Original Article



Spontaneous reporting of medication errors in pediatric university hospital*

Notificação espontânea de erros de medicação em hospital universitário pediátrico

Notificación espontánea de errores de medicación en un hospital universitario pediátrico

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ABSTRACT

Objective: To analyze medication errors notified at a pediatric teaching hospital in São Paulo city. **Methods:** Retrospective and descriptive study in which 120 error events and 115 spontaneous notifications were analyzed, between January 2007 and December 2008. **Results:** The error rate was 1.15 per 1000 patients-day; 27.5% of notifications referred to the school age range and the Pediatric ICU was the sector with most notifications. The error type related to wrong infusion speed predominated (25%). The human factor dimension in the performance deficit category (54%) was the most frequent cause of error events. **Conclusion:** The safety culture is a continuous process in institutions and the notification of adverse events is part of the strategies. Improvement measures should be incorporated based on their analysis, whether related to the review of the work process or to team training **Keywords:** Medication errors; Pediatrics; Nursing; Notice

RESUMO

Objetivo: Analisar os erros de medicação notificados em um hospital universitário pediátrico no Município de São Paulo. **Métodos**: Estudo descritivo retrospectivo no qual foram analisadas 120 ocorrências de erros de medicação registradas em 115 notificações espontâneas, entre janeiro de 2007 e dezembro de 2008. **Resultados**: O índice de erros foi o de 1,15 por 1.000 pacientes-dia; 27,5% das notificações envolveram pacientes na faixa etária escolar. A Unidade de Terapia Intensiva Pediátrica (UTIP) foi o setor com o maior número de notificações. Predominou o tipo de erro relacionado à velocidade de infusão errada (25%). A dimensão fator humano na categoria desempenho deficiente (54%) foi a causa mais frequente para ocorrência do erro. **Conclusão**: O índice de erros de medicação foi de 1,15 por 1.000 pacientes-dia, com predomínio na faixa etária escolar (27,5%) e na UTI Pediátrica (35%). Diante desses resultados, medidas de melhoria devem ser incorporadas na instituição selecionada, sejam elas relacionadas à revisão do processo de trabalho ou à capacitação da equipe. **Descritores:** Erros de medicação; Pediatria; Enfermagem; Notificação

RESUMEN

Objetivo: Analizar los errores de medicación notificados en un hospital universitario pediátrico en el Municipio de Sao Paulo. **Métodos:** Estudio descriptivo retrospectivo en el cual fueron analizadas 120 ocurrencias de errores de medicación registradas en 115 notificaciones espontáneas, entre enero del 2007 y diciembre del 2008. **Resultados:** El índice de errores fue de 1,15 por 1.000 pacientes-dia; el 27,5% de las notificaciones involucraron pacientes en el grupo etáreo escolar. La Unidad de Cuidados Intensivos Pediátrico (UCIP) fue el sector con el mayor número de notificaciones. Predominó el tipo de error relacionado a la velocidad de infusión errada (25%). La dimensión factor humano en la categoría desempeño deficiente (54%) fue la causa más frecuente para la ocurrencia del error. **Conclusión:** El índice de errores de medicación fue de 1,15 por 1.000 pacientes-dia, con predominio en el grupo etáreo escolar (27,5%) y en la UCI Pediátrica (35%). Frente a estos resultados, deben ser incorporadas medidas de mejora en la institución seleccionada, estén ellas relacionadas a la revisión del proceso de trabajo o a la capacitación del equipo.

Descriptores: Errores de medicación; Pediatría; Enfermería; Notificación

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INTRODUCTION

The search for quality care in hospital services has attracted increasing attention among health professionals, especially regarding patient safety. According to the World Health Organization, patient safety is defined as the "absence of preventable harm to a patient during the process of health care"⁽¹⁾.

In this context, medication administration is noteworthy because this frequent procedure involves different phases during the medication system, including medication standardization and purchase, prescription, transcription, distribution, preparation and administration. Error events in any of these phases can jeopardize patient safety and inflict harm on people's health, besides compromising the multiprofessional team and the institution.

