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#### REFERÊNCIA

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# Factors related to medication errors in a Brazilian hospital

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## ABSTRACT

The risk factors associated with medication errors in an internal medical unit of a Brazilian hospital were analyzed. A prospective, analytical, and exploratory quantitative study was carried out in a regional hospital, from March to May, 2014. One nursing assistant and 17 nursing technicians observed during the prescription, preparation, and administration of medications. The study observed 415 doses and 648 errors were found, organized into five main categories: preparation (29.47%), time (18.36%), and administration (42.12%), as well as 21 (3.24%) omissions and 44 (6.79%) dose errors. For every ten prescribed doses, eight resulted in errors, raising financial and personal costs. Quantitatively errors were related to risk factors of professional category, age, correct use of techniques, type of medication, and route of administration. The results helped identify the weaknesses in the medication system.

**Keywords:** Medication error; Nursing; Electronic prescription; Patient safety; Risk management.

## 1. INTRODUCTION

Nursing care is a complex activity, involving procedures which must be successfully performed to achieve its objectives. At the same time, for an adverse event to occur, a series of factors must coincide and permit the error (1,2).

Mistakes are observed in all health units that perform activities related to administration of medications. However, although unexpected, such errors are preventable. To avoid errors, the medication system needs to be constantly reviewed, from medical prescription, medication dispensing, to its administration by nurses (3).

Errors may occur in any of the mentioned steps, usually related to prescription information, inadequate storage of medications, or non-compliance with the preparation techniques. These vulnerable situations should be avoided (2,4).

Adverse events in the medication process represent the eighth leading cause of death in the United States. In hospital care, an estimated 98,000 deaths per year (4) occur, of which 7,000 are related to medication errors (5).

In Brazil, a similar scenario is found with regard to medication errors. The situation is worrying because analyzed statistics indicate that during the period of hospitalization, each patient will suffer at least one medication error related to any step or professional category, an error that is often avoidable.

Moreover, national studies have shown occurrence rates of medication errors ranging from 30 to 80%, while the international rate, described in the literature, indicates 50% medication errors (6-10).

Although errors may occur in several circumstances, some factors are associated with the knowledge of the professional handling the medication, the number of patients under their care, the increasing supply of medicines on the market, the readability of the prescription, and the correct dispensation and distribution (2,6).

However, new technologies provide greater patient safety. International and national studies have demonstrated that implementing a computerized system in the medication process can increase patient safety up to 50% (10-11).

The medication process can be relegated, making it more vulnerable to mistakes. However, a study shows that after the implementation of a computerized system, the time required to register the procedures was reduced by 30%, which allowed nursing professionals more time for caretaking activities (12).

Research in this area can be motivated by many factors, for example, personal and economic cost. The personal cost refers to the damages caused by such events to the patients and professionals involved, and the financial cost to the financial loss of the institutions that are responsible for avoiding their occurrence through effective management (9-10).

The present study aims to analyze the risk factors associated with adverse events in the medication system in an internal medical unit of a hospital in Brazil's Federal District, as well as to identify the prevalence of medication errors.

## 2. METHOD

This prospective, analytical, and exploratory quantitative study used primary and secondary data sources in the electronic medical record. Data collection occurred from March to May 2014.

The study was carried out in a hospital of the Federal District of Brasília, due to its link with public and private universities, computerized registration system, public nature, and large capacity. The regional hospital is located in an administrative region with approximately 200,000 inhabitants, 86.50% of which use the public health network, and 64.56% of these opt for the regional hospital, while the rest are serviced in other units (13).

In the institution, the activities related to the medication system are developed in two spaces: Internal Medical Unit and pharmacy. The medical unit of the referred hospital has 26 beds, intended for patients with chronic-degenerative diseases. They are usually given a large and varied range of medications during treatment, which generally requires responsible for carrying out the activities related to the medication system in its different stages.

