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# Pediatric patient safety and the need for aviation black box thinking to learn from and prevent medication error?

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**Abstract**

Since the publication of "*To Err Is Human: Building a Safer Health System*" in 1999, there has been much research conducted into the epidemiology, nature and causes of medication error in children, from prescribing and supply to administration. It is reassuring to see growing evidence to improve medication safety in children, however based on media reports, it can be seen that serious and fatal medication errors still occur. This critical opinion article examines the problem of medication errors in children and provides recommendations for research, training of healthcare professionals and a culture shift towards dealing with medication error. There are three factors that we need to consider to unravel what is missing and why do fatal medication errors still occur, 1. Who is involved and affected by the medication error? 2. What factors hinder staff and organisations learning from mistakes? Does the fear of litigation and criminal charges deter healthcare professionals from voluntarily reporting medication errors? 3. What are the educational needs required to prevent medication error? It is important to educate future healthcare professionals of medication error and human factors to prevent these from happening.

Further research is required to apply aviation's "black box" principles in healthcare to record and learn from near misses and errors to prevent future events. There is an urgent need for the black box investigations to be published and made public for the benefit of other organisations that may have similar potential risks for adverse events. International sharing of investigations and learning are also needed.

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## Key Points

Medication errors in children are complex; they may involve and affect more than just the patient and healthcare professional, as the parent may also be involved in their occurrence.

Fear of litigation and lack of immunity hinders and deters healthcare professionals from voluntarily reporting medication errors.

The way forward to prevent medication errors in children requires increased learning by healthcare professionals from adverse events and near misses as well as increased education on human factors. Education should also be expanded to the public to increase awareness of patient safety.

## Manuscript

### 1. Introduction

Almost two decades since the publication of the seminal Institute of Medicine (IoM) report *To Err is Human: Building a Safer Health System* [1], the question remains whether patient safety has improved? This issue is particularly relevant to the delivery of medical care to children. The pediatric population are at a higher risk of medication errors in comparison to adults [2-3], and have been shown to be three times more likely to be harmed when they occur [4].

Since the IoM report in 1999 [1], there has been much research conducted into the epidemiology, nature and causes of medication error in children, from prescribing and supply to administration. Medication error has been studied using many methods, such as prospective observations of wards by trained data collectors given a definition

of medication error defined as errors in drug ordering, dispensing, administering or monitoring [4], as well as direct observations of drug charts and ward rounds to identify medication administration errors specifically [2]. Medication error theory has also been used to measure the impact of electronic prescribing and the reduction of medication errors as a result of its implementation in children [5].

There have been many studies that have targeted areas at which pharmacists could make interventions and prevent errors from happening in children for example preventing medication errors at the interface of care from hospital admission to discharge and post discharge [6-9], and reducing prescribing errors via pharmacist intervention [10-11]. One of the areas in patient safety that has been recently explored relates to the potential for medication discrepancies to occur across the interface of care from hospital admission to discharge. In 2006, the World Health Organization (WHO) included medication reconciliation as one of the five standardized patient safety solutions (known as the High 5s) [12]. Medication reconciliation is a process where medication lists are compared when a patient is transferred from one care setting to another – for example at hospital admission from home. In the UK, the National Institute of Health and Care Excellence (NICE) 2007 produced a guideline advising hospital providers to conduct medication reconciliation in adults who were admitted into hospital to reduce medication errors. This guideline did not include children under the age of 16 years [6]. This exclusion, led to UK studies being conducted to build the body of evidence to establish if medication reconciliation was required in this age group. A multi-site study in four different hospitals around England (Birmingham, London, Leeds and North Staffordshire) indicated that the incidence of potentially clinically harmful medication discrepancies occurring, in the absence of a pharmacist's medication reconciliation, was 32% [7]. A small study in Ireland of 40

admissions into a general pediatric ward showed that 37.5% of patients had at least one unintended medication discrepancy at hospital admission [8]. At hospital discharge, it has been found that one in three discharge medication letters prior to a pharmacist amendment had at least one medication discrepancy [9].

