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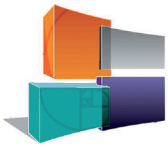

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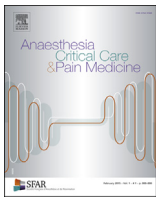

Original Article

Critical incidents in a French department of paediatric anaesthesia

Elisa Kupersztych-Hagege, Caroline Duracher-Gout, Rocio Ortego, Pierre Carli, Gilles Orliaguet *

Department of Anaesthesiology and Critical Care Medicine, Hôpital Universitaire Necker–Enfants-Malades, AP–HP, University Paris Descartes, 149, rue de Sèvres, 75743 Paris, France

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ABSTRACT

Background: Several studies have highlighted the importance of critical incident (CI) reporting in order to enhance patient safety. We have implemented an anonymous procedure for CI reporting in our department of paediatric anaesthesia. This study aims at analysing those CIs so as to improve patient care and risk management.
Material and methods: CIs were reported by the anaesthetic team using the World Health Organization classification and analysed using the ORION methodology. CIs were classified according to type, surgery and complications. Risk factors and consequences for patients and for the institution were analysed. Risk factors with high degree of harm for the patient were identified using a univariate analysis and odds ratios (OR).
Results: Over an 18-month period, 114 CIs were reported for 103 patients (median age: 7.0 years [95% CI: 3.6–9.8]). We found that 29.9% of reported CIs had consequences for the patients and 76.3% were considered preventable. The two main types of CI were "respiratory" (28.8%) and "drug-related" (22.8%) incidents. The main risk factor was 'human error' (42.3%). Several consequences for the patient and the hospital were identified. An ASA score $\geq$ 3 (OR: 2.52; [95% CI: 1.10–5.78]) was an independent risk factor for a high degree of patient harm.
Conclusion: Improving quality of care must be a priority for paediatric anaesthesiologists as most of the CIs observed are preventable and have consequences for the patient and the institution.

1. Introduction

Anaesthesiology is a medical domain with an increased risk of morbidity and mortality due to high-risk surgeries or procedures performed on patients with severe comorbidities. In order to reduce perioperative risks, operating theatre monitoring tools and the statistical analysis of anaesthetic incidents have been recently developed. Indeed, it is now proven that analysing risky situations increases patient safety [1–3]. Thus, several countries such as England, Australia and New Zealand have established national registries for critical incidents (CI) that have led to modifications in their national practice guidelines [4,5]. In France, anaesthetic event reporting and analysis are still limited. Several safety improvement methods have been described such as morbi-mortality conferences, but so far no national registry has been established. Moreover, numerous studies suggest that most paediatric anaesthetic incidents may be preventable [6,7]. To understand critical incident mechanisms and to analyse their triggers, we have implemented a comprehensive critical incident and near-misses database relying upon voluntary and anonymous reports. The aim of the study was to review and analyse all CIs reported, to identify factors decreasing patient safety and to determine if such CIs were preventable.

2. Materials and methods

This prospective observational and descriptive study, analysing critical incidents in paediatric anaesthesia, was conducted between August 2011 and May 2013 in the Department of Paediatric Anaesthesia at the Necker University Hospital (Paris, France).

Abbreviations: CI, critical incident; N/A, not available; WHO, World Health Organization; OR, odds ratio.

* Corresponding author at: DAR et SAMU de Paris, Hôpital Universitaire Necker–Enfants-Malades, AP–HP, 149, rue de Sèvres, 75743 Paris, France.
Tel.: +33 1 44 49 44 58; fax: +33 1 44 49 41 70.
E-mail address: gilles.orliaguet@aphp.fr (G. Orliaguet).

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For the purposes of this study, a critical incident (CI) was defined as any incident where the safety margin of the paediatric patient decreased or could have decreased while under anaesthetic care.

Critical incident report forms were pinned in the operating theatre for easy access. In order to gather the most detailed feedback as possible, all incident reports were voluntary and anonymous. Any member of the anaesthesia team (the anaesthesiologist in charge of patient, the anaesthetic nurse or students) present in the operating room or in the post-anaesthesia care unit could report the incident.

