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Research Article
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Artículo de Investigación

Administration of anti-infectives in critically ill patients: proactive risk management

Administração de anti-infecciosos em pacientes críticos: gestão proativa de riscos

Administración de antiinfecciosos en pacientes críticos: gestión proactiva del riesgo

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ABSTRACT

Objective: to analyze the proactive risk management of the anti-infective administration process in an Intensive Care Unit. **Method:** qualitative study, in action research, with participant observation and focus group, from 2019 to 2021. The process was mapped, risks analyzed, improvement actions planned and the process redesigned. **Results:** the prescription occurred in an electronic system and the administration records in printed form. The anti-infective administration process had 19 activities, two sub-processes, 16 failure modes and 23 potential causes. The failure modes were related to asepsis and dose error in the preparation of anti-infectives and the identified causes were human error in violating techniques and memory lapse. Five specialists redesigned the process resulting in changes in activities and in the system. **Conclusion:** proactive risk management applied to the anti-infective administration process was effective in identifying risks, their causes and prioritizing improvement actions.

Descriptors: Intensive Care Units; Patient Safety; Risk Management; Healthcare Failure Mode and Effect Analysis; Anti-Infective Agents.

RESUMO

Objetivo: analisar a gestão de riscos proativa do processo de administração de anti-infecciosos em Unidade de Terapia Intensiva. **Método:** estudo qualitativo, em pesquisa-ação, com observação participante e grupo focal, realizado de 2019 a 2021. Foi mapeado o processo, analisados os riscos, planejadas ações de melhorias e redesenhado o processo. **Resultados:** a prescrição ocorria em sistema eletrônico e os registros da administração em impressos. O processo de administração de anti-infecciosos possuía 19 atividades, dois subprocessos, 16 modos de falhas e 23 causas potenciais. Os modos de falhas foram relacionados à assepsia e erro de dose no preparo de anti-infecciosos e as causas apontadas foram a falha humana na violação das técnicas e o lapso de memória. Cinco especialistas redesenharam o processo resultando em alterações de atividades e no sistema. **Conclusão:** a gestão de riscos proativa aplicada ao processo de administração de anti-infecciosos propiciou identificar riscos, suas causas e priorizar ações de melhorias, o que pode viabilizar tomadas de decisões apropriadas.

Descritores: Unidades de Terapia Intensiva; Segurança do Paciente; Gestão de Riscos; Análise do Modo e do Efeito de Falhas na Assistência à Saúde; Anti-Infecciosos.

RESUMEN

Objetivo: analizar la gestión proactiva de riesgos del proceso de administración de antiinfecciosos en una Unidad de Cuidados Intensivos. **Método:** estudio cualitativo, en investigación-acción, con observación participante y grupo focal, que tuvo lugar del 2019 al 2021. Se mapeó el proceso, se analizaron los riesgos, se planificaron acciones de mejora y se rediseñó el proceso. **Resultados:** la prescripción ocurrió en sistema electrónico y los registros de administración en forma impresa. El proceso de administración de antiinfecciosos tuvo 19 actividades, dos subprocesos, 16 modos de falla y 23 causas potenciales. Los modos de falla estuvieron relacionados con la asepsia y error de dosis en la preparación de antiinfecciosos y las causas identificadas fueron error humano por violación de técnicas y lapsus de memoria. Cinco especialistas rediseñaron el proceso generando cambios en las actividades y en el sistema. **Conclusión:** la gestión proactiva de riesgos aplicada al proceso de administración de antiinfecciosos fue efectiva para identificar riesgos, sus causas y priorizar acciones de mejora, lo que puede factibilizar la toma de decisiones adecuadasa.

Descriptores: Unidades de Cuidados Intensivos; Seguridad del Paciente; Gestión de Riesgos; Análisis de Modo y Efecto de Fallas en la Atención de la Salud; Antiinfecciosos.

INTRODUCTION

Risk management enables the traceability of possible failure modes in a systematized and organized way to enable decision-making, improve the relationship between the different stages of the process, directing the planning of more effective actions and minimizing possible surprises with the results[1].

Hospital medication use systems are complex, with interconnected actions, carried out by professionals from different categories that require human decisions in manual activities and multiple interactions with equipment and software. Such characteristics lead to the occurrence of errors in the prescription, dispensing and administration of medications. Therefore, the use of medicines in hospitals is the focus of risk management[2,3].

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Medication error has been commonly conceptualized in the literature as any preventable event that can cause or lead to inappropriate use of medication or harm to the patient while the medication is under the control of the healthcare professional, patient or consumer[3,4].

In the medication administration process, there are a variety of types of errors such as: wrong patient; wrong medicine; administer unnecessary medication; error of omission of dose or medication; wrong dose (higher or lower than prescribed); double doses; wrong route of administration or in the wrong laterality; wrong pharmaceutical form; preparation error (including incorrect crushing or fractionation), incorrect handling and/or packaging; incorrect administration technique regarding infusion time, administration speed or simultaneous administration of incompatible medications; wrong administration time; wrong administration frequency; expired medication; deteriorated medicine; medication with known allergy; and incorrect record about administration[5,6].

The widespread use of anti-infectives in hospitals occurs in patients with multiple comorbidities and healthcare-associated infections (HAIs) affect them significantly, resulting in antimicrobial resistance. Risk management in the context of Intensive Care Units (ICU) can contribute to HAI prevention and control programs, to achieve an effective, controlled anti-infective use system with continuous monitoring of results[3,7,8].

Errors in the use of anti-infectives can directly impact public health, due to the risk of increasing antimicrobial resistance and the emergence of infectious agents causing diseases for which there is no anti-infective treatment option. It is a global problem, which led the WHO to declare antimicrobial resistance one of the 10 threats to human health[7,8].

Surveys on the magnitude and occurrence of incidents resulting from errors in prescribing, dispensing and administering medication are increasingly frequent, but present different methodologies and results[6,9]. In a review of medical records and notifications of incident records in 138 ICU patient records, medication errors such as omitted doses were found in 29.6% of the records[10].

Another study on the dose administration error rate for anti-infectives identified 4.34% for medications in general, 6.75% for anti-infectives and a higher frequency of omitted doses for carbapenems, prescribed to be administered intravenously and at 8:11 p.m.