The identification of prescribing errors by pharmacists is another area of patient safety that has been explored. A thirteen hospital site observation of documented pharmacist interventions revealed that 20.6% of 3330 patient charts had at least one medication error. The most common type of error related to incorrect dose [10].

The most recent patient safety strategy aimed at reducing prescribing errors in a Pediatric Intensive Care Unit (PICU) and Neonatal Intensive Care Unit (NICU) was the application of a site specific and defined “Zero Tolerance Policy” for prescribers. This policy governed i) who should write charts in the intensive care unit e.g. PICU/NICU staff with the exception of those preparing intrathecal preparation, ii) where and when prescriptions should be written, for example not during ward rounds and in an environment where nurses cannot distract the prescriber and iii) rules in relation to prescribing medication for patients [11]. The results of this study showed that implementing the concept of a site-specific “Zero Tolerance Policy” potentially decreased the risk of doctors making prescribing errors at a London (UK) Specialist Pediatric Hospital, with an absolute risk reduction of 44.5% (95% CI 40-48%) [11]. A recently reported study, published at a conference (2016), used the same “Zero Tolerance Policy” principle in a separate hospital setting across two audit cycles [13]. In the first cycle of the audit, 376 prescriptions were accessed according to the local “Zero Tolerance” standards and individualised feedback reports were given to prescribers on their prescribing error rate and types. Additional reports were also generated to create posters that were displayed across the unit and were discussed

at clinical governance meetings. This cycle was then repeated after a month and in the second cycle 275 prescriptions were assessed. A comparison of the prescribing across the two audit cycles showed no significant difference or reduction of the medication error rate, however there was a reduction when comparing individuals between each cycle which demonstrated that feedback for prescribers did lead to changes and improvements in prescribing practice [13].

It is reassuring to see growing evidence to improve medication safety in children through identifying areas where errors occur in order to target resources and interventions, through improving education provided in relation to pediatric prescribing [14] and having pharmacists present to make interventions [10]. The research that has been done has not specifically focused on strategies to reduce errors that have the potential to cause serious harm, which may be a reason behind why harmful errors continue to occur. Based on media reports, it can be seen that serious and fatal medication errors still occur. This poses the question: what are we missing?

The aims of this review are to discuss the current problem of serious medication errors and interventions that are in place to deal with these, the factors that affect and hinder error reporting and to identify any potential solutions and areas that require further research.

## 2. The existing problem of serious medication errors and factors contributing towards it

There are three factors that we need to consider to unravel what is missing and why fatal medication errors still occur: -

1. Who is involved and affected by the medication error?
2. What factors hinder staff and organisations learning from mistakes?

3. What are the educational needs required to prevent medication error?

Each of these questions are discussed in detail in the next sections.

## 2.1 Medication error – who is involved and affected? Patient, healthcare professional and the caregiver

Firstly, we need to know who is involved and affected by the medication error. One example reported in the media was that of the case of an infant who died as a result of a tenfold overdose of furosemide. [15] The patient was having difficulties keeping down the amount of liquid prescribed due to the volume of the oral solution and so the family physician decided to prescribe a stronger concentration of furosemide liquid in order to reduce the volume required. However, the parent was unaware that the furosemide liquid preparation concentration had changed and continued to give the same volume of the liquid to the patient which led to the overdose. [15] The error not only resulted in the death of the baby, but subsequently led to the death of one of the parents which was reported solely by a tabloid newspaper [16]. In terms of human factors, the medication error operator, for example the doctor who wrote the prescription is often referred to as the second victim, however this case illustrates that given the complexity of pediatrics where dosing and administration will often involve the parent, there is a hidden third victim. Identifying these additional second and third victims is important – the healthcare provider and caregiver responsible for the medication error can potentially suffer a medical emergency equivalent to post-traumatic stress disorder and become a “patient” to the healthcare system themselves [17].

Another case report, this time from a peer-reviewed journal, highlighted the impact that an error can have of those involved whereby a 50-year-old nurse committed

suicide just 7 months after making a calculation error that led to an overdose and subsequent death of a critically ill infant [17].

### 2.2 Factors hindering learning from mistakes

Secondly, we need to understand what is hindering healthcare professionals from learning from and preventing medication errors. In the aviation industry, when there is a major air disaster or a near miss event, there is a full forensic investigation including the black box recording that the investigational team can refer to.