The inclusion criteria for study participants included professionals that work in the unit, are directly involved in the steps of the medication process, and agreed to participate in the study. Those on leave during the period of data collection were excluded from the study.

Thus, the final sample was composed of 17 nursing technicians and one nursing assistant, all responsible for the preparation and administration of medications. The other nurses, who worked in the unit but did not participate directly in these activities, are focused on bureaucratic responsibilities and specialized care.

Through observing the context of the nursing work, we sought to estimate the frequency of errors in preparation and administration of medication, characterizing the situations and risk factors for their occurrence.

A nurse and nursing graduate did the observations, and both observed the participants during the preparation and administration of the medications. They were properly trained to perform at this endeavor, specifically regarding basic concepts of medication error, hospital medication systems, objectives of the study, methods, readings, and discussions on the subject.

Observation were carried out for 18 days through all the steps of the medication system, with the objective of learning the complex system. Twelve days (March 16 to May 11) were required for the observations of the drug preparation and administration steps.

The observation schedules were organized around the routine administration of the medicines, which occurred in the morning at 8, 10, and 12; evening at 14, 16, and 18; and night at 20, 22, and 23. Observations were done on Friday, Saturday, and Sunday, due to the availability of the observers. These students and professionals were active in another unit and in the different shifts, because studies show that events occur at different times (6).

It was made clear to the participants that the research did not intend to evaluate them during the performance of their activities, but to analyze the medication system with the intention of improving it. They were assured anonymity and guaranteed that they would not suffer any kind of punishment. If an error was detected during the observation of the participants, at the time of preparation and administration of the doses, the observers were instructed to interrupt the procedure, which did not every become necessary.

The interviews followed a semi-structured script, previously tested and adapted from a previous study (8), to collect information about socio demographic characteristics and workload.

To obtain the necessary information for identifying error in the steps of preparing and administering medication, a semi-structured protocol was developed and used in the fourth and final stage of the data collection. It was composed of four parts: 1) socio demographic data of the professional, time of beginning and end of observation; 2) data about the medication (name, dose, route, time of preparation, etc.); 3) administration data (time of administration, interruptions, technical conditions, etc.); and 4) prescription data (the name of the medication to be administered, route, dose, schedule, etc.).

a long period of hospitalization. During the period of data collection, 23 professionals worked in the area: 5 nurses, 17 nursing technicians, and 1 nursing assistant. These 23 nursing professionals, who participated in the study, are responsible for carrying out the activities related to the medication system in its different stages.

After the annotations, the observers went immediately to the computer terminal, to compare what they had observed with the medical prescriptions and to identify any discrepancies found.

The following variables were considered for the development of the study: sex of the observed professional (female / male); age by age group (20 to 30 years, 31 to 40 years, 41 or more); time working at the institution; professional category (nursing assistant, nursing technician); time working in the profession; professional training time; hours worked per day (6 or 12); work in other location outside that unit.

The other information considered and recorded included: day of the week; work shift; if the preparation and administration technique was performed correctly; if infusion of medication was controlled for speed and drip calculation according to prescription; and route of administration. To classify the type of medicine, ATC (Anatomical Therapeutic Classification) standardization was adopted (14).

Errors in preparation, time, and during administration were considered dependent variables. To define the types of errors that could be found during the investigation, a list containing 16 error types and their subcategories was used, as recommended in the literature (15). However, this research found five types: omission error, preparation error, dose error, time error, and administration error, which are described below:

Preparation errors include discrepancies during preparation of the medication, such as doses formulated or manipulated incorrectly or well before the administration time. They also include incorrect dilution, mixing medicinal products that are physical or chemically incompatible, inadequate packaging, contamination of the medicine, non-observance of biosafety techniques, and other mistakes.

Administration errors are discrepancies in how the medication is administered; no control of the infusion; not identifying the patient; and not using biosafety techniques such as gloves for intravenous administration, disinfection of accesses, and antisepsis of the skin to administer medications; as well as not labeling the prepared serums and medicines.

