Reported medication events in a paediatric emergency research network: sharing to improve patient safety

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ABSTRACT

Objective Medication errors are an important cause of preventable morbidity, especially in children in emergency department (ED) settings. Internal use of voluntary incident reporting (IR) is common within hospitals, with little external reporting or sharing of this information across institutions. We describe the analysis of paediatric medication events (ME) reported in 18 EDs in a paediatric research network in 2007–2008.

Methods Confidential, deidentified incident reports (IRs) were collected, and MEs were independently categorised by two investigators. Discordant responses were resolved by consensus.

Results MEs (597) accounted for 19% of all IRs, with reporting rates varying 25-fold across sites. Anti-infective agents were the most commonly reported, followed by analgesics, intravenous fluids and respiratory medicines. Of the 597 MEs, 94% were medication errors and 6% adverse reactions; further analyses are reported for medication errors. Incorrect medication doses were related to incorrect weight (20%), duplicate doses (21%), and miscalculation (22%). Look-alike/sound-alike MEs were 36% of incorrect medications. Human factors contributed in 85% of reports: failure to follow established procedures (41%), calculation (13%) or judgment (12%) errors, and communication failures (20%). Outcomes were: no deaths or permanent disability, 13% patient harm, 47% reached patient (no harm), 30% near miss or unsafe conditions, and 9% unknown.

Conclusions ME reporting by the system revealed valuable data across sites on medication categories and potential human factors. Harm was infrequently reported. Our analyses identify trends and latent systems issues, suggesting areas for future interventions to reduce paediatric ED medication errors.

INTRODUCTION

Children are particularly susceptible to medication errors, especially prescribing errors, because calculations are required based on weight, which varies 30-fold in a child's lifetime.[1–4] In addition, emergency departments (ED) are prone to the entire spectrum of medication errors (ordering, delivery, prescription, transcription, dispensing, administration and monitoring) because the environment is highly complex and chaotic, with a high rate of distractions, and medications are often calculated based on an estimated weight.[5–11] Studies reviewing ED medical records have reported a range of 9–31 prescribing errors per 100 orders in paediatric patients.[2 9 12 13]

Incident reporting (IR) is widely used in US hospitals, but these details are rarely shared outside of individual institutions. Analysis of the type and severity of errors, medications involved, and the human or systems' factors contributing to these errors offers a unique opportunity for hospitals to benefit from this information, especially if the errors are classified in a standardised manner and shared systematically. The objective of this study was to create a standardised method to share and analyse medication events (ME), and subsequently describe paediatric medication errors reported in a national research network.

METHODS

Eighteen EDs within the Pediatric Emergency Care Applied Research Network (PECARN) participated in a 1-year study (July 2007–June 2008) and sent deidentified ED-related incident reports (IRs) to the PECARN central data coordinating centre (DCC). PECARN is a federally funded network of hospitals with broad geographic representation and a diversity of hospital types and patient populations. Ten of the 18 hospitals are freestanding children's hospitals. Detailed descriptions of the PECARN EDs were previously reported.[14–16] Current state and staff perceptions of patient safety in these EDs have been described.[10]

We performed a qualitative study of IRs, which were defined in scope and reporting mechanisms by the standard hospital policy at each institution. The types of IRs, methods for reporting IRs (electronic or paper-based), person responsible for reporting IRs and the format of the IRs varied substantially among the participating EDs. Therefore, we developed a comprehensive manual of operations for IR reviews, including detailed descriptions of study processes, taxonomy and definitions. IRs were entered into the PECARN DCC and were deidentified by site. We excluded incidents if the patient was 18 years of age or older, if the incident did not occur in the ED, if the incident did not involve a patient or an individual accompanying a patient, or if the report was a duplicate.

The investigators (independent primary and secondary reviewers for each IR) were all trained by the primary investigators (PIs) at an in-person network meeting and during conference calls. Training included review of taxonomy, the database and manual of operations for classification.

Discordant responses from reviewers, including incident type, subtype, severity and staff involved, were reviewed and discussed at monthly investigator telephone conferences until consensus was reached.

Based on a review of available medical error taxonomies[17–22] and expert consensus, we developed a classification system for ED IRs. Each deidentified IR was first categorised by type (MEs, behaviour, radiology, blood product, environmental safety, equipment/medical device, fall, laboratory, medical procedure, process variance, unknown and other incidents), followed by severity, personnel involved and contributing factors.

