

## MEDICATION ERRORS AND DEGREE OF PATIENT DAMAGE AT A TEACHING HOSPITAL

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**ABSTRACT:** The objectives in this study were to verify the incidence of medication errors and near misses and the degree of damage to the patient, as well as the association between the degree of damage and sociodemographic and hospitalization characteristics. Descriptive and retrospective study with a quantitative approach, undertaken at a hospital in the interior of the State of São Paulo. The data were collected through the adverse event reporting system and the electronic history between September/2014 and August/2015. In total, 113 error reports were found, mostly related to preparation and administration; a small percentage of near misses was found; the damage was classified: 60 (53.1%) none, 29 (25.7%) mild, 16 (14.1%) moderate and eight (7.1%) severe. More errors were reported at clinical-surgical units, and a relation was found between the severity of the event and intensive care patients. Reporting, measuring and analyzing the event, the degree of damage and relating them with the patient characteristics help the nurse to improve the work process in the prevention and control of medication errors.

**DESCRIPTORS:** Patient safety; Medication errors; Quality indicators; Notification; Hospitals, teaching.

### ERROS DE MEDICAÇÃO E GRAU DE DANO AO PACIENTE EM HOSPITAL ESCOLA

**RESUMO:** O estudo teve como objetivos verificar a incidência de erros e quase erros de medicação e grau de dano ao paciente, e a associação entre o grau de dano e características sociodemográficas e da internação. Estudo descritivo, retrospectivo, com abordagem quantitativa, realizado em hospital no interior do estado de São Paulo. Os dados foram coletados por meio do sistema de notificação de eventos adversos e prontuário eletrônico, entre setembro/2014 e agosto/2015. Verificou-se 113 notificações de erros, a maioria relacionada ao preparo e administração; o quase erro apresentou pequena porcentagem; os danos foram classificados: 60 (53,1%) nenhum, 29 (25,7%) leve, 16 (14,1%) moderado e oito (7,1%) grave. Houve maior notificação em unidades clínico-cirúrgicas, e evidenciou-se relação entre gravidade do evento e pacientes de terapia intensiva. Notificar, mensurar e analisar a ocorrência, o grau de dano e relacionar com as características do paciente auxiliam o enfermeiro a melhorar o processo de trabalho na prevenção e controle dos erros de medicação.

**DESCRIPTORIOS:** Segurança do paciente; Erros de medicação; Indicador de qualidade; Notificação; Hospital de ensino.

### ERRORES DE MEDICACIÓN Y GRADO DE DAÑO AL PACIENTE EN HOSPITAL ESCUELA

**RESUMEN:** Los objetivos en este estudio fueron verificar la incidencia de errores y casi-errores de medicación y grado de daño al paciente, y la asociación entre el grado de daño y características sociodemográficas y de la internación. Estudio descriptivo, retrospectivo, con aproximación cuantitativa, desarrollado en un hospital en el interior del estado de São Paulo. Los datos fueron recolectados mediante el sistema de notificación de eventos adversos y archivo electrónico, entre septiembre/2014 y agosto/2015. Fueron verificadas 113 notificaciones de errores, la mayoría relacionada a la preparación y administración; el porcentaje de casi errores fue pequeño; los daños fueron clasificados: 60 (53,1%) ningún, 29 (25,7%) leve, 16 (14,1%) moderado y ocho (7,1%) grave. Fue encontrada mayor notificación en unidades clínico-quirúrgicas, y fue evidenciada relación entre gravedad del evento y pacientes de terapia intensiva. Notificar, mensurar y analizar la ocurrencia, el grado de daño y relacionar con las características del paciente ayudan al enfermero a mejorar el proceso de trabajo en la prevención y el control de los errores de medicación.

**DESCRIPTORIOS:** Seguridad del paciente; Errores de medicación; Indicadores de calidad; Notificación; Hospitales de enseñanza.