Medication error research has attract researchers' attention around the world, including Brazil, showing how this health care process is fragile, exposing patients to countless risks and errors⁽²⁾. Medication errors (ME) can be defined as:

... any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use⁽³⁾.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP), an American non-governmental organization that aims for ME reporting, knowledge and prevention suggests the following classification of error types: dose omission, improper dose, wrong concentration, wrong medication, wrong dosage formulation, wrong technique, wrong administration route, wrong speed, wrong duration, wrong time, wrong patient, wrong monitoring and deteriorated medication administration⁽³⁾.

There are as of yet few studies on ME in children, which represents a huge area for research, as these are considered vulnerable patients, with a three times higher potential for adverse medication events than in adult patients⁽⁴⁻⁵⁾.

Child health care requires professionals familiar with adequate techniques for care delivery to this population. This includes medication therapy procedures, in view of specificities with regard to age, weight, body surface area, absorption capacity, biotransformation and medication excretion. The medication preparation and administration process should always be judicious, demanding particular attention from the multidisciplinary team⁽⁵⁾.

Numerous factors put children at risk of ME, including differences and alterations in pharmacokinetic parameters among patients of different ages and developmental stages; need to calculate individual doses, according to the patient's age, weight, body area and clinical condition; unavailability of appropriate formulations and concentrations for neonatal and pediatric patients, using extemporaneous doses; and unavailability of data about medication stability, compatibility and bioavailability⁽⁵⁾.

Despite concerns with these problems, knowing the ME and analyzing the factors that put patients' safety at risk is fundamental for the establishment of improvement measures at health institutions. To collaborate with this knowledge, this research aimed to analyze ME notified at a pediatric teaching hospital in São Paulo City.

METHODS

Retrospective and descriptive study with a quantitative approach, developed at a public, tertiary-care pediatric teaching hospital in São Paulo City, with 207 beds and an average 4,365 day-patients per month. Children of up to 17 years are attended, with exceptional patients above this age, who started treatment in the pediatric treatment and received authorization from management.

The institution offers outpatient care and a day-hospital; immediate care; hospitalization and diagnosis and treatment support⁽⁶⁾.

The Nursing Division comprises the division managers; sectorial nurse managers and the nursing team in each work shift, including nurses, nursing technicians and nursing auxiliaries, totaling 430 professionals.

One of the Division guidelines is to monitor nursing quality through indicators, encouraging the notification of adverse events. Therefore, a non-punitive culture for adverse event management is furthered. Since 2007, team members have reported event notifications to the sectorial manager, who completes a print form, distinguishing the event type and context, with further details in case of consequences for patients, and forwards it to the Nursing Division. Notifications are analyzed during meetings with the division and sectorial managers, aimed at planning improvement actions. Thus, the sample for this research comprised ME notified between January 2007 and December 2008.

Approval for the research project was obtained from the Institutional Review Board at the University of São Paulo Medical School *Hospital das Clínicas*, under No 0841/08.

Data were collected in March and April 2009 by reading the notification forms, which contain the patient's identification, date and time and event description. Then, this information was registered in an Excel[®] worksheet specifically prepared for the study.

Four study variables were listed:

Age range: newborns (NB) – children up to 28 days of age; infants I - from 29 days till 11 months and 29 days; infants II - 01 to 02 years, 11 months and 29 days; pre-school children - 03 to 05 years, 11 months and 29 days; school-age - 06 to 10 years, 11 months and 29 days;

pre-pubescent - 11 a 12 years, 11 months and 29 days; adolescent - 13 to 18 years, 11 months and 29 days; and adults, over 19 years⁽⁷⁾.

Sector: Emergency care, Outpatient clinic, Medical specialty clinic, Surgical clinic, Neonatal and Pediatric Intensive Care Unit (ICU), Renal replacement therapy unit, Onco-hematology unit and Nursery.