Time error occurs when medication is administration 30 minutes before or after the scheduled time.

Omission error of is the failure to administer a prescribed dose to the patient before the next scheduled dose, a patient refusing to receive it, or the decision of the nursing professional not to administer it.

Dose error is the inject or delivery of the medication in concentrations other than that prescribed.

After the collection phase, the data were reviewed and organized into Excel® spreadsheets for analysis and then analyzed according to their type. For that, the statistical program, Package for the Social Sciences (SPSS®) - version 18.0, was used for processing. The information was presented in a descriptive way through tables. The level of significance was set at 5%. The odds ratio (OR) was calculated with 95% confidence intervals. For associations, the Chi-square test and Mann Whitney test were used.

The development of the research complied with national and international standards of research ethics involving human subjects, and obtained the approval from the Research Ethics Committee of the Secretary of Health of the Federal District (number 017/2012).

### 3. RESULTS

The participants in the study were 88.1% female, 38.8% were between 20 and 30 years old, 44.4% between 31 and 40 years, and 16.6% over 41 years old.

As for the working day, 50.0% worked 6 hours per day, the other half worked 12 hours, and 61.1% worked only in the unit in question.

The preparation and administration of 415 doses were observed, with a total of 648 errors, which were 29.47% preparation errors; 18.36% time errors; and 42.12% administration errors; 3.24% omission errors, and 6.79% misapplication of the dose. A total error rate of 64.04% was recorded.

Table 1 shows the proportion of errors found in the medication process during the observation period.

Table 1: Proportions of errors found, related to sociodemographic aspects. Brasília, DF, Brazil, 2014.

Variable	Doses				Types of errors					
	415	Preparation Errors n: 191			Time Errors: 119			Administration Technique Errors: 273		
	N* (%)	N† (%)	OR ‡ (CI§ 95%)	P	N¶ (%)	OR ‡ (IC§ 95%)	P	N** (%)	OR ‡ (IC§ 95%)	P
<b>Sex</b>										
M	73(17.6)	35(47.9)	1.09(0.66-1.82)	0.407	27(37.0)	1.59(0.93-2.71)	0.058	42(57.5)	1.0 -	0.068
F	342(82.4)	156(45.6)	1.0 -		92(26.9)	1.0 -		231(67.5)	1.53(0.91-2.57)	
<b>Age of prof.††</b>										
20-30	160(38.6)	80(50.0)	1.53(0.99-2.36)	<b>0.041</b>	29(18.1)	1.0 -	< <b>0.000</b>	105(65.6)	1.01(0.56-1.80)	0.99
31-40	180(43.4)	71(39.4)	1.0 -		60(33.3)	2.25(1.35-3.75)		119(66.1)	1.03(0.58-1.82)	
41+	75(18.1)	40(53.3)	1.75(1.01-3.02)		30(40.0)	3.01(1.63-5.55)		49(65.3)	1.0 -	
<b>Category of prof. ‡‡</b>				0.12			<b>0.014</b>			0.295
Assistant	126(30.4)	52(41.3)	1.0 -		46(36.5)	1.70(1.08-2.66)		80(63.5)	1.0 -	
Technical	289(69.6)	139(48.1)	1.31(0.86-2.01)		73(25.3)	1.0 -		193(66.8)	1.15(0.74-1.79)	
<b>Work day</b>				0.388			<b>0.012</b>			0.404
6 h	148(35.7)	70(47.3)	1.08(0.72-1.61)		53(35.8)	1.69(1.09-2.62)		99(66.9)	1.07(0.70-1.65)	
12 h	267(64.3)	121(45.3)	1.0 -		66(24.7)	1.0 -		174(65.2)	1.0 -	
<b>Other work</b>				<b>0.024</b>			<b>0.001</b>			0.232
Yes	257(61.9)	108(42.0)	1.0 -		88(34.2)	2.13(1.33-3.41)		173(67.3)	1.19(0.78-1.80)	
No	158(38.1)	83(52.5)	1.52(1.02-2.27)		31(19.6)	1.0 -		100(63.3)	1.0 -	

