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Dispensation of anti-infective agents: An Analysis of Failure Modes and Effects

Dispensation of anti-infective agents: Analysis of the Mode and Effect of Failures

Dispensación de antiinfecciosos: Análisis de la Modalidad y Efecto de las Fallas

ABSTRACT

Objectives: Analyze the implementation of Failure Mode and Effect Analysis in the anti-infective dispensing process and build a new process. **Method:** Qualitative, action-research study carried out in a teaching hospital to apply the Failure Mode and Effect Analysis in the process of dispensing anti-infectives from the hospital pharmacy to the Intensive Care Unit and reviewing the process. **Results:** The anti-infective dispensing process had 67 activities, 3 sub-processes, 31 failure modes and 20 potential causes. The failure modes were delay and errors in dose, presentation and concentration, and the identified causes were human error in checking the medication and systemic due to staff shortages. Five specialists redesigned the process with interventions. **Final remarks:** Proactive risk management applied to the anti-infective dispensing process was effective in identifying risks, their causes and prioritizing improvement actions. **Descriptors:** Healthcare Failure Mode and Effect Analysis; Anti-infective agents; Intensive Care Units; Risk management; Patient safety.

RESUMO

Objetivos: Analisar a implementação da Análise do Modo e do Efeito de Falhas no processo de dispensação de anti-infecciosos e construir novo processo. **Método:** Estudo qualitativo, em pesquisa-ação, realizado em hospital de ensino, para aplicar a Análise do Modo e do Efeito de Falhas no processo de dispensação de anti-infecciosos da farmácia hospitalar para a Unidade de Terapia Intensiva e o redesenho do processo. **Resultados:** O processo de dispensação de anti-infecciosos tinha 67 atividades, três subprocessos, 31 modos de falhas e 20 causas potenciais. Os modos de falhas foram atraso e erros de dose, apresentação e concentração, e as causas apontadas foram a falha humana na conferência dos medicamentos e a sistêmica de déficit de pessoal. Cinco especialistas redesenharam o processo com intervenções. **Considerações finais:** A gestão de riscos proativa aplicada ao processo de dispensação de anti-infecciosos foi efetiva ao identificar riscos, suas causas e na priorização de ações de melhorias.

Descritores: Análise do Modo e do Efeito de Falhas na assistência à saúde; Anti-infecciosos; Unidades de Terapia Intensiva; Gestão de riscos; Segurança do paciente.

RESUMEN

Objetivos: Analizar la implementación del Análisis Modo y Efecto de Falla en el proceso de dispensación de antiinfecciosos y construir un nuevo proceso. **Método:** Estudio cualitativo, de investigación acción, realizado en un hospital escuela para aplicar el Análisis Modal de Fallas y Efectos en el proceso de dispensación de antiinfecciosos desde la farmacia hospitalaria a la Unidad de Cuidados Intensivos y revisión del proceso. **Resultados:** El proceso de dispensación de antiinfecciosos tuvo 67 actividades, 3 subprocesos, 31 modos de falla y 20 causas potenciales. Los modos de falla fueron la demora y los errores de dosis, presentación y concentración, y las causas identificadas fueron el error humano en el control del medicamento y la sistémica por falta de personal. Cinco especialistas rediseñaron el proceso con intervenciones. **Consideraciones finales:** La gestión proactiva de riesgos aplicada al proceso de dispensación de antiinfecciosos fue eficaz para identificar riesgos, sus causas y priorizar acciones de mejora.

Descriptores: Análisis de Modo y Efecto de Fallas en la atención de la salud; Antiinfecciosos; Unidades de Cuidados Intensivos; Gestión de riesgos; Seguridad del paciente.

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INTRODUCTION

According to the World Health Organization (WHO), an adverse event is an incident that results in harm to a patient, while a potential adverse event refers to a serious error or incident with the potential to cause harm but which, due to interception or even chance, does not occur[1]. Risk management, in turn, entails implementing ongoing activities to oversee and mitigate the risks associated with an organization's operations or processes. It can be categorized into two types: reactive risk management, which employs methodologies to analyze incidents post-occurrence, and proactive risk management, which examines processes to detect and address potential failures before they materialize.[2,3].

In the context of Brazilian hospitals, as part of the Joint Commission International hospital accreditation process, institutions have begun applying the Failure Mode and Effect Analysis (FMEA) risk management tool[2,3]. FMEA, widely used in industry and applicable to both proactive and reactive risk management, has been adapted for hospital settings under the name Health care Failure Mode and Effect Analysis (HFMEA), or *Análise do Modo e do Efeito de Falhas na Assistência à Saúde* in Portuguese[2,3]. This tool comprehensively maps the process under analysis, identifies failure modes and their possible causes, prioritizes risks to be controlled or eliminated, engages those involved in the process to discuss intervention plans for improvement, and verifies the effectiveness of the implemented process[2-3].

Moreover, risk management ensures traceability of potential failure modes through a systematic and organized approach, facilitating informed decision-making, enhancing the integration between different stages of the process, and enabling managers to devise more effective improvements while reducing the likelihood of unexpected outcomes[4].

Among the strategies and actions for risk management in hospitals, the medication use system stands out, ensuring quality and safety in the prescription, dispensing, and administration of medications[1]. Currently, in the proactive management of medication use, HFMEA is widely employed due to its comprehensive nature and strong applicability in identifying risks, scope, consequences, probabilities, and risk levels. It also generates risk reports and evaluates them, covering all the necessary steps for effective risk management. Additionally, it enables the development of action plans to mitigate or eliminate the risks involved in the process[4].

Hospital medication systems are complex, involving various interconnected actions and different categories of professionals, such as pharmacists, physicians, nurses, nursing technicians and assistants, and pharmacy technicians. Consequently, within this intricate system, the continuous involvement

of professionals in manual tasks requiring human decision-making and interaction with equipment and software may increase the risk of errors, particularly during the prescription, dispensing, and administration phases of medication management[5,6].

The most widely accepted definition of a medication error in the literature is provided by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), which defines it as "any preventable event that may cause or lead to inappropriate medication use or harm to a patient while the medication is under the control of a health care professional, patient, or consumer."[7]. Dispensing errors, on the other hand, refer to deviations from a medical prescription, which may occur due to the pharmacist's interpretation after consultation with the prescriber or as a result of institutional rules or protocols. The most common types of medication dispensing errors include content errors, labeling errors, and documentation errors[8]. Thus, the use of proactive risk management tools is justified in health care services to reduce the risks associated with systems, products, or processes by identifying and analyzing risks in the medication dispensing process to prevent potential medication errors[3,4].

