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Medication errors: descriptive study of medication classes and high-alert medication

Erros de medicação: estudo descritivo das classes dos medicamentos e medicamentos de alta vigilância

Errores de medicación: estudio descriptivo de las clases de los medicamentos y medicamentos de alto riesgo

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ABSTRACT

Objective: The study aims to present the medication classes involved in medication errors occurred at an Intensive Care Unit and to identify which are classified as high-alert medication classes. **Methods:** The population was composed of the documents of occurrence of errors contained in a database created for a previous investigation. We performed a secondary analysis of the available information. **Results:** Overall, 305 events were identified, with an average rate of 6.9 events per patient. Seventy-three medications were found, distributed among 33 classes according to their predominant action, the most frequent of which were: antibiotics (25.2%), gastric acid reducers (19.0%) and antihypertensive drugs (9.2%). Thirty-seven (12.1%) events involving high-alert medication classes were identified, corresponding to five classes, among which venous anesthetics predominated (43.3%). **Conclusion:** These drug types are frequently used at intensive care units and should be accurately monitored, as they can cause further damage when incorrectly used.

Keywords: Medication errors; Medication systems; Intensive care units; Quality of health care.

RESUMO

Este estudo objetivou apresentar as classes dos medicamentos envolvidos nos erros de medicação ocorridos em Unidade de Terapia Intensiva e identificar aqueles que são classificados como medicamentos de alta vigilância. **Métodos:** A população foi composta pelas fichas de ocorrências de erros que constavam em um banco de dados de uma investigação prévia. Foi realizada uma análise secundária das informações disponíveis **Resultados:** Foram identificados 305 eventos, obtendo-se média de 6,9 ocorrências por paciente. Verificaram-se 73 medicamentos distribuídos em 33 classes de acordo com sua ação predominante, sendo os mais frequentes: antibióticos (25,2%), redutores de acidez gástrica (19,0%) e anti-hipertensivos (9,2%). Foram identificadas 37 (12,1%) ocorrências com medicamentos de alta vigilância, que corresponderam às cinco classes, e a dos anestésicos venosos foi predominante (43,3%). **Conclusão:** Estes tipos de medicamentos são usados frequentemente nas unidades intensivas e devem ter um monitoramento acurado, uma vez que podem causar danos maiores se o seu uso for incorreto.

Palavras-chave: Erros de medicação; Sistema de medicação; Unidade de terapia intensiva; Qualidade da assistência à saúde.

RESUMEN

Objetivo: Este estudio presenta las clases de los medicamentos involucrados en los errores de medicación e identifica aquellos que son clasificados como medicamentos de alto riesgo. **Métodos:** La población fue compuesta de los documentos de las ocurrencias de errores contenidos en una base de datos de una investigación previa. Se realizó un análisis secundario de la información disponible. **Resultados:** Fueron identificados 305 eventos, resultando en un promedio de 6,9 eventos por paciente. Fueron verificados 73 medicamentos, distribuidos en 33 clases de acuerdo con su acción predominante, siendo las más frecuentes: antibióticos (25,2%), reductores de acidez gástrica (19,0%) y antihipertensivos (9,2%). Fueron identificadas 37 (12,1%) ocurrencias con medicamentos de alto riesgo, correspondientes a cinco clases. La incidencia con anestésicos venosos fue predominante (43,3%). **Conclusión:** Estos tipos de medicamentos son de uso frecuente en las Unidades de Terapia Intensiva y su monitoreo debe ser adecuado, ya que pueden causar daños mayores cuando utilizados de manera incorrecta.

Palabras-clave: Errores de medicación; Sistemas de medicación; Unidades de cuidados intensivos; Calidad de la atención de salud.

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INTRODUCTION

The concept of system refers to the disposition of the parts or elements of a whole, coordinated with each other and functioning as an organized structure. The system allows subsystems or processes, which have their own functions and objectives and affect the behavior of the set. If there is an action performed by one part, there is necessarily a reaction from the others[1].

The medication system is viewed as complex and dynamic and it encompasses several stages, such as: selection and obtention of the medication; prescription; preparation and dispensation; administration of medications; and monitoring of the patient[2].

The design of a system should be flexible and adequate to the reality of each institution, region or country, judging by the structural and procedural conditions in which it is included. However, independently of the subsystems that constitute it or of the professionals who act in it, the path should be safe, ensuring that the patient receives the drug therapy in an effective, efficient, efficacious and optimized way, in compliance with specific legislations and supported by quality standards[1,2].

