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# Characterization of the reported incidents involving medication use in inpatient units for adults

Caracterização dos incidentes notificados envolvendo o uso de medicamentos em unidades de internação adulto

Caracterización de los incidentes notificados en relación con uso de medicamentos en unidades de internación para adultos

#### **ABSTRACT**

**Objective:** to characterize the reported incidents involving medication use in inpatient units for adults of a university hospital. **Method:** this is an observational and cross-sectional study conducted at a large-size university hospital in the South of the country. We resorted to 1,896 notifications from the institution's electronic system regarding medication errors, between 2015 and 2017, in 13 clinical and surgical inpatient units for adults. A specific instrument and descriptive statistics were employed to analyze the variables. **Results:** the medication incidents were related to prescription (85.9%) and administration (10.1%) and involved delay in prescription (77%) and wrong dose (7.9%), respectively. The errors were concentrated in 2015 (70.2%) and in surgical inpatient units (90%), and the information was partially filled out and/or incomplete in the notifications (70%). **Conclusion:** characterization of the incidents supported the implementation of strategies by the institution's managers, focused on the problem, thus reducing the number of notifications and improving patient care.

**Descriptors:** Medication errors; Patient safety; Risk management; Medication systems; Inpatient care units.

### **RESUMO**

Objetivo: caracterizar os incidentes notificados envolvendo o uso de medicamentos em unidades de internação adulto de um hospital universitário. Método: estudo observacional do tipo transversal, em um hospital universitário de grande porte no sul do país. Utilizaram-se 1896 notificações do sistema eletrônico da instituição referente aos erros de medicação, entre 2015 e 2017, em 13 unidades de internação adulto clínica e cirúrgica. Para análise das variáveis utilizou-se um instrumento próprio e estatística descritiva. Resultados: os incidentes de medicação estiveram relacionados à prescrição (85,9%) e administração (10,1%) e envolviam o atraso da prescrição (77%) e a dose errada (7,9%), respectivamente. Os erros concentraram-se no ano de 2015 (70,2%), em unidades de internação cirúrgica (90%) e verificou-se informações preenchidas parcialmente e/ou incompletas nas notificações (70%). Conclusão: a caracterização dos incidentes subsidiou a implementação de estratégias pelos gestores da instituição, voltadas para a problemática, reduzindo as ocorrências e melhorando o cuidado ao paciente. Descritores: Erros de medicação; Segurança do paciente; Gestão de riscos; Sistemas de medicação; Unidades de internação.

# **RESUMEN**

Objetivo: caracterizar los incidentes reportados relacionados con el uso de medicación en unidades de internación para adultos de un hospital universitario. Método: se trata de un estudio observacional y transversal realizado en un hospital universitario de gran envergadura del sur del país. Se utilizaron 1896 notificaciones del sistema electrónico de la institución sobre errores de medicación, entre 2015 y 2017, en 13 unidades de internación clínica y quirúrgica para adultos. Para analizar las variables se utilizó un instrumento específico y estadística descriptiva. Resultados: los incidentes de medicación se relacionaron con la prescripción (85,9%) y la administración (10,1%) e involucraron retraso en la prescripción (77%) y dosis incorrecta (7,9%), respectivamente. Los errores se concentraron en 2015 (70,2%) y en las unidades de internación quirúrgica (90%), y la información estaba indicada parcialmente y/o incompleta en las notificaciones (70%). **Conclusión:** la caracterización de los incidentes apoyó la implementación de estrategias por parte de los gerentes de la institución, enfocadas en el problema, reduciendo así la cantidad de notificaciones y mejorando la atención provista al paciente. Descriptores: Errores de medicación; Seguridad del paciente; Gestión de riesgos; Sistemas de medicación; Unidades de internación.

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### **INTRODUCTION**

Safety incidents related to medication use are among the most prevalent in hospitals and present multicausal factors, involving various stages and multiprofessional factors such as prescription, dispensing, preparation administration<sup>(1)</sup>. These incidents have imposed high financial and social costs on health systems worldwide, with international estimations up to 2017 indicating that nearly 30% of the in-hospital adverse events are associated with medication use<sup>(2-3)</sup>. A study conducted recently in Australia reinforced such finding, whereas it also found a medication error rate of 1.05 for every 100 hospitalized patients<sup>(1)</sup>.