The use of anti-infective agents in hospitals is crucial for treating most patients with multiple comorbidities, as healthcare-associated infections (HAIs) significantly impact these patients, and antimicrobial resistance is frequently encountered in such cases. To control and prevent HAIs in Intensive Care Units (ICUs), the best risk management practices should be employed, encompassing an effective, controlled, and continuously monitored system for the use of anti-infective agents[6,9,10].

Additionally, the National Patient Safety Program (PNSP) prioritizes the implementation of risk management and the establishment of a Patient Safety Core in hospitals[5]. In 2017, through the World Alliance for Patient Safety, the WHO introduced Medication Without Harm as its third global challenge, aiming to reduce severe and preventable medication-related harm by 50% over five years. This goal is to be achieved by developing safer and more efficient health systems at every stage of the medication use process[6]. Given that errors in the use of anti-infective medications—a global issue—can directly impact public health by increasing antimicrobial resistance, the WHO has declared this phenomenon one of the ten threats to human health[9,10].

In a Brazilian university hospital, a study was conducted involving 5,604 dispensed medications across 1,077 kits/prescriptions, identifying 236 medications with dispensing errors, resulting in an error rate of 4.2%. The primary errors included content errors resulting from quality deviations and omissions, with factors such as night shifts and the presence of interruptions or distractions contributing to an increased like-

lihood of dispensing errors[11].

Given the relevance and need for research implementing HFMEA in the anti-infective dispensing process for critically ill patients as a strategy to manage these medications and control antimicrobial resistance in hospitals, this study posed the following question: Can the use of the HFMEA tool in anti-infective dispensing enhance the understanding of failure modes and effects in the process, enabling the implementation of improvement actions? Thus, this article aims to analyze the implementation of HFMEA in the dispensing process of anti-infective agents from the hospital pharmacy to the ICU and to design a new dispensing process with planned actions to mitigate identified risks.

METHOD

This qualitative action-research study employed participant observation and focus groups to apply the proactive risk management tool known as HFMEA. The study was conducted in two phases: the application of HFMEA and the redesign of the process based on the identified risks. The interactionist essence of the chosen research method aimed to identify the characteristics of situations, events, and organizations through the perspective of human subjectivity. Action research was employed to integrate research with the organizational changes necessary to achieve the study's proposed objectives.

HFMEA was developed by the National Center for Patient Safety of the United States of America (U.S.) Department of Veterans Affairs as an adaptation of FMEA. HFMEA is implemented in five steps by a multidisciplinary team to proactively assess a health care process, aiming to identify critical high-risk points and prioritize actions to eliminate or control these risks[2].

The study was conducted in a medium-sized public teaching hospital in the Federal District, Brazil, with 206 active inpatient beds, 19 of which were designated for ICU care in clinical and surgical specialties. The study setting was the Pharmacy Unit, which had recently undergone reconstruction and expansion, reopening in October 2015. At the time of the study, the fixed staff involved in medication dispensing included 11 pharmacists, four pharmacy technicians, and eight nursing assistants.

First Phase of the Research: Application of HFMEA

The research participants were selected from the following professions: pharmacists, pharmacy technicians, nurses, nursing technicians, and nursing assistants. They met the following criteria: direct involvement in dispensing activities or the investigation of incidents involving the dispensing of anti-infective agents, and availability to participate in weekly meetings. Professionals who were on medical leave or other forms of absence during the data collection period were excluded. Data collection began in August 2019 but was paused from February to August 2020 due to the social isolation measures re-

quired during the COVID-19 pandemic. It resumed in August and was completed in September 2020.

The research was conducted in accordance with the five stages of HFMEA application, which are as follows: Defining the scope of the research, meaning selecting the process to be subjected to risk analysis; Assembling the team or group to carry out HFMEA activities; Graphically describing the process under analysis, identifying all activities, individuals, locations, and tasks involved; Analyzing hazards or failure modes by applying the Risk Prioritization Matrix and Decision Tree to prioritize critical activities with failure modes that lack control measures and/or detectability within the process; Describing necessary actions and improvement measures to control or eliminate risks associated with the prioritized activities from the previous stage[2].

Initially, the setting was assessed to identify research participants, present the project, and obtain consent for the study. The next step involved gathering institutional documents, such as standard operating procedures, policies, and written routines from the pharmacy unit. Subsequently, the process of dispensing anti-infective agents from the hospital pharmacy to the ICU was outlined and mapped to detail activities related to internal stock replenishment, triage, and the dispensing of anti-infectives. The process mapping was carried out through participant observation over the course of ten visits to the hospital pharmacy. The Bizagi Modeler software, version 3.7.0.123, was used to graphically represent the process using Business Process Model and Notation (BPMN) language[12].

A schedule of weekly meetings was then agreed upon with the focus group participants. The meetings took place in the hospital pharmacy's meeting room, during the afternoon shift and within the participants' working hours. Two initial meetings, each lasting two hours, were held to train the group in the application of HFMEA. In six subsequent meetings, also averaging two hours each, the HFMEA for the analyzed process was constructed using the focus group technique.

Following the mapping of the process and subprocesses involved in dispensing, the activities were revisited by the focus group. The facilitator presented the process mapping to the participants, and after reading each activity, posed the following questions to the group: What could go wrong with this activity? Do you recall any instance where this activity could not be performed or was delayed?

All participant responses were recorded in the HFMEA registration form as failure modes and subsequently assessed using the HFMEA Risk Prioritization Matrix, where the group evaluated the severity and likelihood of potential failures.

The Risk Prioritization Matrix (Table 1) is a 4 × 4 matrix applied to failure modes and causes to evaluate the

degree of severity and the likelihood or frequency of their occurrence. Regarding severity, a failure mode and/or cause can be classified as negligible, moderate, critical, or catastrophic, while likelihood can be categorized as remote, rare, occasional, or frequent. By applying the group's evaluation results to the matrix, the Risk Priority Number (RPN) of the failure mode and/or its cause was determined, ranging from 1 to 16. A risk score with an RPN ≥ 8 is considered high risk, requiring the implementation of risk control measures[2].

Subsequently, all identified failure modes were assessed using the HFMEA Decision Tree to evaluate their criticality, absence of controls, and detectability. After determining the RPN, the HFMEA Decision Tree (Figure 1) was applied to identify whether the process itself contained control or detectability measures for the failure mode under analysis. When such measures were present, there was no need to establish additional interventions to control or eliminate the risk. However, when they were absent, actions had to be planned to control or eliminate the risk of the failure mode occurring.