Error types: dose omission, improper dose, wrong concentration, wrong medication, wrong dosage formulation, wrong technique, wrong route, wrong infusion speed, wrong time, wrong patient; wrong monitoring; deteriorated medication administration and others⁽³⁾.

Event causes: were distributed in six dimensions communication (categories: verbal and written communication failure); name mix-up (categories: mixup of commercial or generic names, such as suffixes, prefixes and similar writing); packaging (categorized according to factors related to the product's primary package, rewrapping, print problems and packaging quality); human factor (categories: inferior knowledge, inferior performance, dosage and infusion calculation error, failure to use medication prescription technology, storage error, medication preparation error, transcription error, stress, fatigue and intimidating behavior); labels and designs (categorized according to similar format, color and size of capsules and tablets; bad functioning of infusion pump; difficulty to select infusion options on the infusion pump); and system-related factors (categories: lighting, noise, interruptions, dimensioning, inexperienced staff, policies and procedures)⁽³⁾.

As the sectorial managers can freely describe the events, the primary research classified the types and causes, using the NCC-MERP medication error taxonomy⁽³⁾, besides own experience to categorize related situations. Data were analyzed through descriptive statistics, with absolute and relative frequency distribution, and results were presented as tables.

RESULTS

In this study, 115 notifications were analyzed, totaling 120 ME events, 55 (45.8%) in 2007 and 65 (54.2%) in 2008, evidencing an 18.2% increase in the number of registers from one year to the other.

The error rate corresponded to 1.15 events per 1,000 day-patients. This rate is obtained by dividing the numerator (number of ME=120) by the denominator (total number of day-patients hospitalized in 2007-2008 = 104,777), multiplied by 1,000.

The ME results according to the children's age range are displayed in Table 1, revealing that, in 2007, notifications mainly involved pre-school children (32.7%) and, in 2008, school-age children (38.5%). It is also noteworthy that, during the study period, only one ME notification involved newborns.

Table 1 – Medication error events per patient age range
at a pediatric teaching hospital, São Paulo, 2007-2008.

1 ~ ~ # ~ ~ ~	2	2007	2	2008	Total		
Agerange	n°	%	n°	%	n°	%	
Newborn	-	-	1	1,5	1	0,8	
Infant I	8	14,5	11	16,9	19	15,8	
Infant II	8	14,5	6	9,2	14	11,7	
Pre-school	18	32,7	4	6,2	22	18,3	
School	8	14,5	25	38,5	33	27,5	
Pre-pub escen t	2	3,7	-	-	2	1,7	
Adolescent	8	14,5	14	21,6	22	18,3	
Adult	-	-	3	4,6	3	2,5	
Not informed	3	5,6	1	1,5	4	3,3	
Total	55	100,0	65	100,0	120	100,0	

The following were the main ME types (Table 2): wrong infusion speed (25.0%), dose omission (20.8%) and improper dose (11.7%), totaling the majority (57.5%) of notifications. The main error type in 2007 was dose omission (29.2%) and, in 2008, wrong infusion speed (27.7%). In addition, wrong technique and wrong drug errors showed an important increase from one year to the other, i.e. from 1.8% to 13.8% and 10.8%, respectively.

Table 2 – Medication error events per error type at a pediatric teaching hospital, São Paulo, 2007-2008.

Earoatera co	2007		2	0 08	Total		
Error types	n°	%	n°	%	n°	%	
Wrong infusion speed	12	21,8	18	27,7	30	25,0	
Dose omission	16	29,2	9	13,9	25	20,8	
Improper dose	7	12,8	7	10,8	14	11,7	
Wrong patient	7	12,8	3	4,6	10	8,3	
Wrong technique	1	1,8	9	13,8	10	8,3	
Wrong drug	1	1,8	7	10,8	8	6,7	
Wrong dosage for mulation	2	3,6	5	7,7	7	5,8	
Wrong time	2	3,6	3	4,6	5	4,3	
Wrong monitoring	2	3,6	1	1,5	3	2,5	
Deteriorated drug error	2	3,6	-	-	2	1,7	
Wrong concentration	1	1,8	-	-	1	0,8	
Wrong route administration	1	1,8	-	-	1	0,8	
Others	1	1,8	3	4,6	4	3,3	
Total	55	100,0	65	100,0	120	100,0	