In proactive risk management, tools such as the Health Care Failure Mode and Effect Analysis (HFMEA) or Analysis of the Mode and Effect of Failures in Health Care[12] are currently applied. The application of this tool results in process mapping, enables the identification of the failure mode and possible causes, the prioritization of risks to be controlled or eliminated, the elaboration of an intervention plan by those involved in the process to improve quality and the verification of its effectiveness when implemented[12,13].

Considering the relevance of research that analyzes proactive risk management applied to the process of administering anti-infectives to critically ill patients as a strategy for managing these medications and controlling antimicrobial resistance in hospitals, the following issue emerged for this study: proactive risk management in the administration of anti-infectives can it promote understanding of the ways and effects of failures in the process, as well as direct improvement actions?

Thus, the objective was to analyze proactive risk management in the process of administering anti-infectives in an Intensive Care Unit.

METHOD

Qualitative study, of the action research type, which used the participant observation technique and the focus group to apply the HFMEA. Developed in two phases: application of HFMEA and process redesign.

The qualitative research method was chosen due to its interactionist essence, which aims to identify the characteristics of situations, events and organizations based on human subjectivity, essential for this study. One of the qualitative methodologies used is action research, which is a practical cycle of scientific investigation to discover efficient solutions to a problem or recognize little-known issues. It seeks the discussion of ideas, followed by an attempt to discover the most efficient solution to a problem. Action research was applied in this work, as it links research to organizational change, necessary to achieve the objective of the study developed[14].

Failure Mode and Effects Analysis (FMEA) is a risk management tool widely used in industry that was adapted for use in healthcare and called HFMEA. It is applied in five stages by a multidisciplinary team to proactively evaluate

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a health care process, seeking to identify the critical points of greatest risk to prioritize actions to eliminate or control risks[12,13].

The investigation was carried out in a public teaching hospital in the Federal District, Brazil, with 206 inpatient beds, from August 2019 to October 2021. The setting was the ICU, which had a new physical structure, with 10 beds general and nine cardiological, had 107 professionals on its permanent staff, including 24 doctors, 17 nurses, nine physiotherapists, 55 nursing technicians and two nursing assistants.

Participants were selected for convenience, according to the inclusion criteria: being a nurse or nursing technician; being involved in the administration or investigation of anti-infective incidents; be available for meetings. Those who started taking leave from work during data collection were excluded.

Five nurses and seven nursing technicians from the ICU participated in the first phase. There was a loss of a participant who was on leave from work. The focus group meetings took place in the afternoon, from August 2019 to December 2020, according to the calendar established together with the group participants. The main researcher acted as leader in the group meetings, which had an average of five participants.

The five steps of HFMEA were developed: define the scope of the research; assemble the group to apply the HFMEA; graphically describe the process, identifying all activities, people, locations and tasks; analyze hazards or failure modes by applying the Risk Prioritization Matrix and Decision Tree; describe actions to control or eliminate the risk of failures[12].

Initially, the field was approached to identify the participants, present the project and obtain their consent and collect institutional documents such as standard operating procedures (SOP), norms and routines.

The process of administering anti-infectives in the ICU was mapped using the participant observation technique over six visits. The Bizagi Modeler software version 3.7.0.123 was used to graphically represent the process[15].

Next, focus group training was carried out at HFMEA. In six meetings, lasting an average of two hours each, using the focus group technique, the HFMEA of the process was constructed.

The group was asked the following questions: *"What could go wrong in the activity...?"* and *"Do you remember if there was a time when this activity could not be done or took a long time to be done?"* In activity number 2, related to delaying the prescription, the triggering question was *"What can go wrong in the activity of delaying the prescription?"*

The responses were recorded as failure modes and submitted to the Risk Prioritization Matrix to assess the severity and probability of occurrence of possible failures and causes. Subsequently, all identified failure modes and causes were submitted to the Decision Tree, where the group evaluated their criticality, lack of controls and their detectability.

The Risk Prioritization Matrix is a 4x4 matrix to evaluate the degree of severity and the probability or frequency of failure modes and causes. As for severity, it can be considered as negligible, moderate, critical or catastrophic. As for probability, it can be remote, rare, occasional or frequent. The result obtained from the matrix is the risk probability level (RPL) of the failure mode and/or cause of the failure mode, which can vary from one to 16. NPR ≥ 8 is considered high risk, and it is necessary to establish safety measures. control[12,13].

Once the RPL was obtained, the HFMEA Decision Tree was applied to identify whether there were control or detectability measures for the failure mode. When they existed, it meant that there was no need to establish other interventions. When they did not exist, it meant that actions had to be planned to control or eliminate the risk.

The possible causes of failure modes were identified by the focus group and improvement actions were defined when the failure mode and cause was considered a critical point and/or did not have control measures and/or was not detectable.

The results were analyzed using descriptive statistics in frequency and percentages.

To redesign the process, participants were selected through CV analyzes of the institution's professionals who met the following inclusion criteria: (1) doctor, nurse, pharmacist and/or technology analyst; (2) have a master's or doctorate degree; (3) have extensive knowledge of the process of using anti-infectives; (4) not having participated in the first stage of the research. Those who started taking leave from work during data collection were excluded.

Data collection was carried out in September and October 2021, with two meetings of the focus group of experts to present the mapped process and the risk analysis constructed in the first phase with HFMEA for the group to

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redesign a new process with the planned improvement actions. The meetings were attended by all five participants, took place in the afternoon and were led by the main researcher.

This study is part of the macro project "Design and validation of a risk map of processes in the use of anti-infectives in an Intensive Care Unit" approved by the Research Ethics Committee. Participants were invited and, upon agreeing, were presented and asked to sign the Free and Informed Consent Form.

RESULTS

Application of HFMEA

The focus group considered the infrastructure insufficient and inadequate because: (1) the computers were in sufficient quantity and quality, but the furniture was not ergonomic; (2) the place had a large flow of people, noise from conversations, alarms and telephone; and (3) there were frequent interruptions of the nursing technician's activities by other team members.

The electronic medication prescription system did not have electronic scheduling or checking. Printed prescriptions were timed and with manual dose administration checks.