The possible causes of the failure modes were identified by the focus group, and improvement actions were defined for failure modes deemed critical and/or lacking control measures and/or undetectable.

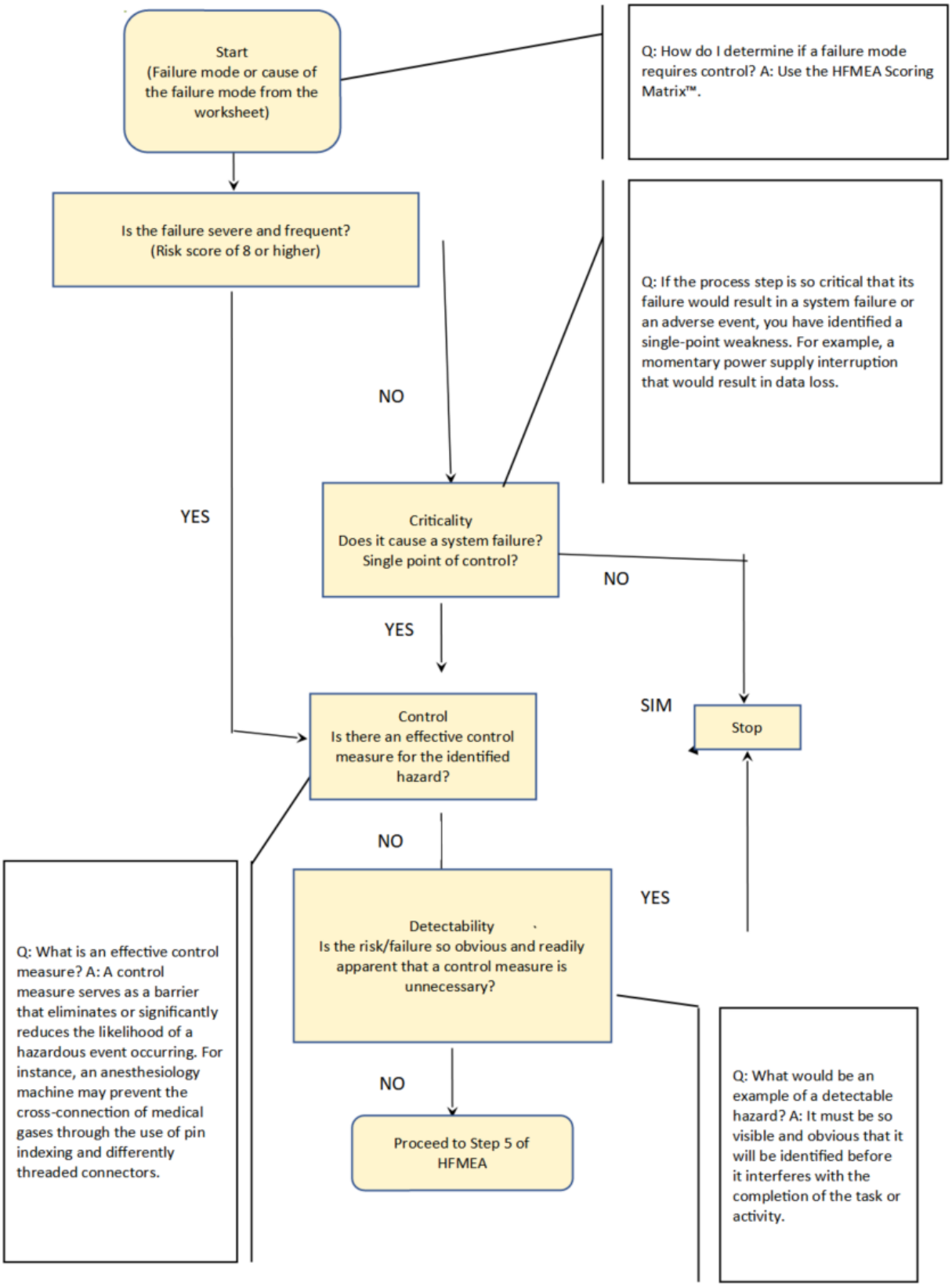
The results were analyzed using descriptive statistics and presented as frequencies and percentages.

Table 1 – Risk Prioritization Matrix for Health Care Failure Mode and Effect Analysis (HFMEA)

Probability	Severity of the Effect			
	Catastrophic	Critical	Moderate	Negligible
Frequent	16	12	8	4
Occasional	12	9	6	3
Rare/Uncommon	8	6	4	2
Remote	4	3	2	1

Note: How to use this matrix:
1. Determine the severity and probability of the risk based on the definitions included in this matrix.
Notes: These definitions are the same as those used in the safety assessment code for root cause analysis.
2. Locate the hazard score in the matrix.
Source: DeRosier, Stalhandske, Bagian, Nudell (2002, free translation).

Figure 1 – Decision Tree for Health Care Failure Mode and Effect Analysis (HFMEA)



Source: DeRosier, Stalhandske, Bagian, Nudell (2002, free translation).

Second Phase of the Research: Redesign of the Dispensing Process

Participants were selected based on an analysis of the professional resumes of those working at the institution during the research period and who met the following inclusion criteria: being a medical professional, nurse, pharmacist, and/or technology analyst; holding a master's or PhD degree; having extensive knowledge of the anti-infective dispensing process; and not having participated in the first phase of the research. Participants who began medical leave or other absences during the data collection period were excluded.

Data collection took place in September and October 2021, through two focus group meetings with specialists. These meetings aimed to present the mapped process and the risk analysis developed in the first phase using HFMEA, allowing the group to redesign the process with the planned improvement actions and others identified by the participants themselves.

Ethical aspects

This research is part of the macroproject "Design and Validation of a Risk Map for Processes in the Use of Anti-Infective Agents in an Intensive Care Unit," approved by the Research Ethics Committee on Human Subjects of the Faculty of Health Sciences at the University of Brasília, under Opinion No. 3.123.845 of 2019. The participants were invited by the principal researcher and, upon agreeing to participate, were presented with the Free and Informed Consent Form. The forms were signed in compliance with Resolution No. 466/2012 of the National Health Council.

RESULTS

Application of HFMEA

Twelve health care professionals participated in the first phase of the study, including four pharmacists, four pharmacy technicians, and three nursing assistants from the Pharmacy Unit, as well as one nurse from the hospital's Patient Safety Core. No participants were lost during the study.

