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Medication errors in pediatrics: Evaluation of spontaneous reports in a pediatric hospital in Porto Alegre, RS, Brazil

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Abstract

This study aimed to quantify medication errors spontaneously reported by professionals working in a pediatric hospital. This was a quantitative and retrospective study carried out in a philanthropic, teaching pediatric hospital, with a total of 184 beds, of which 144 are inpatient beds and 40 are ICU beds. Adverse event data recorded on a form available on the institutional intranet from January 1, 2015 to December 31, 2018 were collected. 471 events related to medication errors were recorded. The incorrect dose with the highest number of notifications in the years 2016, 2017 and 2018 (22.4%, 26.2% and 24% consecutively) stood out. In 2015 the largest number of notified events was related to the omission of dose or medication (20.8%). Dose errors were grouped into three distinct subclasses: overdose, underdose and extra dose. Doses higher than recommended are highlighted in all evaluated years, with rates above 70% of notifications. Highly supervised drugs, antimicrobials, controlled drugs and chemotherapy were the most frequently reported. The quantification of medication errors reported in pediatrics was essential to know their profile and focus on actions to improve processes. Educational actions motivating the registration of notifications by all professionals are essential to strengthen the culture of patient safety.

Keywords: Medication Errors, Patient Safety, Pediatrics.

INTRODUCTION

Drug-related Adverse Events (DAE) represent one of the largest public health problems. They are responsible for high rates of morbidity and mortality and increased costs for health institutions, as they can extend the length of hospital stay by about 2.9 days[1,2,3]. It is very common for DAEs to result from a Medication Error, which can occur without injuries or result in damage to the patient[4].

Medication error is defined as any preventable event that can, in fact or potentially, lead to inappropriate medication use1,5. Medication errors are multifactorial and can be related to professional practice, medications used, procedures performed, dose preparation and distribution by the pharmacy[5]. The different stages of the medication process are also subject to error and thus, they can be divided into different classes such as errors in storage, prescription, dispensing, identification,

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preparation, administration and monitoring of the patient's response[4,6].

Medication errors are used as indicators of patient safety in hospital institutions, as they occur more frequently in these places, and the occurrence rate is three times greater for the pediatric population[7,8]. Studies show several causes for the incidence of errors, such as overworking, lack of nursing experience, little pharmacological knowledge and difficulties in performing the calculations necessary to prepare the dose to be administered. Nursing teams spend 40% of their time preparing medications[9], so reports of difficulties as well as the reporting of errors by these professionals are essential for the development and implementation of strategies to prevent errors[7,10]. Voluntary notification systems for medication errors can serve as a foundation for patient safety programs, which have recently been structured in Latin American countries[11].

The pediatric population ranges from neonates to adolescents and, as a result, there is great variability in the doses of prescribed drugs. As a consequence, countless calculations and fractionations are necessary to individualize doses according to the patient's age, weight or body surface area, a fact that results in a higher risk of adverse drug-related events. In addition, due to its physiological characteristics, the pediatric patient is more vulnerable to suffering damage from DAE[12,13].

The Hospital Care Safety Yearly Report in Brazil, carried out in 2017 by UFMG, collected data from 133 hospitals and demonstrated that patients with reports of adverse events had a hospital stay 3.1 times longer than the expected average hospitalization, which leads to extra costs for hospitals[14]. The most frequent victims were in the extremes of age and there was a higher incidence in patients younger than 28 days of life[14]. Therefore, it is recommended that these patients be prioritized in safety programs while under the hospital's care. In 2016, mortality for patients who experienced adverse events was approximately 10 times higher than those who did not experience any events. Among the populations most frequently affected, newborns were in second place, representing 5.2% of patients[14]. In this context, the third global challenge of the World Health Organization can be mentioned, which aims to reduce serious and preventable damage by 50% associated with medicines, in all countries, within the 5 years after its launch[15].

The aim of this study was to quantify medication errors spontaneously reported by professionals working in a pediatric hospital, between 2015 and 2018, and to verify the barriers created in the processes that seek to reduce the recurrence of errors.

