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#### Research paper

# A prospective observational study of medication errors in a pediatric emergency department

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#### ABSTRACT

We present a prospective, observational study evaluating the incidence of medication errors (ME) in a university hospital pediatric emergency department and describe their characteristics and determinants. A systematic analysis of the handwritten prescriptions was conducted by a clinician and pharmacist. Of 11,573 consecutively studied prescriptions in children under 15 years of age, the ME incidence was 0.9% (n = 102). The incidence of errors found was statistically significantly higher in children older than 5 years (OR = 2.05; P = 0.026). There was no significant difference regarding the time of admission (P = 0.544), the day of the week (P = 0.940), or the affluence of people in attendance at the emergency department. The errors observed were all prescription errors. Most errors were related to analgesic (51%) and antibiotic (30%) treatments. No serious errors were reported.

Conclusion: We found a low incidence of medication errors in this study. The validation of prescriptions by a senior multidisciplinary staff could contribute to limited medication errors. Measures should be continued to further reduce the incidence of drug errors by calling the attention of prescribers to the most common situations at risk of ME.

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#### 1. Introduction

According to the Agence française de sécurité sanitaire des produits de santé, a medication error (ME) is the omission or unintentional creation of an act during care that involves a drug, which can cause a risk or an adverse event for the patient. A ME is any predictable event resulting from the misuse of the drug. By definition, it is avoidable because it reflects a gap between what should have been done and what was done during the patient's drug therapy. In 2009, a national investigation led by the Direction de la recherche, des études, de l'évaluation et des statistiques showed that during the 31,663 days of hospitalization studied, 374 serious adverse reactions occurred and medications were responsible of more than 40% of these [1].

While several ME studies have been conducted on adult patients, there are only a few studies in the pediatric population and almost none specifically in France. Ghaleb et al. reviewed 32 studies related to ME in pediatrics, mostly from the US and

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Canada, and found variable results and methods between these studies showing additional research is needed to evaluate extent of the risk [2]. A multicenter prospective study was carried out in 2006 in several pediatric departments (general pediatrics, pediatric emergency, and intensive care) over a 2-month period, but its exhaustivity was impossible to assess [3]. The study reported 75 drug errors; 28% were errors involving antipyretics and antibiotics, and 21% were administration errors.

Children admitted to pediatric emergency departments have specific characteristics, and these young patients are often at risk of drug error because of their unique metabolic and physiological features, as well as lower tolerance to errors [4]. Pediatric emergency departments are a risky place for drug failure (large population, simultaneous presence of patients with severe or benign pathologies, children's different ages, and high frequency of calculation errors) [5]. In this context, the objective of this study was to evaluate the incidence of MEs in a pediatric emergency department in a French university-affiliated hospital, describe the characteristics, the personnel involved, and the patients who were victims of the drug errors. Our aim was also to identify the determinants of these errors to highlight the situations at higher risk of ME.

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#### 2. Materials and methods

#### 2.1. Population

This prospective study included all patients admitted to the pediatric emergency department at a French university-affiliated hospital from November 10, 2011, to April 10, 2012. The impact of MEs was assessed through a combination of a daily systematic review of the patient records by the medical team, which included a clinician working in the pediatric emergency room (PER) and a pharmacist, and the establishment of a system of spontaneous reporting of MEs in the department.

This study received the approval of the local ethics committee (Groupe nantais d'éthique dans le domaine de la santé) and the data protection agency (Commission nationale de l'informatique et des libertés [CNIL]).

#### 2.2. Data collection

The prescriptions were analyzed from the duplicate of the prescription in the emergency medical folder and if necessary in the medical hospitalization folder. The prescriptions were carried out by a medical doctor or a trainee after validation by a senior staff member. All the prescriptions made in the PER during the study period were analyzed to identify MEs. When no error was detected, prescriptions were not systematically collected in the database during the entire study period but were exhaustively collected over a 2-week period in 2012, from September 10, 2012, to September 23, 2012, except for an epidemic period, to determine the usual prescription procedures for pediatric emergencies. We then constituted a sample of 1033 consecutive patients with 1399 prescriptions and treated this sample of prescriptions as a reference of prescriptions made routinely in PER (reference sample). This cohort is referred to the "control group" in the Results section.

The exhaustiveness of the inclusions was checked with the data recorded by the Medical Information Department for all of the patients admitted during the study period.

#### 2.3. ME classification

Once identified, drug errors were characterized according to the criteria of the NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention) Index: the seriousness of the clinical consequences for the patient, the types and causes of drug errors, and the stage of occurrence in the drug processes were notified. Several drug errors could be identified for the same patient.