The smallest number of notifications was found at the Pediatric ICU (35.0%), with a 111.9% frequency increase between 2007 and 2008. At the Neonatal ICU and Nursery, no notifications occurred in 2007. The same was true for the Medical Specialty Clinic, Renal Replacement Therapy unit and Outpatient Clinic in 2008 (Table 3).

For the sake of clarification, some transcriptions found on the forms are displayed in Figure 1. The range of situations influencing the success of medication treatment is observed, which is linked with the different phases in the same system, involving a significant number of people. Regarding nursing's responsibility in the medication administration process, a lack of mastery is observed in the use of dispensation equipment, accessories and devices, besides collaborators' lack of attention. In the medication process, which the medical team is in charge of, a lack of information readability is found. As for medication dispensation, i.e. linked with the pharmacy team, events can be observed that involve medication duplicity and similar labels. With regard to the patient monitoring phase, which all professionals are responsible for, situations of missing information and education for companions are verified.

Table 3 – Medication error events per sector at a pediatric teaching hospital, 2007-2008.

Units	2	2007	2	2008	Total		
Olifits	nº	%	nº	%	n°	%	
Pediatric ICU	12	21,8	30	46,2	42	35,0	
Surgical clinic	11	20,0	18	27,7	29	24,2	
Onco-hem atology	18	32,7	10	15,4	28	23,3	
Emergency care	6	10,9	2	3,1	8	6,7	
N eona tal ICU	-	-	4	6,2	4	3,3	
Medical specialty clinic	3	5,5	-	-	3	2,5	
R enal replacement therapy	3	5,5	-	-	3	2,5	
Outpatient clinic	2	3,6	-	-	2	1,7	
Nursery	-	-	1	1,5	1	0,8	
Total	55	100,0	65	100,0	120	100,0	

The causes of error events at the institution were studied, considering 100 notification forms (100.0%), resulting in four dimensions and nine categories (Table 4). The causes related to the human factor dimension (80.0%) prevailed over the causes corresponding to the communication (17%), packaging (2.0%) and label and design (1.0%) dimensions. Also, the category insufficient team performance corresponds to more than half of the causes (54.0%). When analyzing absolute figures (27) for this causal factor, however, showed no change during the two-year period. In frequency terms, related to the total number of causes for each year, a decrease from 64.3% to 46.6% was observed. According to primary data, no causes were identified in the name mix-up and system-related factor dimensions.

DISCUSSION

Scientific literature presents countless ME detection strategies, including direct observation of medication administration, medical prescription reviews, analysis of

Table 4 – Distribution of medication error events according to causes at a pediatric teaching hospital, São Paulo, 2007-2008.

Causes		2007 =42)	20 08 (n=58)		Total (n=100)	
Dimension/Categories	n°	%	n°	%	nº	%
Human factor						
Performanæ deficit	27	64,3	27	46,6	54	54,0
Drug preparation error	3	7,1	9	15,5	12	12,0
Knowledge deficit	3	7,1	4	6,9	7	7,0
Miscalculation of dosage or infusion rate	-	-	6	10,3	6	6,0
Stress	-	-	1	1,7	1	1,0
Communication						
Verbal miscommunication	5	11,9	7	12,1	12	12,0
Written miscommunication	4	9,5	1	1,7	5	5,0
Packaging						
Inappropriate packaging or design (similar presentation)	-	-	2	3,4	2	2,0
Labds and design						
Malfunction of infusion pump (devices)	-	-	1	1,7	1	1,0
Total	42	100,0	58	100,0	1 00	100,0