Work overload, distraction, communication failure, incorrect interpretation of the information, absence of institutional protocols and knowledge deficits contribute to the occurrence of medication errors and harms to the patients, regardless of the stage of the process and of the professional involved in the assistance provided<sup>(2-7)</sup>. However, there is diverse evidence that the most frequent errors refer to medication prescription and administration, occurring mainly in intensive care and clinical hospitalization units, with the possibility of leading to an increase in the patient's hospitalization time, temporary or permanent harms, unexpected interventions and even death<sup>(6,8)</sup>. In addition, in the national context, it is highlighted that medication errors are more frequently related to Nursing professionals and to medication dose, administration and omission. They commonly occur in clinical sectors, with a need for intervention in these areas to improve patient safety<sup>(9)</sup>.

Given the above, it becomes indispensable to understand some usual concepts and nomenclatures for a better comprehension of the theme addressed. Thus, according to the World Health Organization (WHO), medication errors are considered as any preventable event that, in fact or potentially, can lead to inappropriate use of medications under the control of health professionals, patients or consumers, whether or not causing harms. On the other hand, incidents are occurrences that can or did result in unnecessary harms to the patients (10). Patient safety refers to absence of avoidable harms during the health care process. In turn, adverse events are related to incidents that caused harms due to preventable failures in the assistance provided. There is also the so-called near miss, an incident that, either for some planned reason or by chance, was intercepted before reaching the patient and that might or might not cause harms<sup>(10)</sup>.

In 2013 and in line with international initiatives, the Brazilian Ministry of Health established the National Patient Safety Program (Programa Nacional de Segurança Paciente, NPSP), which launched a target aimed at improving safety in medication prescription, use and administration, with the purpose of promoting safer practices<sup>(11)</sup>. In this context, the relevance of the theme stands out since, both at the national and international level, the imminent need to identify care failures in the processes associated with medications in health institutions is pointed out. Since emergence of the NPSP, the topic in question remains current and under constant discussion, so that the WHO third global challenge, launched in 2017, aims at reducing by 50% the serious and avoidable harms related to medications in the next five years throughout the world<sup>(3)</sup>.

In order to implement improvements and qualify multiprofessional care, this study had the following guiding question: Which is the profile of medication-related incidents at a university hospital in the South of the country? And, to answer this question, it was sought to characterize the reported incidents involving medication use in inpatient units for adults of a university hospital.

# **METHOD**

This is an observational, cross-sectional and descriptive study linked to a larger research project entitled "Safe zones for drug preparation and administration: A multiprofessional development project", conducted at a large-size university hospital in the South of the country. Methodological detailing and rigor was prepared based on the recommendations and checklist for this type of study, called STROBE (Strengthening the Reporting of Observational Studies in Epidemiology), in its version translated into Portuguese.

In the hospital, study field, when there is any occurrence of some type of safety incident, the professional who identified it is equipped to perform the notification in the electronic system, implemented in 2015, after institutional training. Notifications can be anonymous and are analyzed by the Risk Management (*Gerência de Risco*, GR) area, the Safe Medication Use Group (*Grupo de Uso Seguro de Medicamentos*, GUS) and the Safety and Quality Subcommissions (*Subcomissões de Segurança e Qualidade*, s-COMSEQs). It is noted

that the notification system has no mandatory fields to be filled out.

The s-COMSEQs are divided according to the specificities of the care areas and evaluate the notifications categorizing them into mild, moderate, risk situation and near failure. In turn, the severe incidents and sentinel events are directly analyzed by the GR Executive Commission, with support of the GUS.

Data collection covered the notifications generated in the institutional electronic system between January 2015 and December 2017, and analyzed by the s-COMSEQs, GR and GUS. The time criterion was defined based on two aspects: in 2015, notifications were first implemented at the institution under study; and, in 2017, the third global challenge was launched by the WHO, which motivated the authors to present data prior to this milestone.