In aviation, the black box is a computerized data recording device carried by modern commercial aircraft. Information from this black box can be retrieved in an event where there was an accident or near miss during the flight. The black box consists of a flight data recorder, which records at least eighty-eight important parameters with respect to time, such as the flight path, altitude, basic forces acting upon the aeroplane and resulting in the achieved flight path, the origin of these basic forces as well as a cockpit voice recorder [18]. There have been studies that have explored how this black box principle in aviation can be applied to healthcare. The management of adverse events in aviation and healthcare have been compared by Kapur and colleagues [19] as listed in table 1. This recently published review shows that the management of aviation is more open in terms of its reporting – every event is reported and every report is published, whereas in healthcare, major events (those leading to an adverse patient event or death) are only occasionally featured in the media. In relation to immunity of the error operator, pilot immunity is often part of the reporting culture, however in healthcare, immunity is not necessarily part of the culture.

There is a concern that there is a growing culture among society to criminalise and find a person to blame for fatal mistakes, which may as a result deter aviation and

healthcare professionals from voluntarily reporting their errors [20]. There have been a number of cases of criminal charges brought against healthcare professionals when errors have been made in both adult and pediatric settings. In the UK, a pharmacist Elizabeth Lee incorrectly dispensed propranolol to an elderly patient instead of prednisolone; the patient later died of an underlying issue and unrelated to the error [21]. Elizabeth Lee was given a suspended prison sentence in 2009 which was later substituted with a £400 fine which was reduced to £300 as a result of a guilty plea [22]. A recent case from Northern Ireland shows that another pharmacist, Martin White made the exact same error, incorrectly dispensing propranolol instead of prednisolone to a patient who later died, which echoes and draws resemblance to that of Elizabeth Lee's case [23]. Although a different allied healthcare profession, recently in the UK, there was a report of an optometrist who was prosecuted and taken to court for failing to identify bilateral papilloedema in a child aged 8, who died 5 months after the eye test. Although the parents in this case had called for leniency in sentencing, the optometrist was handed a two-year suspended prison sentence and charged with gross negligence and manslaughter [24]. In both of these cases, little is reported on how the organisations employing them responded to the error. Were there lessons learnt by the organisations where the pharmacists and optometrist worked to help prevent such an event from happening again? Although the organisations may have reviewed procedures and implemented changes, as per aviation procedures, it would have been good for a full investigation to have taken place and also be reported and published for the benefit of the wider profession to learn from.

The issue of litigation and criminalisation of pharmacist errors has also been documented in the USA; one high profile case involved a former pharmacist Eric Cropp who was given a 6-month prison sentence for failing to detect a technician's

chemotherapy mixing error which lead to the death of a 2 year old child [25]. This case was reported in 2009 in the Institute of Safe Medication Practices' (ISMP) medication safety alert. Ten years prior to publishing this care report, the ISMP had banned the use of naming and shaming or "jeering", where the institute would list individuals, organisations and companies that have taken a course of action that have frustrated error prevention efforts, for example hindering the progress of improving patient safety or making it worse. However due to the fatal outcome and criminal prosecution, this error and the individual involved was published in the report [25].

A focus group study conducted by the Canadian Institute of Safe Medication Practice, reported that the potential barriers to medication error reporting were reporter burden, professional indemnity, and fears – such as fear of anticipated negative attitudes from patients and a lack of trust about how error reports would be used [26]. Evidence from the media, safety organisations as well as research on overcoming barriers to medication error reporting suggests that due to fear of litigation, healthcare professionals may be reluctant to voluntarily report errors. There needs to be a culture shift from blame to a just culture. In the UK, there is no immunity for healthcare professionals who openly report their errors and there is no known legislation to protect the professionals from immunity. In the USA, this may also be the case as seen with Eric Cropp's prosecution and imprisonment. It has been recommended in the past that in order to incentivise the reporting of medication errors, reports could be submitted anonymously [1]. The European Commission patient safety and quality of care working group recommends that any error reporting systems should be separated from formal complaints, disciplinary actions and litigation procedures [27]. However, recently (2015) in the UK, healthcare professional regulatory bodies such as the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have

advocated the duty of candour, where a healthcare professional should be open and honest when an error occurs and tell the patient and caregivers that an error has occurred [28]. The fact that there is no guaranteed immunity from prosecution, coupled with the duty of candour to be open and honest about errors, makes it difficult for a healthcare profession to truly remain anonymous outside of the immunity of the voluntary anonymised error reporting system, as they will have to speak with the patients and those affected to let them know that an error has occurred. As a result of acting out the duty of candour, they are not protected from potential litigation which could lead to criminal charges.

