCI), if a hospital decides to reuse single-use products, it must critically assess the conditions of the products cleaning, disinfection, and sterilization department, as well as its procedures and personnel⁸.

According to the World Health Organization (WHO), the reuse of single-use products requires registered formulated policies, and critical and semi-critical products should only be reused by a licensed reprocessor⁸.

For experts, such as professors Axel Kramer and Marc Kraft, from the Medical Technology department in Berlin, "the crucial criterion is that there is a validated procedure for reprocessing a medical product. Whether the product is multipurpose or single-use is irrelevant." For Marc Kraft, "the validation of the reprocessing procedure tends to disregard an increase in risk." In this case, there are no hygienic-related or technical-functional threats⁵.

According to the International Federation of Infection Control, five questions must be positively answered by reprocessors in such a way the reuse of disposable products can be considered safe:

- Does the product remain intact and functional?
- Is it cleanable?
- Can it be sterilized?
- Is reuse cost-effective?
- Who will be responsible if an adverse event occurs?^{8,19}

It is not recommended for single-use products to be reused and reprocessed if:

- it cannot be properly cleaned;
- the sterility of the reprocessed product cannot be safely demonstrated;
- the integrity, functionality, and safety of the reprocessed single-use product differ from the original one.

The safety and effectiveness of the reprocessing of single-use products must be conducted according to standardized and monitored processes, with the same quality assurance as the original products^{2,5-6,8,16}.

There are three practices concerning single-use products that involve discussions about reuse and different conducts adopted by many services:

- single-use products opened, but not used;
- single-use products placed on an operating table, but not used:
- single-use products opened and used on a patient.

Authors argue that open and unused single-use products should be eligible for reuse without discussion. Others defend that each practice requires careful consideration²⁰.

The number of times single-use devices can be reused is also a challenging situation concerning patient safety. Authors state that the maximum sustainable reuse of a disposable product is a fundamental parameter and should be evaluated through physical, chemical, and microbiological analyses in addition to functional testing^{2,12}. This situation can be equally applied to multipurpose products, since they also cannot be indefinitely reprocessed and reused²⁰.

Regarding labels, the statement that the product is single-use or multipurpose is only based on the manufacturers' decision, who qualify a product as single-use for two reasons: because they believe the product is neither safe nor reliable to be used more than once, or because they choose not to conduct the necessary studies to demonstrate that the product can be labeled as reusable. Hence, there is a lack of consistent considerations regarding the definition of single-use by manufacturers^{2,4,5,8,11,16}.

When a medical product is registered as a single-use product, it only means that it can be safely and reliably used once; however, it does not imply that it cannot be safely used more than once, if properly reprocessed. It is worth noting that manufacturers often change labels of reusable products into single-use ones, sometimes without any significant change in design, performance, or material that could compromise safe reuse¹⁵.

Moreover, products can be manufactured in a similar way and differently classified according to the manufacturers' choice, who benefit from the single-use label, since products defined so do not require the same degree of documentation and validation to be registered in regulatory agencies, as opposed to products classified as multipurpose. In addition, regulatory agencies do not require manufacturers to provide evidence that the single-use product cannot be reprocessed, and that reuse may be inappropriate or harmful^{2,4,11,13,15,19}.

In practice, most single-use products are reusable in technological terms. It is estimated that from 10 to 20% of products classified by manufacturers as single-use can be reprocessed a limited number of times¹⁶. Regarding the manufacturers, researchers argue that many single-use products can be safely reprocessed and reused in hospitals^{4,5,16,20}.

The stipulation that single-use products cannot be reused makes healthcare systems and the society financially dependent on what is said by the manufacturers². Some authors are challenging the assumptions that single-use products are strictly developed for a single use, not only due to financial considerations, but also environmental ones^{2,20}.

In Brazil, a study carried out by researchers of the Brazilian Society of Cardiac Arrhythmias on the labels of single-use products registered by manufacturers at ANVISA identified that, of the 121 medical products used in electrophysiology procedures and registered as single-use, 86 (71.7%) labels were in compliance with the regulations in force, and 34 (28.9%) were not. The authors concluded that inconsistencies in the labels of these products can lead to interpretation errors and improper decisions in relation to their use²¹.

