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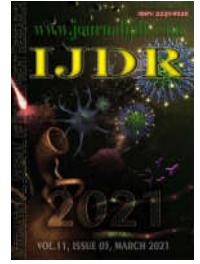
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RESEARCH ARTICLE

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PATIENT SAFETY IN INTENSIVE CARE: DEVELOPMENT AND VALIDATION OF SAFE ICU PROTOCOL

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ABSTRACT

For the World Health Organization (WHO), patient safety can be defined as the reduction of unnecessary risks and damages to an acceptable minimum, and patient care practices are closely related to this process. **Objectives:** To determine the healthcare actions that should make up a safe ICU protocol; Develop a safe ICU protocol; Validate a safe ICU protocol. **Method:** Methodological study. Initially, a systematic review of the literature was performed, which sought to know the risks to the quality and safety of patients in intensive care and to support the construction of the protocol. After the conclusion of the systematic review, the Safe ICU Protocol was created, which was validated through the Delphi Technique, in 3 stages. The first round was attended by a panel of 15 specialists from 5 professional categories, doctors, nurses, physiotherapists, psychologists and nutritionists, who analyzed the consistency, relevance and clarity of the protocol items. The second stage, composed of the judgment of 5 specialists, one from each professional category, conducted the qualitative judgment of the protocol. Finally, the third stage consisted of 46 participants who answered a final questionnaire on the relevance and applicability of the protocol, analyzed quantitatively. **Results:** The protocol obtained a general average of 95.9% of consensus among the participants. **Conclusion:** The average consensus obtained demonstrates the relevance of building the protocol for promoting patient safety in the ICU and its practical applicability.

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INTRODUCTION

Historically, the results of the Harvard Medical Practice Study, conducted in 1991, and publication "To Err is Human" of the Institute of Medicine (IOM) in 1999, are highlighted as important milestones from which the concern with the emergence of patient safety emerged. These studies have shown that the occurrence of adverse events (AE) results in irreversible damage to patients and their families, with a considerable number of annual deaths in the United States resulting from these¹. For the World Health Organization (WHO), patient safety can be defined as the reduction of unnecessary risks and damages to an acceptable minimum, and patient care practices are closely related to this process. Recognizing the magnitude of the problems related to this scenario, in 2004, WHO established the World Alliance for Patient Safety², which was created with the objective of defining and identifying priorities in the area of patient safety at a global level and stimulating the development of

research in the field¹. In Brazil, in 2013, the National Patient Safety Program (PNSP) was instituted by the Ministry of Health (MS), in which, through the implementation of risk management and Patient Safety Centers in health establishments, we seek to the incorporation of assistive, educational and programmatic actions in the daily practice of healthcare in order to reduce events that can lead to any type of damage to the client³. Currently, it is observed that more than half of the adverse events reported in Brazil are classified as preventable. It is necessary to develop a culture of safety, which must incorporate individual and collective values, attitudes, skills and behavior patterns, in addition to confidence in the effectiveness of preventive measures, which are decisive for the commitment to a healthy and safe organization^{1, 3}. Thinking about this reality, the Intensive Care Unit (ICU), being the destination of patients with a high level of severity, is considered the unit where most adverse events and incidents occur, as patients require complex intensive care, becoming more vulnerable to failures in health care. It is evident in the literature that several factors are related to the occurrence of

AE, among which are the characteristics of the environment and the safety culture present in the institution⁴. The critical clinical conditions of the ICU patient, and the constant instability that can lead to the rapid deterioration of bodily functions, significantly increase the risks, the constant vigilance of risk factors being essential to avoid undesirable events⁵. Regarding the Intensive Care Unit, the goal is to achieve the best possible outcome within the clients' severity conditions, although ensuring the safety of critically ill patients is one of the biggest challenges for the healthcare team, since the ICU environment provides patients with the daily performance of numerous procedures, among which there are activities that predispose to a higher risk of errors, potentially capable of causing harm. Given these hostile characteristics of the intensive care environment, risk management with an educational focus is essential for the implementation of preventive barriers at all care interfaces⁵. The Intensive Care Units are intended for the care of critical patients, who need continuous and uninterrupted care, which requires not only technological apparatus, but also highly specialized human resources and who must be free from risks related to possible adverse events⁶. This study is justified by the imminent need for discussion on the strengthening of the safety culture in complex areas of the hospital environment and the promotion of a safe environment and quality care in intensive care units, given the lack of a protocol for Safe ICU, based on the needs of the critical patient and constant educational actions for the health team. As a research question: "Is it feasible for a safe ICU protocol to be a quality and safety instrument for critically ill patients?" The objectives of this study were: To determine the health care actions that should make up a safe ICU protocol; Develop a safe ICU protocol; Validate a safe ICU protocol.

