# Voluntary and anonymous reporting of medication errors in patients admitted to the Department of Pediatrics

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"Any man can make mistakes, but only an foolish persists in his error". Cicero (106 BC - 43 BC)

#### ABSTRACT

Objective. To assess reports of medication errors in hospitalized children to establish their frequency, causes, and adverse events(AEs). Methods. Prospective study of medication errors reported at the Neonatal Intensive Care Unit (NICU), Pediatric Clinic (PC), and Pediatric intensive Care Unit (PICU). Ambulatory Pediatrics reports and incomplete data were excluded. Related variables were evaluated. Results. Out of 989 errors reported in Department of Pediatrics, 401 (41 %) corresponded to medication errors. Of these, 353 (88 %) reached patients and 48 (12 %) were quasi-errors; 42 % occurred in the morning; 24 %, in the afternoon; 17 %, in the morning and afternoon, and 17 %, in the night; differences were not significant (p=0.18). Dosing errors were the most common ones, 118 (33.4 %). In total, 160 reports (45%) corresponded to prescription errors; 149 (42 %), to administration errors; and 44 (2.5 %), to dispensing errors. Dosing errors were more common in prescriptions (p < 0.05). The highest number of errors was reported at the NICU, 179 (50 %); compared to 91 (25.5 %) at the PC and 83 (24.5 %) at the PICU. A total of 91 AEs were reported (22.5 %); most were mild, 53 (58 %), or moderate, 31 (34 %). The NICU reported 53 AEs (58 %); the PICU, 25 (27 %); and the DCP, 18 (19.7 %). No deaths occurred. Conclusion. The rate of medication errors reported in hospitalized children was 41 %. Dosing errors were the most common ones. A total of 91 AEs were reported; most were mild (58 %); the highest number was reported at the NICU (58 %).

*Key words:* pediatrics, medication errors, self-reporting, hospitalization, adverse events.

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### **INTRODUCTION**

Errors are common and happen on a daily basis in every activity carried out by human beings. In medicine, they are caused, in particular, by two factors. The most common factor refers to deficiencies in the hospital system that take place in most actions related to errors in patient care. Higher risk systems at the hospital include patient handoff, change of nurse shifts, communication among the members of hospital teams, communication with the patient at the time of discharge, operating room checklists before a surgery, patient identification, pharmacy drug supply, among others.

The second factor is related to errors made by people, and these are mainly due to lack of attention, stress, burnout syndrome, rules or regulations, and knowledge deficits.<sup>1</sup> Even when errors are part of the human condition, there is no justification for them to occur in health care as a result of individuals.<sup>2</sup>

In the past 25 years or so, multiple measures were taken to achieve adequate patient safety, but an alarming quantity of medical errors is still prevalent. In the United States of America (USA), more than 200 000 patients die every year due to errors, although recent data indicate that the annual mortality rate has jumped to more than 300 000 patients.<sup>3,4</sup>

To reduce errors, it is necessary to change the traditional medical error culture, which encourages hiding

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Received: 1-3-2019 Accepted: 7-5-2019 the error and punishing those responsible for it. Unfortunately, such culture still predominates in most health care facilities,<sup>5</sup> at least in our country, and it is worth noting that communication among the members of a department is inadequate. An effective communication is one of the most relevant measures that can be taken to reduce errors and adverse events (AEs).

Medication errors are the most common type in hospitalized children,<sup>6-9</sup> in particular in the Neonatal Intensive Care Unit (NICU).<sup>10,11</sup> The rate of AEs in newborn infants and children is three times higher than in adults.<sup>8</sup> Errors and AEs are usually the result of failures in the medication process and of health care providers' neglect, usually due to attention deficits.<sup>12-15</sup> The analysis of error causes and the strategies aimed at preventing them help to reinforce the culture of safety in hospital care.<sup>16</sup> The medication process is made up of four stages: prescription, carried out by physicians; administration, carried out by nurses; and transcription and supply, both in charge of pharmacists.

Voluntary error reports are implemented among the health care providers of medical facilities and usually include information about where the error occurred, the type of error and, less commonly, resulting AEs. The main benefit of these reports is to help establishing a change in error culture so as to prevent punitive actions and encourage learning from errors so that they do not happen again.<sup>17,18</sup>

However, reported information is usually incomplete and non-systematic because errors tend to be hidden. Unfortunately, some facilities commonly report mild and moderate events only, not severe ones.<sup>19</sup> Therefore, error reporting systems are not very helpful to determine the extent of safety in hospital care. Notwithstanding this, the increase in error reporting at a health care facility is a good indication that the culture may be improving and, therefore, of a better patient safety because such communication means that health care providers are not so afraid of reporting errors and, this way, punishment will also reduce progressively.<sup>19-25</sup>

The objective of this study was to assess the reports of medication errors in hospitalized children to establish their frequency, causes, and AEs with potential consequences on patients.