The institution used a proprietary electronic system for medication prescription and dispensing called the University Hospital Management Application (AGHU). The hospital employed an individualized, daily, prescription-based dispensing system.

The focus group deemed the infrastructure insufficient and inadequate for the following reasons: Non-ergonomic furniture, despite an adequate number of high-quality computers; High foot traffic in the area, accompanied by noise from conversations and telephones; Frequent interruptions of the pharmacist's activities by other team members working in the same space; An insufficient number of pharmacy technicians available for medication separation during the daytime shift; Frequent shortages of pharmacists for prescription triage.

The hospital pharmacy performed dose fractionation using automated equipment, guided by four internal documents that regulated and standardized internal procedures and workflows related to the stages of the internal dispensing process, the user manual, the anti-infective prescription standard, and the medication use protocol. Additionally, an anti-infective request form—either printed or electronic—was filled out by the prescriber and sent to the hospital pharmacy. The treatment was initiated and dispensed to the patient only after authorization by the physician from the Healthcare-Associated Infection Control Committee (CCIRAS) and the pharmacist responsible for triage in the Pharmacy Unit.

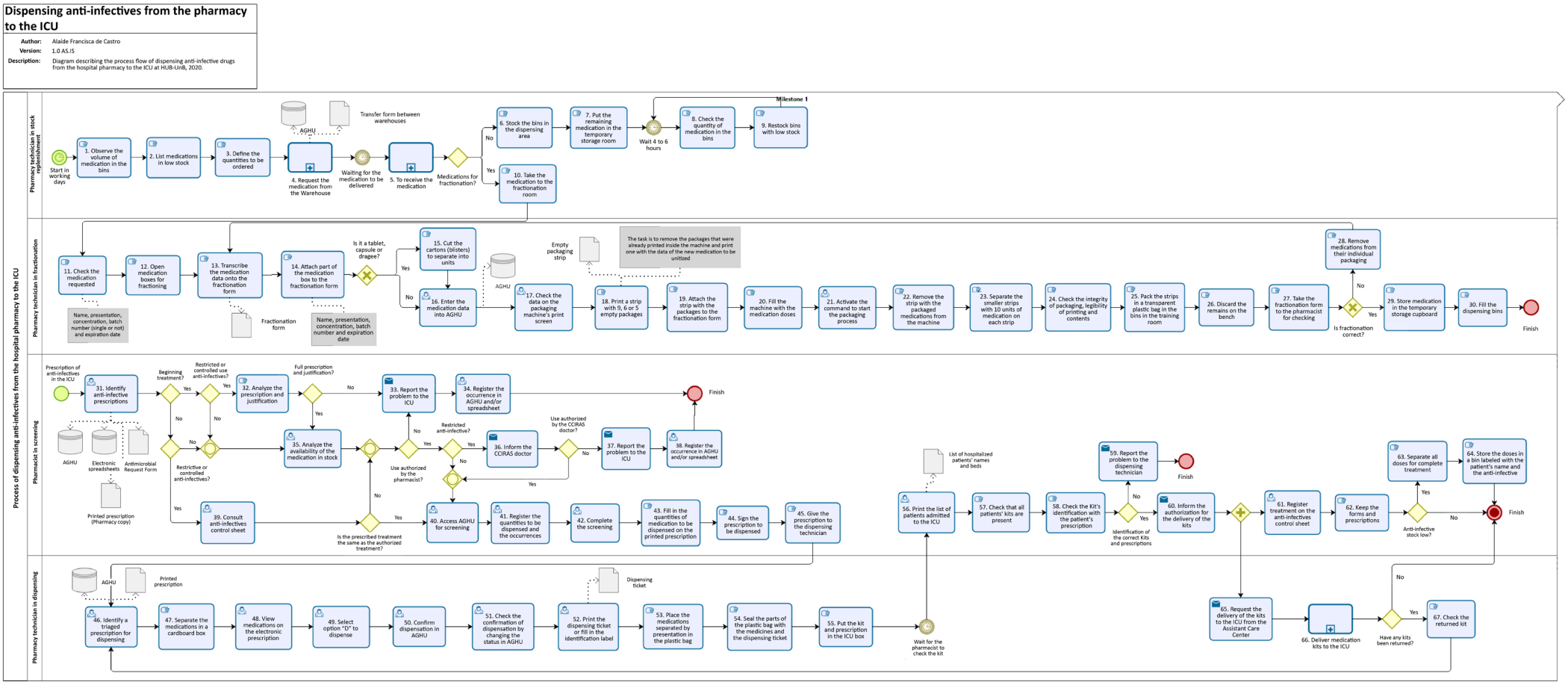
The process mapping for the dispensing of anti-infective agents from the hospital pharmacy to the ICU identified 67 activities and three subprocesses. Figure 2 presents the detailed process mapping in BPMN language, highlighting the four "swim lanes" that separate the activities of the pharmacy technician, including stock storage, dose fractioning, and dispensing, as well as the pharmacist's activities in prescription triage. The blue rectangles represent each of the 67 activities performed throughout the process, while the yellow diamonds indicate the gateways representing the flow paths determined by the responses to gateway questions.

The 67 activities of the process and subprocesses were revisited during six focus group meetings to identify failure modes in the activities. Thirty process activities were identified as having, according to the participants' evaluation, 28 failure modes and 20 possible causes. The most frequently cited failure modes were delays in dispensing anti-infective agents and dispensing errors (dose quantity, presentation, and concentration). The main causes identified were human error during the visual verification of medications and systemic issues related to staffing shortages.

Using the Risk Prioritization Matrix, the severity of the 28 failure modes and their 20 causes was classified as 50% critical, 44% moderate, and 6% negligible. Regarding probability, 46% were considered occasional, 42% frequent, and 12% rare. The RPN ranged from 2 to 12. Subsequently, through the application of the Decision Tree, 11 causes were identified that required the planning of risk control actions. For the other failure modes, it was determined that they were not critical points of the process and/or already had control measures in place and/or were detectable within the process itself. This situation indicated that the risk could be assumed, and no improvement actions were necessary.

Figure 3 outlines the application of HFMEA for the 11 critical failure mode causes, while Figure 4 details the planned improvement actions to control the identified risks.

Figure 2 –– Process mapping for the dispensing of anti-infective agents from the hospital pharmacy to the ICU, Brasília, DF, Brazil, 2020



Source: Castro (2022)(13).