Other complex issues are also important and worthy of discussion regarding the reuse of single-use products:

- The issue of informed consent, which concerns the patients' autonomy in choosing what is best for them;
- Fiscal responsibility for promoting the disposal of a product that can be safely reused;
- Ethical behavior in relation to the environment and the communities where we live.

Thus, the question to be asked is: are we behaving ethically in relation to the environment and the communities where we live by promoting the single use of a product that can be reused^{14,20}?

The analysis of these issues can be done considering the Principlism Theory, or the theory of the four principles, which has greatly contributed to providesolutions in terms of individual and collective ethics: beneficence (obligation to do good and to act for the patients' and the community's best interests), non-maleficence (obligation not to cause harm to patients), autonomy (obligation to respect the individual's will), and justice (a principle that values the appropriate allocation of resources and the need to decide what and who should have prioritized access to goods deemed as finite and scarce). However, these principles, although clear and accessible, also present difficulties in their operation when it comes to the reuse of so-called disposable products: Which patient should receive a single-use product that has never been used and which should receive a reused and reprocessed product? Who is responsible for this decision? Are patients able to choose or should they be informed^{4,16}?

The legal responsibilities are obvious, and healthcare institutions must take responsibility for the reuse of single-use products, since it goes against the manufacturers' instructions, when they, by labeling the product as single-use, are only responsible for the quality and effectiveness of the such solely according to their recommendations^{8,14,16}.

Another aspect regarding the reuse of these products concerns distributive and social justice, which requires the distribution of burdens and benefits among all patients¹². According to the literature, there are many risks related to the reuse of multipurpose products as well and, in this sense, focusing only on the reuse of disposable products diverts attention to the process of decontamination of the so-called reusable products, which, *a priori*, require the same quality and safety standards. Therefore, the safe reuse of single-use products, aiming at improving access to health care, seems to be ethically justified as an attempt to generate conditions of equal opportunity and access to health care and well-being.

Synthesis of the results

This study addressed several emblematic issues regarding the reuse of medical devices, both from a technical-operational point of view and from an ethical, legal, and environmental perspective. According to the published data, authors question such reuse based on technical considerations. Several researchers suggest safety and efficacy in reuse for many products labeled as single-use, and no causal association between harms to the patient and the fact that the single-use product is reprocessed¹¹; however, it is also evident that some single-use products are not safe for reprocessing and reuse, given the impossibility of cleaning and sterilization, a condition also applied to the reuse of products classified as reusable.

In this sense, the decision to use a product, regardless of the single-use or multipurpose labels, requires standardized, validated, and monitored processes to guarantee quality and minimize risks for patients using reprocessed products.

In addition to the proposed issues, labels of single-use products represent a critical node and the fomenting element of dilemmas that permeate the reuse of these products.

The lack of studies, at the time of registration, whose authors prove that a product registered as single-use cannot be reprocessed and that reuse may be inappropriate or harmful to the patient, not only makes the definition of single-use inconsistent, but also creates a conflict situation for regulatory agencies and healthcare services whose authorities follow the manufacturers' instructions.

Thus, demystifying the label of these products is crucial for regulatory decision-making and its consequences. Are products registered as single-use in fact unsafe for reuse or does the manufacturer have other reasons for this label?

This issue is the key point concerning the reuse of medical products. The focus of regulatory policies should be on standardization systems of processes developed for the reuse of healthcare devices, in such a way that manufacturers would not be responsible for classifying the products, considering that, even products classified as reusable, cannot be continuously reused, despite this indication.

FINAL CONSIDERATIONS

The reuse of products stipulated as single-use involves many issues, starting with their very dubious label.

There are reasons for manufacturers to choose this alternative, and authors of studies show that the reuse of these products, when properly carried out, can be safe for the patient, allowing effective health treatment and cost reduction of medical products.

Furthermore, it is worth considering ethics in relation to the environment — land ethic — and, in this growing

profusion of waste disposal, the reuse of single-use products is deemed one of the best practices for environmental protection.

There is still room for this topic to be investigated as for technical, ethical, economic, environmental, and regulatory issues. It is also necessary to understand that some products classified as single-use can be reused, but this practice requires organo-structural conditions of healthcare services, in addition to expertise, adoption of protocols, and supervision of each of the reprocessing steps.

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