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# The Healthcare Failure Mode and Effect Analysis as a tool to evaluate care protocols

*O Healthcare Failure Mode and Effect Analysis como ferramenta de avaliação de protocolos assistenciais*

*El Healthcare Failure Mode and Effect Analysis como herramienta de evaluación de protocolos asistenciales*

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## ABSTRACT

**Objectives:** to identify, classify, and analyze modes of failure in the medication process. **Methods:** evaluative research that used the Healthcare Failure Mode and Effect Analysis (HFMEA) in a service of bone marrow transplant from June to September 2018, with the participation of 35 health workers. **Results:** 207 modes of failure were identified and classified as mistakes in verification (14%), scheduling (25.6%), administration (29%), dilution (16.4%), prescription (2.4%), and identification (12.6%). The analysis of risk showed a moderate (51.7%) and high (30.9%) need of intervention, leading to the creation of an internal quality assurance group and of continued education activities. **Conclusions:** the Healthcare Failure Mode and Effect Analysis showed itself to be a tool to actively identify, classify, and analyze failures in the process of medication, contributing for the proposal of actions aimed at patient safety. **Descriptors:** Medication Errors; Healthcare Failure Mode and Effect Analysis; Patient Safety; Protocol; Nursing.

## RESUMO

**Objetivos:** identificar, classificar e analisar modos de falhas no processo de medicação. **Métodos:** pesquisa avaliativa que utilizou o *Healthcare Failure Mode and Effect Analysis* (HFMEA) em Serviço de Transplante de Medula Óssea, de junho a setembro de 2018, com a participação de 35 profissionais de saúde. **Resultados:** foram identificados 207 modos de falhas, classificados em erros de checagem (14%); aprazamento (25,6%); administração (29%); diluição (16,4%); prescrição (2,4%) e identificação (12,6%). A análise do risco evidenciou a necessidade de intervenção moderada (51,7%) e alta (30,9%), resultando na criação do grupo interno de qualidade e atividades de educação continuada. **Conclusões:** o *Healthcare Failure Mode and Effect Analysis* demonstrou ser ferramenta para identificar, classificar e analisar, ativamente, falhas no processo de medicação, contribuindo para a proposição de ações com vistas à segurança do paciente.
**Descritores**: Erros de Medicação; Análise do Modo e do Efeito de Falhas na Assistência à Saúde; Segurança do Paciente; Protocolo; Enfermagem.

## RESUMEN

**Objetivos:** identificar, clasificar y analizar modos de fallos en el proceso de medicación. **Métodos:** investigación evaluativa que utilizó el *Healthcare Failure Mode and Effect Analysis* (HFMEA) en Servicio de Trasplante de Médula Ósea, de junio a septiembre de 2018, con la participación de 35 profesionales de salud. **Resultados:** han sido identificados 207 modos de fallos, clasificados en errores de chequeo (14%); aplazamiento (25,6%); administración (29%); dilución (16,4%); prescripción (2,4%) e identificación (12,6%). El análisis del riesgo evidenció la necesidad de intervención moderada (51,7%) y alta (30,9%), resultando en la creación del equipo interno de calidad y actividades de educación continua. **Conclusiones:** el *Healthcare Failure Mode and Effect Analysis* demostró ser herramienta para identificar, clasificar y analizar, activamente, fallos en el proceso de medicación, contribuyendo para la proposición de acciones con objetivo de seguridad del paciente.
**Descriptores**: Errores de Medicación; Análisis de Modo y Efecto de Fallas en la Atención de la Salud; Seguridad del Paciente; Protocolo; Enfermería.

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## INTRODUCTION

Considering the complexity of the procedures and treatments in the services that provide health care, there is a real possibility of harm to the patient[1]. This risk requires actions to promote safe care through the identification of potential failures and the search for solutions, such as the use of protocols that standardize and guide professional practice.

This research presents contributions to the topic "patient safety", in regard to drug therapy in hematopoietic stem cell transplants. Also known as "bone marrow transplant", this is one of the main treatments for patients with oncological, hematological, and congenital diseases. This modality of care makes it possible to extend the period of life and may even represent a cure, by replacing the diseased or deficient bone marrow with healthy hematopoietic stem cells[2].

After characterizing the adverse events related to the medication and identifying the medication profile of a Bone Marrow Transplant Service (BMTO), a protocol for the safe drug use was created and validated in 2017[3]. This research is justified by the relevance of continuously monitoring the risks and the evaluation of this protocol, which has been used since April 2018, and the importance of identifying failures and making potential changes, planning new topics, and taking corrective and preventive action.