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**Received:** 27/02/2016

**Finalized:** 11/10/2016

## ● INTRODUCTION

Drug administration is one of the main activities of the nursing team<sup>(1)</sup>. This process involves the acquisition, storage, prescription, dispensation, preparation and administration<sup>(2)</sup>. Due to their complexity, medication errors can happen in any of these phases, entailing risks or even damage for the patient<sup>(2-3)</sup>. The monitoring of medication errors is needed and deserves the team's attention, and should therefore be reported and measured by the nurse in order to serve as a care assessment parameter<sup>(4)</sup>.

Studies developed in different regions of Brazil have demonstrated that the incidence of medication-related errors in general hospital, surgical-clinical wards and intensive care units (ICUs) varied between 14.8% and 24.8%<sup>(5-8)</sup>, reaching 82.3% at a private institution in the interior of the State of São Paulo<sup>(3)</sup>. On the other hand, it is important to highlight cases of underreporting, as proven in a study developed in Rio de Janeiro, in which the incidence of medication errors represented only 4.3% of the adverse events<sup>(9)</sup>.

Error events are caused not only by the human factor, but also by the problems related to the process, to the work burden, the lack of recycling in education and health, incorrect drug manipulation, unsuitable environment or even the patient's clinical condition<sup>(10-11)</sup>.

In clinical practice, medication administration is one of the most relevant activities, but a trend is observed in which the nursing team disregards errors, in the belief that, in most cases, they do not entail further repercussions for the patients<sup>(12)</sup>.

In view of the work demand deriving from the medication administration process and from the fact that the human being is not free from errors and in view of the nursing professionals' disregard of non-severe events, the objectives in this study were to verify the incidence of medication errors and near misses and the degree of damage to the patient and to identify the association between the degree of damage and the sociodemographic and hospitalization characteristics.

## ● METHOD

Descriptive and retrospective study with a quantitative approach, undertaken at a general teaching hospital in the Northwest of São Paulo of special size, offering approximately 700 beds. This tertiary care institution has been accredited for care delivery to highly complex patients, 85% through the Unified Health System (SUS), and others through supplementary and private health services. In addition, it stands out because of its teaching and research activities. It is affiliated with the Sentinel Hospital Network of the National Health Surveillance Agency, which aims to diagnose adverse events and technical complaints related to health products through Risk Management.

The inclusion criteria were, adult hospitalized patients, victims of a medication-related problem, reported through the computer system between September 2014 and August 2015.

The exclusion criteria were: reports of errors and near misses coming from other institutions linked to the hospital which are also monitored by the Risk Management Unit of the study hospital; from units that did not register that indicator, from events involving outpatients and the presence of incomplete data in the hospital information system. In accordance with those criteria, 19 reports from the post-anesthetic recovery sector were excluded.

To calculate the incidence of medication errors and near misses, the formulae from the Manual of Nursing Indicators of the Hospital Management Support Group were used, elaborated in partnership with the Hospital Quality Commitment Program (PCQH). For the medication errors, the calculation was "number of drug administration errors/number of patients-day x 100" and, for the near misses, "number of near misses related to the medication administration process/number of patients-day x 100".

The data were collected from the reporting forms of adverse events, which health professionals completed for the selected period using the computer system. These forms include the identification

of the reporter (name, profession and registration date of the report), event date, patient identification (bedroom, bed, inpatient unit, name and history), type of event, description and severity of the damage. It is important to highlight that, in some cases, more than one incident happened with the same patient.

To determine the severity of the event, the World Health Organization International Classification for Patient Safety was used<sup>(13)</sup>. Besides these data, additional information was investigated in the patient's electronic history, including age, ethnic origin, education, city of origin, profession, religion, health insurance, number of hospitalization days, presence of companion on the day of the incident, transfer from sector on the day of the incident, medical diagnosis according to international classification of diseases (ICD-10) and outcome of the hospitalization.

The data were stored in a database in Microsoft Office Excel®, analyzed descriptively in absolute and relative frequencies and presented in tables for the sake of a better visualization. The mean and standard deviation were calculated for the quantitative variables (age and number of hospitalization days).