Administering drugs to patients at healthcare institutions is a complex process, with multiple steps that depend on a series of decisions and actions that are interrelated. Nevertheless, not always is the system sufficiently safe, and errors occur that may or may not cause damage to the patient. These errors, which are called medication errors (ME), are considered preventable adverse events[3].

There are diverse reasons for the occurrence of ME, ranging from lack of knowledge about the medications, lack of information on the patient, memory slips and lapses, transcription errors, failure in the verification of the administered dose, defective infusion pumps and inadequate monitoring of the patient, to inappropriate storage of the medications or lack of labeling with alerts for use, among others[2-4]. Thus, ME may occur at any part of the medication system and may involve any of the countless medications that are available, including those classified as high-alert medications.

High-alert medications (HAM), also known as high-risk or potentially dangerous medications, are those with higher potential to cause severe or even fatal damage when an error occurs during their utilization. Although occurrences involving this type of medication are less common, the consequences to the user can be more devastating[5]. The report of the North American system MedMarx®, used for ME notification, shows that, in the period from 2006 to 2008, occurrences with HAM corresponded to approximately 7% of the 443,683 reported errors[6].

Studies have indicated that there is a higher frequency of ME at Intensive Care Units (ICUs), with more severe implications to patients, compared to clinical or surgical hospitalization units[2]. The reason is that ICUs are complex environments in which patients present different severity levels, are submitted to countless procedures and receive a great variety of drugs, including HAM.

However, studies have shown that 7% of the ME with HAM occurred at ICUs[6] and also that the nurses responsible for administering these drugs had insufficient knowledge about them[7]. Thus, studying them sheds light on the reasons why they occur and their analysis enables to prevent errors.

Therefore, bearing in mind that deviations from the quality standard of the medication system may cause damage to the patient and that the nursing team is in charge of the medication administration subsystem, the present study aims to present the medication classes involved in ME at an ICU and to identify those which are classified as HAM.

METHOD

This is a descriptive, quantitative study whose population was composed of the documents that registered the occurrences of ME, which were part of a database of a previous investigation called *"Erros de medicação em unidade de terapia intensiva geral de um hospital universitário do município de São Paulo"* (Medication errors at a general intensive care unit of a university hospital in the city of São Paulo), approved by the Committee for Ethics in Research of UNIFESP under number 0449/05[2].

The study whose data originated this one was descriptive/exploratory and quantitative. It was carried out at a general ICU of 16 beds, during 30 days, in the year of 2006. The strategy for data collection was spontaneous notification, interview with the professionals involved in the provision of care and verification of the medical prescriptions of the 44 patients who were hospitalized at the period. The documents that registered the occurrences of ME contained information related to the population (characterization of the subjects and reasons for hospitalization), to the medication (prescribed drugs, classes of drugs and HAM involved in ME), occurrence (strategy of error verification, shift of the occurrence and the professional who notified it), types of errors, probable causes, and consequences to the patient[2].

For the present study, all the documents containing registered occurrences were revised and a secondary analysis of the data[4] was performed, allowing to investigate the variables related to medication.

To identify the medication classes according to the predominant action, the adopted reference was the pharmacotherapeutic guide of the *Universidade Federal de São Paulo* (UNIFESP), after the names (generic or brand) of the medication involved in ME were noted down[8].

The framework of the Institute for Safe Medication Practices (ISMP) was used to identify the HAM[5]. This institute is a North American non-governmental organization for the education of healthcare professionals and of consumers concerning safe medication practices. Its representativeness has been formalized in Brazil since 2009. In addition, it maintains a list of HAM based on literature findings, experts' inputs and error reports submitted to the "Medication errors reporting program" of the institute itself[9]. The most recent list was reviewed by the members of the clinical staff and of the advisory board of the ISMP, and also by safety experts in the United States of America. The list was published on the institute's website in February 2012 and it presents 22 classes/categories of drugs and 10 specific medications[5].

RESULTS

The total number of documents with registers of occurrences was 305, and the obtained mean was 6.9 (± 6.8; median = 5) occurrences per patient. The daily mean of 14.6 prescribed medications per patient was found.

