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Characterising the types of paediatric adverse events detected by the global trigger tool - CareTrack Kids

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Patient safety, paediatrics, global trigger tool, adverse events

Abstract

Introduction

A common method of learning about adverse events(AEs) is by reviewing medical records using the global trigger tool(GTT). However, these studies generally report rates of harm. The aim of this study is to characterise paediatric AEs detected by the GTT using descriptive and qualitative approaches.

Methods

Medical records of children aged 0-15 were reviewed for presence of harm using the GTT. Records from 2012-2013 were sampled from hospital inpatients, emergency departments, general practice and specialist paediatric practices in three Australian states. Nurses undertook a review of each record and if an AE was suspected a doctor performed a verification review of a summary created by the nurse. A qualitative content analysis was undertaken on the summary of verified AEs.

Results

A total of 232 AEs were detected from 6,689 records reviewed. Over four-fifths of the AEs (192/232, 83%) resulted in minor harm to the patient. Nearly half (112/232, 48%) related to medication/intravenous(IV) fluids. Of these, 83% (85/112) were adverse drug reactions. Problems with medical devices/equipment were the next most frequent with nearly two-thirds (32/51, 63%) of these related to intravenous devices. Problems associated with clinical processes/procedures comprise one in six AEs (38/232, 16%), of which diagnostic problems (12/38, 32%) and procedural complications (11/38, 29%) were the most frequent.

Conclusion

Adverse drug reactions and issues with IVs are frequently identified AEs reflecting their common use in paediatrics. The qualitative approach taken in this study allowed AE types to be characterised, which is a prerequisite for developing and prioritising improvements in practice.

Introduction

A high-quality health system should deliver care that is free from avoidable harm to patients. However, despite 20 years of focus by policy makers, clinicians and researchers, patients continue to suffer adverse events.¹ Most studies on adverse events are focussed on adult care.^{2,3} However, increasingly, care for children is being studied. For example, in children, seven studies in five countries show rates of hospital admissions associated with an adverse event to range from 5 to 34%.⁴⁻¹⁰ In three studies, where measured, adverse events are estimated to be preventable in 44%, 50% and 78% of cases.^{5,8,9} Few studies of adverse events have been undertaken in children's healthcare in Australia.^{2,11}

One method that has been used to detect, count and characterise adverse events is medical record review.¹² One medical record review technique is the Institute of Healthcare Improvement's (IHI) Global Trigger Tool (GTT) which was developed for use in hospitals.¹² The GTT uses occurrences, prompts or flags ("triggers") that may suggest an adverse event has occurred and serve as a cue for reviewers to investigate further.¹² The GTT is modifiable and has been adapted for use by customising sets of triggers in paediatric hospitals, neonatal intensive care units, paediatric intensive care units, paediatric otolaryngology and primary care.^{4-7, 10, 13-19}

Studies on adverse events in children using the GTT have focussed mainly on counting harm rather than characterising events.^{4,6,7,10} They describe the severity of harm, the triggers and their positive predictive values.^{4,6,7,10} However, we do not understand, in detail, the incident types that children are exposed to, and are detected by, the GTT.

The CareTrack Kids program was designed to determine the quality of care of Australian children aged 0 to 15 years received for 17 common conditions from a range of Australian paediatric healthcare practice types (hospital, general practice and specialists) over a two year period from 2012 to 2013.²⁰ The CareTrack Kids findings have been reported elsewhere.²⁰ As a related study to CareTrack Kids, this study set out to characterise paediatric adverse events detected with the GTT, using descriptive and qualitative approaches, which are related to at least one of the 17 CareTrack Kids conditions.

Methods

The main stages of the study are outlined below. Inclusion criteria were determined, health services were recruited and sampled, medical records were sampled, and then data collected and analysed. Further details of the sampling strategies are provided in our paper outlining the results of assessing the quality of care delivered to children in Australia.²⁰

Inclusion criteria

Children aged <16 years who were managed for at least one of 17 CareTrack Kids conditions were included in the study. CareTrack Kids conditions were identified on the basis of published research,^{21, 22} burden of disease,²³ prevalence, frequency of presentation and national priority areas.²⁴⁻²⁶ The 17 conditions were: *acute abdominal pain, acute bronchiolitis, acute gastroenteritis, anxiety, asthma, attention deficit hyperactivity disorder (ADHD), autism, croup, depression, diabetes, eczema, fever, gastro-oesophageal reflux disease (GORD), head injury, otitis media, tonsillitis, and upper respiratory tract infection (URTI)*.²⁰

Sampling strategy

A multistage, randomised stratified sampling plan was designed.²⁰ Three Australian states (Queensland, New South Wales and South Australia) which comprise 60% of the Australian population aged <16 years were sampled. Care provided to children as inpatients, in emergency departments, general practice, and specialist paediatric practices was assessed. A pre-specified number of medical records was selected from each healthcare provider type, which aimed to achieve the initial sampling target of 400 per condition; *anxiety* and *depression* were treated as a single condition for sampling purposes.