In 2005, there was a case where due to human factors, a patient, Emily Bromiley died during a routine Ear Nose and Throat (ENT) surgical operation. The patient's husband, Martin Bromiley a commercial airline pilot, ensured that her case was reported and made publically available so that lessons could be learnt [29]. All the staff that had been involved in the incident returned to work. It was found in this case that the fatal outcome of this event was not due to clinical inability of the staff but human factors [30]. In 2007 a Clinical Human Factors Group was set up – a coalition of healthcare professionals, managers and service users who have partnered with experts in Human Factors from healthcare and high risk industries to campaign for changes in the UK National Health Service (NHS) – a nationalised healthcare system for the UK [31].

## 2.3 The need for medication error theory, learning from near misses and human factors in the education of healthcare professionals and the public

Finally, medication error theory and human factors need to be incorporated into the education of healthcare professionals and especially the training of pediatric doctors, nurses and pharmacists. The public may also need to be educated and made aware that medication errors occur and "*to err is human*". A medication safety resource that can be used to assist education establishments and applied internationally would be the WHO report on the role of pharmacovigilance centres in reporting and learning systems for medication error, of which human factors is mentioned as a potential tool to learn from errors [32]. James Reason in 1995 reported that knowledge of human factors is required to understand adverse events in medicine and that managing human risk can never be 100% effective. It is acknowledged from his report that human fallibility can be moderated but not eliminated; people do not act in isolation and that the likelihood of an unsafe act being committed is heavily influenced by the nature of the task and the workplace condition [33].

Human factors is defined as: *"*Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings*."* [34]. Although human factors has been known since the 1990s, there have been very few published articles on addressing medication safety using a human factors approach with only two studies that have related it to medication and patient safety in intensive care units [35-36]. In terms of education, a report in 2009 highlighted that there were gaps in the curricular content with regards to the epidemiology of adverse events and errors, root cause analysis and quality assessment in the undergraduate education of healthcare professionals. The report

found that theoretical aspects of the curricular content for example epidemiology of adverse events, and how it could be applied to directly to an organisational context was found to be either absent from the healthcare professional undergraduate course content or covered with limited exposure [37]. A systematic review of patient safety education for undergraduate medical students in 2011 showed that the addition of patient safety education into the medical school curriculum was most commonly implemented in medical schools in countries such as the USA and the UK [38]. The GMC report in 2015 regarding patient safety titled “First do no harm”, was written to focus on the importance of patient safety in driving up standards of education and to support medical schools’ patient safety initiatives [39]. This report, based on a GMC conference, concluded that curricula needed to address several key areas including: inter-professional working, including with non-clinical managers; the science of human error, and the system and human factors involved; clinical governance – including root cause analysis and other tools used to learn from incidences; the importance of quality improvement science in making care safer; lessons learnt from other industries with a strong safety culture; and the importance of challenging unsafe practice and the ways in which this could be done effectively [39]. Several UK medical schools have mapped their safety teaching to the WHO multi-professional patient safety curriculum guide [40]. The General Pharmaceutical Council (GPhC) in the UK specifies that “there must be clear procedures to address concerns about patient safety arising from initial pharmacy education and training. Concerns must be addressed immediately” and also as a learning outcome, students must know how to identify, report and prevent errors and unsafe practice [41]. How this is achieved is open to interpretation by the higher education institutions accredited to teach pharmacy undergraduates. The Royal College of Nursing (RCN) have included patient safety and human factors as their