Error type	Situations				
Wrong in fusion speed	"The infusion pump was programmed for 5ml/hour, while the prescription said 0.5 ml/hour"; "The program was set to infuse 42.5 ml/hour, and the prescription said 42.5 ml/hour".				
Dose omission "She left the drug with the companion who did not administer it"; "She did not see that it was prescribed at 22 hours"; "Time dhe the drug was available in the drawer".					
Improper dose	"The member of family had already administered the drug"; "Medication dispensed twice".				
Wrong patient	"Lack of attention when identifying the patient"; "Medication refused by the patient, alleging that it was not for him".				
Wrong technique	"Equipment inverted in the infusion pump"; "Use of another patient's buretle, whose support was nearby".				
Wrong drug	"Added calcium gluconate to the saline solution while the prescription said calcium chloride"; "Phenobarbital was dispensed instead of Furos emide because the labels are similar".				
Wrong dosage formulation	"No distilled water was added to the saline solution"; "6.5ml of glucose was added, while 65 ml had been prescribed".				
Wrong time	"Administered two hours in advance"; "Administered on the wrong day after preparation and dispensation by the pharmacy".				
Wrong monitoring	"Did not check the blood pressure before administering the anti-hypertensive drug".				
Deteriorated drug error	"Failure to check the validity of the vaccine".				
Wrong concentration	"Prescription with erasure, hard to read".				
Wrong route administration	"Filgrastim administered through the intravenous instead of subcutaneous route".				
Others	"Precipitation".				

Figure 1 – Situation records in medication error notifications, classified per error type at a pediatric teaching hospital, São Paulo, 2007-2008.

doses returning to the pharmacy, interviews with professionals, observation of shift handover, verification of patient complaints, also including spontaneous notification of events⁽⁸⁾. All entail advantages and disadvantages regarding spontaneous notification, with research demonstrating that event notifications are less numerous than actual events⁽²⁾. These same studies, however, do not dissuade from this detection form, but recommend that leaderships demonstrate the importance of notification and even suggest combined forms with a view to ME detection^(2,8). It is urgent, however, for institutions not to use the information deriving from these strategies to take disciplinary measures, but apply educative measures to improve the system^(2,4,8). This fact was verified in this study, through concerns with involving the team in event notification, discussing their causes during formal meetings, aimed at the establishment of preventive actions. This conduct suggests that the nursing team received feedback to its efforts to notify ME-related problems, enhancing their adherence to the method the Nursing division implanted, as the year-to-year increase in the number of reports demonstrates.

ME in pediatric patients constitute a relevant problem in health systems all over the world. According to the detection strategy used, more or less events can be found, representing a monitoring and management indicator. In the present research, the error rate corresponds to 1.15 events per 1,000 day-patients, considerably higher than the 0.51 errors per 1,000 day-patients at a British pediatric hospital, in a study accomplished in the year 2000 through the same method⁽⁹⁾.

The most incident age ranges for ME were preschool in one year and school age in the other. A search for parallels in literature reveals a wide range of age groups involved, sometimes exhibiting predominant errors in pre-school children and infants⁽¹⁰⁾ or in small children and neonates⁽⁹⁾. It can be affirmed that there is no age group predisposing to these errors, but that they can affect any age for all kinds of patients.

A small percentage of errors were notified for the neonatal population though, as opposed to studies indicating that, for every six to eight Neonatal ICU hospitalizations, one is accompanied by medication errors. The complexity of procedures involving premature and very low-weight patients can facilitate error events. The team may not notice them, as some effects can mimic a typical infection, characterized by apnea, peripheral perfusion disorder, electrolyte and acid-base alterations⁽¹¹⁾. It is also supposed that the lack of error notification identifies some teams' nonadherence to the strategy the Nursing division set up.