Recruitment of health care providers

Health care providers were recruited by direct mail, telephone and face-to-face contact. Within the selected states, we targeted all hospitals that had the minimum patient volumes;²⁷ 34 of 37 (92%) of eligible hospitals that were approached agreed to participate.²⁰ General practices and specialists paediatric practices were recruited through advertising, internet searches, and personal contacts; non-responses and refusals were not tracked, so response rates cannot be calculated.

Sampling of medical records

Health care providers sent to the researchers electronic lists of medical record numbers of patients whom they identified as having one of the CareTrack Kids conditions from the ICD-10-AM (International Classification of Diseases, Tenth Revision, Australian Modification), SNOMED (Systematised Nomenclature of Medicine), or their own classification system in their patient management system. The study team then randomly selected patient record numbers from these.

Data collection and associated tools

We used a modified version of the GTT to collect data. GTTs use a series of ‘triggers’ to screen a medical record for a potential adverse event. The presence of a trigger signals the need for an in-depth review.

Collate and ratify triggers

Triggers applicable to Australian paediatric healthcare settings were developed. We searched the literature to collate existing paediatric tools and triggers^{5-8, 10} and generated three lists of candidate triggers - one for hospital use (encompassing emergency department visits and inpatient admissions), one for general practices and one for specialist paediatric practices. Using a two-round Delphi process, 15 specialist paediatricians and 5 general practitioners voted on the most applicable triggers within the three lists. The final three lists of triggers are shown in Appendix 1.

Data collection tool

A module was added to a web-based tool developed for the CareTrack Australia study²⁷⁻³⁰ to include the collection of adverse events. The tool enabled data to be entered during the review of the medical records and enable subsequent data analysis. The tool was hosted on dedicated laptop computers which supported secure data access, data encryption, offline data collection and subsequent database synchronisation to mitigate against the problems of fire walls and poor internet connectivity in various healthcare settings.

Surveyors and reviewers

Two types of researchers were involved in the data collection: ‘surveyors’ and ‘medical adverse event reviewers’. Nurses were employed to simultaneously act as surveyors for this study and the parallel study of appropriateness of care.^{20, 27} Nine surveyors, all experienced

registered paediatric nurses, were engaged across the three states, and underwent five days of training and competency assessment. Surveyors reviewed medical records manually on-site at each healthcare provider during March–October 2016. As healthcare providers were separated by up to 3,000 kilometres, the standard GTT protocol of two nurses assessing each record¹² and assessment of inter-rater reliability between surveyors on real records was not feasible. Medical practitioners were recruited as ‘medical adverse event reviewers’ to undertake a confirmation review of the information collected and recorded by the surveyor.

Data collection process

Surveyors conducted reviews of medical records using all available information relating to patient visits or admissions including discharge summaries, tests and investigations and letters.¹² Medical records relating to the calendar years 2012-2013 were reviewed. For hospital inpatient admissions and emergency department presentations, one index admission or presentation related to the CareTrack Kids condition was reviewed. If a child had more than one admission in the two-year period, a random number was generated and the notes for the corresponding visit were reviewed. For general practices and specialist paediatric practices, all admissions associated with CareTrack Kids conditions were reviewed. The surveyors did not have access to healthcare providers’ incident reporting systems.

If a surveyor did not detect any triggers, the review was considered complete. If one or more triggers were detected, the surveyor undertook an in-depth review of the record to search for adverse events. If a surveyor detected a potential adverse event, they recorded it. The medical adverse event reviewer was then notified, securely entered the web-based tool, reviewed the information supplied by the surveyor, and provided a judgement on the presence of an adverse event.