The ICU had five documents that regulated the administration of anti-infectives: (1) SOP for Intravenous Medication Administration; (2) SOP for Administration of Anti-infectives in Dialysis Patients; (3) Anti-infective Dilution Manual; (4) Anti-infective Dilution Table; and (5) Protocol for the Safe Use of Medicines.

The mapping of processes involved in the administration of anti-infectives in the ICU identified 19 activities and two sub-processes. It is noteworthy that the process underwent changes during the period and was updated.

The activities were revisited in six focus group meetings and 16 process activities were identified in which, in the participants' view, 16 failure modes and 23 possible causes would occur. The most frequently cited failure modes were related to asepsis practices and dose errors when preparing the anti-infective. The causes cited were human error in violating correct preparation techniques and memory lapses.

When applying the Risk Prioritization Matrix, the severity of the 16 failure modes and their 23 causes were considered moderate in 62% of the assessments and 38% critical. Regarding probability, 92% were considered frequent, 5% occasional and 3% rare. The NPR ranged from 4 to 12 (Figure 1 and 2).

Process Activity	Fail mode	Cause	Risk Prioritization Matrix			Decision Tree			
			S	P	R	CP	CM	DT	C
4. Inform the nursing technician about the prescription.	Do not inform the technician of the medication prescription.	→	M	O	6	N	-	-	N
5. Contact the pharmacy to request the dispensing of the anti-infective.	The pharmacy phone is busy or unanswered.	→	M	F	8	-	Y	-	N
7. Separate the dose to be administered at the time.	Separate the dose into the wrong quantity.	→	M	F	8	-	N	N	Y
		7.1. Error in interpreting the prescription.	M	F	8	-	N	N	Y
		7.2. Task interruption.	M	F	8	-	N	N	Y
		7.3. Memory lapse due to work overload and/or stress and/or inattention.	M	F	8	-	N	N	Y
9. Inform the nurse to assess the schedule.	Not checking whether the patient is on hemodialysis or not informing the nurse.	→	M	RR	4	Y	N	Y	N

Figure 1: Analysis of dangers and failure modes of activities in the anti-infective administration process in the ICU – NPR 4 to 9. Brasília, DF, Brazil, 2021.
Notes: (S) Severity; (P) Probability; (R) Risk Score; (CA) Catastrophic; (CP) Critical Point; (CM) Control Measure; (DT) Detectability; (C) Continue; (F) Frequent; (O) Occasional; (RR) Rare; N (No); Y (Yes).

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Process Activity	Fail mode	Cause	Risk Prioritization Matrix			Decision Tree			
			S	P	R	CP	CM	DT	C
13.1. Transcribe the prescription onto the label.	Not filling out the label completely and correctly.	→	M	F	8	-	N	N	Y
		13.1.1. Violation of the technique stage by the professional.	M	F	8	-	N	N	Y
		13.1.2. Data transcription error.	M	F	8	-	N	N	Y
13.2 Clean and disinfect the preparation counter.	Do not clean and disinfect the preparation counter.	→	CR	F	12	-	N	N	Y
		13.2.1. Violation of the technique stage by the professional.	CR	F	12	-	N	N	Y
		13.2.2. Lack of tray for preparation.	CR	F	12	-	N	N	Y
13.4. Sanitize your hands.	Do not perform hand hygiene.	→	CR	F	12	-	N	N	Y
		13.4.1 Violation of the technique stage by the professional.	CR	F	12	-	N	N	Y
		13.4.2. Task overload.	CR	F	12	-	N	Y	N
		13.4.3. Lack of soap, paper and/or alcohol preparation.	CR	O	9	-	Y	Y	N
13.6. Disinfect the vials and/or ampoules.	Do not disinfect vials and/or ampoules.	→	CR	F	12	-	N	N	Y
		13.6.1. Lack of awareness of the need to carry out the activity.	CR	F	12	-	N	N	Y
		13.6.2. Violation of technique by the professional.	CR	F	12	-	N	N	Y
13.12. Aspirate the dose to be added to the solution.	Aspirating the wrong dose.	→	M	F	8	-	N	N	Y
		13.12.1. Error in interpreting the prescription.	M	F	8	-	N	N	Y
		13.12.2. Task interruption.	M	F	8	-	N	N	Y
		13.12.3. Memory lapse due to work overload and/or stress and/or inattention.	M	F	8	-	N	N	Y
13.16. Identify the team.	Do not place identification on the equipment.	→	CR	F	12	-	N	N	Y
		13.16.1 Violation of technique by the professional.	CR	F	12	-	N	N	Y
13.18. Register a tick mark above the scheduled time.	Do not signal that the medicine has been prepared.	→	M	F	8	-	Y	-	N
16.1 Assess venous access.	Do not evaluate access.	→	M	F	8	-	N	N	Y
		16.1.1. Violation of the technique by assuming that the access is patent due to the use of several medications.	M	F	8	-	N	N	Y
16.3. Disinfect the road to be opened.	Do not disinfect the road.	→	CR	F	8	-	N	N	Y
		16.3.1. Violation of technique by the professional.	CR	F	12	-	N	N	Y
16.7. Enter the volume, time and flow parameters into the infusion pump.	Entering wrong data.	→	M	F	8	-	N	N	Y
		16.7.1. Error in interpreting the prescription.	M	F	8	-	N	N	Y
		16.7.2. Task interruption.	M	F	8	-	N	N	Y
		16.7.3. Memory lapse due to work overload and/or stress and/or inattention.	M	F	8	-	N	N	Y
16.13. Control the drip according to the desired number of drops/minutes.	Do not infuse the medicine due to gravity.	→	M	F	8	-	Y	-	N

Figure 2: Analysis of dangers and failure modes of activities in the anti-infective administration process in the ICU – NPR 4 to 9. Brasília, DF, Brazil, 2021
Notes: (S) Severity; (P) Probability; (R) Risk Score; (CP) Critical Point; (CM) Control Measure; (DT) Detectability; (C) Continue; (CA) Catastrophic; (CR) Critical; (M) Moderate; (D) Despicable; (F) Frequent; (O) Occasional; (RR) Rare; (RM) Remote; N (No); Y (Yes).

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The focus group prepared the plan with actions to mitigate the risks found (Figure 3).