standard of education and training which they envisage being adopted by all healthcare professionals in the future. Their focus however, has been on interventions such as communication, leadership, safety culture, stress and fatigue, teamwork and work environment, rather than directly addressing error prevention and learning from previous adverse events [42]. The main principle focus, of the RCN patient safety initiatives was on the impact that nurse staffing levels could potentially have on health. A guideline was published by the RCN on safe nurse staffing levels in the UK [43-44]. The NMC standard number 36 for pre-registration nursing education states that "Knowledge on management of adverse drug events, adverse drug reactions, prescribing and administration errors and the potential repercussions for safety" – is required, however there is no specific information on how this can be achieved in the education of the nursing student [45]. In the North East of England, UK, the organisation – Health Education North East, has a faculty of patient safety, which works across a region in England aimed at delivering education based on the needs of the patients as well as curriculum requirements in order to improve patient care. Examples of some of the initiatives from the faculty include guidelines for healthcare-related undergraduate students to recognise and initially treat sepsis and recognise acute kidney injury [46].

Finally, near misses and the study of these events, is equally as important as studying and investigating major (serious and fatal) adverse events [47]. A recent study from aviation has suggested that commercial airlines can benefit from learning from all near misses rather than certain near misses that are considered important. Although this is considered labour and resource intensive, they can theoretically, offer a mechanism for continuing safety improvements, above and beyond learning gleaned from observable adverse events [47].

## 3. Summary and the way forward

In order for medication and patient safety to move forward and improve, a change of culture is required from not just organisations but the public with regards to the fact that to “err is human” and that there are often many causes contributing to the occurrence of an error. It can be seen through the media that there is still public interest in the prosecution of the person at the end of the chain of error. Little is done however to examine the cause of the error using a holistic approach which will examine the root cause and organisation factors that may have contributed to the error. This, along with the fear of healthcare professionals reporting medication error, means that there is a possibility that learning opportunities from black boxes are being concealed. It is important to note that there needs to be a thorough and open investigation to highlight the potential multifactorial cause of error and that fear of prosecution among staff and carers being blamed for negligence before the end of the investigation may hinder the identification of the causes. The results of these investigations also require reporting and publishing so that similar events do not happen in other organisations that may have the same adverse event risk due to human factors.

Further research is required to identify a black box in healthcare which can take shape as an open loop system that can potentially give investigational teams access to the exact situation when a potentially serious error occurs. The black box can be used to create simulations of real life scenarios to train future healthcare professionals to operate safe and effectively which can be incorporated into the curriculum. The black box should include a method of recording and retrieving the events that lead to medication errors during the prescribing, supply and administration process, without

the potential of being tampered with. As it is not known what the nature of the potential errors will be, it will need to be sensitive and flexible to capture the error and event holistically. An investigational team would ideally be independent from the organisation and should have a robust method of keeping record of the incident investigations in the form of a repository. Finally, there should be national and global initiatives to enable healthcare professionals across the globe to learn from errors. The theme of the WHO 3rd Global Patient Safety Challenge is medication safety and is due to be launched in the first quarter of 2017 [48]. The aim of the Challenge is to reduce the harm associated with medication through greater involvement and commitment by professional bodies and governments. There is a need to address medication safety and a black box recording system to address the medication safety issue in patients, in particular in pediatrics.

## Compliance with ethical standards

All authors CH, ICKW, JC-W, DT and SM declare that they have no conflict of interest and all authors did not receive any financial assistance to construct to conduct this current opinion review nor with the preparation of the manuscript. No funding was received to prepare this article.

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**Table 1 – comparison of adverse event management in aviation and healthcare (adapted from Kapur et al 2016 [19])**

| | **Aviation** | **Healthcare** |
|---|---|---|
| **Adverse event** | - Major adverse events are always investigated by a national body<br><br>- Major adverse events are often featured in the media<br><br>- Pilot immunity is often part of the reporting culture<br><br>- Adverse event investigation reports are always published. | - Major adverse events are usually only investigated at a local level within the organisation, though may occasionally be subject to a wider investigation<br><br>- Major adverse events only occasionally feature in the media<br><br>- Immunity is not necessarily part of the reporting culture, and disciplinary procedures are wide-ranging<br><br>- Adverse event investigation reports are seldom published |