Figure 1 shows the total number of reported events (3,794), with a sample consisting of

1,896 notifications referring to medication errors that occurred in clinical and surgical inpatient units for adults during the period stipulated for data collection. All the notifications of medication errors generated by the electronic system in the hospital's 13 clinical and surgical inpatient units for adults (seven surgical and six clinical) were included, except for those related to other sectors such as Obstetrics, Emergency, Intensive Care, Outpatient services, Hemodialysis, units from the hospital annex, Operating Center, surgical recovery room and Oncohematology, due to care complexity and specificities.

Those notifications in which at least 50% of the fields of the variables listed for the study had not been filled out were excluded and called "incomplete". The notifications that were partially filled in, that is, with more than 50% of the fields filled out, were included, which gave rise to the "Field not reported" datum next to the results of some variables.

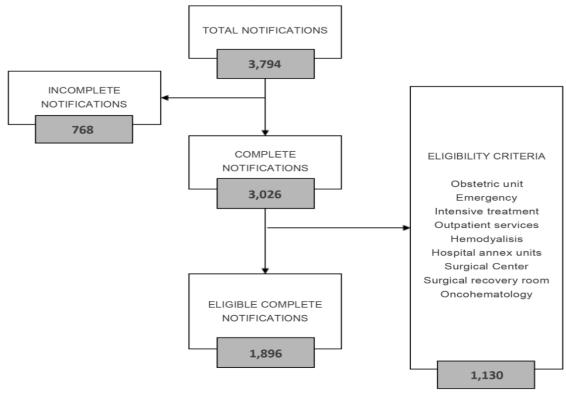


Figure 1 - Flowchart corresponding to the eligibility criteria to comprise the sample

Source: Prepared by the authors (2021).

Considering the sample size, it was decided to double-check the data collected between two duly qualified researchers in the study, in order to minimize possible biases in selection of the notifications. The authors developed an instrument in a spreadsheet model in *Microsoft Excel* with the variables of interest to organize the

diverse information collected, namely: process stage, professional category (who reported the incident), year, month (grouped by trimesters), notifying shift, inpatient unit, it reached the patient, there was harm, harm severity, class of the medication, classification of the event, classification of the type of medication error, and

outcome. Such variables were extracted from the fields of the notifications made by the health professionals in the electronic system, except for year and outcome, which were added from their review.

Regarding classification of the type of medication error, the basis adopted was the PNSP safe medication use protocol<sup>(12)</sup>: delay in prescription, dose omission, wrong dispensing, wrong dose, wrong patient, wrong medication, wrong time, wrong route and wrong record. "Other reasons" and "Not reported" were also added, referring to the partially filled-out notifications. The medication-related incidents were classified according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), an independent American body comprised by health institutions that promote safe medication use<sup>(13)</sup>.

For data analysis, the Statistical Package for the Social Sciences (SPSS) software, version 22.0, was used, employing descriptive statistics and describing the categorical variables contained in the collection instrument, such as absolute (n) and relative (%) frequencies. Regarding the ethical precepts, the Guidelines and Norms set forth in

Resolution 466/12 of the National Health Council were met and the matrix project, which foresaw a specific objective related to the analysis of incidents in the medication process, was approved by the institution's Research Ethics Committee under opinion number 1,717,036. The professionals involved and the adverse events reported had their identities preserved in order not to generate any embarrassment and/or type of personal or institutional damage.

#### **RESULTS**

In the period from 2015 to 2017, a total of 3,794 notifications related to medication errors were identified; however, after applying the selection criteria, the final sample resulted in 1,896. Regarding the process stages, there was predominance of notifications related prescription, with 1,629 (85.9%). It is also worth mentioning the results related to the medical professional category (1,597 [84.2%]) and to the year 2015 presenting a high number of notifications (1,331 [70.2%]) with emphasis on the trimester (658 [34.7%]), shift (1,459 [77.0%]) and inpatient surgical units (1,706 [90.0%]), as shown in Table 1.

Table 1 - Characterization of the notifications in the institution's electronic system regarding process stage, professional category, year, trimester, shift and inpatient unit. Porto Alegre, Brazil, 2021.