METHODS

This quantitative and retrospective research was carried out in a pediatric, philanthropic and teaching hospital, located in the city of Porto Alegre. With a total of 184 beds, 144 of which are inpatient beds, 40 ICU beds, a chemotherapy outpatient clinic and a surgical block consisting of 6 operating rooms and one for endoscopic procedures. The hospital is a point of reference for the treatment of congenital diseases of high complexity and provides assistance to patients aged 0 to 18 years.

Notifications of adverse events are spontaneous and can be registered by any health professional, in a standardized form that is available on the institutional intranet, where the identification of the user is not mandatory. All events that occurred, including those that did not cause harm to the patient, related to any stage of the medication process, such

as prescription, dispensing, identification, preparation, administration or monitoring of the response, must be reported. The pharmacovigilance service is composed of a multidisciplinary team formed by doctors, nurses, pharmacists, physiotherapists and other professionals, notifications are received and sent for evaluation according to the areas involved. All notifications involving medication errors and adverse drug reactions (ADRs) are passed on to pharmacists. There is a separate registration form for medication errors and ADRs, which were not included in this study. The registered notifications are evaluated by the multidisciplinary team, which subsequently prepares action plans with the notified sectors, seeking to increase barriers and reduce the recurrence of errors.

Notifications data were collected from January 1, 2015 to December 31, 2018. Notifications were tabulated in an Excel® spreadsheet and subsequently evaluated and classified into 14 categories based on the National Coordinating Council for Medication Error[16]: incorrect dose; omission of dose or medication; wrong medication; infusion rate; administration schedule; preparation, handling or packaging error; route of administration; deteriorated medication; wrong patient; administration technique; monitoring; pharmaceutical form; non-adherence and others.

The variables collected were: date of prescription, reporting unit, medication involved and description of the event. For statistical analysis, the software Statistical Package for the Social Sciences (SPSS) v.25 was used and the results were presented in absolute numbers and percentages. The Chi-square test was used to compare the frequencies of the types of notifications over the study period.

This study was approved by the Research Ethics Committee (CEP), under Opinion number 2.563.270.

RESULTS

During the study period, 471 events related to medication errors were recorded (Table 1). The distribution of errors was not proportional over the years evaluated ($p<0.001$). The incorrect dose with the greatest number of notifications in the years 2016, 2017 and 2018 (22.4%, 26.2% and 24% consecutively) stood out. In 2015 the largest number of notified events was related to the omission of dose or medication (20.8%). It is observed that the second highest incidence reported in 2015 was the incorrect dose (15.1%), in 2016 the incorrect infusion rate (17.6%), in 2017 and 2018 the wrong medication (17.2% and 20.9%, respectively). In the category "others", notifications of occurrences were included, such as the following examples: patient pulled and disconnected the infusion device, problems with the equipment, verbal suspension of the medication by the prescriber.

Dose errors were grouped into three distinct subclasses, namely: overdose, underdose and extra dose. It is possible to verify that the dose higher than the recommended is highlighted in all the years evaluated, with rates above 70% of the notifications (Table 2).

The service sectors that performed the most notifications were the Inpatient Units (IUs) followed by the Intensive Care Units (ICU).

The number of notifications made by other sectors, such as the operating room, the emergency room and the chemotherapy clinic, is still low. It was identified that there was no record by the professionals in the

surgical unit in 2016. Similarly, in 2017 there was no record by the chemotherapy outpatient clinic (Table 3).

When evaluating the classes of drugs, we found that highly supervised drugs (HSD), antimicrobials, controlled drugs (Ordinance 344) and chemotherapy are the most involved, together representing more than 50% of the notifications (Table 4).

Table 1- Frequency of reported medication errors, according to class and year of notification. Porto Alegre, RS, 2019.

