Archives de Pédiatrie xxx (2018) xxx–xxx

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EM|consulte
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Research paper

Risk analysis in pediatric inpatients

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ARTICLE INFO

Article history:
Received 7 December 2017
Accepted 15 August 2018
Available online xxx

Keywords:
Pediatric
Risk
Analysis
Method
Reduction
Inpatient

ABSTRACT

The complexity and vulnerability of the pediatric population make them unique to risk management. Risk analysis is particularly demanding here and requires comprehensive identification of hazardous situations. Few data are published on methods to prevent medication errors in pediatric inpatients, reducing the possibility for healthcare institutions to prioritize the actions to take. This paper summarizes the proactive risk analysis methods described in the literature, the failures identified, and the corrective actions applied to reduce the risks in pediatrics.

1. Introduction

"Magnesium chloride instead of B46" headlined the newspaper *Le Parisien* after the death of a 3-year-old child in 2008 following a fatal infusion error. Admitted to the hospital for simple tonsillitis, the doctor had prescribed a rehydration solution and the nurse, without checking the labeling of the vial, administered a magnesium chloride solution used for the preparation of nutrient solutions. This solute should never have been present in the clinical unit. Hence, a chain of hazardous events led to a tragedy that could, without doubt, have been avoided by a medication risk minimization method applied to the drug circuit. The pediatric hospital thus concentrates high risk factors that are fully dependent on human and technical performance. The diversity of hospital activities generates interactions that produce unforeseen situations related to specific risks in the pediatric area. Most particularly, medication management is a sensitive area with high risk factors in hospitalized children.

The literature reports many publications documenting medication errors, from prescription to administration in the hospital [1–11]. An American study reported a threefold increase in prevalence of prescribing-related adverse events in children compared to adults [1]. A review of the literature conducted from 2000 to 2012 identified a rate of 83 medication errors per 100 days of inpatient hospitalization involving errors in preparation, dosing, treatment error, and off-indication therapy [3]. Adverse events in these studies were strongly correlated to the use of unauthorized medications in children [4–11]. The shortage of drugs in a suitable dosage form for pediatric patients further reinforces iatrogenic adverse events [12–15]. As a consequence, physicians are compelled to adjust their prescriptions depending on available adult data. Likewise, nurses are frequently requested to crush tablets or open capsules from adult forms and dilute the resulting powder in a liquid such as mineral water. These practices all lead to a higher incidence of medication errors [16–19]. To limit these risks in pediatric inpatients, methods to prevent medication errors have become a prerequisite for hospital certification processes. Because of the paucity of literature in this domain, this paper provides a comprehensive review of risk-analysis methods implemented in France and internationally.

2. Methods

To find the related articles, the keywords "failure modes effects analysis (FMEA)", "hospital", "pediatric", "risk analysis", "preliminary risk analysis (PRA)", "preliminary hazard analysis (PHA)", and "inpatient" were searched in the Medline and Google Scholar databases. The inclusion criteria were:

- the paper must be in English or French;
- the paper must have mentioned a detailed risk analysis method;
- the method used to analyze risk must have been implemented in pediatric care processes in a hospital;

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https://doi.org/10.1016/j.arcped.2018.08.005
0929-693X/

Table 1
Summary of articles consulted on risk analysis in pediatric inpatients.

Authors	Country	Publication year	Title	Process	Participating team	Clinical unit
Lolito et al.	France	2014	Mapping of medication risks in pediatrics	Interdiag®	Pediatricians Pharmacists Nurses	82 Clinical units
Pourrat et al.	France	2014	Oral administration of medications to infants: implementation of a preliminary risk analysis in a hospital service of pediatrics	PRA	Pediatricians Pharmacists Nurses	General pediatric unit
Delaborde et al.	France	2017	A priori risk mapping of the infusion process in neonatal and pediatric reanimation	FMEA	Physicians Nurses Hygienists Pharmacists Quality manager	Neonatal intensive care unit
Hfaiedh et al.	France	2017	Performing a preliminary hazard analysis applied to administration of injectable drugs to infants	PRA	Pharmacists Nurses Pediatricians	General pediatric unit
Lago et al.	Italy	2012	Use of FMEA analysis to reduce risk of errors in prescribing and administering drugs in paediatric wards: a quality improvement report	FMEA	Doctors Residents Nurses Patient safety experts Risk management experts Pharmacists	Neonatal intensive care unit Pediatric hematology-oncology unit General pediatric ward Emergency care unit

FMEA: failure mode and effective analysis; PRA, preliminary risk analysis.