Data fields

If a trigger was positive within a medical record, the following data fields were recorded: positive trigger: a free text field describing the circumstances of the potential adverse event; a description of the healthcare provider type that the adverse event primarily originated (community was added for adverse events that occurred outside of formal healthcare provider facilities e.g., an insulin pump failure at home); incident type from the WHO’s International Classification for Patient Safety (ICPS);³¹ and level of outcome or severity using the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) scale.³²

Analysis of data

A qualitative content analysis was undertaken,³³ which allowed both deductive and inductive analytic approaches to be incorporated. For this analysis, we followed the items in the Standards for Reporting Qualitative Research: A Synthesis of Recommendations (SRQR)³⁴. Two researchers (PH, AD) undertook the analysis. Both researchers had over 15 years of experience reviewing and analysing patient safety data including incident reports, coroner's reports, root causes analysis reports, and medico-legal claims. The descriptive reports of the adverse events written by the surveyors in the three most frequently occurring incident types (Table 1) were analysed separately. The two researchers iteratively read each adverse event and extracted themes or concepts related to the relevant incident type, and then developed consensus.³⁵ Different themes were developed for each incident type and were described.

The reasons for not attempting to measure rates of harm were that: the GTT protocol states that the tool is not designed to collect all adverse events;¹² the highly disparate rates of adverse events reported in studies and the reasons for these differences are methodological differences and disparate reviewer interpretations;² data were collected from different types of healthcare providers types; the adverse events had origins in different healthcare providers so a denominator was not able to be calculated; and the GTT should be used primarily as a method to characterize the most frequent types of adverse events for prioritization for quality improvement.^{2, 36, 37}

Ethical Approval

Ethics approval was obtained from hospital networks and individual hospitals in each sampled state (Sydney Children's Hospital Network: HREC/14/SCHN/113, Children's Health Queensland Hospital and Health Service: HREC/14/QRCH/91, Women's and Children's Health Network: HREC/14/WCHN/68), and the Royal Australian College of General Practitioners (NREEC 14-008). Australian human research ethics committees can waive requirements for patient consent for external access to medical records if the study entails minimal risk to facilities, clinicians, and patients; all relevant bodies provided this waiver. Ethical approvals for this study do not permit reporting of overall performance by health care provider. Participants were protected from litigation by gaining statutory immunity for this study as a quality assurance activity from the Federal Minister for Health under Part VC of the Australian Health Insurance Act 1973.

Results

A total of 232 adverse events were collected by surveyors and ratified by medical reviewers from 6,689 records. Nearly half of the adverse events related to medication/intravenous (IV) fluids (112/232, 48%)(Table 1). Medical devices/equipment was the next most frequently recorded incident type with nearly two-thirds (32/51, 63%) of these adverse events related to problems related to IV devices such as infiltration (not shown in tables). The most frequent CareTrack Kids condition where management of the condition was directly associated with an adverse event was diabetes (22/232, 9%)(not shown in tables).

Table 2 describes the origin of the adverse events by healthcare provider type. Nearly half (109/232, 47%) originated in hospital. For specialist paediatricians and general practices, most adverse events related to medication (21/22 (95%) and 52/59 (88%) respectively). For hospitals, medical devices/equipment comprise 42% (46/109) of adverse events, compared to 22% (51/232) of all adverse events. Clinical process or procedure problems comprised one in six of all adverse events (Table 1, 38/232, 16%) but more than one in three of those in emergency departments (11/29, 38%). Over half of clinical process or procedure (6/11, 55%) adverse events in emergency departments related to diagnosis or assessment and over half (12/21, 63%) in hospital inpatients related to procedures or treatments (not shown in tables).

Table 1: Adverse event incident types (n, %)

Incident types	Total	%
Medication/IV Fluids	112	48
Medical Device/Equipment*	51	22
Clinical Process/Procedure^	38	16
Healthcare Associated Infection	12	5
Patient accidents	9	4
Behaviour	4	2
Falls	3	1
Resources/Organizational Management	2	1
Clinical Administration	1	<1
Total	232	100

* Associated with equipment insulin pumps, tourniquet use, intravenous catheters

^For example, diagnostic error or procedural complications

Table 2: Adverse event origins and incident type (n, %), three most frequent incident types

	Hospital inpatients	General practice	Emergency department	Specialist paediatric	Community	Total
	25 (23)	52 (88)	12 (42)	21 (95)	2 (15)	112 (48)