MEs, including those involving intravenous fluids, were further classified into medication errors and adverse events without error (eg, allergic reaction in a patient without known allergies). Medication errors were classified as wrong dose, wrong medication, wrong route, wrong patient, delayed or missed dose, event involving a drug allergy (when allergy was known), or other medication-related error. We used the National Coordinating Council for Medication Error Reporting and Prevention classification to assign severity of the ME[19] as follows: unsafe conditions, near-miss events due to either chance or active intervention, events that reached the patient without harm, events that reached the patient with harm ranging from temporary to death, and events with unknown severity. Reviewers also noted the specific medication involved, staff involved and contributing factors when documented in the IR. In cases where two medications or two patients were involved, we performed separate analysis of each event. Corrective action taken as a result of the IR was generally unavailable and, therefore, was not abstracted. Contributing factors included one or more of the following for each incident: human provider, equipment, environmental, information technology systems, patient or guardian or other systems.

Descriptive statistics were used to present the proportion of ME types, severity, staff involved and contributing factors. Cochran–Mantel Haenszel tests were used to test for associations between type of ME and severity of patient injury adjusting for correlation within-site. A significance level of 0.05 was used for all statistical tests. Data analyses were performed using SAS/STAT software (V.9.2, SAS Institute Inc, Cary, North Carolina, USA). The institutional review boards for all participating hospitals and the data centre approved the study.

RESULTS

From the study year, 3106 IRs were submitted, and 597 (19%) involved MEs. The presence of pharmacists in the ED (three sites) did not correlate with higher IR rates. All MEs were considered to have occurred due to medical errors except 36 (6%); 17 adverse reactions and 19 newly discovered allergies to medications. Types of MEs reported are listed in table 1.

The most commonly reported MEs were: wrong dose, incorrect medication and delayed or missing doses. Wrong medication doses were most often related to incorrect weight (20%; eg, pounds instead of kilograms or other incorrect weight used, such as the patient's temperature recorded as the weight, or an estimated weight or weight documented from another hospital that proved incorrect), duplicate doses (21%), and calculation errors (22%) (including decimal point errors (5%), failure to divide daily dose (3%), calculations exceeding maximum doses (4%), and other calculation errors (10%)). Over one-third (36%) of incorrect medications were related to look-alike/sound-alike medications, including incorrect intravenous fluids. The categories of medications involved in the reported MEs are listed in table 2.

Table 1 Type of medication events

	n (%)
Category or subcategory	
Allergy	44 (7)
Failure to heed noted allergy	21
Unknown allergy	19
Other	4
Delayed or missed dose	94 (16)
Adverse reaction	17 (3)
Altered vital signs	4
Altered behaviour or mental status	2
Other/unknown adverse reaction	11
Wrong dose	235 (39)
Calculation error	51
10-fold error	12
Maximum dose exceeded	10
Failure to divide total daily dose	6
Other calculation error	23
Wrong weight	47
Wrong weight (pounds vs kilograms)	28
Wrong weight (other)	19
Duplicate dose	50
Other/unknown	87
Wrong medication	104 (17)
Look-alike, sound-alike	37
Intravenous solutions	18
Automatic medication dispensing machine drawer error	9
Other/unknown wrong medication	40
Wrong patient	34 (6)
Wrong route	6 (1)
Other	63 (11)

The most commonly reported ME medications were anti-infective agents and analgesics, followed by intravenous fluids and medications used to treat respiratory conditions, such as albuterol and oral corticosteroids. Severity of the injury to patients could be determined in 91% of incidents (table 3).

No deaths or permanent disability occurred as a result of the reported MEs. Approximately half the reported incidents

Table 2 Categories of medications involved in events

	n (%)
Anti-infective	148 (25)
Analgesics	124 (21)
Intravenous fluids	72 (12)
Respiratory	64 (11)
Unknown	31 (5)
Cardiovascular	26 (4)
Sedatives	25 (4)
Other	21 (4)
Anticonvulsants	17 (3)
Antihistamines	15 (3)
Antidiabetics	13 (2)
Gastrointestinal	12 (2)
Hormones	8 (1)
Anaesthetics	7 (1)
Contrast	7 (1)
Blood modifiers	4 (1)
Vaccine	4 (1)
Psychotherapeutic	3 (1)
Migraine medicines	3 (1)