Causes of failures	Type of action	Planned improvement actions	Expected results
7.1. Prescription interpretation error. 13.12.1. 16.7.1.	To control	1. **Implement signaling SOPs** with a highlighter pen when prescribing antimicrobials. 2. **Train** staff on safe medication administration every 6 months. 3. Implement **double checking** in the administration activity of antimicrobials such as Polymyxin, Ertapenem, Vancomycin and Amphotericins (because there are many differences between doses and/or routes of administration). **Increase nurse supervision** in administration activities.	New SOP and double checking implemented. Greater involvement of nurses with the antimicrobial administration process. Reduction in antimicrobial administration errors.
7.2. Task interruption. 13.12.2. 16.7.2.	To control	1. **Redesignate a separate location**, protected from noise and with restricted access for the medication preparation area. 2. Request **adequacy of the physical structure**. 3. Develop **medication preparation protocol in the area**. 4. Compose **individualized team for the preparation and dilution area**. **Train staff** on safe medication preparation.	Medicine preparation room available for use. Standardization of medication preparation method. Team qualified to work in the preparation and dilutions area. Reduction in antimicrobial administration errors.
7.3. Memory lapse due to work overload and/or stress and/or inattention. 13.12.3. / 16.7.3.	To control	Idem 7.1. 1. Publicize the **Cuidar Project** in the unit. 2. Encourage the participation of professionals in Project Cuidar activities.	To reduce stress and fatigue at work.
13.1.1. Violation of the technical step by the professional. 13.2.1. /13.4.1. 13.5.2./ 13.6.2. 13.16.1 / 16.1.1. 16.3.1.	To eliminate	Idem 7.1. 1. Request **adequacy of information** on the medication label. 2. Insert the label **check item into the bed audit instrument** ("Daily ICU/UCO Check"). 3. Refer cases of repeated violation of the technique for investigation of responsibilities.	Medicine labels with all necessary data. Team qualified to prepare medication. Greater involvement of nurses with the antimicrobial administration process. Reduction of failures and errors in medication preparation activities. Prevent violations of medication preparation techniques.
13.1.2. Data transcription error.	To control	Idem 7.1.	
13.2.2. Lack of tray for preparation.	To eliminate	Idem 7.1. Request the **acquisition of trays** for preparing medication.	Adapt the structure of the unit for the preparation of medication.
13.5.1. The use of procedural gloves during medication preparation is not standardized at the institution.	To eliminate	1. Update **the SOP for intravenous medication administration**. 2. Update the Safe Medicine Use Protocol. Idem 7.1.	Standardize the use of procedural gloves and surgical masks when preparing intravenous medication. Team qualified to prepare medication. Greater involvement of nurses with the antimicrobial administration process. Reduction of failures and errors in the medication preparation activity. Reduction of healthcare-related infections.
13.6.1. Lack of knowledge of the need to carry out the activity.	To eliminate	Idem 7.1.	

Figure 3: Action plan to control the risks of the anti-infective administration process in the ICU. Brasília, DF, Brazil, 2021

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Process redesign

Five experts participated in the focus group, including an infectious disease doctor, a pharmacist, two nurses and a technology and risk management analyst. In two meetings, the process for administering anti-infectives in the ICU was redesigned. The new process has 19 activities and one subprocess. The process mapping was represented in the Business Process Model and Notation (BPMN) language of the Bizagi application.

The sub-process of preparing anti-infectives was removed, as it is a standard technique performed by nursing. Therefore, it was decided not to provide details, as they follow the step-by-step SOP implementation process already established. However, failure modes and causes were maintained in the analysis and planned actions.

The activity of using a signaling vest was included to communicate that the professional should not be interrupted while preparing medication.

In the medium and long term, the implementation of a separate and exclusive room for the preparation of medicines was planned, as well as the change in the work processes of the nursing team to enable supervision and double checks in the preparation of medicines.

Figure 3 demonstrates the mapping of the process that was redesigned by the focus group of experts with adaptations for Word.