Regarding error types, the highest incidence in this research was for wrong infusion speed. A study demonstrates that this error type is closely related with infusion pump programming, in function of mistaken adjustments, indicating the need for professional training⁽¹¹⁾. Medication administration omission, classified as the second most frequent error type, is not that uncommon in literature^(2,10-12), suggesting the need for change proposals in the medication distribution, preparation and administration phases, with a view to enhancing the optimization of professionals' work process. Other error types are found with different frequencies, with a significant increase for wrong technique and wrong drug in this context. It cannot be affirmed that some error type is better or worse than another, that it entails greater or lesser consequences, as it depends on what drug is administered, patient conditions, the person's health history, among other factors. Professionals' attention to medication therapy is acknowledged as a fundamental element, knowing what consequences can affect patients in this care aspect⁽⁴⁻⁵⁾.

ICUs deliver care to severe and risk patients. Countless professionals work there, diverse and different technologies are used, involving a huge number of drugs with uncountable particularities. Therefore, ME studies are performed and their results are analyzed to propose preventive solutions^(2,11). In this research, the Pediatric ICU sector displays the highest ME notification rate, also revealing professionals' involvement in event communication through the year-to-year numerical increase. Based on this fact, it cannot be concluded that the Pediatric ICU is the place where most ME occur, but that the team most notifies these errors. Similarly, it cannot be affirmed that fewer ME occur at units with lower notification rates. Studies recommend the adoption of other detection forms, with a view to knowing the problems' dimension, permitting health care system quality assessment^(8,11).

There are many studies about ME causes, which present situations related to local structural and work process conditions^(2,9,11). Each research site has its own characteristics and, in the present study, the human factor dimension stood out, with performance deficit as the category with the highest rates. Performance deficit is considered as the form or conditions in which medication therapy-related activities are performed, and not necessarily as the condition inherent in their accomplishment, although this category is present; it was not considered very frequent though. Many aspects interfere in professional performance and there is evidence that the professionals' workload and the daily occupation rate are relevant factors in error genesis⁽¹¹⁻¹²⁾. It is known that a heavy workload, in combination with fatigue and sleep privation, can reduce professionals' ability to pay attention, enhancing the possibility of error events. Experience demonstrates that nursing professionals frequently have double work journeys, making them vulnerable to the accomplishment of unsafe procedures. In this study, errors at different units could not be related with the occupation rate and nursing

staff dimensioning, in order to assess the impact of these variables on ME incidence rates.

The findings from the reports described in the ME notifications were classified to permit a didactical presentation. This presentation, however, demands accurate reading of the text and the use of established taxonomies, which permits the establishment of a historical series of indicators and information exchange within or beyond institutions. According to research, however, when only one person performs this activity, this may suggest some interpretation subjectivity, as events define that an error type can also be classified under another type. To minimize this situation, authors propose using more refined methods to reach consensus, like the Delphi Technique or double classification, involving experts on this issue⁽³⁻⁴⁾.

Solving ME-related problems is not simple, but analyzing the causes permits recognizing each institution's weaknesses and take suitable actions for their prevention, whether by reviewing the work processes, training professionals, incorporating technological resources, creating protocols, using barriers, creating a range of stratagems to enhance patient security aspects⁽¹²⁾.

This study comes with some limitations, which should be taken into account when interpreting the results. The number of spontaneous notifications permitting the

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analysis of these errors based on the notifications themselves, even knowing that the subjects ignored some errors or did not report them on purpose. It is known, however, that leaderships should value this important tool and use it to review processes and set up health system improvement strategies.

CONCLUSION

This research permitted the following conclusions: the ME rate amounted to 1.15 per 1,000 day-patients; the prevalent age range was school age and the Pediatric ICU was the sector with the highest number of ME notifications.

The most frequent ME types were: wrong infusion speed, dose omission and improper dose, totaling more than half of all events. As for the error causes, the human factor dimension stood out in the performance deficit category.

It is known that spontaneous notification can be biased with regard to the total number of errors. Nevertheless, analysis data provide important information for institutions to improve their systems.

As this study was developed at an exclusively pediatric hospital, its importance as a reference for other research in the area is inferred.

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