Figure 3 – Analysis of Hazards and Failure Modes in the Activities of the Anti-Infective Dispensing Process from the Hospital Pharmacy to the ICU, Brasília DF, Brasil, 2020

Process Activity	Failure Mode	Cause	Risk Prioritization Matrix[1]			Decision Tree[2]			
			S	P	R	PC	MC	DT	C
31. Identify the prescription of the anti-infective agent.	Failure to identify the prescription, inclusion, or new modification.	31.1. Failure to check the prescription from the previous day.	CR	F	12	S	N	N	S
		31.2. Failure to correctly read prescription modifications when changes such as "from - to" occur.	CR	F	12	S	N	N	S
		31.3. Communication failure within the team during shift changes.	CR	F	12	S	N	N	S
		31.4. Work overload due to a reduced number of professionals.	CR	F	12	S	N	N	S
		31.5. Inattention (memory lapse).	CR	F	12	S	N	N	S
32.2 Analyze the prescription and justification.	Failure to identify a prescription error in dose or administration route.	32.2.1. Lack of access to patient information regarding weight and age.	CR	F	12	S	N	N	S
		32.2.2. Insufficient team training.	CR	O	9	S	N	N	S
		32.2.3. Frequent interruptions (memory lapse).	CR	F	12	S	N	N	S
39. Consult the anti-infective justification spreadsheet.	Failure to consult the spreadsheet daily.	39.1. Lack of standardized workflow protocols to be followed by all professionals in the department.	M	O	6	S	N	N	S
		39.2. Multiple locations for retrieving the same information.	M	O	6	S	N	N	S
47.1 Separate medications in a cardboard box.	Separate the wrong medication (similar names, incorrect presentation, or concentration).	47.1.1 Task overload due to performing all steps of dispensing (separation, system dispensing, and sealing the kit).	C	O	9	S	N	N	S

(1) S = severity; P = probability; R = risk score; CA = catastrophic; CR = critical; M = moderate; D = negligible; F = frequent; O = occasional; RR = rare; RM = remote.
(2) PC = critical point; MC = control measure; DT = detectability; C = continue; N = no; S = yes.
Source: Castro (2022)(13).

Redesign of the Dispensing Process

Five specialists participated in the focus group, including one infectious disease physician, one pharmacist, two nurses, and one risk management and technology analyst. In two meetings, the process for dispensing anti-infective agents from the hospital pharmacy to the ICU was redesigned, incorporating the actions planned in the HFMEA as well as additional changes identified by the participants.

The new anti-infective dispensing process included 48 activities and three subprocesses. Figure 4 details the process mapping in BPMN language, illustrating the three "swim lanes" that separate the activities of the pharmacy

technician and the pharmacist. The blue rectangles represent each of the 48 activities performed throughout the process, while the yellow diamonds indicate the gateways representing the flow paths determined by the responses to gateway questions.

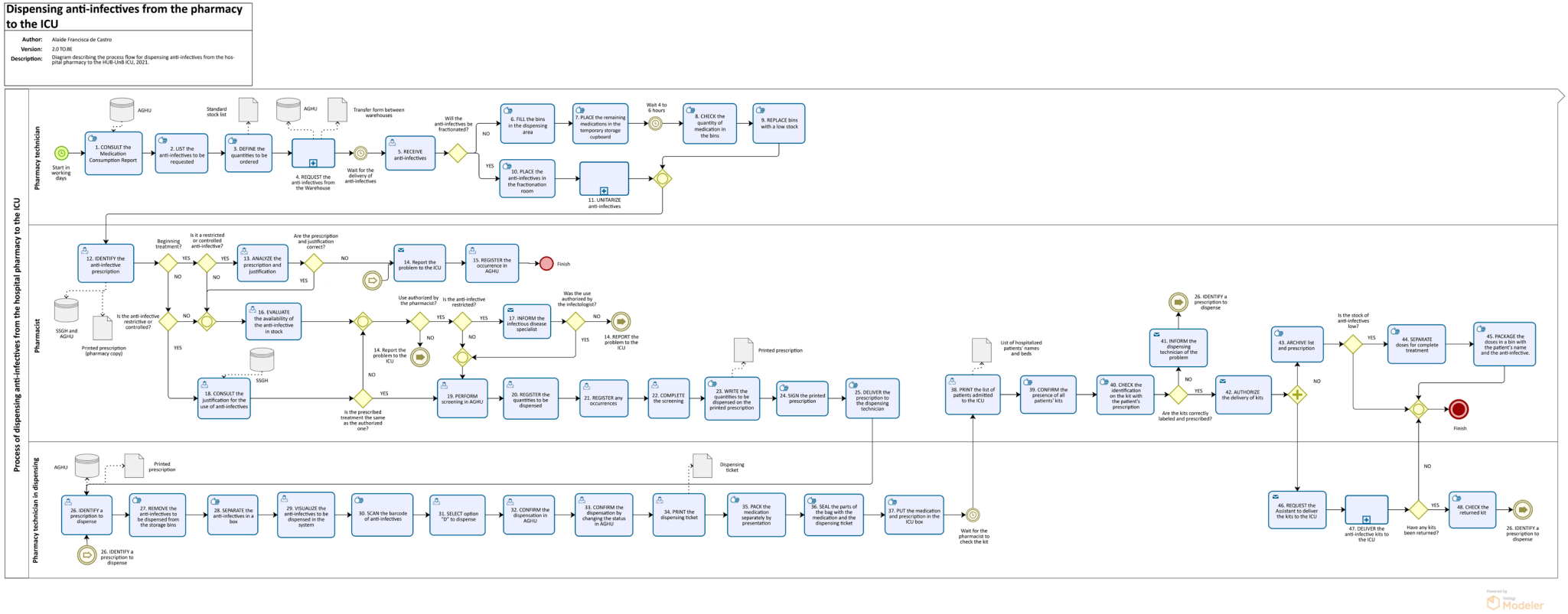
The main changes proposed by the participants for future implementation included transforming dose fractionation into a subprocess and replacing the electronic form for anti-infective prescription justifications with a new electronic system capable of fully identifying the patient's personal data, weight, and allergies.