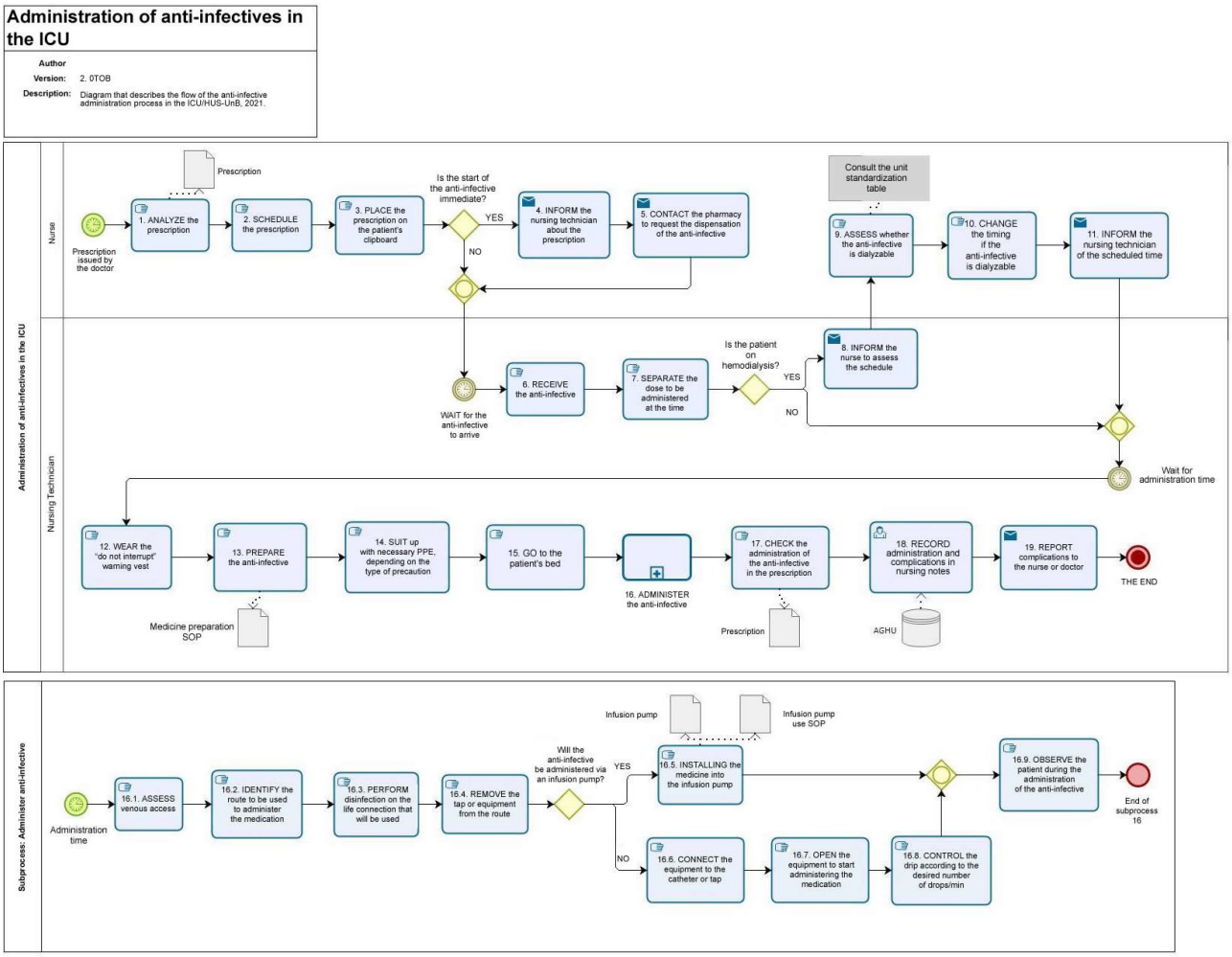

Figure 4: Process mapping redesigned by the focus group of experts. Brasília. DF, Brazil, 2021.

DISCUSSION

Based on the results of the proactive risk management analysis of the anti-infective administration process in the ICU constructed in the study, two thematic categories emerged for discussion: (a) systemic failure evidenced by

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inadequate physical structure, technological limitations, lack of inputs, insufficient SOPs and incipient training; (b) human error in manual activities that lead to administration errors and lack of supervision of activities.

Systemic failures

Systemic failure evidenced by inadequate physical structure

The main highlight of the study was to highlight that, in the participants' perception, the physical structure of the area was inadequate for the process, despite being a new unit, with a physical structure in accordance with national resolutions.

The ICU has 19 beds and an occupancy rate above 90%, where at least ten nursing technicians and two nurses worked per shift in the medication administration process, which requires a robust and large physical structure, availability of supplies and materials for all professionals and organization of the flow of use of the preparation area, so as not to compromise the process. In the central area of the ICU were benches for preparing medications. The place had a large circulation of people, conversation noises and alarms, which made it difficult for professionals to concentrate. Furthermore, there were frequent interruptions in the work process, which is another risk factor that predisposes to failures.

A study carried out in Brazil, with the application of HFMEA in a bone marrow transplant service, identified 207 failure modes, distributed in checking errors (14.0%), scheduling (25.6%), administration (29.0 %), dilution (16.4%), prescription (2.4%) and identification (12.6%). In the risk analysis, they were classified as moderate risk (51.7%) and high frequency (30.9%). Interruptions during the medication preparation activity were also highlighted, resulting in actions involving changes to internal documents and protocols, continuing education and formation of a quality intern group[16].

Systemic failure evidenced by technological limitations

In the medication preparation technique, possible failures due to incorrect or incomplete label filling were highlighted. The use of technologies that can be incorporated into the electronic system to automatically fill out medication and infusion labels can help to avoid such failures.

Systemic failure evidenced by the lack of inputs

The insufficient number of trays for the preparation of medicines by the team and the unavailability of supplies for hand hygiene, compromising compliance with aseptic practices by professionals, constitute systemic failures, which must be resolved immediately. Actions planned to intervene in the problem, such as increasing the quantity and frequency of input replacement, can contribute.

Systemic failure evidenced by insufficient SOPs

Although there are five documents standardizing activities involved in the administration of anti-infectives, participants pointed out the need to develop new SOPs.

The complete quality improvement cycle consists of the preparation of documents (which must be accompanied by their application in daily practice), frequent internal training programs (so that operational protocols and procedures are continually disseminated) and supervision of their application with data collection and dissemination of result indicators and processes. Therefore, the actions planned to intervene in the problem regarding the implementation of new SOPs, periodic training, expanded supervision and the inclusion of double checking in the process for some groups of anti-infectives may result in better results.

In a study carried out in Argentina, through reactive analysis after events that occurred, the needs for changes to internal work processes, implementation of new routines and training to reduce medication errors in a medical clinic unit were also raised, where the proportion of errors was 8.4 errors/patient and 88.6 errors/100 patients/day[17].

Systemic failure evidenced by insufficient training

Regarding training, a study established seven competencies for the ICU nurse's competency matrix: professional autonomy, scientific knowledge, knowledge of medication indication, technical knowledge, continuing education, nine certainties in the safe administration of medications and responsibility[18].

Currently, educational activities that involve realistic simulation with high-fidelity simulators and/or scenarios have been used in the continuing education of professionals.

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A systematic review of the literature found seven published studies with rigorous design evaluating interventions to improve medication administration. Five were randomized controlled trials (including one crossover trial) and two were non-randomized controlled trials. Interventions were training (n = 4; medication-dedicated nurses, interactive digital media program, simulation-based learning, pharmacist training program) and technology incorporation (n = 3; computerized prescription and automated dispensing systems). All had a high risk of bias due to the lack of blinding in the evaluation of results. The meta-analysis found no effect of the interventions. The review found no evidence that an intervention can effectively reduce administration errors[19].

Human failures

Human error in manual activities that lead to administration errors

The theory of Human Error, known as "The Swiss Cheese Model", by psychologist James Reason, makes it possible to understand how failures occur. The personal approach to unsafe acts, which are errors or violations by people who are directly involved in the process that may arise through corrupted mental processes, such as forgetfulness, inattention, lack of motivation, carelessness, negligence and imprudence[20].

Interruptions by people from the team, also cited as causes of failure, increase the risk of errors, since the interruption of the action affects memory, predisposing the professional to return to the previous process without fully reasoning about the activity[21].