In this context, and considering the tools for the evaluation of protocols and the management of risks, the methodology Failure Mode and Effect Analysis (FMEA) stands out. Its objective is avoiding, through an analysis of potential mistakes and the proposal of improvements, failures in the project of a product or process, to diminish the chances of failure in this product or process[4].

Although this tool was developed by engineers and was, at first, used in highrisk industries, such as aviation and nuclear energy, the HFMEA is currently used for the proactive evaluation and improvement of the safety of complex health care processes. This methodology is also recommended by international organizations, such as the Joint Commission, the Institute for Healthcare Improvement, and the Institute for Safe Medication Practices[5]. The Healthcare Failure Mode and Effect Analysis (HFMEA) is an adaptation that makes it possible to identify and reduce proactively the potential problems related to the safety of the patient in a hospital environment[6].

## OBJECTIVES

To identify, analyze, and classify the failure modes in the process of medication.

## METHODS

### Ethical aspects

This research is part of the project "Nursing actions in the essential care of hematopoietic stem-cell transplants", approved by the Research Ethics Committee from the *Universidade Federal do Paraná* and the UFPR general hospital.

### Design, period, and place of study

This is an evaluative research, with the application of the HFMEA methodology, starting in June 2018 at the BMTO of the general hospital complex at the *Universidade Federal do Paraná* - Brazil. Since this research aimed to improve the quality of the processes, the design of the study was created in accordance with the tool SQUIRE 2.0.

### Sample, criteria of inclusion and exclusion

All 65 professionals from the nursing team who used the protocol "Safe Drug Use" were invited to participate, regardless of how long they had been working in the unit. The pharmacist who was responsible for the chemotherapy drug sector of the research hospital and a BMTO physician recommended by the heads of the department were also invited. There was no exclusion criteria. The intentional sample of this research included the 58 professionals who formally accepted participating

### Study protocol

The participants were separated in two groups (1 and 2) and received capacitation and training to use the HFMEA tool in workshops that lasted for one hour. Initial data regarding the medication process and the use of the protocol were obtained in the meetings with Group 1 formed by 38 nurses, 17 nursing technicians, and one nursing auxiliary and analyzed and classified by Group 2 formed by one pharmacist, one physician, and the main researcher of the study. Complementarily, during the meetings, data about drug related adverse events in the service were used and discussed, concerning the period from April (first month of implantation of the protocol) to August 2018 (when the meetings ended).

### Analysis of results and statistics

Data were organized in an Excel spreadsheet and analyzed using the software IBM SPSS Statistics v.20.0 (Armonk, NY: IBM Corp). They were described using absolute and relative frequency and subsidized the planning of action by the participants after the analyses. This research is part of the project "Nursing action in the essential care for hematopoietic stem cell transplants", approved by the Research Ethics Committee.

## RESULTS

There were 18 meetings with Group 1, distributed equally in work shifts. 42 failures were found in the medication process. These were added to the 165 ones identified by consulting the notifications of adverse events, leading to a total of 207 failures analyzed and classified by Group 2 (Figure 1).

According to the HFMEA methodology, the Risk Priority Number (RPN) calculated was mostly moderate (Figure 2), making it possible to guide actions for prevention and control.

After the failures were classified and the risk priority was calculated, the participants in the Groups 1 and 2 proposed actions and recommendations to be incorporated to the protocol and to the routine of the BMTO, to prevent failures in the medication process (Chart 1).