Variables	n	%
Process stage		
Prescription	1,629	85.9
Administration	191	10.1
Dispensing	39	2.1
Preparation	37	1.9
Professional category		
Physician	1,597	84.2
Nurse	197	10.4
Pharmacist	27	1.4
Mixed	75	4.0
Year		
2015	1,331	70.2
2016	438	23.1
2017	127	6.7
Trimesters (2015 – 2017)		
1 <sup>st</sup>	658	34.7
2 <sup>nd</sup>	476	25.1
3 <sup>rd</sup>	407	21.5
4 <sup>th</sup>	355	18.7
Shift		
Morning	235	12.4
Afternoon	1,459	77.0
Night	139	7.3
Not reported	63	3.3
Inpatient unit		
Surgical	1,706	90.0
Clinical	190	10.0
Total	1,896	100
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Source: Study data.

For the "it reached the patient", "there was harm", "harm severity" and "class of medication" variables, the highest number of answers was concentrated on the "Not reported" option, with percentages above 70% in all corresponding to partially filled-out notifications. Regarding classification of the event, category "C -An error occurred, it reached the patient, but did not cause harms" stood out with 1,592 (83.9%). Referring to the type of medication error, delay in prescription and wrong dose were evidenced, with 1,409 (74.3%) and 149 (7.9%) respectively. The "Others" subitem (137 [7.2%]) included situations related to prescription of a medication where the patient reported being allergic, prescription with duplicate items, wrong infusion, wrong technique, drug interaction, printed but unused prescription, medication expiration and deteriorated medication. Such information can be seen in Table 2.

In the outcome stage, which is also shown in Table 2, 1,481 (78.1%) incidents stand out, most of them linked to delay in the current medication, which can be related to delay in prescription, described next to the type of medication error in Table 1. Other detail factors also emerged, such as hyperglycemia, hypotension, hypoglycemia, cardiorespiratory arrest, allergic reaction, hypertension, impossibility of performing the surgery, pruritus, test results collection not performed, anxiety/agitation, dehydration, convulsion, bilateral hearing loss, nausea, pain, skin rash, septic shock, blurred vision, decreased level of consciousness, and system error.

Table 2 - Characterization of the notifications in the institution's electronic system regarding the "it reached the patient", "there was harm", "harm severity", "class of medication", "classification of the event", "the type of medication error" and "outcome" variables. Porto Alegre, Brazil, 2021.

Variables	n	%
It reached the patient		
Yes	358	18.9
No	200	10.5
Not reported	1,338	70.6
There was harm		
Yes	29	1.5
No	339	17.9
I don't know	116	6.1
It might have caused harm	76	4.0
Not reported	1,336	70.5
Harm severity		
Mild	6	0.3
Moderate	6	0.3
Severe	3	0.1
No harm	389	20.5
Not classified*	12	0.7
Not reported	1,480	78.1
Class of medication		
Antibiotic	88	4.6
Anticoagulant	63	3.3
Analgesic	57	3.0
Psychotropic	38	2.0
Physiological and glycated solutions	37	1.9
Anti-hypertensive	27	1.5
Insulin	25	1.4
Other medications	95	5.0
Not reported	1,422	75.0
Near misses	44	2.3
Classification of the event		
A: Risk situations capable of generating errors	16	0.8
B: Error that does not reach the patient (near miss)	191	10.0
C: It reached the patient, but caused no harm	1,592	83.9
D: It reached the patient and requires monitoring to confirm that it did not	44	2.4
result in any harm		

(continue)

Variables	n	%
E: Temporary harm that needs intervention	2	0.2
F: Temporary harm that needs hospitalization	1	0.1
G: Permanent harm to the patient	1	0.1
H: It needs intervention	5	0.1
I: Death	-	-
Not reported	44	2.4
Type of medication error		
Delay in prescription	1,409	74.3
Dose omission	44	2.3
Wrong patient	38	2
Wrong medication	34	1.8
Wrong dose	149	7.9
Wrong dispensing	28	1.5
Wrong time	28	1.5
Wrong route	21	1.1
Wrong record	-	-
Others	137	7.2
Not reported	8	0.4
Outcome		
Incident	1,481	78.1
No outcome	303	16.0
Not reported	112	5.9
Total	1,896	100

<sup>\*</sup>Not classified within the "mild", "moderate", "severe" and "no harm" parameters.