Latent conditions are the internal pathologies of the system and arise through senior management decisions that may or may not lead to errors. These can be manifested by errors caused by working conditions, such as pressure in relation to time to perform activities, lack of personnel, inadequate equipment for carrying out work, fatigue and inexperience. Or, errors that cause long-lasting holes and weaken defenses, such as unreliable alarms and indicators, impractical procedures and deficiencies in construction projects[20].

Latent conditions, when combined with active failures and triggers, can generate incidents and can be identified and corrected more easily than active failures, which are difficult to trace. Understanding these failures leads to proactive rather than reactive management[20-26].

Participants cited the violation of techniques as human error and the lack of available materials as a systemic failure for the lack of hand hygiene, not wearing gloves, failure to perform cleaning and disinfection tasks of countertops, trays, ampoules and medication bottles before and during the preparation of medications, do not clean the medication route before administration or do not identify the equipment.

In another qualitative research in a Brazilian ICU, the types of incidents reported by nurses were incorrect dose (17.4%) followed by incorrect dilution (16.2%). Lack of attention (23.1%) followed by work overload (18.3%) were the most cited contributing factors and 25.5% of participants reported that there was harm to the patient. The most common behaviors adopted after the incidents point to observation of the clinical picture and communication to the coordination, and the hindering factors for notification were fear of punishment and judgment[27].

A systematic review on the influence of nursing workload required in the ICU found workload as a risk factor for the occurrence of adverse events, such as infection, pressure injuries and/or medication errors in six of the eight studies analyzed[28].

Human error from lack of supervision

Training teams and supervising the execution of techniques can contribute to improving the process. However, it is necessary to complement it with periodic and systematic audits with feedback to the teams on monitored indicators regarding adherence to hand hygiene, use of PPE and percentage of compliance in adherence to medication preparation practices.

In Canada, a study analyzed 2,164 medication errors, of which 301 (14%) were in anti-infective medications. The majority (95%) of errors in anti-infectives did not result in consequences for the patient. Omission (26%) and administration of the wrong dose were the most reported. Eighty percent (n = 242/301) of medication errors occurred during administration, and only 8% (n = 24/301) during prescription. These indices can be used to improve the risk management system[29].

Failure to verify the possibility of administering the medication at the scheduled time due to the patient's hemodialysis cycle and errors in anti-infective doses compromise the efficiency of treating infections. Furthermore, some anti-infectives, such as Amphotericin B, are considered potentially dangerous and must have their

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administration process standardized, supervised and carried out by trained people, maintained in a continuing education program in line with the actions planned in the study[30].

A study that analyzed medication errors across 1,276 error reports across five US hospitals showed that nurses play an important role in safely administering medications. The class of medications most associated with errors was cardiovascular (24.7%), anti-infectives were the second class most associated with errors (19.1%) and Vancomycin was the most common (6.1%). Errors occurred more in medical-surgical and intensive care units, 10% affected patients with harm, and 11% of patients had increased monitoring. The study concluded that understanding the contributing factors related to errors, addressing and eliminating the risk of errors in hospital units, and providing education and resources for nurses can help reduce medication errors[31].

In the ICU studied, there is a high frequency of patients undergoing hemodialysis and using broad-spectrum anti-infectives, which reflects an increased risk of failures in the administration process of these medications. When preparing and administering medications, especially potentially dangerous or high-alert medications, it is good practice for more than one professional to review or check (double-check) the activities that involve calculating doses and administering them to the patient[9, 21, 30].

It is important to highlight that, in the flow described, there was no recommendation to check with the prescribing doctor the need to administer a new dose of anti-infective after dialysis therapy and should be added as an activity in areas where there are no flows and routines for prescribing anti-infectives. medications that include the prior prescription of extra doses when necessary. In this sense, the role of the clinical pharmacist in the context of the use of anti-infectives, both in the prescription and administration stages and in dispensing, can be an important component for minimizing the risk of failures in the administration process.

Although there were internal protocols with guidelines for double checking, the administration of potentially dangerous medications was still carried out by nursing technicians without double checking. In the applied HFMEA, changes were planned in the SOPs on the administration of medicines with the inclusion of double checking on potentially dangerous anti-infectives and others that the team identified that had variability in the way of preparation.

Double checking, a technique developed exclusively to detect errors, is a form of redundancy that can be used at various points in the system. It can be done independently, or asynchronously (isolated and separate from each other), when two professionals check the procedure, each component of the medication use process is checked and then they compare the results. Double checking can be done in joint verification with simultaneous verbal and/or visual review, synchronously, when one professional observes the other's calculation or even do and show, when a professional shows the result of the calculation to a second professional, who check if it is correct. There is no consensus on what the best way is to do this, but it is argued that working together in a synchronous verification can lead to confirmation bias[32].

The difficulty in understanding how to perform the procedure results in low adherence to the technique, and other causes are described, such as the greater time spent looking for another professional to perform the double check, interruptions in work due to the request, the time invested in the procedure itself and the need for autonomy at work[33]. The double-checking technique is valuable; however, it should be used with caution, reserved for application to a small number of medicines, especially potentially dangerous ones that have a greater risk of causing serious harm. Fewer checks done correctly for tasks that pose the greatest risk are much more effective than an abundance of poorly executed double checks[21,33].

The involvement of patients and family members in care in hospital environments should be encouraged by nurses by keeping them informed about the reasons for drug therapy with clear information in language that the patient understands, if possible, printed on the types and times of medication to be administered. Patients and family members must be encouraged to act collaboratively with the healthcare team so that everything goes according to plan, acting as barriers to possible failures in the process[32].

In the ICU, however, most of the time, the patient's involvement in safety care is unfeasible, due to conditions or changes in consciousness. However, companions can and should be encouraged to participate and their presence in critical care areas must be guaranteed.

In the participants' perception, violations must be prevented by expanding security barriers, incorporating technologies and better supervision strategies that facilitate the work to be carried out within the standardized process, minimizing the execution of completely manual tasks. The determinations of responsibilities and penalties

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identified as necessary in situations where violations are recurrent show that participants understand the concepts of just culture and the need for accountability in recurrent violations.

From the results it can be stated that the proactive risk management applied to the process of administering anti-infectives in the studied ICU allowed the understanding of the modes and effects of failures in the process to direct improvement actions to be developed in contribution to the program management of anti-infectives and rational use in combating antimicrobial resistance.

