

**ORIGINAL ARTICLE** 

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# Medication incidents in an outpatient emergency service: documental analysis\*

Incidentes com medicamentos em unidade de urgência e emergência: análise documental Incidentes con fármacos en unidad de urgencia y emergencia: análisis documental

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#### **ABSTRACT**

**Objective:** To characterize medication incidents occurred in an outpatient emergency service. **Method:** Descriptive, documental, retrospective and quantitative research. The International Classification for Patient Safety was the theoretical reference for the construction of the instrument used to collect and analyze the data from 119 notification and investigation forms of incidents occurred in 2014 in a teaching hospital. Data were collected twice, compared, corrected and transcribed to an Excel worksheet. The SPSS 19.0 Software and the non-parametric Mann-Whitney test were used in the analysis; p<0.05 indicated statistical significance. **Results:** A total of 142 incidents were analyzed, most of them involving the nursing team; 93.7% were avoidable; one-third involved high-alert medications; the majority involved parenteral administration. Harm was rare but proportional to the time elapsed for error detection. Management failures prevailed, especially omission. **Conclusion:** Most of the incidents analyzed were characterized as potentially harmful and avoidable, with emphasis on personnel factors as contributors.

#### **DESCRIPTORS**

Patient Safety; Medication Errors; Risk Management; Nursing Assessment.

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# **INTRODUCTION**

Health care services and especially hospitals are complex systems that contain elements of risk related to the diversity of technologies and the high number of professionals involved in the care process. Drug therapy is an example of an element of risk. Medications are widely used in these settings and are beneficial for treating patients, but errors in its use can inflict harm on patients.

Studies show that medication incidents affect 1.6% to 41.4% of patients<sup>(1)</sup> and can generate an additional cost estimated between 25 and 35 million dollars per year in large hospitals<sup>(2)</sup>. This scenario is aggravated in services that provide care for critically ill patients, due to the patients' clinical condition and the large number of medications administered, among other factors<sup>(3)</sup>.

The identification of incidents is important for evaluating the quality of care. However, in order to increase patient safety, it is necessary to understand the characteristics of these incidents. In this context, the diversity of methods and the use of non-standard terminology, especially for medication incidents, undermine this understanding<sup>(4)</sup>.

In order to promote learning, the World Health Organization published in 2009 the International Classification for Patient Safety (ICPS), which describes the concepts related to patient safety<sup>(5)</sup>. In addition to standardizing the language, the document proposes a methodology for investigation, analysis and classification of incidents that can be used in all health services and countries, regardless of their level of development. The objective of this study was to characterize the medication incidents occurred in an outpatient emergency service, using the ICPS<sup>(5)</sup> as theoretical reference.

# **METHOD**

This is a descriptive, retrospective, documental study with quantitative approach carried out in 2015. The data sources were the notification and investigation forms of medication incidents occurred in 2014 at the outpatient emergency service of a public teaching hospital in the south of Brazil. This unit provides care to critically ill non-trauma adult patients and includes the emergency services, semi-intensive and intensive care.

Incidents are notified in this institution through an exclusive, printed form, with the record of the patient's data, brief description of the incident, date, time and place of occurrence, immediate consequences for the patient and actions taken. The identification of the notifier is not mandatory and, if known, it is classified. Periodically, a group of members of the institutional patient safety program and of the care units involved investigates the incident and records it on its own form. The notification and investigation forms are stored as a single document, and were the document source of this research.

# CONSTRUCTION AND TESTING OF THE DATA COLLECTION INSTRUMENT

For the data collection, an instrument based on the ten conceptual classes proposed in the ICPS<sup>(5)</sup> was constructed. It was tested on ten notification forms and respective investigation forms, which were also document sources in this study.

Variables which were constant in the document sources but did not belong to the ICPS<sup>(5)</sup> were included in the instrument, since they were relevant to characterize the incidents regarding beginning and end dates of the investigation and avoidability of the incident.

The other variables of interest, according to the conceptual classes of the ICPS(5), were: Class 1. Incident Type - medication involved, route of administration, process and usage problem; Class 2. Patient Characteristics - gender, age and reason for admission (procedure or diagnosis); Class 3. Incident Characteristics - people involved, detection and notification of the incident; place, date and time of occurrence, detection and notification of the incident; phase of care in which the incident occurred; Class 4. Patient Outcomes - type, degree and impact of harm; Class 5. Detection – detection process; Class 6. Contributing Factors – staff, patient, work and organization factors; Class 7. Organizational Outcomes; Class 8. Mitigating Factors – factors directed to staff, to patient, to an agent and/or to the organization; Class 9. Ameliorating Actions - actions related to the patient and/or the organization; and Class 10. Actions Taken to Reduce Risk – actions related to the patient, staff, organization or environment and/or workers/equipment.