Error classification	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Incorrect dose	16 (15.1)	19 (22.4)	32 (26.2)	38 (24)	105 (22.3)
Missing dose or medication	22 (20.8)	07 (8.2)	17 (10.7)	17 (10.8)	59 (12.6)
Wrong medication	14 (13.2)	12 (14.1)	21 (17.2)	33 (20.9)	80 (17)
Infusion speed	9 (8.5)	15 (17.5)	10 (8.2)	17 (10.8)	51 (10.8)
Administration schedule	16 (15.1)	2 (2.4)	10 (8.2)	10 (6.3)	38 (8.1)
Preparation, handling or packaging error	4 (3.8)	2 (2.4)	7 (5.8)	11 (7.0)	24 (5.1)
Route of administration	3 (2.8)	5 (5.9)	3 (2.5)	7 (4.4)	18 (3.8)
Deteriorated medication	7 (6.6)	4 (4.7)	0 (0)	5 (3.2)	16 (3.4)
Wrong patient	1 (0.9)	8 (9.4)	2 (1.6)	0 (0)	8 (1.7)
Administration technique	0 (0)	3 (3.5)	4 (3.3)	1 (0.6)	8 (1.7)
Monitoring	4 (3.8)	0 (0)	2 (1.6)	0 (0)	2 (0.4)
Pharmaceutical form	0 (0)	2 (2.4)	0 (0)	0 (0)	2 (0.4)
Non-adherence	0 (0)	0 (0)	1 (0.8)	0 (0)	1 (0.2)
Others	10 (9.4)	6 (7.1)	17 (13.9)	19 (12.0)	52 (11.0)
Total	106 (100)	85 (100)	122 (100)	158 (100)	471 (100)

Table 2- Frequency of dose error subclasses, according to the year of notification. Porto Alegre, RS, 2019.

Incorrect dose	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Overdose	13 (81.2)	17 (89.5)	23 (71.8)	30 (78.9)	83 (79.0)
Underdose	2 (12.5)	0 (0)	7 (21.9)	3 (7.9)	12 (11.5)
Extra dose	1 (6.3)	2 (10.5)	2 (6.3)	5 (13.2)	10 (9.5)
Total	16 (100)	19 (100)	32 (100)	38 (100)	105 (100)

Table 3- Frequency of notifications registered by sector and year. Porto Alegre, RS, 2019.

Sector	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Inpatient units	32 (30.2)	49 (57.6)	72 (59)	82 (51.9)	235 (49.9)
Intensive care units	63 (59.4)	20 (23.5)	25 (20.5)	47 (29.8)	155 (32.8)
Emergency unit	8 (7.6)	14 (16.5)	20 (16.4)	19 (12.0)	61 (13.0)
Surgical Center	1 (0.9)	0 (0)	5 (4.1)	7 (4.4)	13 (2.8)
Outpatient chemotherapy	2 (1.9)	2 (2.4)	0 (0)	3 (1.9)	7 (1.5)
Total	106 (100)	85 (100)	122 (100)	158 (100)	471 (100)

Table 4- Occurrence of medication errors, by the class of drugs. Porto Alegre, RS, 2019.

Class of drugs	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Highly supervised drugs	21 (19.8)	21 (24.7)	17 (13.9)	28 (17.7)	87 (18.5)
Antimicrobials	27 (25.5)	7 (8.2)	26 (21.3)	25 (15.8)	85 (18.0)
Controlled drugs	17 (16.0)	15 (17.7)	12 (9.9)	25 (15.8)	69 (14.7)
Chemotherapy	2 (1.9)	9 (10.6)	16 (13.1)	9 (5.8)	36 (7.6)
Others	39 (36.8)	33 (38.8)	51 (41.8)	71 (44.9)	194 (41.2)
Total	106 (100)	85 (100)	122 (100)	158 (100)	471 (100)

DISCUSSION

One of the main limitations of voluntary notification is underreporting, which may be related to the professionals' fear of guilt, in addition to difficulties in accessing notification systems. Several strategies are used to detect the occurrence of DAEs in pediatric patients such as voluntary notification, analysis of administrative data, retrospective monitoring, the use of trackers and clinical pharmacy services, however none of them can detect all events that have occurred. Therefore, combining two or more techniques to measure the failures is reccommended[1,9,17]. The existence of underreporting is a factor that can have an impact on the results of this study, but it does not prevent the development of strategies and barriers to minimize errors and improve procedures.