Medical Device/Equipment	46 (42)	0 (0)	1 (3)	0 (0)	4 (31)	51 (22)
Clinical Process/Procedure	21 (18)	4 (7)	11 (38)	1 (5)	1 (8)	38 (16)
Other	17 (17)	3 (5)	5 (17)	0 (0)	6 (46)	31 (14)
Total	109 (100)	59 (100)	29 (100)	22 (100)	13 (100)	232 (100)

There were three adverse events in the highest severity categories G and H (Table 3). These related to: a difficult intubation of a child needing resuscitation, leading to a cardiac arrest; delay in diagnosis of a brain tumour; and bilateral methicillin-resistant *Staphylococcus aureus* (MRSA) otitis media acquired in a paediatric intensive care unit. Of the 36 Category F adverse events, 40% were clinical process/procedures (compared with 16% of all adverse events), about one quarter related to medication/IV fluids (8/36, 24%) compared with 48% of all adverse events, and one-sixth (6/37, 16%) comprised healthcare associated infections, compared with 5% of all adverse events.

Table 3: NCC MERC Index of severity ratings (n, %)

Category	n	%
Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	193	83
Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	36	16
Category G: An error occurred that may have contributed to or resulted in permanent patient harm	1	0
Category H: An error occurred that required intervention necessary to sustain life	2	1
Total	232	100

Medication adverse events

The most frequent medication adverse event was adverse drug reactions (93/112, 83%) followed by “wrong dose” (7/112, 6%). Table 4 outlines the frequency of adverse drug reactions by known medication class. Over half relate to antibiotics (41/76, 54%) (see Table 5, AE#1 for an example) with the next most frequent class being central nervous system (CNS) stimulants (13/76, 17%) (Table 5, AE#2) and vaccination (13/76, 12%). These three classes comprise 83% of the adverse drug reactions. Of the antibiotic adverse drug reactions, over half related to the management of otitis media (12/41, 30%) or tonsillitis (10/41, 24%) (not shown in tables). For the CNS stimulant ADRs, 11/13 were for the management solely of ADHD, with the remaining two being for a combination of ADHD and autism.

Table 4: Medication class of adverse drug reactions (number and %)*

Medication class	n	%
Antibiotic	41	54
Central nervous system stimulant	13	17
Vaccination	9	12
Selective Serotonin Reuptake Inhibitor	2	<3
Steroid	2	<3
Anaesthetic	1	<2
Analgesic	1	<2
Anticonvulsant	1	<2
Anti-psychotic	1	<2
Contraceptive	1	<2
Laxative	1	<2
Paracetamol agonist	1	<2
Proton pump inhibitor	1	<2
Psychotropic agent	1	<2
Total	76	100

* The medication class of 17/93 or 18% of adverse drug reactions was unknown

Table 5: Descriptors of examples of adverse events (AE)