# **DATA COLLECTION AND ANALYSIS**

Data was collected in three stages, as described below: Stage 1: a) Reading the incidents notification and investigation forms and filling the printed data collection instrument, named A, with the data obtained; b) Re-reading the incidents notification and investigation forms and filling in a second printed collection instrument, named B, with the data obtained;

Stage 2: Comparing A and B forms and correcting divergent data by consulting the document sources, thus resulting in a single set of data;

Stage 3: Transcription of the data from stage 2 to the database constructed in Excel.

All the stages were carried out by the researcher. For this research, in notifications involving more than one drug and/or with the record of more than one incident, each case was considered individually.

Data were analyzed descriptively using the SPSS 19.0 Software in which frequency, percentage, mean, median and standard deviation were calculated. The non-parametric Mann-Whitney test was used to verify significant association between variables, with p<0.05 indicating statistical significance.

The drugs involved in the incidents were classified according to the Anatomical Therapeutic Chemical Code – WHO Collaborating Centre for Drug Statistics Methodology<sup>(6)</sup> and the list of high-alert medications of the Institute for Safe Medication Practices<sup>(7)</sup>.

The study followed the norms of ethics in research involving human beings and obtained approval from the Research Ethics Committee under Resolution no. 880.461/2014.

# **RESULTS**

The results are presented according to the ten conceptual classes of the ICPS and its variables, which were presented in the method.

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The analysis covered a total of 119 notifications and respective investigation forms, in which 142 incidents were documented. Women were more frequently affected (64.1%, N=91), and the mean age of the patients was 57 years (Standard deviation ±17; Mode=48 years).

The administration process represented 76.8% (N=109) of the incidents analyzed, and the error of omission was prevalent (40.9%, N=58); 18.3% (N=26) of the problems identified could not be classified by the  $ICPS^{(5)}$  and were mostly related to reportable circumstances, that is, situations with potential to cause harm (Table 1).

**Table 1** – Usage process and problem related to medication incidents – Curitiba, Paraná, Brazil, 2014.

Medication use process	N (%)
Administration	109 (76.8)
Preparation	16 (11.3)
Storage <sup>1</sup>	9 (6.3)
Prescription	7 (4.9)
Dispensing	1 (0.7)
Problem in the use process	N (%)
Omission	58 (40.9)
Dose	27 (19.0)
Frequency	12 (8.5)
Expiration	6 (4.2)
Delay	5 (3.5)
Route	4 (2.8)
Quantity	2 (1.4)
Storage	1 (0.7)
Patient	1 (0.7)
Unclassified <sup>2</sup>	26 (18.3)

<sup>&</sup>lt;sup>1</sup> Medication control in the inpatient unit

Parenteral routes were used in 55.6% (N=79) of the incidents, and the intravenous route was the most frequent; high-alert medications were involved in 28.2% of the 142 incidents analyzed. Medications that act on blood and blood forming organs and on the nervous system were predominant (Table 2).

**Table 2** – Route of administration and action of drugs involved in incidents – Curitiba, Paraná, Brazil, 2014.

Intravenous Oral Intra-arterial Intramuscular	65 (45.8) 46 (32.4) 9 (6.3) 4 (2.8)
Intra-arterial	9 (6.3)
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Intramuscular	4 (2.8)
Inhalation	4 (2.8)
Subcutaneous	1 (0.7)
Not informed	13 (9.2)
Action <sup>1</sup>	N (%)
B Blood and blood forming organs	27 (19.0)
N Nervous system	27 (19.0)
J Anti-infectives for systemic use	26 (18.3)
C Cardiovascular system	24 (16.4)
A Digestory tract and metabolism	17 (12.0)
H Systemic hormonal preparations, excluding hormones sexuais e insulinas	7 (4.9)
R Respiratory system	7 (4.9)
D Dermatological drugs	4 (2.8)
G Genitourinary system and reproductive hormones	1 (0.7)
M Musculoskeletal system	1 (0.7)
Not specified '	1 (0.7)
High-alert medications <sup>2</sup>	40 (28.2)

<sup>&</sup>lt;sup>1</sup> Classification according to the Anatomical Therapeutic Chemical Classification System, First Level – anatomical group<sup>(6)</sup>

In 119 (83.8%) incidents no harm was recorded, 22 incidents (15.5%) resulted in mild harm and in one case the incident was related to the death of the patient.