#### POPULATION AND METHODS

This was an observational, prospective study to assess the reports of medication errors in patients admitted to the Department of Pediatrics of Hospital Italiano de Buenos Aires between January 2<sup>nd</sup>, 2016 and December 30<sup>th</sup>, 2017. Data were collected from the anonymous and voluntary electronic error reporting system, where reports were electronically entered using the hospital's intranet, which could only be accessed by the hospital's health care providers.

Licensed nurses who were members of the Patient Safety Committee collected all anonymous error reports in a prospective manner and then selected those who had taken place at the Department of Pediatrics.

Medication errors reported at the Pediatric Clinical (PC), the Pediatric Intensive Care Unit (PICU), and the NICU for patients from birth to 16 years old were included. Reports of medication quasi-errors were also included, i.e., errors that did not reach the patient.

Reports made at outpatient pediatric offices or with incomplete or missing data were excluded.

At Hospital Italiano, drugs are prepared by the Pharmacy Department and then supplied to each area. Prescription at each area depended on physicians; and nurses, together with pharmacists, were in charge of preparing the drugs indicated in the prescription. This took place in a closed room, free of noise and with no access to mobile phones or telephones, so that they would not be distracted.

The study was approved by the Research Ethics Committee of Hospital Italiano de Buenos Aires (no. 3505). It was defined that it was not necessary to obtain informed consent because reports were anonymous and none included patients' names.

The following outcome measures of reported errors were evaluated

**Error origin:** Prescription by physicians, administration by nurses, and drug supply by pharmacists.

**Type of medication errors:** Dosing error, prescription of the wrong drug, error in drug dilution, drug omission, error in frequency of administration, wrong patient, error in route of administration, error in drug concentration, wrong drug presentation, dispensing the wrong drug, administering the wrong drug, error in the rate of intravenous infusion.

**The day when the error occurred:** Mondays through Fridays or Saturdays and Sundays.

**Nurse shift:** In the morning, afternoon or night.

**Area of the Department of Pediatrics:** Errors were reported at the PC, PICU or NICU.

**Frequency of AEs and harmful effects:** Mild (no test required), moderate (requiring lab tests and greater care) or severe (requiring tests and special management).

#### Statistical analysis

For each outcome measure mentioned here, data were described using discrete quantitative outcome measures, with frequency and percentage values. Errors were described as absolute and relative frequency. A statistical analysis was done to compare the proportion of errors by origin (prescription, administration) and nurse shift. AEs and their potential harmful effects were also described. In all cases, a p < 0.05 difference was considered statistically significant. The  $\chi^2$  test or Fisher's exact test were used for low expected frequencies.

## RESULTS

A total of 4986 errors were reported at the hospital; 989 (20 %) occurred at the Department of Pediatrics, and 401 (41 %) corresponded to medication errors, which were the most common ones. Of these, 353 (88 %) errors reached the patients, whereas 48 (12 %) were quasierrors. Dosing errors were the most common type, 118 (33.4 %), followed by drug omission, 47 (13.3 %) (Table 1). Seventy-nine dosing errors (67 %) were related to drug prescription and 39 (33 %), to drug administration (p = 0.07); no dispensing errors were reported. A total of 283 reports (80 %) were made on Mondays through Fridays, whereas 70 (20 %) were made on the weekend. Also, 149 reports (37 %) were made in the morning shift; 84 (21 %), in the afternoon shift; 60 (15 %), in the morning and afternoon shift (Saturdays and Sundays); and 60 (15 %), in the night shift; the differences were

TABLE 1. Type of error

not significant, p = 0.8. The most common errors were prescription errors, which accounted for 165 reports (46.7 %); 144 (40.8 %) accounted for administration errors; and 44 (12.5 %), dispensing errors. Dosing errors were significantly more frequently made in prescriptions (p < 0.05). The highest number of errors were reported at the NICU, 179 (50 %); compared to 91 (25.5 %) at the PC and 83 (24.5 %) at the PICU. A total of 91 AEs (22.5 %) were reported; 54 (58 %) were mild; 32 (34 %), moderate; and 5 (1.4 %), severe. The NICU reported 53 AEs (58 %); the PICU, 20 (22 %); and the PC, 18 (19.7 %); the difference was not significant, p = 0.09. No medication errorassociated mortality was observed. The analysis of reported quasi-errors showed that 23 (48 %) were potentially mild; 19 (39.5 %), potentially moderate; and 6 (12.5 %), potentially severe.

## DISCUSSION

This study assessed multiple outcome measures associated with voluntary reporting of medication errors in patients admitted to the Department of Pediatrics of Hospital Italiano de Buenos Aires.