AE#1: Medication – adverse drug reaction	<p>Patient was a 2 year old female. Quote from the medical record: "patient halfway through IV flucloxacillin dose, onset of pruritis++ and cough - scratching 'like mad' "</p> <p>Patient has had increased itch with previous doses of flucloxacillin with the onset of symptoms ~5-10minutes after starting administration. This dose was different with the itch being unbearable and the new symptom of cough.</p> <p>This was Day 2 of IV flucloxacillin - dose 6. There was no mention in the nursing notes of itch during previous doses although evening shift on day one stated that patient would not settle until IV antibiotics were finished.</p> <p>IV flucloxacillin ceased after resident medical officer review as above.</p>
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<p>AE#2: Medication – adverse drug reaction</p>	<p>A 9 year old boy was previously diagnosed with ADHD and prescribed short acting methylphenidate (Ritalin) 10mg bd with symptoms well controlled. The boy was seen by paediatrician who ceased the short acting methylphenidate and commenced him on a trial of extended release methylphenidate (Concerta) 27mg OD. One week later, the boy attended the general practitioner complaining of nausea, vomiting, abdominal pain, headache, insomnia, and audible hallucinations.</p> <p>The boy’s parents had already ceased the medication after 2 days before attending the general practitioner.</p> <p>The paediatrician was unavailable as they were on leave for 1 month. The general practitioner prescribed a trial of long-acting methylphenidate (Ritalin LA) 20mg OD. 3 months later, the GP noted that the long-acting methylphenidate (Ritalin LA) was ceased as ineffective and patient was recommenced on prescribed short acting methylphenidate ritalin 10mg bd by general practitioner and re-referred to paediatrician at that visit.</p>
<p>AE#3: Equipment – intravenous</p>	<p>A 2 year old female patient was triaged on [date] in the emergency department for an infected intravenous catheter (IVC) site to right foot following discharge from [other hospital]. A registered nurse noted "tender red swollen ankle outer aspect, post recent IVC insertion under admission to [other hospital] for immunology work up. The IVC was removed and the patient was discharged yesterday. Patient’s mum noticed swelling, redness and limping this morning." Mum had brought the patient to her local hospital for review. Doctor reviewed and commenced patient on a week of oral sulfamethoxazole and trimethoprim (Bactrim) and flucloxacillin.</p>
<p>AE#4: Equipment – insulin pump failure</p>	<p>Insulin pump failure at home leading to DKA in 22 month old baby. A 22 month old female baby was diagnosed at 16 months with Type 1 Diabetes. The baby had several admissions to hospital for fluctuating blood sugar levels (BSLs). The diabetes was under good control at 22 months but there was an insulin pump failure at home. Mum was unable to closely monitor BSL and baby developed diabetic keto-acidosis. Mum quickly realised problem and took the baby to the emergency department where an insulin infusion was set up and care attended. The baby quickly stabilised and was able to be discharged home with proper equipment.</p>
<p>AE#5: Clinical process / procedure – diagnostic adverse events</p>	<p>Parents took child to general practitioner in morning with symptoms diabetes, including drowsiness, reduced food intake and weight loss of 3 kg over 3 weeks. The general practitioner gave infant anti-emetic and sent child home. Parents became concerned and took child to the emergency department on the same day where he was treated and transferred to a tertiary Hospital. By time of emergency department admission child showing increasing signs of drowsiness and diabetic keto-acidosis. Very close call if relative (who was home with the parents) was not aware of seriousness of child. Child not far from diabetic coma.</p>

AE#6: Clinical process / procedure – procedural complications	16 year old female presented to the emergency department with complaints of bleeding from a surgical wound post-tonsillectomy 5 days previous. Also complained of throat pain and dizziness. On examination, blood pressure was low and a dark clot had formed in right tonsillar fossa. Patient was commenced on antibiotics and transferred to tertiary care facility.

Wrong dose

Seven adverse events involved “wrong dose”, all overdoses. Three overdoses involved teenage patients in diabetic keto-acidosis (DKA); whilst the other conditions (and IV / medications) involved asthma (salbutamol), pneumonia with a complex presentation (sedative), head injury (fluids), and bronchiolitis (gentamicin).

Equipment adverse events

Intravenous catheters access and use

Thirty-two adverse events related to problems with intravenous (IV) access in children aged between 11 days and 15 years (see Table 5, AE#3). Of these, three quarters (24/32, 75%) were associated with infiltration or extravasation of fluid into tissues. Other problems were IV site infection (n=3), multiple attempts at insertion (n=2), re-cannulation injury (n=2) and an IV cannula being *in situ* for six days. The emergency department was identified as being the location of IV insertion for nearly half the adverse events (14/32, 44%).

Insulin pump failures leading to wrong doses

There were four adverse events related to insulin pump failures with patients at home, with three resulting in hyperglycaemia and one DKA (Table 5, AE#4). Patient ages ranged from 22 months to 13 years. Three patients’ signs resolved with management at the emergency department, with one needing to be admitted overnight. There was one other adverse event involving an insulin pump which involved a patient admitted to hospital with hyperglycaemia on a background of cellulitis at the insertion site of insulin pump.

Other equipment adverse events

In 15 adverse events a problem related to medical devices not already reported as IVCs or insulin pumps was identified. These included four adverse events that involved face masks all causing pressure ulcers, skin tears or blisters, and two incidents involved tourniquets, one with a rash and another with pain and discoloration due to being applied too tightly.

Clinical process / procedure adverse events

Diagnostic adverse events

Twelve adverse events involved delayed or failed diagnosis, nearly one-third (12/38, 32%) of the clinical process/procedure adverse events (Table 5, AE#5). Two related to children presenting with multiple complex conditions. The conditions included were acute gastroenteritis, diabetes with previous multiple visits to the general practitioner, brain tumour, head injury, tonsillitis, bronchiolitis, ADHD, respiratory failure, and tracheobronchomalacia (likely treated on seven occasions as croup).