To analyze the data, Spearman's correlation test was applied, using the software Prisma version 6.01, in order to identify the relation between the severity of the event and the patient's sociodemographic variables. Significance was set at 5%.

The following variables were tested: sex, age range, city or origin, education, type of health insurance, inpatient unit, presence of companion, transfer from unit on the day of the incident, number of hospitalization days, medical diagnosis and clinical outcome of the hospitalization; selected according to the relevance for the study.

The project followed all ethical requirements and approval was obtained from the Research Ethics Committee (CEP) at Faculdade de Medicina de São José do Rio Preto – FAMERP, under opinion 1.050.829, on 05/05/2015.

## ● RESULTS

In Table 1, indicators are presented of 113 error and near miss reports by month. As observed, the incidence of near misses was much lower than that of the errors. The highest error indicator was found in May 2015 and the lowest in March 2015.

Table 1 – Incidence of medication errors and near misses. São José do Rio Preto, SP, Brazil, 2016

Period	Error Indicator	Near Miss Indicator
September/2014	0.09	-
October/2014	0.08	0.005
November/2014	0.05	-
December/2014	0.04	0.008
January/2015	0.09	0.008
February/2015	0.04	-
March/2015	0.007	-
April/2015	0.1	-
May/2015	0.12	-
June/2015	0.05	0.007
July/2015	0.02	-

In view of the low frequency of near misses, the medication errors were considered in the patients' characteristics. The sociodemographic characteristics and data on the patients' hospitalization period are displayed in Tables 2 and 3, respectively, as well as the results of the association tests between each of the variables and the severity of the event.

Table 2 – Sociodemographic characteristics. São José do Rio Preto, SP, Brazil, 2016

Sociodemographic data	n(%)	p†
Sex		-
Male	65(57.6)	-
Female	48(42.4)	0.4318
Age range	Mean: 59/ SD 18.19	-
< 40 years	19(16.8)	-
41 to 60 years	36(31.9)	-
61 to 80 years	49(43.4)	-
> 80 years	9(7.9)	0.4386
Ethnic origin		-
White	99(87.6)	-
Black	7(6.2)	-
Mulatto	3(2.7)	-
No information	4(3.5)	-
Education		-
Up to Unfinished Primary Education	72(63.7)	0.6681
Up to Unfinished Secondary Education	7(6.2)	-
Up to Unfinished Higher Education	21(18.6)	-
Up to Specialization	6(5.3)	-
No information	7(6.2)	-
Profession		-
Retired/Pensioners	53(46.9)	-
Paid job	34(30.1)	-
Housewife	14(12.4)	-
Student	4(3.5)	-
No information	8(7.1)	-
Religion		-
Catholic	84(74.3)	-
Evangelical/Pentecostal	13(11.5)	-
Others	7(6.2)	-
None	1(0.9)	-
No information	8(7.1)	-
City of Origin		-
São José do Rio Preto	43(38.1)	0.8607
Region of São José do Rio Preto	67(59.3)	-
Other state	3(2.6)	-
<b>Total</b>	<b>113(100)</b>	<b>-</b>

† Spearman's test: association between damage severity and sociodemographic data

Table 3 – Hospitalization characteristics. São José do Rio Preto, SP, Brazil, 2016 (continues)

Hospitalization	n(%)	p‡
Health insurance		-
SUS	100(88.5)	-
Supplementary Health	13(11.5)	0.0431
Inpatient unit		-
Open units	70(62)	-

Closed units	43(38)	0.0012
Medical diagnosis		-
Group 1§	48(42.5)	0.0162
Group2††	38(33.6)	-
Group3‡‡	19(16.8)	-
Group4§§	8(7.1)	-
Days of hospitalization	Mean: 28/ SD: 27.76	
Up to 7 days of hospitalization	22(19.5)	-
8 to 15 days of hospitalization	20(17.7)	-
16 to 30 days of hospitalization	36(31.8)	-
> 30 days of hospitalization	35(31)	0.0238
Companion on the day of the incident		-
No	59(52.2)	0.0571
Yes	51(45.1)	-
No information	3(2.7)	-
Transfer on the day of the incident		-
No	100(88.5)	0.523
Yes	13(11.5)	-
Outcome of hospitalization		-
Discharge	76(67.3)	0.0061
Death	37(32.7)	-
<b>Total</b>	<b>113(100)</b>	<b>-</b>

‡ Spearman test: association between severity of damage and hospitalization characteristics.