Source: Study data.

### DISCUSSION

The medication errors are concentrated in 2015, mostly linked to the prescription stage and to delay in its elaboration. In terms of assistance, such findings showed that the patients remained without a medical prescription for a period of time and that the Nursing team was unable to fetch the medications from the institution's pharmacy, causing delays in their administration. It is noted that, in the same year, the institution standardized a schedule for preparation and completion of the medical prescriptions, which resulted in a 40.4% reduction in notifications related to this stage in the subsequent years: 2016 and 2017.

A number of research studies (6,8) have pointed out that prescription errors are one of the main failures in the patient safety process as far as medications are concerned. To minimize these occurrences, it is suggested that the use of electronic systems allows for better diagnoses and for correction of these failures, in addition to providing visibility as to their incidence<sup>(7,14)</sup>. In addition to that, they provide support for decisionmaking, such as warning signs when prescribing and dispensing the medications, which represent highly effective measures to reduce errors. Another strategy cited as efficient is the promotion of educational actions targeted at patient safety with the professionals involved, thus strengthening the care defenses<sup>(15)</sup>.

An important aspect to be highlighted, which also harms patient safety, corresponds to the errors that occur in relation to the last barrier of the medication process: administration. It is noted that approximately 40% of the Nursing team's working time is devoted to the preparation and administration of medications<sup>(14)</sup> and, when there is harm to a patient, the systemic failures related to wrong dilution, omission and wrong patient are the main contributing factors<sup>(6)</sup>. It is estimated that only 5% of the errors involving Nursing professionals are reported, due to the idea of punishment, guilt and/or shame in the face of the event<sup>(14)</sup>, evidencing the need to promote a fair safety culture in health organizations.

Other important factors that contribute to medication errors are the absence of care protocols, interruptions during preparation and administration, and negligence (4,7). In this sense, there is diverse evidence that the errors related to the preparation and administration of medications often occur with nurses in training or recent graduates due to lack of experience<sup>(14)</sup>. However, it is possible to minimize these occurrences through practices such as double-checks in the preparation and administration stages, inclusion of a nurseleader with at least two years of clinical experience in the health unit, and development of permanent education activities. Some strategies recently employed are as follows: bedside preparation and administration of the medication, which provides greater safety and concentration of the professional due to the reduction of external noises; and the use of electronic medication dispensers, which allows creating a proper place for storage and preparation of the medications (14,16,17).

When addressing the "type of medication error" variable, the current study identified the highest percentage in the "wrong dose", "wrong patient" and "wrong medication" items. On the other hand, a research study coordinated in a hospital from Saudi Arabia showed that the errors were due to wrong frequency and dose concentration<sup>(8)</sup>. Based on this information, it is important to mention that there are differences across health institutions due to cultural and sociodemographic characteristics, which precludes establishing a single standard in dealing with the incidents.

In relation to the high rates of unreported data regarding the "it reached the patient", "there was harm", "harm severity" and "class of medication" variables, there is no prior justification that clarifies the incomplete notifications. A number of authors (14,15,18) emphasize that health professionals generally do not report errors for fear of punitive consequences, lack of time to fill out the diverse information in the notification and/or training system on patient safety, or even absence of a feedback culture. However, it is necessary that the errors are reported and notified, so that it is possible to contribute to the identification of risk factors, plan collaborative measures and provide means for training and for the elaboration of protocols<sup>(4)</sup>.

Regarding classification of the event, it can be divided into three main groups: error potential (A), there was no harm (B, C and D) or there was harm (E, F, G, H and I)<sup>(13)</sup>. In this research, a high rate was found in the "there was no harm" category and there was concentration of notifications in the day shift, specifically in the afternoon, a result that was influenced by the problem related to delay in the prescriptions and to the diversity of times when they start to be in force, aspects prior to the standardization and unification of timetables in the institution. There are recommendations for distribution of the medications to be similar between the morning, afternoon and night shifts, in addition to the presence of a pharmacist in the everyday activities of the inpatient units and in the dispensing stage, aiming to qualify the processes with the care teams and minimize possible failures through double-checks<sup>(7,19)</sup>.