Chart 1 –– Action Plan to Control Risks in the Process of Dispensing Anti-Infective Agents from the Hospital Pharmacy to the ICU, Brasília, DF, Brazil, 2020

Type of Action	Planned Actions to Control Risks	Expected Outcomes
31.1 Control	1. Update the SOP to include a schedule for checks and verification of additions or changes, with one check per shift by the technician. 2. Train the team on the new routine.	New routine implemented, ensuring timely identification of anti-infective prescriptions.
31.2 Control	1. Conduct periodic training sessions. 2. Request a change in the order in which modifications appear in the system. 3. Ensure that the pharmacy's copy of the prescription includes all AGHU information on respective modifications/additions.	Team correctly interpreting modifications and system improvements facilitating the identification of changes and additions.
31.3 Control	1. Update the SOP for recording occurrences in a logbook. 2. Implement a shift handover checklist.	Improved communication between shifts, ensuring service continuity.
31.4 Control	1. Assess the required staffing levels. 2. Request additional personnel hiring.	Adequate staffing levels to meet service demands.
31.5 Control	1. Implement double-checking (intern/resident and pharmacist). 2. Reassess some staff members' capacity to perform tasks and replace those deemed unfit. 3. Increase monitoring of the dispensing error indicator.	Reduced dispensing errors and better distribution of tasks aligned with staff capabilities.
32.2.1 Control	1. Request improvements in AGHU to display patient weight and age on the pharmacy's copy of the prescription. 2. Include clinical pharmacist participation in the ICU multidisciplinary team. 3. Make patient weight and age mandatory fields in anti-infective usage justifications.	Prescription triage with accurate dose assessment based on patient weight and age.
32.2.2 Control	1. Implement permanent, ongoing, and onboarding education programs.	Teams trained and standardized in task execution.
32.2.3 Control	1. Divide triage tasks among pharmacists (two for same-day prescription triage, one for handling additions/changes and telephone inquiries). 2. Adjust staffing levels.	Update the SOP to include a schedule for checks and verification of additions or changes, with one check per shift by the technician.
39.1 Control	1. Update the SOP to include a schedule for checks and verification of additions or changes, with one check per shift by the technician. 2. Train the team on the new routine.	New routine implemented, ensuring timely identification of anti-infective prescriptions.
39.2 Control	1. Standardize a single method for submitting justifications, preferably electronic.	Streamlined work process, facilitating consultations.
47.1.1 Control	1. Reassess staffing levels. 2. Request the hiring of pharmacy technicians. 3. Enhance the dispensing structure with an additional workstation. 4. Revise dispensing SOPs, prioritizing task separation to allow double-checking. 5. Adjust the automated system with a barcode scanner for all presentations.	Adequate staffing and infrastructure to reduce dispensing errors. Improve job satisfaction, and decrease complaints and conflicts with the ICU team.

Source: Castro (2022)[13].

Figure 4 – Mapping of the Redesigned Process for Dispensing Anti-Infective Agents from the Hospital Pharmacy to the ICU, Brasilia, DF,



SOURCE: Castro (2022)[13].

DISCUSSION

Human Error Theory, also known as the Swiss Cheese Model, introduced by psychologist James Reason in 1990, explains how failures occur. The personal approach focuses on unsafe acts, represented by errors or violations committed by individuals directly involved in the process. Unsafe acts can arise from corrupted mental processes, such as forgetfulness, inattention, lack of motivation, carelessness, negligence, or recklessness. Traditionally, organizations blame individuals involved in the process for errors, viewing them not as causes but as consequences[14].

Latent conditions refer to the systemic flaws inherent to the organization, arising from decisions made by senior management, which can lead to errors. These conditions can manifest through adverse causes related to working conditions, such as time pressure to complete tasks, understaffing, inadequate equipment for job performance, fatigue, and inexperience[14]. There are also errors that create long-term vulnerabilities and weaken defenses, such as unreliable alarms and indicators, impractical procedures, and deficiencies in system or infrastructure design[15].

When combined with active failures and triggers, latent conditions can lead to incidents. However, latent conditions are easier to identify and correct than active failures, which are harder to trace. Understanding these failures enables proactive rather than reactive management[14].

In this study, based on the results of the proactive risk management analysis of the hospital pharmacy's anti-infective dispensing process to the ICU, two thematic categories emerged for discussion: Systemic failures highlighted by structural and technological limitations, lack of standardized operating procedures, insufficient training, and staffing shortages. Human error in manual tasks leading to dispensing errors.

Systemic Failures Evidenced by Structural and Technological Limitations, Lack of Standardized Operational Procedures, Insufficient Training, and Staffing Shortages

The use of anti-infective agents in the hospital begins with the prescription process, which in the ICU is performed by a medical prescriber. Once the prescription process is completed, the dispensing process begins. According to the Federal Pharmacy Council (CFF) Resolution No. 357/2001, the evaluation and interpretation of prescriptions concerning technical and legal aspects is the responsibility of the pharmacist during dispensing[16]. In the studied institution, the evaluation and interpretation stages of prescriptions were performed by pharmacists during the triage process in the Pharmacy Unit, in compliance with the CFF Resolution.

In medication dispensing, pharmacists must interpret prescriptions in terms of therapeutic aspects, individual appropriateness, contraindications, and potential drug interactions. During the prescription analysis, prescribing errors may be identified, enabling correction before reaching the patient[16]. When the prescribed medication dosage or regimen exceeds pharmacological limits, or the prescription shows incompatibility or interaction with other medications prescribed or

being used by the patient, the pharmacist must request confirmation of the prescription from the prescriber and may refrain from dispensing the medication if confirmation is absent or denied. Pharmacists are entitled to decline dispensing any prescription, provided the decision is duly justified[16]. Internal hospital policies outlined a communication flow between medical and pharmacy teams, ensuring that dispensing was only carried out after necessary prescription adjustments and consensus among the involved parties.

In health care institutions, pharmacists' responsibilities during medication dispensing include evaluating prescriptions, making pharmaceutical prescriptions, conducting pharmacotherapeutic follow-ups, and engaging in pharmacovigilance[16]. In the study hospital, pharmacists not only performed prescription triage in the Pharmacy Unit but also participated in pharmacotherapeutic follow-ups as part of clinical pharmacy activities with the multidisciplinary team during ICU rounds and pharmacovigilance actions in collaboration with the Patient Safety Core. It can thus be stated that the three primary activities recommended by the CFF were implemented in the institution.

The way doses are distributed in medication dispensing systems varies across hospitals. Dispensing systems can be collective, individualized, mixed, unit-dose, or automated[15,17]. Collective distribution systems dispense medications collectively for all patients in a specific inpatient service. This system is considered unsafe due to the existence of medication sub-stocks outside the pharmacy under the nursing staff's responsibility, which is a major concern and should be eliminated from health care institutions. Individualized distribution systems dispense medications per patient every 24 hours according to medical prescriptions. This system is safer than the collective one but less secure than unit-dose systems. Mixed systems involve both collective and individualized approaches coexisting within the same location[15].