Among the 23 incidents with harm, 13 (56.5%) involved the use of high-alert medications and 18 (78.3%) were administered via intravenous route. The sensory (26.1%, N=6) and cardiovascular (26.1%, N=6) systems were the most harmed and were related to pain, hypertension and hypotension symptoms. The endocrine, integumentary and excretory systems were affected in 9 (13%) incidents with harm and the immune and digestive systems, in two (4.4%).

Organizational outcomes were reported in only 24 (16.9%) incidents, all related to the increase in the resources necessary for the treatment.

Most of the incidents (68.3%, N=97) occurred in the semi-intensive care unit, followed by the intensive care unit (23.9%, N=34) and by emergency care (7.8%, N=11). The incidents occurred more frequently at night (47.9%, N=68) when compared to morning (26.8%, N=38) and evening shifts (16.9%, N=24), and occurred predominantly at 8 a.m., 4 p.m. and 12 midnight. In 60.6% (N=86) of the incidents it was not possible to identify the shift; 28.2% of the incidents (N=40) were detected in the morning, 6.3% (N=9) in the afternoon and 4.9% (N=7) at night. The most frequent hours of detection of the incident, per shift, were 8 a.m., 2 p.m. and 8 p.m.

In only six incidents with harm and 26 incidents without harm it was possible to identify the time elapsed between the occurrence and the detection of the incident. This was due to the absence of one or both information in the collection sources. The mean time to detect the incidents with harm was 11 hours and 10 minutes, and for the incidents without harm the mean time was 06 hours and 35 minutes, with no statistical significance between the groups (p=0.087).

In 71.8% (N=102) of the incidents the detection occurred during the review of the medical prescriptions or in the medication control in the inpatient unit; in 23.3% (N=33) of the cases the incident was detected due to recognition of error and in 4.9% (N=7) due to a clinical alteration of the patient. Nurses were responsible for 91.6% (N=130) of the notifications and in 85.2% (N=121) of the cases the nursing team was involved in the occurrence of the incident.

The time elapsed to start the investigation of the incident varied from immediately after detection up to 36 days later, and the mean duration of the investigation was 13 days. The investigations found that 93.7% (N=133) of the incidents were avoidable and the analysis was inconclusive in 6.3% (N=9) of the cases.

In the investigative process, 233 contributing factors were identified (Table 3). Most of them were related to personnel factors, with emphasis on behavior. In this aspect, inattention (44.2%, N=103), noncompliance (12%, N=28) – understood as not following the right techniques of preparation and administration – and forgetfulness (3.4%, N=8) were the behaviors most frequently reported.

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<sup>&</sup>lt;sup>2</sup> Problem not classified by the ICPS<sup>(5)</sup>

<sup>&</sup>lt;sup>2</sup> List of high-alert medications<sup>(7)</sup>

**Table 3** – Contributing factors for drug incidents – Curitiba, Paraná, Brazil, 2014.

<b>Contributing Factors</b>	N(%)
Staff	189 (81.1)
Cognitive	13 (6.0)
Behavior	139 (59.7)
Communication	26 (15.5)
Organizational	31 (13.3)
Organizational decisions/culture	20 (8.6)
Organization of teams	9 (3.9)
Resources/workload	2 (0.9)
Environment/Work	7 (3.0)
Infrastructure/physical environment	5 (2.1)
Remote/Long distance from service	2 (0.9)
Patient	3 (1.3)
Forgetfulness	1 (0.4)
Pain	1 (0.4)
Severity	1 (0.4)
External	3 (1.3)
Products, Technology and infrastructure	3 (1.3)

There was no record of mitigating factors in 43 (30.3%) incidents, and in 19 (13.4%) no actions were taken. In the other 80 incidents, 92 mitigating factors were recorded, among which were error correction (60.9%, N=56) and factors directed to the personnel (29.4%, N=27), to the patient (5.4%, N=5) and to the organization (4.4%, N=4).

The actions taken to reduce the risk of recurrence of incidents were directed to the staff on 87.4% (N=125) of the 142 preventive actions, and were related to the orientation of the team. The other actions were aimed at the overall improvement of the safety culture. In 83.8% (N=119) of the incidents without harm, no improvement actions were taken. In four (2.8%) of the 23 incidents with harm, actions related to the patient and to the team were taken, and in the others (N=19, 13.4%) no action was recorded.