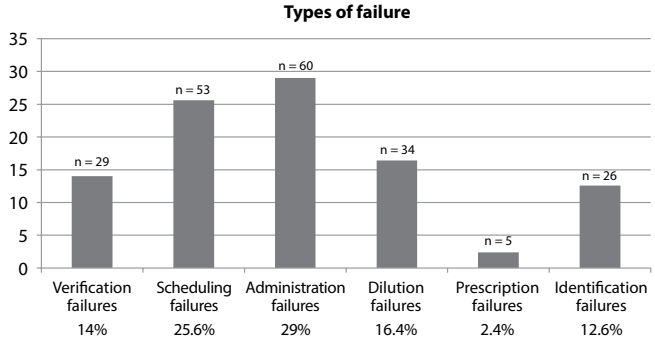


**Figure 1** — Types of failure in the medication process, Curitiba, Paraná, Brazil, 2018

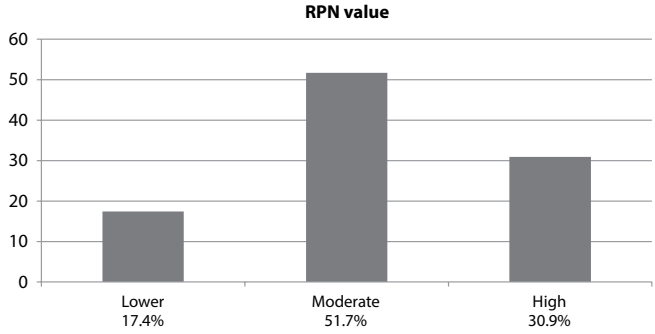


**Figure 2** — Risk priority of the failures in the medication process, Curitiba, Paraná, Brazil, 2018

**Chart 1** — Matrix of recommendations for the protocol of safe medication use, Curitiba, Paraná, Brazil, 2018

| |
|---|
| 1. To create an integral quality group focused on the medication process. |
| 2. To insert the drug table in all wings and in the room of the physicians on duty. |
| 3. To elaborate a checklist for medical prescriptions. |
| 4. To include all antibiotics and antifungals in the protocol and on the recommendation table for drug use, which is available in the sector. |
| 5. To include the drug "anidulafungin" in the protocol. |
| 6. To include the drug "ampicillin" in the protocol. |
| 7. To include the drug "amikacin" in the protocol. |
| 8. To include the drug "lipid amphotericin B" in the protocol. |
| 9. To review the dilution of "hydrocortisone" for patients with water restriction. |
| 10. To dilute the acyclovir in 5 ml of distilled water, to reach a final concentration of 7 mg/ml. |
| 11. Physical barrier to the laminar flow. |

## DISCUSSION

The use of the HFMEA methodology made it possible to identify and analyze the failures in the medication process, classifying them and establishing the priority of the actions then planned. The nursing team has an essential role in the medication process, since many of the activities involved are the responsibility of these workers, such as the dilution and administration of drugs. Therefore, it is extremely important to have updated knowledge in order to properly monitor the patient and take measures to prevent mistakes[7-8]. In this regard, the HFMEA was shown to be a tool that can be used by the group responsible for the medication process, not only enabling the identification of failures but also allowing this group to take the main role in the planning of corrective and preventive actions, basing them on their professional experiences.

This research identified and analyzed 207 failures related to the medication process, which were classified according to the type of mistake. The "drug administration" was the most common failure (29%), corroborating the results from a literature revision study that investigated the scientific production about the theme in the care practices of the nursing team[9]. The drug administration stage is crucial, since it is the last opportunity to avoid a mistake. Therefore, it is essential that professionals recognize its relevance, giving the action the attention it deserves and verifying whether patient, dosage, route, and time of administration are correct.

Scheduling mistakes corresponded to 25.6% and verification mistakes to 14%. In the setting of this research, the nurse is responsible for scheduling and for diluting and elaborating the drugs, except for chemotherapy medication. However, nursing technicians also make the scheduling, albeit under the supervision of a nurse. Considering the complexity of the scheduling of medical prescriptions, this should only be done by nurses, who have scientific training to prevent the complications that may arise from drug interactions[10]. Nonetheless, a study has shown that, even in places where the scheduling of the prescriptions is made by nurses, there are failures[11]. Due to that, this study highlights how important the work of the nursing team is, as well as that of all those involved, through the revision of the prescriptions as shifts change and during audits. To this end, it is essential to invest in continued education to equip the professional with the instruments to correctly schedule drug administration, considering potential drug interactions.

Failures in the elaboration stage corresponded to 16.4% of the total, ratifying a study carried out in a public hospital in the countryside of São Paulo, Brazil, where, from 180 dosages investigated, 125 (69.5%) had at least one dilution mistake, with no form of record or evaluation and/or monitoring of these mistakes[12]. The administration and elaboration of drugs demand focus, since interruptions increase the likelihood of mistakes, and the difficulty to remember which stages were already concluded may lead to the omission of important steps[13]. In the setting of this research, there is a laminar flow station where the medication of the sector is diluted. This is an isolated environment, where only the nurse and the flow auxiliary selected are allowed. However, the research participants have reported that the nurse is constantly interrupted by noise and by the rest of the team. The participants suggested the creation of a physical barrier to the flow station, which would diminish the interruptions and potentially contribute to avoid failures related to the elaboration of drugs.