\* N – number of doses/† N – number of preparation errors/‡ OR - Odds Ratio/§ CI - Confidence Interval/|| P - p value/¶ N = number of time errors/\*\* N = number of administration technique errors/††. Age of prof.= age of professional/‡‡ Category of prof. = Category of professional

Women were responsible for 82.4%, and gender of professional did not represent a variable risk factor for the occurrence of errors.

The age of the professional was a risk factor in the medication system, and the risk for preparation error occurring was 1.75-fold greater for the group above 41 years. The time errors were higher for the group of 30 to 40 years, with a risk of 2.25-fold greater for this group. The risk for the occurrence of the time error was 3.01-fold higher for the group older than 41 years (P <0.000).

The nursing technicians were responsible for most of the doses performed; however, the nursing assistant category had 1.7-fold greater time errors. In addition, working 6-hour days increased the risk of time errors by 1.69-fold.

Table 2 shows the proportionality of errors regarding the route of administration and classification of the drug, according to the international standardization of anatomical therapeutic classification (ATC).

Table 2: Proportions of medication errors with respect to the route of administration and anatomical therapeutic classification (TCA). Brasília, DF, Brazil, 2014.

Variable	Doses				Type of Error					
	415	Preparation Errors no: 191			Time Errors: 119			Administration Technique Errors: 273		
	N* (%)	N† (%)	OR ‡ (CI§ 95%)	P	N¶ (%)	OR ‡ (IC§ 95%)	P	N** (%)	OR ‡ (IC§ 95%)	P
<b>Via</b>				< <b>0.000</b>			< <b>0.000</b>			< <b>0.000</b>
IV	71(17.1)	57(80.3)	52.92(14.25-196.51)		30(42.3)	5.41(1.90-15.40)		42(59.2)	2.49(1.17-5.27)	
Oral	97(23.4)	74(76.3)	41.82(11.81-148.06)		39(40.2)	4.97(1.79-13.77)		57(58.8)	2.45(1.20-4.98)	

Subcutaneous	49(11.8)	40(81.6)	57.77(14.54-229.45)	14(28.6)	2.96(0.96-9.07)	18(36.7)	1.0 -
Inhalation	144(34.7)	15(10.4)	1.51(0.41-5.49)	26(18.1)	1.63(0.58-4.54)	112(77.8)	6.02(2.98-12.15)
NGT††	42(10.1)	3(7.1)	1.0 -	5(11.9)	1.0 -	40(95.2)	34.44(7.42-159.76)
Topical	10(2.4)	-	-	3(100)	-	3(100)	-
Gastro‡‡	2(0.5)	2(100)	-	2(100)	-	1(50)	1.72(0.10-29.24)
<b>ATC§§</b>			<b>&lt;0.000</b>			<b>0.034</b>	<b>&lt;0.000</b>
A	60(14.5)	20(33.3)	2.20(0.92-5.25)	16(26.7)	2.90 (1.04-8.09)	46(76.7)	6.57(1.08-39.74)
B	54(13.0)	10(18.5)	1.0 -	6(11.1)	1.0 -	50(92.6)	25.00(3.45-180.97)
C	93(22.4)	43(46.2)	3.78(1.70-8.40)	28(30.1)	3.44(1.32-8.97)	56(60.2)	3.02(0.52-17.37)
D	23(5.5)	5(21.7)	1.22(0.36-4.08)	8(34.8)	4.26(1.27-14.26)	18(78.3)	7.20(1.00-51.39)
G	6(1.4)	4(66.7)	8.80(1.41-54.91)	3(50.0)	8.00(1.30-48.95)	2(33.3)	1.0 -
H	1(0.2)	1(100)	-	-	-	1(100)	-
J	56(13.5)	40(71.4)	11.00(4.47-27.01)	24(42.9)	6.00(2.20-16.31)	28(50.0)	2.00(0.33-11.81)
L	1(0.2)	-	-	-	-	1(100)	-
N	65(15.7)	27(41.5)	3.12(1.34-7.28)	19(29.2)	3.30(1.21-9.00)	48(73.8)	5.64(0.94-33.66)
R	56(13.5)	41(73.2)	12.02(4.85-29.76)	15(26.8)	2.92(1.04-8.23)	23(41.1)	1.39(0.23-8.25)