The unit dose distribution system is the distribution in doses ready to be administered. The medication dose is prepared, packaged, labeled, and dispensed ready for administration, without requiring transfers, calculations, or prior handling by the nursing staff. Examples include pharmacy unit services that prepare total parenteral nutrition and/or chemotherapeutic agents. The unit-dose system, however, is considered safer than the other systems mentioned[15].

In an automated system, care areas are equipped with electronic dispensing devices capable of managing all prescriptions or operating according to the institution's protocols. These devices support the unit-dose system by replacing ward stock for the dispensing of initial doses, including controlled substances and urgent medications. Regardless of the dose dispensing method used in an institution, it is considered best practice for all prescriptions to be reviewed by a pharmacist [15].

The dose distribution system at the study site was of the individual type, highlighting a structural limitation. The available infrastructure, technologies, workflows, and human resources did not allow for unit-dose or automated dispensing, which are considered the safest me-

thods. The focus groups tasked with planning improvement actions discussed the issue and concluded that transitioning from the individual dose dispensing system to a unit-dose system for anti-infective medications or acquiring automated dispensing equipment was unfeasible at that time or in the short to medium term. Such changes would demand extensive structural modifications and substantial financial investment.

Electronic systems for prescribing medications that are integrated with dispensing systems streamline dispensing activities by consolidating key patient information and data. This supports prescription analysis, reduces the risk of prescribing medications not available in stock. Thus, they can help mitigate the risks associated with illegibility, such as dispensing errors caused by misinterpreting prescriptions, missed doses due to stock supply failures, and facilitate the identification of prescription errors by the pharmacist during analysis[15].

In the context of dispensing anti-infective agents in hospitals, pharmacists should be integrated into the anti-infective use management program, participating in the analysis of prescriptions to ensure compliance with the protocols established for the rational and safe use of these medications and in the educational activities of the program[10,18].

Another study conducted in a Brazilian teaching hospital analyzed 565 prescriptions for 37 hospitalized patients diagnosed with HIV/AIDS to identify opportunities for pharmacists to promote the rational use of medications. The study identified 5,512 errors in 7,204 prescribed medications: 41% were dosage errors (incorrect concentration, dose intervals, overdoses, underdoses, "as needed" prescriptions, and incomplete dilution/reconstitution instructions); 40% were administrative or documentation errors (missing patient or prescriber identification, illegible handwriting, incorrect medication names, pharmaceutical forms, or routes of administration); and 19% were therapeutic errors (prescriptions for contraindicated medications, therapy duplications, and failure to adjust doses for renal or hepatic impairment). The research concluded that electronic prescription systems and clinical pharmacy activities could help prevent prescription errors[18].

Participants in the present study identified limitations in the technologies used in the workflow. The absence of critical information in prescriptions, such as the patient's weight and age, compromised the evaluation of the correct dose of anti-infective agents during the pharmacist's screening process. Another limitation of the system used at the institution was the lack of information on the unit where the patient was hospitalized on the dispensing ticket, which caused process failures.

The dispensing of anti-infectives was performed manually, without the support of any technology, such as a barcode scanner. A study evaluating the use of barcode scanners demonstrated that this technology is effective in detecting potential errors in the dispensing process, as well as eliminating content errors, which have the highest incidence[19]. Moreover, safety barriers built into systems developed with artificial intelligence, which use algorithms to cross-reference information in patient records and prescriptions,

blocking or creating alerts for inappropriate prescriptions, can contribute to mitigating these risks[6,20].

The present study showed that pharmacists identified issues such as missed prescriptions, alterations, or inclusions caused by workload overload due to the reduced number of professionals in the service. Pharmacy technicians and assistants highlighted workload overload, as all team members performed every step of the process (selection, system dispensing, and kit sealing). The shortage of pharmacy technicians also led to the inclusion of nursing assistants in the task of selecting medications for kit assembly. This practice may increase the risk of dispensing errors, as nursing assistants lack the specific training required for this role.

A French study that applied FMEA to analyze medication dispensing risks also identified systemic failures related to inadequate human resources and non-standardized workflows. Errors identified included dispensing medication to allergic patients, failure to communicate potential drug interactions, patient identification errors, failure to check dispensing carts, dispensing incorrect medications due to similar names, confusion between the use of anti-infectives for surgical prophylaxis or treatment, and stock shortages caused by poor inventory control. After implementing corrective measures, the risks associated with the process were reduced. Causes of these risks included workload overload, insufficient staffing, or even the absence of pharmacists in critical hospital pharmacy processes[21].

Dispensing errors involving switched dispensing windows and dose calculation errors for chemotherapy drugs due to workload overload were also identified in another study that applied HFMEA[22].

A qualitative study conducted in Iran explored and described the causes of medication errors in 16 ICUs across seven teaching hospitals from the perspectives of physicians, nurses, and clinical pharmacists. The four main categories identified were: low attention by health care professionals to medication safety, lack of communication and professional collaboration, environmental determinants, and management determinants. The study concluded that incorrect prescriptions by physicians, unsafe medication administration by nurses, insufficient knowledge among pharmacists and health care teams, and weak professional collaboration compromise medication safety. It is therefore necessary to promote interprofessional collaboration and the participation of clinical pharmacists in ICUs[23].

This study also identified a systemic failure in the pharmacy unit: the absence of standardized operating procedures (SOPs) detailing all stages of anti-infective dispensing, uniformly followed by all involved in the process. The lack of standardized activities suggests managerial disorganization, as differing methods among professionals performing the same task can lead to varied outcomes.

The findings of this study align with other research that applied FMEA or HFMEA to prevent failures in medication prescription, dispensing, and administration processes due to non-compliance or the absence of SOPs and lack of periodic staff training[3,21-25]. The need for periodic team training was also highlighted by the HFMEA group as a key action in the risk control plan for dispensing failures. Edu-

cational activities proposed in the action plan established in this study could enhance adherence to best practices outlined in existing SOPs and those yet to be developed.

Human Error in Manual Activities Leading to Dispensing Failures

In the pharmacists' triage activities, violations were associated with failure modes such as "failing to identify new prescriptions, modifications, or additions, and neglecting to consult the justification for anti-infective use." Specific issues included not reviewing prescriptions from the previous day, misinterpreting prescription changes classified as "from-to," and failing to consult the anti-infective justification log on a daily basis.