§Diseases of the Circulatory, Respiratory, Digestive and Genitourinary Systems.†† Infectious, Parasitic and Neoplastic Diseases.‡‡ Abnormal findings on laboratory tests, external causes or their consequences and factors influencing the health status. §§ Others (diseases of the nervous system; blood diseases; endocrine system diseases; mental disorders; diseases of the eye and adjacent tissues; musculoskeletal and joint tissue diseases; pregnancy, delivery and postpartum).

Spearman's correlation analysis showed a significant correlation between the most severe incidents and the patients attended through the supplementary health system ( $p=0.0431$ ), hospitalized at closed units ( $p=0.0012$ ), with long hospitalization periods( $p=0.0238$ ) and with discharge as the outcome( $p=0.0061$ ).

As for the characteristics of the reported event, the type of medication error and the degree of damage caused are displayed in Table 4. In 99.1%, the nurse reported the event and the reporting date differed from the event date in 62.4%, as the system permits retroactive reporting.

Table 4 – Incident characteristics. São José do Rio Preto, SP, Brazil, 2016

<b>Incident</b>	<b>n(%)</b>
Type of error	
Related to the five rights of medication	58(51.3)
Non-administered drug	32(28.3)
Others	23(20.4)
Degree of damage	
None	60(53.1)
Mild	29(25.7)
Moderate	16(14.1)
Severe	8(7.1)
<b>Total</b>	<b>113(100)</b>

## ● DISCUSSION

It is estimated that adverse events in hospitals affect around 10% of the inpatients<sup>(14-15)</sup>, but studies appoint that this percentage can range between 5%<sup>(9,16)</sup> and 41%<sup>(16)</sup>. Damage-free incidents represented 82% of the events in a study undertaken in the Central-West of Brazil<sup>(6)</sup>.

Among the possible adverse events, the percentages of medication errors, appointed in different studies, range between 3% and 54%<sup>(2,5-7,9,17-18)</sup>. It is important to highlight that, like other adverse events, they should be reported, as that it the only way to produce care quality indicators<sup>(19)</sup>.

As verified, most of the patients for whom a medication-related event was reported while in hospital were male, in line with other studies<sup>(12,18)</sup>. The literature appoints that, overall, adverse events affect men<sup>(5,9)</sup>. Most patients were elderly, between 61 and 80 years of age, representing 43.4% (mean: 59/ SD 18.19)<sup>(5,9,12)</sup>.

Concerning education, most patients had not finished primary education, and some were even illiterate. The majority was hospitalized at medical-surgical clinical units<sup>(3)</sup>, according to the institution's profile.

For 41.9% of the patients, the medical diagnosis referred to Diseases of the Circulatory, Respiratory, Digestive and Genitourinary System, followed by 33.4% for Infectious, Parasitic and Neoplastic Diseases, in line with findings from another study developed at an accredited institution in the State of São Paulo<sup>(5)</sup>.

The mean length of hospitalization was 28 days, 72 patients (62.8%) being hospitalized for more than 15 days, differently from studies undertaken at surgical clinical and intensive care units, where the mean length of hospitalization was 4 and 8 days, respectively<sup>(6,20)</sup>. Despite the long hospitalization, 67.3% of the patients were discharged, as evidenced in studies in the State of São Paulo<sup>(12,21)</sup>. It is important to highlight, however, that for 32.7%, the clinical outcome of the hospitalization was death, five times higher than at a hospital in the city of Rio de Janeiro<sup>(18)</sup>. As regards the 11.5% of the patients transferred on the day of the incident, the question is raised whether this fact favored the error event, as communication errors contribute to the occurrence of medication errors<sup>(22)</sup>.