#### 2.4. Statistics

Based on the results of Ross et al. [6], the estimated minimum frequency of drug errors in a pediatric emergency department is 0.15%. To highlight a similar incidence of drug errors in the pediatric emergency department of a French university-affiliated hospital – with the objective of a 95% confidence interval (CI), an alpha risk of 5%, and a power risk target of 80% in the bilateral approach, we needed a cohort of 13,000 patients for this investigation. For comparisons between groups, the significance of the tests was set at a 5% threshold in the bilateral formulation. The Pearson Chi-squared test (or the Fisher exact test if the theoretical numbers were lower than 5) was used for the qualitative variables, the Student *t*-test to compare the normal quantitative variables, and the Mann-Whitney U-test for the nonnormal distributions. The statistical analyses were performed with SPSS 19.0 software. Univariate and multivariate logistic regression

analyses were conducted to determine the risk factors associated with the drug errors.

#### 3. Results

Over the study period, 11,573 patients were included. The incidence of MEs was 0.9% (n = 102) (Table 1). The sex ratio was 1.2. A vital emergency occurred for 80 children (0.7%). After emergency department admission, 9180 patients (79%) returned home. The number of daily pediatric emergency admissions during the study was 92 ( $\pm$  14). The ME population and the reference sample with usual prescriptions did not differ except for age (6.8 years old [ $\pm$  4.9] vs. 5.0 years old [Table 2]). The errors occurred in 59 boys (57.8%; 95% CI: 48.2–67.4). We observed that 61 patients with MEs (59.8%; 95% CI: 50.3-69.3) were admitted to the medicine sector, 72 MEs (70.6%; 95% CI: 61.8-79.4) occurred on weekdays and between 6 pm and 2 am in 38 cases (37.3%; 95% CI: 28.4-47.2). A ME occurred for two patients among those admitted with a vital emergency, in 28 cases (27.4%; 95% CI: 18.7-36.1) of patients admitted with a relatively urgent situation, and for 72 cases (70.5%; 95% CI: 61.8–79.4) of patients who were admitted for a consultation. Two patients experienced two MEs during the same episode. After admission to the pediatric emergency department, 93 patients with a ME returned home (91.2%; 95% CI: 85.7–96.7), five were hospitalized in the pediatrics department and four were hospitalized in an intensive care unit. The drug administration was oral in 91 (89.2%; 95% CI: 83.2–95.2) and intravenous in seven (6.9%; 95% CI: 2–11.8). Four MEs were observed with intrarectal or inhaled administration treatments (3.9%; 95% CI: 0.1-7.7).

The most frequent medications implicated in errors were analgesics (51%; 95% CI: 41.3–60.7) and antibiotics (30%; 95% CI: 21.1–38.9). The analgesics involved were paracetamol (n = 27, 26.5%), ibuprofen (n = 11, 10.8%), and codeine (n = 10, 9.8%). Amoxicillin was the antibiotic the most frequently involved in

**Table 1** Population study.

	n=11,573
Medication errors, n (%)	102 (0.9)
Average age in years $(\pm SD)$	$5.3~(\pm 4.6)$
Gender $n$ (%)	
Male	6409 (55.4)
Female	5164 (44.6)
Sex ratio (M/F)	1.2
Average number of daily admissions $(\pm SD)$	92 ( $\pm 14$ )
Average length of stay in min ( $\pm$ SD)	$204~(\pm 36)$
Priority admission $n$ (%)	
Priority 1 (vital emergency)	80 (0.7)
Priority 2 (urgent consultation)	2747 (23.7)
Priority 3 (non-urgent consultation)	8638 (74.6)

SD: standard deviation.

**Table 2**Comparison of the population with medication errors (MEs) and control group prescriptions.

	ME population $n = 102$	Reference sample n = 1399
Average age (years ± SD)	6.8 (±4.9)	5.0 (± 4.5)
Sex ratio (M/F)	1.4	1.3
Medicine sector (n)	61 (59.8%)	465 (45%)
Surgical sector (n)	41 (40.2%)	568 (55%)
Average daily admissions $\pm$ SD	89.6 ( $\pm 13$ )	83.6 ( $\pm 10$ )
Average length of stay (min $\pm$ SD)	$202.0 (\pm 31)$	$182.5~(\pm20)$
Analgesics (n (%))	52 (51.0%)	755 (54.0%)
Antibiotics (n (%))	31 (30.4%) <sup>a</sup>	93 (6.6%)
Corticosteroids $(n \ (\%))$	6 (5.9%)	102 (7.3%)

SD: standard deviation.

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 $<sup>^{\</sup>rm a}$  P < 0.05 compared to the usual population.

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