There was a low level of failures in regard to prescription and identification. These results could be connected to certain irregularities incorporated to the routine of the service, which tends to attribute to the nursing team difficulties in interpreting

the prescription. Although the number of failures in this stage was less pronounced, it stands out that the medical prescription is fundamental to prevent mistakes. The physician must avoid imprecise prescriptions, abbreviations, or words that are incomplete, illegible, or have erasures, factors that may lead to errors[14]. To be adequate, the prescription must have an identification of the patient, the physician, and the institution, and the date; it must be legible; there must be no abbreviations; and the dosages must be indicated[15]. These precepts were observed in the setting of this research.

Among the many medication mistakes, the prescription stands out due to its potential to cause harm to the patients, and because it represents a significant proportion of the avoidable drug-related problems[15].

Considering that the HFMEA is a methodology used to map, evaluate, and propose the control of failures before they take place, by detecting the hidden incidents in the system, it contributes to systematically evaluate the critical points of processes. This tool also allows for a classification of the severity of the potential effects of the failure and the likelihood of it to occur, providing the opportunity to prioritize which risks should be controlled by corrective and preventive actions. Therefore, after the occurrence, its severity, and the likelihood of a potential failure were determined, the Risk Priority Number (RPN) must be calculated, by multiplying the values attributed to each item[16].

Using this tool, we found that the RPN values were from moderate (51.7%) to high (30.9%). The frequencies, summed, result in more than 80%. The HFMEA method states that, when the RPNs are moderate, medium-term actions should be started; when the risk for failure is high, these actions must be carried out in the short-term and a detailed evaluation of the data found must be carried out. As a result, after the preliminary results were described and indicated the high index of moderate and high risk, it was necessary to take action to minimize these failures.

To do so, in September 2018, an internal quality assurance group was created in the BMTO. This group, in addition to monitoring the failures that occur, audits prescriptions to detect undernotification cases. Furthermore, it promotes capacitations during the service, clarifying doubts and providing feedback about the audits carried out. This study made it possible to identify and analyze the notifications related to patient care, and the creation of this group aimed at promoting the application of safe practices, minimizing the failures in the medication process. Establishing this group was thought to be an important improvement to the safety of the patient, especially as it was carried out by the health care team themselves, which provided actual audits.

The application of the HFMEA in the daily work can significantly improve the quality and safety of drug therapies, in addition to directing the workers in the elimination of mistakes from the medication process and involving them in said process. As a result, this methodology was found to be a modality of continued education.

The matrix of recommendations was constructed by the workers who participated in the research, highlighting: the absence of some drugs in the protocol (that were commonly used in the service) and the revision of medications. It is worth mentioning that, during the meetings with Group 1, the participants indicated the need to make the protocol available for the medical team, to standardize prescriptions and make it possible to consult which drugs are being used. Furthermore, there were recommendations regarding the use of a checklist for medical prescriptions, that included all essential elements for the safe prescription of drugs as an educational strategy.

### Study limitations

As a limitation of the study, it stands out that the participants did not know the tool that was applied, and a training session was necessary for them to use it correctly.

### Contributions to the field of nursing

This research contributed to actively and systematically identify individual and collective errors in the drug administration process, leading to the implementation of measures to prevent them.

## CONCLUSIONS

The HFMEA was found to be an instrument easy to understand and apply to identify and classify the modes of failures in the process of medication. It is a methodology that subsidizes the proposal of actions to promote patient safety in the complex process of medicating. It was found to be a safe system to detect failures in the medication process, and its use in the day-to-day care may help professionals in the prevention of adverse events. In this research, the use of the HFMEA subsidized the participative elaboration of a matrix of recommendations that proposed systematic action, based on the identification, classification, and analysis of modes of failures.

The analysis of failures according to risk priority, being the risk considered to be moderate and high, allowed for more self-criticism and culminated in the implantation of an internal quality group, targeted at the safety of the patient. The main objective of the group was to reduce failures in the medication process, adding to their audits training sessions and capacitation. This group provides support to the nursing team based on the failure identified, collaborating for an active process to improve the quality during this critical process of bone marrow transplant.

This research contributed for individual and collective failures in the process of medication to be actively and systematically identified, and for measures to prevent them to be implemented. We believe that the results are useful to inform nursing professionals about the importance of being aware of the failures during the medication process, allowing for an in-depth perception of the topic and making a safe care practice possible.

## SUPPLEMENTARY MATERIAL

This research results from the MS dissertation of its main author, named "Using the HFMEA method to evaluate the safe drug use protocol in a bone marrow transplant service". This dissertation is available in the digital library of the Universidade Federal do Paraná. Available from: https://acervodigital.ufpr.br/handle/1884/62262.

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