Procedural complications

There were 11 procedural complications (11/38, 29% of the clinical process/procedure adverse events) with six of these related to tonsillectomy or adenotonsillectomy (Table 5, AE#6). Four of these tonsillectomy or adenotonsillectomy adverse events were associated with bleeds; the age range was 3 to 16 years old, and they presented 6-10 days post-operatively. Two other patients aged 4 or less presented unwell post-tonsillectomy, at emergency departments. Two patients had laparoscopic appendectomy complications – one with a fluid collection (presented 4 days post-operatively) and one with vomiting and epistaxis on the same day. A 4-year old patient with presented a large bleed post-operative circumcision on day 2 and then another bleed on day 5. Two other complications were feeling faint and nauseous after a blood test and a breakdown of a gastrostomy button site.

Discussion

In our review of 232 adverse events detected by the GTT, 86% were related to the three most frequently occurring incident types – “medication”, “clinical process/procedure”, and “equipment”. Some three-quarters of these involved only minor harm to the patient. There was a greater proportion of adverse events resulting in higher severity of harm to patients in the clinical process/procedure category (40% vs 16% in all categories).

Incident types frequently reported in this study relate to problems commonly encountered in paediatric emergency departments and hospitals - medications and IV lines/access. Nearly half (48%) of the adverse events in this study were related to medications. Whilst other paediatric GTT studies report medication incidents (Table 6), they are generally related to adverse drug reactions associated with medication triggers of the GTT. These studies do not disaggregate the incident types to identify more specific types such as “wrong dose”. The identification of problems with wrong dose are not surprising, with many drug dosages in paediatrics posing challenges including being calculated individually, based on each patient’s age, weight or body surface area.³⁸

The subject of the World Health Organisation’s Third Global Patient Safety Challenge is Medication Without Harm, and our study has re-emphasised the frequency of occurrence of medication incidents in healthcare. Given that the steps in the medication pathway in hospitals are complex and interconnected, substantial improvements in medication safety require comprehensive systems, human-factors, and technological approaches that integrate all aspects of the medication pathway.³⁹ Our study is also a reminder that medication risks manifest in the community, for example, related to central nervous stimulants for children with ADHD.

Over one in five of the adverse events related to equipment (22%) with nearly two-thirds of these (32/51, 63%) IV lines/access. This is an unusual finding for studies collecting adverse events in the paediatric population using the GTT – the only other study having >5% of adverse events related to IVs was Unbeck et al (2014)(Table 6).⁸ The management of virtually all emergencies involves an IV line, whether for medication, fluids, blood products, or contrast injection.⁴⁰ Although significant harm related to IV was not detected in this study, the extravasation of any IV fluid, site infection, haematoma, and phlebitis can cause serious and potentially permanent harm.⁴⁰ Adverse events associated with IV access are largely preventable, although the safe management of IV lines requires many reliable processes to be undertaken over hours or days.⁴⁰ Our study may point to further quality improvement projects being warranted in emergency departments and inpatient units related to management of IV lines.⁴¹

Table 6: Healthcare setting and incident types as a % of adverse events in paediatric GTT studies for incident types with a greater than 5% frequency in our study^a

Study	Hibbert (2020) – this paper	Chapman (2014) ⁷	Solevag (2014) ¹⁰	Kirkendall (2012) ⁶	Unbeck (2014) ⁸	Matlow (2012) ⁴
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Healthcare setting	Hospital, general practice, specialist paediatrician	Hospital	Hospital	Hospital	Hospital	Hospital
Incident type						
Adverse Drug Events	48	10 ^b	6 ^c	68 ^d	23 ^e	14 ^f
IV problems	14	^g	^g	^g	7 ^h	^g
Non-IV equipment problems	7	^g	^g	^g	^g	^g
Diagnostic issues	5	^g	^g	^g	^g	14 ⁱ
Procedural complications	5	18 ^j	35 ^j	13 ^k	4 ^l	15 ^m
Healthcare associated infections	5	9 ⁿ	19 ^o	11 ^p	15 ^q	^g
Total (%) of AEs related to the main categories in this study	76	37	60	92	49	43
Adverse event types with >5% not in our study		Tissue damage or pressure ulcer (8%) ^r	^s		Skin and blood vessel harm. Thrombophlebitis (17%); pain (21%); transfusion (12%); failures in cardiovascular, respiratory, or neurological function (19%); induced delivery (15%) ^t	Surgical (33%); other clinical management (20%)

a-Studies were included in the table if they accessed “generic” adverse events or incidents in paediatrics. Stockwell et al(2018)⁹ was excluded, because although this study used a comprehensive classification system, it was very different to the system used in Table 6 and there was no congruence between the categories in Table 6 and Stockwell et al (2018)

b- Anti-emetic given, abrupt medication stop, hypoglycaemia (<3mmol/L), drug level out of range, chlorpheniramine given, high INR (>5) or APTT>100s, naloxone given, vitamin K given (except for routine neonatal dose), flumazenil given.