Based on the above, this work resulted in contributions in the fields of health care, management, research and teaching. In health care, it contributed to the establishment of new work processes. In the field of management, the application of a proactive risk management tool was demonstrated as a contribution to the anti-infective management system. And for research and teaching, the contribution of risk management to the use of anti-infectives in hospitals was demonstrated and knowledge gaps were raised about the best practices applicable to the anti-infective administration process in the context of critical care.

Study limitations

The limitations of the study are those related to the method used, typical of action research, the results represent the risks in the institution studied and the perception of participants and researchers that cannot be used in a generalized way. However, the identified failure modes and effects and their causes may be present in the context of the use of anti-infectives in the ICUs of other establishments and the proposed solutions may serve as examples for other hospitals.

CONCLUSION

The objectives of the study were achieved when, through the analysis of proactive risk management of the process of administering anti-infectives in the ICU with the application of HFMEA, it was possible to understand the modes and effects of failures, analyze the risks, plan actions to control risks and, consequently, increase the quality and safety of processes, contributing to the anti-infective management program at the studied institution.

Mapping the administration process made it possible to understand details about how, when and by whom the various activities are carried out and the identification of critical points.

By measuring the degree of severity and the probability of failure modes occurring in the activities of the mapped process, it was possible to identify the risks with the greatest potential to cause harm to the patient and the frequency with which they occur.

The main failures highlighted were related to asepsis and dose error when preparing the anti-infective. Interventions included changes to the physical, technological and personnel structure, changes to work processes with updates to SOPs, implementation of double checks and training. These are comprehensive and feasible actions considering the institutional context and which may contribute to mitigating the identified risks.

Finally, the results of this study point to the need for greater investment and development of human and technological resources, as well as highlighting gaps in knowledge and research in the area. There are many recommendations based on good practices for implementing interventions and incorporating technologies that can be effective in reducing the risks of medication errors. The big challenge is incorporating such technologies, including proactive risk management on an ongoing basis, into its organizational processes.

REFERENCES

1. Associação Brasileira de Normas Técnicas. Catálogo ABNT NBR ISO 31000:2018. ABNT; 2018 [cited 2020 Jul 30]. Availabe from: https://www.abntcatalogo.com.br/norma.aspx?ID=392334
2. Ministério da Saúde (Br). Agência Nacional de Vigilância Sanitária. Portaria Nº 529, de 1º de abril de 2013. Institui o Programa Nacional de Segurança do Paciente. Brasília (DF): Ministério da Saúde; 2013. [cited 2020 Jul 30]. Availabe from: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html
3. World Health Organization. Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. WHO; 2021 [cited 2022 Fev 27]. Available from: https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan
4. National Coordinating Council for Medications Errors Reporting and Prevention. About Medication Errors. NCCMERP; 2020 [cited 2020 Oct 30]. Available from: https://www.nccmerp.org/about-medication-errors
5. World Health Organization. The Conceptual Framework for the International Classification for Patient Safety (ICPS). WHO; 2010. [cited 2020 Oct 20]. Available from: https://www.who.int/patientsafety/implementation/taxonomy/ICPS-report/en/