Due to the lack of specific categories in the form, the information related to the following variables were not recorded: primary reason for seeking care, impact of the harm caused by the incident, person reporting, the time of the notification and the phase of care in which the incident occurred.

# **DISCUSSION**

The medication administration process is the last barrier against medication incidents. However, weaknesses in the interception of errors can be found, for example, in prescribing and dispensing errors<sup>(8)</sup>. The actions in the critical stages of the hospital medication system, in a non-bureaucratic context of direct care, associated with the difficulty in intercepting problems in processes prior to the administration of medication can increase the number of incidents attributed to the nursing team. However, this study found omission as the main problem associated with the administration process, which represents non-delivered nursing care.

The omission of medication was present in 34.6% of hospitalizations in a cross-sectional Brazilian study that assessed 735 admissions<sup>(9)</sup>. This is one of the problems with

the highest impact on the clinical condition of patients<sup>(10)</sup>. A systematic review of national studies showed that 14.5% of the patients suffered harm due to omission<sup>(11)</sup>. However, it should be noted that medication incidents may not generate immediate measurable damage, which may generate underestimated data.

In this study, more than half of the 23 incidents that caused harm involved the use of high-alert medications, and 78.3% of them involved intravenous administration, a noteworthy fact considering this route poses higher risk of causing serious consequences to the patient<sup>(12)</sup>. The administration of intravenous medications has a 3% greater likelihood of causing harm for each drug administered, according to a study conducted with critically ill patients<sup>(3)</sup>.

Another study did not find a significant association between the risk of medication incidents and the work shifts<sup>(10)</sup>. However, in this study, most of the incidents corresponded to the administration of the drugs with 8 hour intervals (8 a.m., 4 p.m. and 12 midnight). The administration of medication at specific hours – rarely uneven ones – is an alternative found by nurses to organize the work process to comply with the work load and with the time-consuming medication system<sup>(13)</sup>. However, this can increase the occurrence of errors. Studies found that organizational factors exert considerable influence on the occurrence of incidents, especially regarding workload and working conditions<sup>(14-16)</sup> and safety culture<sup>(17-18)</sup>. The involvement of nursing teams is emphasized, since nursing professionals are responsible for the process of administering medications along with other demands of care<sup>(19)</sup>.

Preparing and administering medication requires a high level of reasoning, concentration and memory; interruptions during these processes may lead to errors and to the omission of important steps<sup>(20)</sup>. In addition to providing staff, structural changes to minimize distractions can contribute to the reduction of incidents<sup>(20-21)</sup>, especially in critical care units, where agility in problem-solving is reflected in the clinical outcome. Therefore, awareness programs based on human factors associated with error can increase sensitivity in the medication process and reduce medication errors<sup>(22)</sup>.

In agreement with the results presented, a systematic review identified personnel factors as major contributors to incidents. However, the authors consider that the research framework gave more attention to human factors than to system factors<sup>(23)</sup>. The contributing factors recorded in this study indicate that the problems are addressed individually. This is evidenced by the actions taken to reduce risk of reoccurrence, which are mainly directed toward personnel. The results also demonstrate the weakness of the investigative method, mostly related to delays in the beginning of the investigations, with potential clinical worsening and harm to the patient.

The document sources used in this research provide a general context of the incident and are limited to the day of its occurrence, informing the immediate and local consequences. This way, the most evident organizational consequence is the increase of resources required to care for the patient, mainly related to correcting the error and/or the symptoms resulting from it. This corroborates the mitigating factors applied.

The agility in the mitigating factors is decisive for the outcome of the incident, since they are designed to minimize the harm to the patient after the error has occurred<sup>(5)</sup>. Thus, the lack of mitigating factors in more than one third of the cases may be partially related to the delay in the detection of the incident: in this study, detection occurred approximately 8 hours after the error. This result, although unsatisfactory, is an improvement from the results found in a study carried out in a similar scenario using ICPS, in which in 99% of the cases there was no record of actions adopted in relation to the incidents<sup>(24)</sup>.

It should be noted that, even though this had no statistical significance, harm was associated with longer time elapsed between occurrence and detection of the incident. Therefore, even though the review of prescriptions and control of medications were efficient actions, it is necessary to promote or develop methods of detection that anticipate the onset of symptoms, since they already constitute harm to the patient.