Interruptions by members of the same team, also cited as causes of failure modes, increase the risk of errors. Such interruptions disrupt workflow and memory, predisposing professionals to resume previous tasks without fully regaining their focus on the activity[20]. Failures in dispensing caused by unqualified personnel, distractions, interruptions, and haste have been identified in proactive risk analyses across different services[3,21-24].

The causes of failure modes, such as "lack of work process protocols followed by all professionals in the sector" and "lack of team training," highlight vulnerabilities in the dispensing process and may be directly linked to individual failures.

"Team communication failures during shift handovers" were identified by pharmacists as a risk factor. Planned actions to mitigate this risk included updating the SOP for recording incidents in a logbook and implementing a shift handover checklist. Shift handovers are considered essential tools for preventing failures and errors in patient care[5,6,15,17,20].

Another significant cause identified was the presence of multiple locations to retrieve the same information about the justification for prescribing anti-infective agents. The better the technology applied to the dispensing of anti-infectives, the greater the safety in work processes, establishing systemic barriers to potential errors.

The separation of medications was considered a critical activity, with two identified failure modes: "incorrect medication separation," whether due to similar names, wrong presentation, or concentration; and "placing the dispensing ticket in the wrong patient's box." The causes of these failures indicated by participants included "staff overload," "a single printer being used by all employees," and "the ticket lacking the patient's clinic location".

Another study on dispensing practices in a teaching hospital in Natal, Brazil, identified the same failure modes as those found in this study's risk map, associated with staff overload and technological limitations[26]. It is noteworthy that the shared failure modes and some common causes across studies suggest the likelihood of similar issues being present in other hospital pharmacies[3,21-26].

The experience from this study also demonstrated that process mapping was useful for identifying necessary changes. In the workflow for dose fractionation, the pharmacist verified the information on the form and the labels of the packages at the end of the day, after all the medications had been fractioned and packaged. If incorrect data was identified, all the

packaged fractioned doses were discarded. This verification activity was moved to occur immediately after the form was created and the first package printed. This change avoided packaging all doses with incorrect identification data, reducing time and resource waste.

Medication use systems must have adequate resources and specificities for each function, considering the training and experience of health care professionals to ensure control over all used medications and standardize usage environments or clinical/therapeutic protocols. Medication information should be made available to the responsible health care professionals, ensuring accountability and enabling performance checks at every step[15,17,20].

The medication use system must be continuous, as disruptions in activities can lead to undesirable outcomes. System weaknesses should be identified to maintain logical connections and prevent interruptions in subsequent steps. Risk management should be applied to the system to reduce the likelihood of errors[3,15,17,21-26].

Systemic and human errors discussed align with Reason's Swiss Cheese model of systemic theory, demonstrating that latent conditions can serve as precursors to human errors. Both the group's risk analysis and the planned actions highlighted participants' high awareness of risks in their activities and the systemic and human dimensions of errors.

From the participants' perspective, violations must be curbed by expanding safety barriers and incorporating technologies that facilitate standardized work processes, minimizing fully manual tasks. The accountability investigations, along with the application of penalties deemed necessary in cases of recurring violations, demonstrated that the participants understood the concepts of a just culture and the importance of accountability in instances of repeated breaches.

This study contributed to health care delivery, management, research, and education. In health care, it contributed to the establishment of new work processes aimed at incorporating safety barriers to mitigate the risks associated with identified failure modes, thereby enhancing the quality of care and minimizing dispensing errors of anti-infective medications. In management, the proactive risk management tool was effectively applied, contributing to the anti-infective management system to improve outcomes. For research and education, the study demonstrated its contribution to risk management in the complex system of anti-infective use in hospitals and highlighted knowledge gaps that call for further studies. These future investigations should explore the best practices applicable to the anti-infective dispensing process in the context of critical care, aiming to minimize the risks of systemic and human failures.

The limitations relate to the action-research method, as the results represent the risks identified within the studied institution's context, reflecting participants' and researchers' perceptions, and cannot be generalized. However, the identified failure modes, effects, and causes may be present in the context of anti-infective use in ICUs of other establishments. Additionally, the proposed risk reduction solutions could serve as examples for other hospitals.

FINAL CONSIDERATIONS

The study's objectives were achieved through the analysis of HFMEA implementation in the anti-infective dispensing process from the hospital pharmacy to the ICU. This approach enabled an understanding of failure modes and effects, risk assessment, planning of actions to control these risks, and, consequently, improvements in process quality and safety. It also contributed to the institution's anti-infective management program by developing a new process ready for implementation.

The application of the tool proved to be straightforward, feasible for implementation in a public teaching hospital, and facilitated interdisciplinary collaboration. This can be seen as an incentive for health care services to optimize their anti-infective management systems, aiming to improve processes and enhance quality and safety in the dispensing of these medications, particularly in critical care settings.

The process mapping of the dispensing workflow, represented graphically using Bizagi Modeler, provided greater clarity and detail regarding how, when, and by whom the various activities involved in the process were performed, as well as the identification of critical points by those involved. The process is complex, encompassing 48 activities, three interconnected subprocesses, and involving four different professional categories.

By measuring the severity and likelihood of failure modes occurring in the activities of the mapped process using the HFMEA Risk Prioritization Matrix, it was possible to identify the risks with the highest potential to harm patients and the frequency of their occurrence. Most calculated RPN were high, ranging from 2 to 12, with RPN 6 being the most frequent (37.5%), followed by RPN 12 (33.0%) and RPN 9 (12.5%).

The main failures identified included delays in dispensing anti-infective agents and dispensing errors (dose quantity, presentation, and concentration). Latent conditions included structural and technological limitations, lack of standardized operational procedures, insufficient training, and staff shortages. Active failures in manual activities were the most frequently cited causes of process failures.

The actions planned by the focus group participants included interventions targeting the identified failure modes, changes to physical, technological, and staffing conditions, as well as workflow modifications, such as updating SOPs and implementing double-check systems. These actions are comprehensive and feasible within the institutional context and have the potential to mitigate the identified risks effectively. Furthermore, modifying workflows can contribute to economic sustainability by reducing waste of time and resources.

Finally, the results of this study highlight the need for greater investment in personnel development and technological resources, as well as revealing gaps in knowledge and research in the field. These gaps pertain both to the managerial aspects of organizing hospital pharmacy services and the underlying theories that support them. Many recommendations are based on best practices for implementing interventions and adopting technologies that can effectively reduce the risk of medication errors. The major chal-

lenge for health care institutions lies in integrating these technologies, including proactive risk management, into their organizational processes on an ongoing basis.

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