- the publication date of the paper must be after 2010. To determine the eligibility of the articles, those including one of the keywords in their titles or abstracts were first selected. In the second step, the whole texts of the selected articles were investigated by a risk expert. After reading the papers, seven remained and 21 were excluded. The data were extracted as shown in Table 1. The data collected from the papers included: name of the first author, country/city, year of publication, the risk analysis method, cooperating team, and the clinical study unit.

3. Results

3.1. Methods to prevent medication errors

In the seven articles selected, three methods to prevent medication errors were implemented using the Interdiag® tool, failure mode and effective analysis (FMEA), and preliminary risk analysis (PRA).

3.1.1. The Interdiag® method

The Interdiag® tool was elaborated by the Agence Nationale d'Aide à la Performance (ANAP). The purpose of this computer-based tool is to provide a self-assessment of medication risk in healthcare institutions. It contains 177 questions covering the themes of safety policy in the healthcare unit, safety of medication management, and safety of medication storage in the unit. These topics are divided into nine safety areas: prevention, pilotage, patient admission and discharge, prescription, dispensation, preparation and administration, storage of drugs, stock management, and emergency cart management. The questionnaire takes 2–2.5 h to complete for each care unit. The Interdiag® tool provides risk mapping of patient medical care for each healthcare unit. Subsequently, a global overview of the risk provides a consolidated action plan at the institutional level. To ensure the most representative assessment of the risk situation at the time of the evaluation, it is strongly recommended that the evaluation include at least the head of the unit, a caregiver, a doctor, a pharmacist, a pharmacy dispenser, and a member of the quality or risk management department.

3.1.2. Failure mode and effective analysis

Failure Mode and Effective Analysis (FMEA) was initially used by the US military in 1949 and then by NASA in 1960 to enhance and check their programs' reliability. Since the 2000s, FMEA has been used successfully in healthcare organizations to improve healthcare-related management. FMEA is defined as "a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change" [20]. FMEA includes a review of the steps in the process, failure modes, failure causes, and the consequences of each failure. For each mode and effect, severity, ease of detection, and rate of occurrence are analyzed. Then criticality scores derived from these measures are used both to identify modes of protection against errors and to monitor prevention efficacy indicators. This method is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed corrective action.

3.1.3. Preliminary risk analysis

The preliminary risk analysis (PRA) fields are multiple, covering industrial, military, financial, environmental, and healthcare activities. PRA is a systemic, rigorous, and inductive approach performed in two steps: the PRA system and the PRA scenario [21]. The PRA system determines the general and specific hazardous situations and constructs the risk map. The PRA scenario associates each hazardous situation with a level of severity, probability, effort, and acceptance of risk level. Then a criticality matrix derived from these measures is built to score the hazardous situations and identify whether or not they are critical. The map highlights the initial and residual risks after establishing a plan to reduce these risks.

3.2. French and international data

3.2.1. French data

In France, few data have been published based on widely differing complexity methods to prevent medication errors in pediatric inpatients [22–24]. A study conducted by the Grenoble University Hospital analyzed the risks of medication management in 82 pediatric care units by mapping risks using the Interdiag® tool [22]. The aim of the study was to identify the medication risk

Please cite this article in press as: Schlatter J. Risk analysis in pediatric inpatients. Archives de Pédiatrie (2018), https://doi.org/10.1016/j.arcped.2018.08.005