The analysis of CIs was based on the ORION method using the International Classification for Patient Safety published by the World Health Organization (WHO) and was used in accordance with institutional guidelines. As a second step, CIs were classified by the severity of their consequences for the patient.

2.1. The ORION method

The ORION method provides a general analysis grid that may be applied regardless of the severity of the incident. Based on the Reason's concept, it was used for the analysis of incidents with multiple and complex causes [8,9]. Indeed, risk results from consecutive errors and the ORION method enables tracking the risk chain that lead up to the incident [10]. This analysis relies upon six steps, which are managed by an external "pilot":

- data collection: individual interviews, debriefing, written statements;
- incident history reconstitution;
- discrepancy identification: gaps between what happened and what should have happened according to best practices and protocols;
- identification of contributing factors: situations or actions that are considered to have incurred or at least influenced a higher risk in patient care;
- action proposal: corrective measures proposed by the pilot and accepted by the staff members to eliminate contributing factors;
- analysis report writing.

2.2. The WHO classification

The International Classification of Patient Safety, established by the WHO, is a framework for classifying incidents and binding them with the corresponding corrective measures [11,12]. For each incident type, the classification helps understand whether or not the incident was preventable.

This classification consists of 6 incident types [11] (Table 1):

- healthcare-associated harm: harm arising or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury;
- near-miss: the incident did not affect the patient;
- no harm incident: an incident, which affected the patient, but no discernable harm resulted;
- adverse reaction: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred;
- side effect: a known effect, other than that primarily intended, related to the pharmacological properties of a medication;
- harmful incident (adverse effect): an incident that resulted in harm to a patient. Harms are divided into 5 categories: disease (physiological or psychological dysfunction), injury (damage to tissues caused by an agent or event), suffering (the experience of anything subjectively unpleasant), disability (any type of impairment of body structure or function, activity limitation, and/or restriction of participation in society, associated with past or present harm) and death.

Table 1
WHO critical incident classification.

Definition	Critical incident	Patient		
		Harm	Affected	Expected
Near-miss	No	No	Yes/No	No
No harm incident	Yes	No	Yes/No	No
Healthcare-associated harm	Yes	Yes	Yes	No
Adverse event	Yes	Yes	Yes	Yes
Side effect	Yes	Yes	Yes	Yes
Adverse reaction	Yes	Yes	Yes	No

WHO: World Health Organization.

2.3. Organization of critical incident analysis

Each form was first analysed individually by one member of the multidisciplinary working group (including nurse executives, certified registered nurses in anaesthesia and staff anaesthesiologists). This person presented the case and highlighted the dysfunction to the working group during a monthly meeting. The working group used the ORION method and then classified the incident. The incident type, the facts history and the contributing factors were detailed and analysed. In accordance with the WHO classification, the incident was classified as "preventable" or "non-preventable" by the person in charge of the analysis and followed by final approval by the working group. Consequences for the patient and the hospital were assessed. The working group then decided on corrective measures and assigned a person to implement them. After each working meeting, each incident was registered in an Excel (Microsoft, Redmond, WA, USA) spreadsheet and a summary was sent to all members of the working group.

2.4. Statistical analysis

As our data did not follow a normal distribution (Kolmogorov-Smirnov), the results are presented as medians [95% confidence interval: 95% CI] and as numbers of cases (%). Incidents were analysed according to: type of surgery, type of complications, contributing factors and consequences for the patient and the institution. We also sought to identify risk factors for critical incidents with "severe harm" to the patient using a univariate analysis, and calculating their odds ratio [95% CI]. With this in mind, critical incidents were grouped into two categories:

- "low harm": incident with no harm or transient harm (i.e. transitory effect) to the patient;
- "severe harm": injury, suffering, disease, disability or death of the patient.

3. Results

From August 2011 to May 2013, 15,792 procedures were performed under general anaesthesia in our Department of Paediatric Anaesthesia (outpatient, cardiac and ophthalmic surgery were excluded). Over this 18-month period, 112 report forms were recorded. A total of 114 reported critical incidents concerning 103 patients were analysed (Fig. 1). The prevalence of reported critical incidents was 0.7%.

The median age of the patients was 7.0 years [95% CI: 3.6–9.8 years]. Twenty-one (17.9%) patients were younger than 1 year of age. The percentages of children falling into each ASA class were

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