\* N – number of doses; † N - number de preparation errors; \*\* N = number of administration technique errors; ‡ OR - Odds Ratio § CI - Confidence Interval; || P - p value; ¶ N = number of time errors; †† NGT – nasogastric tube; ‡‡ Gastro – Gastrostomy; §§ ATC – Anatomical therapeutic classification

Risk factors relating the administration route to the preparation error were the subcutaneous, intravenous, and oral routes, which presented a risk of 57.77, 52.92, and 41.82-fold for the preparation error (P <0.000), respectively. That is, for each 8 doses of medication administered subcutaneously and intravenously, at least 8 had preparation errors.

Among the different classes of medications, the ones that represented the greatest risk for preparation error were: respiratory system (12.02-fold), antimicrobial (11), genitourinary and hormonal (8.80), cardiovascular (3.78), and nervous system (3.12) (P <0.000). The risk for time error was observed in practically all classes, and highest for the genitourinary and hormonal system (8), antimicrobial (6), dermatological (4.26), and cardiovascular (3.44) (P <0.034). In almost all the hematopoietic class drugs (B) (92.6%), administration error was observed, increasing the risk 25-fold, which for class A was 6.57-fold; or from every four doses of the class of medications for the gastrointestinal system, three contained an error.

#### 4. DISCUSSION

The results are relevant because they evidence the context that medication errors occur, with consequences for the patient. The study showed high prevalence of risk factors and vulnerabilities in the medication system.

A transition in Brazilian labor legislation is leading to an increased number of professionals who will retire soon (16), triggering a change in the socio-professional profile. It is important to consider the increase in the risk of error in the age group above 41 found in this study, which corroborates the hypothesis that the greater the age of the professional, the greater the risk of medication errors (11).

Administering medications without checking the prescription compromises the patient's safety, in most cases, the prescriptions contain medicines familiar to the professionals, who are overconfident in their memory. However, due to the constant launching of new drugs, with different names, presentations, and preparations, it is necessary to constantly

update professionals to avoid adverse events related to medication (17-19).

The medication system is complex and thus requires the attention of all professional staff and the use of technologies currently available for safe administration of medications, namely: electronic prescription/electronic medical record system, single dose, intelligent infusion pumps or the traditional, automated dispensation, and barcode drug administration system (11-12,17-18,20-21).

The hospital chosen to carry out this study is a pioneer in the implementing a system for electronic medical records in the Federal District, guaranteeing the maximum updating and verification of the software so that the system can be constantly revised. Research shows that the implementation of an electronic medical record system reduces the time spent on records, enables greater understanding among professionals, reduces the incidence of errors, and supports the decision-making process. Studies also found that after the implementation of computerization of care the frequency of errors reduced from 18% to 8% (11-12,15,22-23).

Adverse events to the medication process are multidisciplinary in nature and may occur at any stage of the therapeutic chain, but they were most frequent during administration, according to the present study (5). The repercussions of these failures fall under two categories: personal (patient and family) and increased institutional expenditure, which should be sufficient to motivate the adoption of measures to reduce the incidence of errors (4, 7, 10, 18). Of all doses analyzed during the study, approximately one-third were related to injectable drugs (28.9%), as demonstrated in another study (7).