Once harm has occurred, ameliorating actions can be taken. These are defined as actions aimed to make better or compensate any harm after an incident<sup>(5)</sup>. The small number of ameliorating actions registered in the documentary sources of this research was possibly related to the degree and amount of reported harms. Partial lack of information, lack of clarity, difficult readability, misunderstandings in the document sources, as well as possible underreporting of incidents were considered limiting factors inherent in documental research.

The use of the ICPS<sup>(5)</sup> represents a difference between the analytical studies addressing the occurrence of medication incidents and results in a situational diagnosis that contributes to the analysis, planning and implementation of preventive measures and to the alteration of the content that should be recorded in the instruments used. The use of the ICSP<sup>(5)</sup> also allows a future comparison between studies and institutions, since it uses standardized terminology and the methodology recommended by the World Health Organization in this topic.

# **CONCLUSION**

The incidents were mostly related to the drug administration process and omission was the main problem identified. Important opportunities for detecting incidents were emphasized, such as the review of medical prescriptions and the control of medications, actions carried out by the nursing team. The nursing team was highlighted not only on the detection of incidents, but also on their occurrence and notification.

Parenteral medications were involved in more than half of the incidents; about one third of the cases were associated with high-alert medications. The resulting harm was proportional to the time elapsed for the detection of the incident, and alterations in the clinical status of the patient were the most frequent indicator of harm. Behavior factors contributed to the incidents, the correction of errors of the work process was mitigating, and orientation constituted a preventive action.

The predominance of contributing factors attributed to personnel, with emphasis on inattention, indicates the need to take preventive actions beyond the orientation of the teams, focusing on providing a workforce compatible with the demands, a physical structure and technologies that minimize distractions, and an environment and work processes that are conducive to safety in the use of medications, which can reduce human failures.

Conclusively, most of the incidents analyzed were potentially harmful and, given the contributing factors involved, avoidable.

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#### **RESUMO**

Objetivo: Caracterizar incidentes com medicamentos ocorridos em unidade de urgência e emergência. Método: Pesquisa descritiva, documental, retrospectiva e quantitativa. A Classificação Internacional para a Segurança do Paciente constituiu referencial teórico para construção do instrumento de coleta e análise do conteúdo de 119 fichas de notificação e investigação de incidentes ocorridos em 2014 em hospital de ensino. Os dados foram coletados duas vezes, comparados, corrigidos e transcritos para planilha Excel. Utilizou-se do Programa SPSS 19.0 e do teste não paramétrico de Mann-Whitney para análise; valores de p<0,05 indicaram significância estatística. Resultados: Foram analisados 142 incidentes, a maioria envolvendo a equipe de enfermagem; 93,7% evitáveis; um terço com medicamentos potencialmente perigosos; a maior parte de uso parenteral. Os danos, embora raros, foram proporcionais ao tempo de detecção do erro. Prevaleceram falhas de administração, principalmente a omissão. Conclusão: A maioria dos incidentes analisados caracterizou-se como potencialmente danoso e evitável, com destaque aos fatores de pessoal como contribuintes.

#### **DESCRITORES**

Segurança do Paciente; Erros de Medicação; Gestão de Riscos; Avaliação em Enfermagem.

#### **RESUMEN**

Objetivo: Caracterizar incidentes con fármacos ocurridos en unidad de urgencia y emergencia. Método: Investigación descriptiva, documental, retrospectiva y cuantitativa. La Clasificación Internacional para a Seguridad del Paciente constituyó marco de referencia teórico para la construcción del instrumento de recolección y análisis del contenido de 119 fichas de notificación e investigación de incidentes ocurridos en 2014 en hospital de enseñanza. Los datos fueron recogidos dos veces, comparados, corregidos y transcritos en la planilla Excel. Se utilizó el Programa SPSS 19.0 y la prueba no paramétrica de Mann-Whitney para análisis; valores de p<0,05 señalaron significación estadística. Resultados: Fueron analizados 142 incidentes, la mayoría involucrando al equipo de enfermería; el 93,7% evitables; un tercio con fármacos potencialmente peligrosos; la mayor parte de uso parenteral. Los daños, aunque raros, fueron proporcionales al tiempo de detección del error. Prevalecieron fallos de administración, especialmente la omisión. Conclusión: La mayoría de los incidentes analizados se caracterizó como potencialmente dañoso y evitable, con énfasis en los factores de personal como contribuyentes.

#### **DESCRIPTORES**

Seguridad del Paciente; Errores de Medicación; Gestión de Riesgos; Evaluación en Enfermería.

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