METHODS

This is a methodological study. To elaborate the safe ICU protocol proposed in this study, a systematic review was carried out to raise the greatest risks that permeate the routine of care for patients admitted to intensive care units, covering situations of potential and / or real risk for iatrogenesis. From this survey, a pilot protocol was built, which was sent to a panel of experts, with the aim of evaluating its content, as to its reliability and practical applicability, with a view to validation. In the methodological trajectory of the research, the Delphi technique supported the validation steps of the proposed protocol. The technique consists of questionnaires that are answered sequentially, individually by the participants, based on the summary information from the group's responses to the previous questionnaires, making a kind of dialog between the participants of the different stages, gradually building a collective response⁷. To accomplish this process, validation occurred in 3 stages, the first of which was the identification of the actual and potential risks inherent in the care of the ICU, patient, through a systematic review registered in Prospero under number 42019108255. From this survey, a pilot protocol covering the risks highlighted in the literature was created and qualified by a group of experts. These experts were selected according to the following criteria: Being a professional with a degree in healthcare; composing the multidisciplinary team of the NICU; Being part of the strategic planning of patient care in the NICU. The sample was composed of 3 nurses, 3 physicians, 3 physical therapists, 3 nutritionists, and 3 psychologists, with an $n = 15$ for this phase. It should be noted that for this phase, each professional received only the protocol items corresponding to their professional category, added to those of interdisciplinary characteristics. In this way, the experts judged only the protocol content that pertained to their professional expertise. The protocol was then reformulated (Beta Version) according to the considerations pointed out by the experts in the previous step. The second stage was performed after the reformulation of the protocol, when a professional from each professional category, ($n = 5$), being a nurse, a doctor, a physiotherapist, a nutritionist and a psychologist performed the analysis of the second version of the protocol, participating semi-structured interview about its content. An interview was scheduled with those who agreed to participate, which contained a brief questionnaire regarding the demographic data and followed a semi-

structured script with 4 open questions. The objective of this stage was for professionals to analyze the content of the protocol from a multi-professional perspective and judge the applicability and relevance of the content. Finally, the third and final step took place with the construction of the final version of the protocol, which was posted on Google Forms, Google's open tool, which allows the submission of an online questionnaire, and was sent to health professionals with experience in the ICU to judge its practical applicability. The approach of these professionals took place through the sending of emails and messages in the Whatsapp application, using the "snowball" technique. Those who agreed to participate in the research by signing the informed consent form were sent the protocol in its final version, containing a questionnaire for socio-demographic data and three objective questions for each item of the protocol, so that the participants could assess the applicability of the content in practice, the relevance to patient safety and the contribution to the care of patients admitted to the ICU. The research was conducted with the approval of the project by the Research Ethics Committee (CEP), of the institution of origin, under opinion numbers 3.049.049 and 3.059.407, as recommended by Resolution 466/12 of the National Council of Health⁸.

RESULTS

The construction of the safe ICU protocol was designed based on the main adverse events related to the intensive care environment that emerged from a systematic review, namely: ventilator-associated pneumonia - VAP, unscheduled device traction, delay or failure to perform diagnostic procedures, pressure injuries - PPI, adverse events associated with medication errors, healthcare-related infections - HAI, which included urinary tract infections - UTI, primary bloodstream infections, and surgical site infections, falls, and phlebitis. Based on the above adverse events, checklists for safe admission, safe shift, and patient-centered multi-professional visits, the assignments of each professional category to prevent each of these adverse events, and finally, general preventive measures to minimize their incidence were prepared. The Alpha version was submitted to expert review and the results of the first validation phase are presented in Table 1. It is important to note that the items prevention of VAP and prevention of phlebitis had a smaller number of experts who evaluated them, since not all professional categories had actions described in the prevention of these adverse events and the experts received in this phase only the items that contained assignments intended for their professional category. In addition to evaluating the quantitative data for this phase using simple statistical methods, the adaptation suggestions proposed by the experts were considered, and subsequently the beta version of the safe ICU protocol was constructed. The beta version was subjected to 5 cognitive interviews, and the data obtained in this phase show the experts' consensus on the relevance of the protocol's content and its relevance to patient safety. The qualitative analysis performed in this phase allowed the identification of the following content categories: Relevance / difficulties in the application of protocols for patient safety; quality management: standardization of conducts in intensive care; lack of unified and interdisciplinary protocols for patient safety in the ICU; communication as a strategy to prevent adverse events; team in favor of the same focus: the patient - human beings caring for human beings; different perspectives on safety items in the multiprofessional team and continuing education actions as a strategy to promote patient safety. After analysis by the second panel of experts, the Beta version of the protocol was submitted to the judgment of 46 health professionals with experience in intensive care, who judged its content regarding relevance to patient safety, practical applicability of the items, and contribution to the safety of critically ill patients. The data obtained in this phase show that the average item acceptance reached a consensus higher than 91% in all items, the overall average consensus among experts was 95.9% after the last validation phase, demonstrating the relevance of the protocol construction for the promotion of patient safety in the Intensive Care Unit and the continuous improvement of the health team's care practices.