Table 3 Severity of medication events

	n (%)
1. A. Unsafe condition	35 (6)
2. B. Near-miss event	146 (25)
B1. Near-miss (chance)	2
B2. Near-miss (active recovery efforts)	144
Not categorised further	0
3. Event without harm	282 (47)
C. No harm, no increased monitoring	164
D. No harm, increased monitoring	89
Not categorised further	29
4. Event with harm	78 (13)
E. Temporary harm, required treatment	68
F. Temporary harm, required (prolonged) hospitalisation	9
G. Permanent harm	0
H. Near death	0
I. Death	0
Not categorised further	1
Unknown impact on patient	56 (9)

reached the patient, but did not cause harm, and an additional third were near-miss events or unsafe conditions. Temporary patient harm occurred in 13%. After adjusting for hospital centre, events involving patient harm were more likely to be adverse reactions, allergy-related events, or delayed or missed doses (Cochran–Mantel Haenszel $p<0.001$) types.

ME reports yielded varying degrees of qualitative information about the human factors involved in these incidents across the network. Examples are listed in table 4, demonstrating different error mechanisms. Reviewers were able to extrapolate contributing factors for most reports based on the text provided in 93% of IRs, but only 45% of reports had the contributing factors clearly listed as a routine part of the report. Human factors were documented in 85% of reported MEs, most commonly failure to comply with established procedures (41%), communication failures (20%), and errors in calculation (13%) or judgment (12%). Systems factors were specifically identified as contributing factors in only 11% of reports. Equipment (4%) or information systems problems (4%) were uncommon.

DISCUSSION

The standardised method of sharing ME and our classification system were able to give us important data from 18 hospital EDs demonstrating the types of events, with high rates of discernible contributing factors. Although most incidents reported did not cause harm, the qualitative analysis of precursor events (unsafe conditions, near misses and events without harm) did provide important contextual information concerning the situations and human factors contributing to errors,[23] and can be used to redesign processes and improve safety behaviours to prevent errors in the future. For example, a 10-fold overdose of amoxicillin is unlikely to cause significant harm, but the same safety behaviour and drug delivery process that allowed such an error could be fatal in the delivery of morphine or digoxin, unless these are corrected.

IR and analysis have been used successfully in other high-risk industries to identify near misses and latent errors in order to improve systems, and can be applied to patient safety.[24] A significant barrier has been the unwillingness of hospitals to share incident data because of liability concerns. We have successfully addressed these concerns in this research network, allowing the sharing of confidential risk management data.

Due to the recognised under-reporting through voluntary IR systems, we must also consider identification of errors through other methods, including the use of trigger tools for specific medication issues, enhanced reporting rates by improving the culture or safety, or incentives to staff. Better data may involve the use of common formats for reporting, such as used by Patient Safety Organisations and the Agency for Health Care Research and Quality. EDs must become high-reliability organisations (HROs), managing risk in a highly stressful, fast paced and changing environment.[25] HROs are preoccupied with their failures, learn from their mistakes, and improve their operations based on their errors. Sharing of information and stories across institutions is one important step to help change ED culture to focus on patient safety.

The most common ME for children in IRs from across our ED network was failure to determine the correct dose (39%), often related to calculation errors or use of the wrong weight. These findings support a standard approach across all EDs for medications, such as the proposal by the American Academy of Paediatrics for a National Quality Forum quality metric. The recommendation is for EDs to be evaluated by the proportion of children less than 18 years of age whose weight is recorded correctly in kilograms. The literature suggests that medication prescribing in paediatrics is the most common type of error because it requires manual dosing with calculations based on weight.[1–3 26] Studies looking specifically at medication errors for children in teaching hospital EDs have found in-house prescribing errors in 8.7%–12.5% of orders, with 1.6%–8.7% due to wrong dose; ED prescribing errors increase when the child is seriously ill or injured with rates of 11%–20%.[12 27]

Table 4 De-identified examples of medication event reports

	Medication subtype	Severity	Contributing factors
ED nurse reports finding a vial of sennoside in the automatic medication dispensing drawer bin that should contain ibuprofen	Wrong drug; look-alike packaging	Unsafe condition (A)	Human error; look-alike medications
Physician ordered 0.5 mg/kg of dilaudid. Order was co-signed by another physician. Intercepted by nurse	Wrong dose; decimal point error	Near miss, active intervention (B2)	No CPOE with decision support; human error; second physician did not calculate dose independently
Physician ordered 200 mg/kg of ampicillin. Medication administered.	Wrong dose; failure to divide total daily dose	Reached the patient; no harm (C)	Human error; supervision of trainees; lack of nursing dose check.
Twice the intended dose of ketamine given to a 4-year-old child for sedation; error noted and patient monitored	Wrong dose; pounds versus kg error	Reached the patient; no harm but required increased monitoring	Nurse weighed patient and told parents the weight in pounds when asked; entered weight in pounds instead of kilograms in CPOE
Patient given ibuprofen despite known allergy; had swelling of eyes and face and wheezing	Allergy; failure to heed noted allergy	Reached the patient; required treatment and admission (E)	Human error; 'alert fatigue' in CPOE; nurse did not confirm allergy status prior to administration

ED, emergency department; CPOE, computerized physician order entry.