Of the medications involved, there was a high prevalence of those related to the circulatory system, with an emphasis on antithrombotic, supporting the main medications considered potentially dangerous related to the cardiovascular system and metabolism (19). The costs of adverse events related to antimicrobials are high, due to the possible reversion of the patient's condition, as well as the acquired antimicrobial

resistance, added to the polypharmacy, a characteristic situation of the patients studied (7,10,18).

Dosing errors (giving more or less) are worrisome for antimicrobials because they interfere in the therapeutic effectiveness by provoking the selection of microorganisms and consequent mechanism of resistance, which increases the period of hospitalization and makes the patient prone to other events. Reports point to a lower number of errors in antibiotic prescriptions and the reduction of time and cost of hospital admissions after the implantation of the electronic medical records (7,10).

Another possible and efficient measure in preventing the error would be individualized dosage, which is already used in the hospital setting of this study. However, the ideal would be the single dose, which allows greater control in the preparation stage, although it is a more expensive alternative (17,24).

In the present study, in which the incorrect preparation technique resulted in 22.3-fold greater risk for error, the single dose would be a beneficial resource for nursing. This would reduce preparation time, which could be used to obtain information about the drug, its relationship with the patient's clinical condition, better monitoring of the patient, and checking and review of their medical history. Therefore, the medication process could focus on the rationalization of care based on the needs of the patient (24).

One of the measures recommended by ANVISA to reduce medication errors is the protocol for the safe use of medication associated with a bar code system to rapidly identify the patient. The adoption of the protocol avoids medication errors in up to 93%, ensuring that there are no discrepancies between the prescribed and the administered medications, and integrates the process into the electronic system by means of bedside computers as a resource to ensure the proper identification of the patient (7,11,17-18,21).

The inclusion of bar code identification system has some advantages, such as preventing the patient from being identified by his diagnosis, bed, or pathology, for example (20). However, its use does not exclude multiple conferences and good practices in preparation and administration. Identifying and reporting the error is the first step in prevention (8,25). Thus, we propose for its minimization, the system of notification recommended by ANVISA, which starts with the identification of the event, its detailed description and, from then on, identification of the vulnerabilities of the system to permit direct action. In this way, the performance in the system would be according to its circumstances, tailored its needs, with personalized assistance (8,17).

It is fundamental to address episodes of errors as a learning possibility, an indicator for individual changes and in the system, which is complex and flawed. To blame the professional alone is not enough. Instead, we must discuss the error and analyze it according to a problem-based approach, based on the risk areas to construct a safe method (25).

## 5. CONCLUSION

The study enabled the identification of the main risk factors for medication errors and detection of areas susceptible to their occurrence. Patient safety involves a multi-centered system that needs to be well delineated to avoid mistakes. The incidence of errors in the unit was high, especially those related to the administration, involving professionals in the over 41 age group.

The present study confirms the need to adopt some measures, for example: electronic prescription, use of single doses; computerized interventions, especially in the preparation and administration stages; implementation of human resource management strategies (for example change in number of hours worked); and time reconciliation. It is believed that as long as

the preparation and administration steps are not computerized and incorporated into the system, it will remain fragile.

The patient cannot be considered only a passive subject in this process, but participant, with the duty to contribute to their own safety. The applicability of this study in other countries is possible considering the cultural reality and the technological advances, since the need for informatization evidenced in the researched environment induces the results found, whereas it would be interesting to associate the same points evaluated in an environment with adequate structure verifying the accuracy of the points found.

In the area of nursing, it is necessary to train and support nurses to identify and use evidence-based practices related to patient safety, and to recognize, in assistance of the team, factors that may impair the success of care.

## Limitation of the study:

The main limitation of the study is the phenomenon known as the Hawthorne effect, in which the interference of an observer during the execution of the medication process leads to a possible manipulation of actions and a possible bias.

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