The number of medications involved in the occurrences was 73, and they were grouped according to their predominant action[8], distributed among 33 classes, as presented on Table 1.

Of the total number of medications involved in ME, the class of antibiotics totaled 77 (25.2%) events, followed by the class of gastric acid reducers (58, or 19.0%) and by antihypertensive drugs (29, or 9.2%). Together, the three classes represent the majority (53.4%) of the findings. It was also verified a frequency of 16 (5.2%) events with venous anesthetics, 14 (4.6%) with antiemetics, 13 (4.3%) with electrolyte replenishers and 10 (3.3%) with anticoagulants, representing, together with the above-mentioned drugs, more than 70% of all the occurrences. These are drugs that are routinely used at ICUs, fundamental to the patients' therapeutic needs.

Of the 33 classes of medications grouped on Table 1, five are included in the HAM framework of the ISPM[5], as presented in chart 1.

It was found that 37 (12.1%) occurrences were related to HAM. The class of venous anesthetics predominated, corresponding to 16 (43.3%), as shown by Table 2. All the medication classes deserve special attention during all the stages: prescription, dispensation, administration or patient monitoring.

DISCUSSION

The studied institution assists patients in severe health conditions, with varied pathologies and who are submitted to countless procedures and interventions. However, it was verified that the proportion of ME per patient, when compared to other ICU investigations, is considered very high. In a study carried out at a teaching hospital in the city of São Paulo, based on notifications of events, 44.1% of occurrences with medications, within a total of 103 occurrences, which affected 103 patients hospitalized at the ICU, corresponding to 0.4 ME per patient[10].

Nevertheless, the amount of events should be discussed in light of the strategies to detect errors adopted in the studies. In the present research, the documents with registered occurrences considered the information derived from three strategies to detect errors, while in the literature findings, the analysis was based on event notification reports, whose ME are known to be undernotified[11]. In addition, it is believed that one single technical detection modality is not sufficient to perform adequate samplings within such a complex system as that of medication. Therefore, it is believed that many detection forms can be utilized, with the objective of providing reliable data and allowing to perform a better analysis of the situation, such as non-participant

Table 1. Distribution of the occurrences according to the medication's predominant action. São Paulo, 2007

Class	n	%	% cumulative
Antibiotic	77	25.2	25.2
Gastric acid reducer	58	19.0	44.2
Antihypertensive	28	9.2	53.4
Venous anesthetic (opiates and non-opiates)	16	5.2	58.6
Antiemetic	14	4.6	63.2
Electrolyte replenisher	13	4.3	67.5
Anticoagulant	10	3.3	70.8
Narcotic analgesic	8	2.6	73.4
Diuretic	7	2.3	75.7
Neuroleptic	7	2.3	78.0
Anti-inflammatory hormone	5	1.6	79.6
Antiparasitic	5	1.6	81.2
Thyroid hormone	5	1.6	82.8
Vitamins	5	1.6	84.4
Analgesic, antipyretic, non-hormonal anti-inflammatory	4	1.3	85.7
Anti-infective and anti-inflammatory, ophthalmic use	4	1.3	87.0
Cardiotonic	4	1.3	88.3
Hypnotic/sedative/anxiolytic	4	1.3	89.6
Antagonists of neuromuscular blockers	3	1.0	90.6
Antiarrhythmic	3	1.0	91.6
Bronchodilator	3	1.0	92.6
Hypocholesterolemic	3	1.0	93.6
Coronary vasodilator	3	1.0	94.6
Antiplatelet	2	0.7	95.3
Anticonvulsant	2	0.7	96.0
Antidepressant	2	0.7	96.7
Antifungal	2	0.7	97.4
Antidiabetic	2	0.7	98.1
Immunosuppressive	2	0.7	98.8
Nasal decongestant	1	0.3	99.1
Blood volume expander	1	0.3	99.4
Vasoconstrictor	1	0.3	99.7
Cerebral vasodilator	1	0.3	100.0
Total	305		

Chart 1. Correspondence between the medication classes involved in the medication errors

Medication class according to the predominant action	Medication class and specific high-alert medications
Antihypertensive	Adrenergic antagonists
Venous anesthetic (opiate and non-opiate)	Anesthetic agents, general, inhalational and intravenous
Anticoagulant	Antithrombotic agents, including anticoagulants
Narcotic analgesic	Narcotics and opiates, intravenous, transdermal and oral
Antidiabetic	Insulin, subcutaneous and intravenous

Guia Farmacoterapêutico[8]; ISMP's List of High-Alert Medications[5].