Table 1. Results of the first stage of validation of the safe ICU protocol

Protocol item	Qualification of experts						
	Clarity		Pertinence		Coherence		Total experts
Interdisciplinary Items							
Bed identification model	n=15	100%	n=15	100%	n=13	87%	15
Safe admission flowchart	n=14	93%	n=14	93%	n=11	73%	15
Flow chart of safe shift changeover	n=15	100%	n=15	100%	n=14	93%	15
General preventivemeasures							
Active search	n=15	100%	n=15	100%	n=15	100%	15
Permanent Education	n=15	100%	n=15	100%	n=15	100%	15
Assessment of delirium	n=14	93%	n=14	93%	n=13	87%	15
Dimensioning of the multidisciplinary team	n=15	100%	n=15	100%	n=14	93%	15
Tasks of the multiprofessional team							
Ventilation-associated Pneumonia Prevention	n=12	100%	n=12	100%	n=11	91%	12
Prevention of unscheduled device traction	n=13	87%	n=13	87%	n=13	87%	15
Prevention of delay or failure to perform diagnostic methods	n=11	73%	n=11	73%	n=11	73%	15
Pressure injury prevention	n=15	100%	n=15	100%	n=13	87%	15
Prevention of medication errors	n=15	100%	n=15	100%	n=15	100%	15
Prevention of healthcare-related infections	n=15	100%	n=15	100%	n=14	93%	15
Fall prevention	n=14	93%	n=14	93%	n=14	93%	15
Phlebitis prevention	n=6	67%	n=6	67%	n=8	89%	9

Source: Research data, 2019.

DISCUSSION

It can be identified in the specialists' speeches, that even after a long period of work with intensive care professionals may have doubts about safety actions, or even, not pay attention to these issues due to the complex routine of ICUs. It can also be learned that the team considers the use of scripts and checklists as positive strategies to promote quality in intensive care. Corroborating the above statement, a 2016 study highlights that team training and empowerment practices and the use of protocols and checklists intended for their interventions support safer and more efficient professional practice, and higher quality for the patient⁹. Currently, not all sectors of a hospital have their own safety protocol, based on their specific needs. One notices, for example, the absence of a safe ICU protocol, although this is one of the most favorable environments for the occurrence of incidents involving patient safety. Another study published in 2016, shows in its results that after the implementation of a protocol in intensive care units, there was a considerable decrease in urinary tract infections. According to the authors, educational actions and maintaining the use of the protocol can be favorable in reducing infections¹⁰. The client's profile directly interferes with the incidence of adverse events, patients in serious condition are more susceptible to the occurrence of adverse events, because due to instability they require a greater number of interventions. Thus, it can be said that patients in the intensive care unit (ICU) are those with the highest risk of iatrogenesis. This is explained in the studies by Novaretti et al. (2014), where about 98% of the patients hospitalized in these units suffered some type of AE, even if without injury, and, by Gonçalves et al. (2012) that shows that the average occurrence of AE / 1 in ICUs was 1.3 to 2.2 per patient-day^{11,12,13}.

The study by Mello and Barbosa (2013) also contributes to this statement, as it shows that the risk of adverse events in highly complex health care, specifically in the ICU, is exacerbated, due to the characteristics of the need for interventions by patients hospitalized units, so the ICU is considered a high-risk care setting. Intensive, continuous, agile and dynamic care involves many interventions and a large and varied number of professionals, where communication must be effective and constitute a care tool to minimize the risk of incidents¹⁴. Another very recent study clearly reveals that communication is the predominant impediment to transitions in safe and high-quality neurocritical care¹⁵. Thinking from this perspective, the implementation of protocols can contribute to make the communication between the multiprofessional team more effective and their actions more standardized. Organizations need to structure their processes safely, reducing the chances of errors on the part of professionals, for this, it is necessary that all aspects are analyzed and screened through risk management, so that preventive

and corrective actions can be implemented that contribute with the system and reduce the occurrence of errors⁹. Reflecting on this scenario, communication is emphasized as one of the international objectives for patient safety, with the shift being able to influence the different dimensions of care¹⁶. In this context, continuing education emerges as a possibility to rescue the role of health professionals in reducing risks and promoting quality and patient safety¹⁷. Another study also elucidates the relevance of continuing education actions in creating a culture of quality and patient safety, since it promotes work transformations that converge with a critical, reflective, committed and competent practice¹⁸. Currently, the execution of projects focused on quality improvement is not only the routine of health professionals, but also a legal obligation for them in several countries, such as the United States and Canada¹⁹.

CONCLUSIONS

This study demonstrated the importance of developing protocols, which support the practices of the multiprofessional healthcare team, to promote quality and patient safety. The proposed objectives were achieved and it was possible to conclude that a safe ICU protocol can be a quality and safety tool for critically ill patients. Currently, the issue of quality and patient safety is present in the daily life of hospital institutions, but the culture of quality is still very fragile, among several factors, due to the issue of punishment and accountability of individuals and not of processes, being necessary the strengthening of actions that show that only the appointment of "guilty" is not enough to correct systemic errors and to promote continuous improvement. The validation process made it possible to assess the reliability of the proposed content of the protocol. The participants' consensus was 95.9%, demonstrating the relevance of the protocol construction for the promotion of patient safety in the intensive care unit and the continuous improvement of the health care team's practices. For the assertive intention of promoting a safe environment for the patient, there must be uninterrupted discussions about risk factors for unwanted incidents and the construction of protocols that constitute safety barriers against errors, continuously reinforcing the safety culture, in addition to educational practices that allow constant updating on the subject.

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