The voluntary error reporting initiative at health care facilities has reached a greater prevalence in the beginning of the century; its main objective is to bring about a change in the traditional patient safety culture, which, based on prejudice, considers that errors are only caused by human beings and that, therefore, they should be punished.

Still today, such culture persists in many health care facilities. The rate of publications about error reporting has increased mostly in developed countries, especially the USA and Western Europe, where health care systems prioritize health care safety.<sup>3,5,19,22-26</sup>

	N	%	
Dosing error	118	33.4	
Drug omission	47	13.3	
Prescription of the wrong drug	36	10.2	
Error in drug dilution	27	7.7	
Error in frequency of administration	24	6.8	
Wrong patient	23	6.5	
Dispensing the wrong drug	22	6.2	
Administering the wrong drug	17	4.8	
Error in route of administration	13	3.7	
Miscellaneous	26	4.9	
Total	353	96	

It is worth noting that published studies correspond mostly to errors reported in adults, whereas only a few have been conducted in pediatric patients.<sup>16,18</sup> However, several publications related to reports in pediatrics have mostly approached medication errors and their potential consequences.<sup>6-12,14,27-30</sup> Still, in Latin American countries, reporting studies are very scarce compared to developed countries. So much that, to our knowledge, this is the first Argentine study that focused exclusively on reports of medication errors in hospitalized children.

Error reporting is very helpful to detect system failures, quasi-errors, and AEs but, as pointed out, it would be particularly useful to change the patient safety culture in health care facilities. Voluntary reporting is only one of the multiple pieces that are required at hospitals to reduce and detect errors and AEs in order to improve patient safety.<sup>21,23-25,30-32</sup>

As observed in this study, medication errors are most commonly reported in a voluntary manner. Most likely, these errors are more easily detected in hospitalized children, by both health care providers and patients' parents, who are usually the first ones to notice them.<sup>33,34</sup>

AEs are more common in medication errors than in other types of errors; in our study they also occurred more often than usual. Likewise, some studies have observed that AEs resulting from medication errors account for a much higher risk than other errors.<sup>25</sup>

Spontaneous and voluntary reporting systems for health care providers are expected to report any error and all AEs. An open, non-punitive, strictly confidential approach will promote voluntary reporting. However, at health care facilities, several health care providers still fear disciplinary or legal actions against those who report errors. Because of this, most reports should be anonymous and voluntary so that there are less chances of punishment on reporting health care providers.

The results of this study were mostly similar to those observed in different investigations done in other countries<sup>6,9,10,14,17,29,31</sup> and, although the frequency may differ, many consistencies can be seen. Among others, it is worth mentioning that the rate of prescription errors was higher than that of administration errors, which has been described in most published studies, both in adults and children.<sup>29,31</sup> The same is true for the fact that dosing errors were the most common type of errors. In addition, more than half of errors were reported at the NICU, which was also consistent with other studies.<sup>67,9</sup> This is mostly due to the intricate process entailed by the preparation of drugs for newborn infants which, among other things, requires multiple dilutions, especially in the case of very small preterm infants.<sup>10,22,30,31</sup>

Moreover, the studies that analyzed errors reported in hospitalized children at the Department of Pediatrics found that the rate of AEs at the NICU was higher than the rest<sup>8,12,29,34-36</sup> and this was also observed in our study, where more than half of all AEs occurred at the NICU. The 3 severe AEs that occurred at the NICU corresponded to dosing errors: 1 in the physician's prescription and 2 due to drug dilution mistakes made by nurses.

Even with the several limitations pointed out in relation to anonymous and voluntary reports of errors in patient safety, the data collected in this study have been very useful to establish the frequency of reported medication errors and also accurately detect AEs and their consequences. It was also possible to perform root-cause analyses applied to severe or sentinel AEs, and this enabled the identification of failures in hospital systems and health care providers in charge of patient care. In this way, a greater knowledge was obtained about error causes and reasons.

We also included reports of errors that did not reach the patient, known as "quasi-errors," and this was very helpful to detect how they occurred and, thus, the barriers that prevented them from reaching the patients. This is a very relevant aspect because error prevention barriers are one of the most important measures in patient safety to reduce or avoid AEs.<sup>9,10,25,27,32-35</sup>

## CONCLUSION

The primary objective of this study was met: assessing medication error reports in terms of error frequency, causes, and resulting AEs and consequences. Out of all error types, dosing errors were the most common ones, three times more frequent than the second leading type. Mild AEs predominated and accounted for two-thirds of all AEs. The highest rate of medication errors at the Department of Pediatrics was reported at the NICU, as well as the highest AE rate. Most reports were made by physicians, and prescription errors. No errors were reported in relation to deceased patients. ■

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