Table 2. Distribution of the occurrences according to high-alert medication classes and examples of products. São Paulo, 2007

Class	n	%
Venous anesthetic (Fentanyl; Propofol, Midazolam)	16	43.3
Anticoagulant (Heparin)	10	27.0
Narcotic analgesic (morphine sulfate, tramadol hydrochloride)	8	21.6
Antidiabetic (insulin)	2	5.4
Antihypertensive (Propranolol)	1	2.7
Total	37	100.0

observation, analysis of the patients' clinical parameters, return of medications to the pharmacy, trigger tool (tracking information in the patient's medical record, searching for signs of possible adverse events), safety patrols and interventions of the pharmacist working at the ICU[4,7,12,13].

Patients hospitalized at ICUs usually receive a higher number of drugs when compared to those hospitalized at other units[13]. In the studied ICU, the mean was 14.6 prescribed medications, per day, per patient. This finding confirms the complexity and severity of the patients hospitalized in this type of unit. The drug therapy proposed for health recovery and life maintenance accompanies the quick oscillations - between normality and abnormality - that derive from organic instability, which requires immediate modification of the medications, with efficient decision-making. These situations of temporal pressure favor the occurrence of adverse events and, when associated with the severity of the patients' condition, they may cause irreparable damage to them, thus requiring maximum attention on the part of the professionals[10,13]. Therefore, the recognition that such events occur shows that an analysis of their causes is extremely important, as detection of deviations from quality standards during the care process is what enables preventive attitudes, with the implementation of strategies that ensure the quality of care[4].

The administration of a high number of medications per patient reveals the importance of monitoring patients regarding their response to the adopted therapy. This aspect includes

recognizing adverse reactions and detecting errors that are the responsibility of all, and this should encompass, whenever possible, patients and their relatives. It should also be emphasized that the professionals must pay attention to the interactions that can occur between medications and nutrients or environmental chemicals, and warn patients of possible undesired responses concerning the therapy[12,14].

The documents that register the occurrences derived from an investigation carried out at a general ICU; thus, a high amount of classes of prescribed medications was expected, in view of the patients' clinical conditions. However, a high number of ME, divided into 33 classes, was verified, and the class of antibiotics predominated.

Therapy with antibiotics is indicated to combat pathogenic microorganisms and its choice is based on sensitivity testing of the pathogen and on the drug's potential toxicity to the patient. Whenever possible, the selection of antibiotics should be preceded by culture and sensitivity testing, and many times, their indication is prophylactic and based on the assessment of the risk factors that may contribute to the development of infections, such as: extensive surgical procedures, obesity, previous conditions (diabetes, chronic obstructive pulmonary disease), use of immunosuppressive drugs, malnutrition and extreme age groups (children and elderly individuals). However, the indication is the result of the physician's clinical judgment, and its monitoring depends on the specific knowledge of the multiprofessional team at all the stages of the treatment[14].

The characteristics of the units at which patients are hospitalized should be observed, as some medications are more commonly used in certain areas or specialties than others. For example, a higher number of occurrences with cardiovascular drugs is expected to be found at clinical ICUs compared to surgical ICUs.

The present study detected that the majority of ME are related to the classes of antibiotics, gastric acid reducers and antihypertensive drugs. A North American study that investigated the frequency of adverse events with medications according to their class found a higher frequency of errors related to cardiovascular drugs (17%), antibiotics (15%) and sedatives (14%)[15].

Thus, when the profile of the hospitalized patient is taken into account - severe and unstable -, it is worrisome to verify the high number of medication classes involved in the occurrences

of ME. Therefore, it is important to emphasize that the causes of the errors must be analyzed and the proposals for improvement, implemented, in order to ensure the adequate functioning of the medication system[4,12].

The HAM should be accurately monitored at any hospital, as they can cause further damage when their use is incorrect[9]. In this study, in particular, they corresponded to 37 (12.1%) occurrences, and the medications that were classified as venous anesthetics predominated.