The high incidence of dose error may be related to the off-label use of medications and the need to extrapolate adult doses to calculate the pediatric dose. Many drugs do not have adequate formulations for this population, which results in the need for manipulation of the pharmaceutical forms and, consequently, in countless calculations for the preparation of the correct dose[9,18]. This high number is similar to the study carried out through a questionnaire answered by nurses working in pediatrics, in 5 hospitals in Iran, which verified the incorrect dosage as the most common error, representing 36.64% of the evidenced errors[10]. Eshetie and collaborators[20] also found dose errors to be the most common. Another study evaluated clinical pharmacy services as a strategy for increasing drug safety in pediatrics and found that 17% of pharmaceutical interventions were related to inadequate doses, resulting in the second largest reason for pharmaceutical interventions. In Minnesota, Tripathi *et al.*[21] evaluated pharmaceutical interventions over 11 years, and also found a greater number of errors related to inadequate dosing. This study shows that multidisciplinary involvement in pharmacotherapeutic monitoring increases safety and reduces costs in pediatric care. Our study identified that 79.0% of notifications of incorrect doses were of doses above those recommended. In order to reduce these failures, the maximum doses of the highest-risk medications were registered in the electronic prescription system and alerts were sent to the doctor informing them about the therapeutic limits of the medication at the time of prescription.

The low number of reports by the chemotherapy, emergency and surgical units must be addressed, motivating the notification of errors by the teams. A similar study evaluated adverse events related to drugs in a pediatric hospital in four sectors and also identified higher rates of errors in inpatient units followed by the ICU[19]. Yamamoto and collaborators[22] found higher rates of notifications for the ICU (21.8%), surgical clinic (20%) and onco-hematology (32.7%). Seeking to increase the number of notifications by the areas, educational actions were carried out, such as training the nursing teams on where, how and what should be reported. It is important, for the motivation of the professionals, to reinforce that the notification is anonymous

and will help in creating barriers so that errors do not recur or are minimized.

Ensuring safety in the use of medications is essential, especially for highly supervised medications, which are at greater risk of causing serious harm to the patient when used improperly[17,23]. Alternatives to increase safety in the use of HSDs, such as the implementation of protocols for standardization of doses, dilutions in an electronic prescription system and training of teams on the importance of care and the risks involved, were cited as essential in a study on errors related to HSD in a neonatal intensive care unit[8]. The high percentage of errors involving these drugs, found in our study (18.5%), requires actions to reverse this indicator. In order to increase safety in the use of HSDs, the list of medicines was revised after the data was evaluated. In addition, a differentiated identification was created on its packaging, using a pink color, and the dispensing was now in packaging separate from the other medication, with a visible identification on the packaging. Training was also carried out by pharmaceutical professionals in the care units, informing about the new list, guiding the importance of attention in its use and reinforcing the risks related to HSDs and the severity of the damage caused by these drugs.

The number of drugs available for appropriate use in pediatrics is limited, which leads nurses to perform a large number of manipulations and calculations to obtain the correct dose, a fact that significantly increases the potential for errors[24]. Medication errors, as well as other adverse events, are often linked to system failures and not only to health professionals' lapses and weaknesses. Studies on the perception of professionals in relation to medication errors report factors that are relevant to the management of the service and patient care, such as the lack of staff, work overload and relationship difficulties among the multidisciplinary teams[25,26]. As an alternative, a systematic review study pointed out specific interventions that can reduce errors such as administration of medication assisted by bar code to reduce misidentifications (patient, medication, dose) as well as continuing education aimed at improving knowledge about medication administration[3]. Other strategies for preventing errors such as providing standardized and updated consultation materials, standardized electronic prescriptions, electronic dispensaries, use of smart infusion pumps and pharmaceutical monitoring are also important[7].

It is important to develop strategies so that notifications are not linked to punishment but to learning instruments, in addition to intensifying the education of professionals to motivate spontaneous notifications[27].

CONCLUSION

The quantification of medication errors reported in pediatrics was essential to know their profile and focus on actions to improve procedures. Dose errors were more frequent, showing the need for more appropriate pharmaceutical formulations for pediatrics. The results made it possible to create barriers in the electronic prescription system, such as alerts for doses above those recommended, as well as adaptation in the process of dispensing highly supervised drugs. In order to strengthen the culture of patient safety in institutions, it is important to carry out educational actions in order to motivate the registration of notifications by all health professionals.

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