As for the error type, 51.3% were related to the five rights in medication administration (right patient, drug, dose, route and time)<sup>(5,23)</sup>, inferring that most errors happened during the preparation and administration. Non-administered drugs represented 28.3%, similar to other studies<sup>(2-3,5,7,12,17)</sup>.

The errors related to the drug prescription, transcription and dispensing represented 0.85% of the incidents. It is noteworthy that, at institutions without an electronic prescription system, these types of errors can represent almost half of the incidents<sup>(22)</sup>.

Most incidents, 60 (53.1%), did not cause any damage to the patient but, in 53 (46.9%) of the cases, there was some degree of damage, being 29 (25.7%) mild, 16 (14.1%) moderate or eight (7.1%) severe, as opposed to a study developed at a hospital in the Sentinel network, in which the incident of mild damage was higher, and as opposed to one death associated with a medication error<sup>(6)</sup>. It should be emphasized that the reporting professional classifies the degree of damage, entailing the possibility of subjective interpretations. To give an example, 3.4% of the notifications corresponded to a near miss, highly different from the results of a study undertaken at a public hospital in São Paulo, where near misses represented 60.4% of the incidents<sup>(24)</sup>.

The highest percentage of errors involving damage affected patients hospitalized over long periods at closed units. This can be explained by the fact that these units receive more severe patients, taking a larger number and more complex medication therapy<sup>(5)</sup>.

The occurrence of medication errors is more frequently associated with the professionals' activities, such as non-compliance with standards and protocols<sup>(9)</sup>, lack of attention<sup>(22)</sup>, communication errors<sup>(2)</sup>, among others. Medication errors and near misses can be harmful for the patients involved, but the consequences of these incidents also affect the nursing team, such as the increased workload<sup>(12)</sup> and the need for clinical and administrative measures<sup>(21-22)</sup>.

Aiming to prevent new events, the main prevention activities were surveyed in a multicenter study, based on the professionals' suggestions, being: improvement of the professionals' individual attitudes, intensification of continuing education, restructuring of staff, among others<sup>(22)</sup>.

In 99.1% of the cases, the nurse reported the event, as opposed to a study developed at a similar institution, where the multiprofessional team reported the events<sup>(19)</sup>. When comparing the medication error rates among the general hospitals with more than 50 beds which participate in the Hospital Quality Commitment (CQH) program and groups, the medians were 0.11 and 0.08 in September/2014 and July/2015, respectively, rates that are variably similar to the rates calculated at this service. As for the near misses related to the medication administration process, the medians corresponded to 0.05 and 0.02 during the months in question, rates highly different from the present findings, suggesting the occurrence of underreporting<sup>(25)</sup>.

In view of evidences of underreporting, deriving from the fear of possible ethical-legal sanctions, efforts are needed to stimulate the reporting and to improve and develop a safety culture. Considering the medication errors as outcome indicators can contribute to a new look on this type of event. Valuing these incidents is fundamental, not only due to their numerical relevance, but due to the consequences they can cause for the patient<sup>(12)</sup>.

The possibility of underreporting represents a limitation. It is important to highlight that the percentage of near misses was low.

## ● CONCLUSION

Most patients were hospitalized through the Unified Health System and at clinical-surgical inpatient units, but a larger number of error reports involving patient damage was found for Intensive Care Unit patients and patients attended through the Supplementary Health system.

This study highlights the importance of reporting, measuring and analyzing medication errors and near misses, as this helps the nurse to improve the work process, to provide continuing education to health professionals and to prevent and control medication errors. Among the events, 60 (53.1%) did not cause damage to the patient, 29 (25.7%) caused mild damage, 16 (14.1%) moderate and eight (7.1%) severe.

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