"Class of medication" presented the highest value in the unreported data; however, when the professional who notified the medication error provided more accurate data, antibiotics and anticoagulants stood out. A systematic review<sup>(20)</sup>, which included 54 studies aimed at critically evaluating the diverse evidence available between 1990 and 2019 on the prevalence and nature of medication-related errors and harms after hospital discharge, identified a median rate of 53%, with emphasis on antibiotics, analgesics, hypoglycemics and cardiovascular medications.

According to the WHO, failure and misuse in the administration of antibiotics are considered a problem of significant magnitude due to antimicrobial resistance, which increases the mortality rate due to sepsis, especially in low- and middle-income countries<sup>(21)</sup>. After an analysis in 65 countries, it was identified that Brazil presents a high rate of mean density of daily consumption of antibiotics per 1,000 inhabitants when compared to other countries, such as Bolivia, Paraguay, Canada, Costa Rica and Peru. This fact reinforces the urgent need to implement measures for reducing unnecessary use of antibiotics<sup>(16)</sup>.

The incidence of errors in surgical units was higher in relation to the clinical inpatient units, which can be related to the high number of notifications regarding delay in the medical prescriptions. In addition to that, the high turnover of patients in this specialty is highlighted, which leads to a significant everyday number of prescribed, mainly medications antibiotics, anticoagulants, analgesics and opioids. A study carried out in Spain helps illustrate this idea, revealing the increase in adverse events in surgical and clinical units due to the care demand attributed to the professionals. It also suggests the implementation of tools to warn against the possibility of harms in prescription and in care, in order to prevent them<sup>(22)</sup>.

More detailed analysis initiatives, such as root cause identification for the prevention of adverse events, enable more accurate error classification as well as encourage a fair reporting culture<sup>(16)</sup>. It is from tools such as Root Cause Analysis, the Ishikawa Diagram, Pareto Analysis, Healthcare Failure Mode and Effect Analysis, Patient Safety Assessment in Drug Administration and cause trees, for example, that the implementation of improvements for care quality and patient safety becomes possible<sup>(23,24)</sup>.

### **CONCLUSION**

The study allowed characterizing the incidents with medications, identifying their relationship with medical prescriptions and with administration by the Nursing team. The highest concentration of errors was recorded in 2015, especially regarding "delay in prescription". This element was presented to the institution's managers, triggering schedule standardization and, consequently, a reduction in the number of notifications in the subsequent years and improvements in patient care.

In the classification of the incidents, the data indicated that the errors did occur and reach the patients, although causing no harms. Antibiotics and anticoagulants stood out among the medications with the highest number of reported incidents. The need to develop other studies in hospital inpatient units is highlighted since, when reviewing the literature, several studies were found on medication errors in critical areas such as intensive and emergency care. The importance of conducting intervention studies comparing the implementation of improvements is also noted.

Based on this research, it is suggested to develop interventions related to notifications in hospitals, aiming at filling them out through simple and mandatory topics, in addition to educational activities on the quality of reporting and the patient safety taxonomy. The importance of permanent education with the multiprofessional team is reinforced, mainly with regard to aspects related to a fair culture linked to the topic of patient safety and drug administration.

As for the study limitations, the notification system in which it was carried out does not have mandatory fields to be filled out, generating a high number of unreported data, which, if reported, could contribute to a more accurate diagnosis of the areas. Added to this aspect, it is noted that the database of this research consisted of diverse information from the notifications and impressions of the professionals who recorded them, with no validation of the classification indicated. In addition, the current study was developed in a single hospital with specific characteristics, and in clinical and surgical adult inpatient units, making it necessary to expand the aspects addressed to other scenarios in order to have a broader analysis of the problem. The descriptive analysis method may have precluded some inferences and generalizations, as well as making associations between the variables, which turns it into a limiting factor of the research.

The study contributes to the development of a safety culture, promoting the implementation of tools aimed at reducing the number of incidents caused in health institutions, as it provides a profile about the incidents in a large-size hospital, supporting the hospital management regarding reformulation of the prescriptions and the search for safe care in the preparation and administration of medications.

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