Incidents where children received the wrong medication were the second most commonly reported ME. Over half these IRs involving wrong medication were related to look-alike (including intravenous fluid bags) or sound-alike medication errors. Many of the remaining MEs reported included failure to give the medication at the right time (delayed or missed doses), to the right patient, and less commonly, by the right route. The literature and reports from our network suggest that simply holding providers 'accountable' or more 'vigilant', and asking them to confirm the 'five rights' of medication safety will not be sufficient to guarantee reasonable safety in medication as consistently as we really want for patients.[28] Vigilance supports a system that will leave us with a defect rate of approximately one in 10. To achieve the next level of reliability, the use of independent double checks/verification, particularly on high-risk medicines, catches a good number of errors that one vigilant provider may make, and has been shown to improve reliability to closer to one in 100 defects.[29]

Human factors were found to be the contributing factor in MEs in over 80% of reports, including failure to comply with standard procedures, and failure to adequately communicate. This may partly reflect the fact that reporting in an IR system tends to emphasise human elements and, too often, blame. However, our results are consistent with the Unites States Pharmacopeial (USP) Center for the Advancement of Patient Safety report of MEDMARX data from EDs over a 5-year period; the top five causes for errors in the ED were related to human error (performance deficit, procedure/protocol not followed, documentation, communication and knowledge deficit).[30] Similarly, the most common contributing factor to ME reports across our network was the failure of ED staff to comply with established procedures. Duplicate dosing, another major cause of wrong dose errors in our study, are predominantly due to communication problems in the ED environment.[31 32] EDs are particularly prone to medication error from human factors, as the environment is highly complex and hectic.[5 7 33] In particular, medication errors are more common when ED census is high[8] and when patients are sicker.[13 27] Fatigue, level of experience or training, and ineffective teamwork have all been found to be associated with increased error.[3 6 24] Reducing distractions and workload may also be key to preventing medication errors in EDs.[11] Effective error prevention and mitigation strategies will require careful attention to reducing these latent errors (ie, unsafe conditions).

It is important to understand the limitations of this study. First, and most importantly, IR is voluntary and clearly does not reflect the real medication error rate. Second, across the network, there was wide variation of reporting rates. It is unclear how much of this represents a difference in reporting culture, use of alternative reporting paths, or true differences in medication error rates.[10] Third, in many cases, we could not determine whether medication errors were related to prescribing, transcribing, documenting, dispensing, administration or monitoring. This is a weakness of the current IR systems in most institutions, which may be improved with implementation of AHRQ's common format. Fourth, local institutional review of IRs in detail may be in use for IRs, but our study did not have access to any of that data that may have better delineated human factors or systems issues around the ME. IRs offer descriptive, qualitative data on MEs throughout the network, but may not reflect the actual distribution of ME type or severity. MEs with harm across the hospitals reporting in the network are likely to be under-represented due to use of other methodologies for such reports, including direct contact with risk management, root cause analyses, or morbidity and mortality conferences. Understanding if the rates of common MEs are proportionate to rate of prescribing in departments was not available for this study. We could not analyse data about medications associated with higher harm scores, as others have noted in previous studies,[34] because we did not have such events reported. Fifth, it is clear that the substantial variation in the format and level of detail provided in hospital-specific IRs across the institutions limited our ability to identify human factors or systems issues for every report. Finally, there was almost no data provided about safety improvements made in response to reported events.

CONCLUSIONS

ME reporting through hospital IR systems in a paediatric ED network has been able to give us important qualitative data, which can be used to improve medication safety at our institutions and elsewhere. Based on data from this national network of EDs, areas for focused interventions should include correct recording of children's weight in kilograms, providing decision support for calculations, labelling for look-alike/sound-alike medications, and improving latent conditions to reduce human error. The distribution of severity included precursor reports, many with no harm and few with significant harm. The introduction of the common format for IR of critical medication errors, a shared reporting system in networks, and an improved culture of safety and reporting would improve data on safety events.

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