DOI: http://dx.doi.org/10.12957/reuerj.2023.75415

6. Instituto para Práticas Seguras no Uso de Medicamentos Brasil. Programa Nacional de Segurança do Paciente: indicadores para avaliação da prescrição, do uso e da administração de medicamentos – parte II. ISPM Brasil; 2016 [cited 2022 Mar 16]. Availabe from: https://www.ismp-brasil.org/site/wp-content/uploads/2016/07/Boletim-ISMP-Brasil-Indicadores-II.pdf.
7. World Health Organization. Global antimicrobial resistance and use surveillance system (GLASS) report 2021. WHO; 2021 [cited 2021 Jul 20]. Available from: https://www.who.int/publications/i/item/9789240027336
8. Agência Nacional de Vigilância Sanitária (Br). Plano de Contingência Nacional para Infecções causadas por Microrganismos Multirresistentes em Serviços de Saúde – PLACON-RM. Brasília (DF): Anvisa; 2021 [cited 2022 Fev 17]. Availabe from: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/servicosdesaude/publicacoes/placon-nacional-mr-09-11-2021.pdf
9. Ministério da Saúde (Br). Programa Nacional de Segurança do Paciente – Anexo 03: Protocolo de segurança na prescrição, uso e administração de medicamentos. Brasília (DF): Ministério da Saúde; 2013 [cited 2022 Mar 16]. Availabe from: https://portaldeboaspraticas.iff.fiocruz.br/biblioteca/protocolo-de-seguranca-na-prescricao-uso-e-administracao-de-medicamentos/
10. Souza RF, Alves AS, Aencar IG. Adverse events in the intensive care unit. J Nurs UFPE online. 2018 [cited 2020 Jul 30]; 12(1):19-27. DOI: https://doi.org/10.5205/1981-8963-v12i1a25205p19-27-2018.
11. Castro AF, Oliveira JP, Rodrigues MC. Anti-infective medication administration errors by dose omission. Acta Paul Enferm. 2019 [cited 2020 Jul 30]; 32(6):667-73. DOI: https://doi.org/10.1590/1982-0194201900092
12. DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis: the VA National Center for Patient Safety's Prospective Risk Analysis System. Jt Comm J Qual Improv. 2002 [cited 2020 Oct 20]; 28(5):248-67. DOI: https://doi.org/10.1016/s1070-3241(02)28025-6
13. Anjalee JAL, Rutter V, Samaranayake NR. Application of failure mode and effect analysis (FMEA) to improve medication safety: a systematic review. Postgrad Med J. 2021 [cited 2022 Fev 20]; 97:168-74. DOI: https://doi.org/10.1136/postgradmedj-2019-137484
14. Cooper DR, Schindler P S. Métodos de Pesquisa em Administração. 12. ed. São Paulo: AMGH Editora, 2016.
15. Bizagi Modeler. Software de mapeamento. Versão. 3.7.0.123. 2020.
16. Abi AXCF, Cruz EDA, Pontes L, Santos T, Felix JVC. The Healthcare Failure Mode and Effect Analysis as a tool to evaluate care protocols. Rev Bras Enferm. 2022 [cited 2023 Fev 20]; 75(3):e20210153. DOI: https://doi.org/10.1590/0034-7167-2021-0153.
17. Salamano M, Palchik V, Botta C, Colautti M, Bianchi M, Traverso ML. Seguridad del paciente: aplicación de gestión de calidad para prevenir errores de medicación en el circuito de uso de medicamentos. Rev Calidad Asistencial. 2013 [cited 2023 Fev 20]; 28(1):28-35. DOI: https://doi.org/10.1016/j.cali.2012.05.004.
18. Belarmino GM, Renovato RD. Matriz de competências relacionadas aos medicamentos para o enfermeiro em unidade de terapia intensiva. Rev Enferm UFSM. 2020 [cited 2023 Fev 20]; 10(e99):1-17. DOI: https://doi.org/10.5902/2179769247447.
19. Berdot S, Roudot M, Schramm C, Katshian S, Duriex P, Sabatier B. Interventions to reduce nurses' medication administration errors in inpatient settings: a systematic review and meta-analysis. Int J Nurs Stud. 2016 [cited 2023 Fev 20]; 53:342-35. DOI: https://doi.org/10.1016/j.ijnurstu.2015.08.012
20. Reason J. Human error: models and management. BMJ (Clinical research ed.). 2000 [cited 2020 Oct 20]; 320(7237):768-70. DOI: https://doi.org/10.1136/bmj.320.7237.768
21. Instituto para Práticas Seguras no Uso de Medicamentos Brasil. Prevenção de erros relacionados às interrupções dos profissionais durante o processo de medicação. Boletim ISMP Brasil; 2019 [cited 2020 Oct 30]. Availabe from: https://www.ismp-brasil.org/site/wp-content/uploads/2019/06/BOLETIM-ISMP-BRASIL-INTERRUPCOES-JUN-19.pdf
22. Costa PCA, Nunes VMA, Pimenta IDSF, Bezerra TS1, Piuvezam G, Gama ZAS. Failure mode and effect analysis in the preparation and dispensation of chemotherapy. Enfermería Glob. 2020 [cited 2022 Fev 20]; 58(1):96-108. DOI: https://doi.org/10.6018/eglobal.389551
23. Vida MAC, Plata JEM, Morales-Molina JA, Lázaro JJP, Robles PA. Identification and prioritisation of risks in a hospital pharmacy using healthcare failure mode and effect analysis. Eur J Hosp Pharm. 2019 [cited 2022 Fev 20]; 26:66-72. DOI: https://doi.org/10.1136/ejhpharm-2017-001242.
24. Farzi S, Irajpour A, Saghaei M, Ravaghi H. Causes of medication errors in intensive care units from the perspective of healthcare professionals. J Res Pharm Pract. 2017 [cited 2022 Fev 20]; 6:158-65. DOI: https://doi.org/10.4103%2Fjrpp.JRPP_17_47
25. Atienza-Martín F, et al. El método AMFE (Análisis Modal de Fallos y Efectos) aplicado a la anticoagulación de pacientes con fibrilación auricular no valvular. SEMERGEN. 2019 [cited 2022 Fev 20]; 45(3):169-79. DOI: https://doi.org/10.1016/j.semerg.2018.04.011
26. Instituto para Práticas Seguras no Uso de Medicamentos Brasil. Prevenção de Erros de Prescrição. Boletim ISMP Brasil; 2021 [cited 2022 Mar 16]. Availabe from: https://www.ismp-brasil.org/site/wp-content/uploads/2021/03/Boletim_ismp_prevencao_erros_prescricao_.pdf
27. Costa MP, Picanço CM, Batalha EMS. Vivência de enfermeiras(os) acerca dos incidentes relacionados à administração de medicamentos em terapia intensiva. J Nurs Health. 2018 [cites 2020 Oct 30]; 8(2):e188207. DOI: https://doi.org/10.15210/JONAH.V8I2.13458.
28. Oliveira AC, Garcia PC, Nogueira LS. Nursing workload and occurrence of adverse events in intensive care: a systematic review. Rev Esc Enferm USP. 2016 [cited 2022 Fev 20]; 50(4):679-89. DOI: https://doi.org/10.1590/S0080-623420160000500020.
29. Bérard C, Cotteret C, lebel D, Bussières JF. Étude pilote dnes erreurs médicamenteuses liées aux anti-infectieux par rapport à leur consommation. Arch Pediatr. 2016 [cited 2022 Fev 20]; 23:561-9. DOI: https://doi.org/10.1016/j.arcped.2016.03.006.
30. Instituto para Práticas Seguras no Uso de Medicamentos Brasil. Anti-infecciosos: erros de medicação, riscos e práticas seguras na sua utilização. Boletim ISMP Brasil; 2019 [cited 2020 Oct 30]. Availabe from: <https://www.ismp-brasil.org/site/wp-content/uploads/2019/10/BOLETIM-ISMP_SETEMBRO_2019_anti-infecciosos.pdf

DOI: http://dx.doi.org/10.12957/reuerj.2023.75415

31. Muroi MS, Shen JJ, Angosta A. Association of medication errors with drug classifications, clinical units, and consequence of errors: are they related? Appl Nurs Res. 2017 [cited 2022 Fev 20]; 33:180-5. DOI: https://doi.org/10.1016/j.apnr.2016.12.002.
32. Paparella S F. Taking another look at independent double checks. J Emerg Nurs. 2013 [cited 2022 Fev 20]; 39:631-2. DOI: https://doi.org/10.1016/j.jen.2013.08.013.
33. Barbagelata EU. Implementación de estratégias de prevencíon de errores em el processo de administración de medicamentos: um enfoque para enfermeira em cuidados intensivos. Rev Méd Clín Condes. 2016 [cited 2022 Fev 20]; 27(5):594-604. DOI: https://doi.org/10.1016/j.rmclc.2016.09.005

Authors' contributions

Conceptualization, AFC and MCSR; methodology, AFC and MCSR; formal analysis, AFC and MCSR; investigation, AFC and MCSR; resources, AFC and MCSR; data curation, AFC; manuscript writing, AFC and MCSR; manuscript review and editing, AFC and MCSR; visualization, AFC and MCSR; supervision, AFC e MCSR; project administration, AFC and MCSR; financial aquisition, AFC and MCSR. All authors have read and agreed to the published version of the manuscript.