The use of this type of medication is frequent at ICUs to sedate patients, due to their very clinical condition and to invasive and painful procedures and exams, which bring discomfort and anxiety. Sedation is employed in a controlled manner to reduce the level of consciousness. There are many levels of sedation, ranging from minimal sedation to general anesthesia, which differ from one another by the patient's capacity to maintain protective reflexes and patent airways. As it is difficult to accurately define the limits that separate the different sedation levels, the patient may transit quickly to the deeper ones. This aspect shows the importance of the professionals who prescribe and administer HAM at ICUs. Both the medical and nursing teams should be qualified to know and handle medications, to monitor the different levels of sedation, to evaluate the patients' responses continually, and to recognize adverse reactions and the interaction of drugs[16].

A study about the incidence of errors with HAM, based on the North American computer system, identified that 45% of these events involved insulin and 21%, heparin and warfarin in equal proportions, revealing the need of a rigorous monitoring in 23% of the patients to prevent damage[6].

Studies have warned of the need to monitor the HAM used in diverse areas of a hospital, especially in units like the pediatric or oncology ones. They mention that the most common type of error is that of "wrong dose", and report on the danger of the patient receiving a dose, for example, 10 times higher than the indicated one - this may even result in the patient's death[7,15].

As a proposal for the safety of the medication system, focusing specifically on HAM, there are procedures that can be adopted to prevent ME with these drugs, such as: having a list of HAM, which should be broadly disseminated; implementing guidelines to the prescription, dispensation, preparation, administration and storage of these drugs; labeling the medications with different colors or alert signs on the package; adopting double-check in drug dispensation, preparation and administration; restricting the number of presentations and concentrations at institutions; banning concentrated electrolyte solutions, specifically injectable potassium chloride solutions, from infirmaries and outpatient clinics; providing a continuing education program about medications to the professionals involved; managing, with specific indicators, ME with HAM; implementing a specific program of safety of patients hospitalized at ICUs concerning the use of medications[5,9,13,14].

The adoption of the double-check system is recommended for safe practices at any stage of the medication system, mainly when medications that may bring greater risk are involved. This working process involves two persons in the execution of the activity. Traditionally employed in the industry, its function is to minimize the chances of errors or mistakes when a product that needs to have full operation is to be launched. When this methodology is applied to the healthcare area, it can ensure that procedures which are known to have critical points receive greater attention from professionals. For its execution, the agents that will be part of the process must be identified, as well as the steps that must be followed and the place for documenting the action[17].

The area of information technology has conducted research in order to provide subsidies for the performance of the double-check procedure when there are problematic working conditions, like interruptions and distractions or a busy clinical environment. The computer program iDoseCheck helps professionals to calculate the dose and volume of the drug morphine that should be administered to pediatric patients. The results of tests with the use of the program, when compared to calculations made on paper, are seen as promising concerning the development of guidelines to other opiates, so as to ensure the provision of drug therapy for patients[18].

The educational aspects should not be neglected concerning prevention of ME with HAM. Nurses need and expect to have a permanent education program on the safe administration of these medications[7], approaching the medications' action in the physiological level and their relation to disease, appropriate techniques for preparation and administration, and also the choice of specific material and technological resources for safe practices[14].

The prevention of any adverse event is fundamental regarding the management of the system of medication use. All professionals involved in assistance should feel responsible for guaranteeing the quality of the system and the safety of the patient[13]. The institutions' leaders should ensure that the occurrences are informed and analyze their causes so that improvements can be made.

The limitation of this study is the fact that the theoretical institutional framework was utilized in the distribution of the medication classes, hindering comparisons with other national or international studies.

CONCLUSION

It was verified that a high number of medications was involved in the occurrences, and they were distributed among 33 classes according to their predominant action. The majority of the occurrences was related to the class of antibiotics, gastric acid reducers and antihypertensive drugs. As the studied unit was a general ICU, with diverse admission diagnoses, severe pathologies and severe health conditions of the patients, the classes of the involved medications indicate fragility in the subsystems of distribution and administration, negatively affecting the result of the assistance provided for the patient, a situation that deserves close attention from managers.

Occurrences with HAM were identified and corresponded to five classes. The class of venous anesthetics was the predominant one, confirming that the use of this type of medication is

frequent and that they are involved in errors, reiterating the need of intense monitoring of the patient at the ICU and educational practices for the assistance team.

It is expected that further studies are conducted on the theme, so as to compare interventions in structural and procedural conditions and their impacts on the number of ME and their consequences to the patient.

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