c – hypoglycaemia (<3 mmol/L)

d – Total medication triggers

e - Other side-effect of drug or anaphylactic reaction or unplanned drug withdrawal or naloxone administration, or rising serum creatinine or antidote administration or partial thromboplastin time (PTT) greater than 100 seconds or glucose <3mmol/liter or administration of 300mg/ml or 500 mg/ml glucose or vitamin K administration (excluding newborns) or too high or too low drug concentration

f – Drug

g – equivalent code not used in the study

h - Infiltration/extravasation of intravenous injection/infusion

i – Diagnostics error

j - Complication of procedure or treatment

k - Any procedure complication or any operative complication

l - Occurrence of any postoperative complication or anesthesia related harm

m - Medical procedure

n – Surgical site infection or nosocomial pneumonia or positive blood culture
o – Positive blood culture or nosocomial pneumonia or surgical site infection or hospital acquired urinary tract infection
p - Health care-associated infection of any kind
q – Positive culture from central line catheter or insertion site or ventilator associated pneumonia or post-operative infection or fungal infection or other infection or pneumonia or antibiotic treated urinary tract infection or viral gastroenteritis or clostridium difficile positive stool or positive bold culture or pneumonia
r – Readmission to hospital and unplanned admission were both >5% however they are consequences of an adverse event not an adverse event type
s – Transfer to a higher level of care type was >5% however it is a consequence of an adverse event not an adverse event
t – Occurrence of mistake and readmission within 30 days were >5% but were not adverse event types

Delayed or failed diagnose comprise about one-third of the clinical process/procedure adverse events and 5% of all. The conditions involved are highly varied and no pattern emerges from the low number of adverse events involved. Matlow et al (2012) was the only other paediatric GTT study which reported diagnostic problems in 5% or more of adverse events (14%)(Table 6).⁴ In a study analysing incidents related to primary care and paediatrics, 2% were associated with diagnosis or failure to identify high-risk patients.⁴² Diagnostic incidents are under-recognised as a patient safety issue because of the difficulty in detecting and measuring them,^{43, 44} even though about one in ten people have reported that they, or someone close to them, has experienced a diagnostic error.⁴⁵ They present a particular challenge for incident reporting systems due to difficulty in defining them precisely, they seldom comprise a concrete, identifiable ‘event’, and doctors, who are most likely to be involved in diagnostic incidents, are less likely than other health care staff (e.g. nurses) to report incidents.⁴⁶ The GTT is likely to provide a more targeted method of identifying diagnostic adverse events than incident reporting systems, however it needs to be complemented with other detection methods including medico-legal claims analysis, algorithmic surveillance of electronic medical and medication records, reviews of diagnostic testing results, and clinician and patient surveys.⁴⁷ Organisations should consider using the GTT to detect and characterize incident types such as diagnostic problems that are under-reported in incident systems.²

Our study reviewed records across a variety of healthcare provider types, unlike the rest of the studies in Table 6 which just reviewed records in hospitals. We also included some chronic conditions that are mainly managed outside hospital, e.g., ADHD and depression. This and that CareTrack Kids conditions did not include surgical conditions, may partially explain some differences in incident type profiles between our and other studies. For example, the percentage of procedural complications in our study was 5%, which is at the lower range of other studies (4-35%).^{6, 7, 8, 10}

There has been only one other generic paediatric study characterising the incident types of adverse events detected by the GTT in a detailed manner.⁹ However, this study classified the adverse events using body systems as the primary classification and the results are not directly comparable to our study, and therefore, was not included in Table 6.⁹ The other studies tend to report adverse events against the GTT triggers. The type of adverse event can be inferred from some of these triggers, for example surgical site infection or nosocomial pneumonia, but the types could be unclear, with, for example, triggers related to readmission or medication stop. Five studies reported adverse events type aligned with the trigger descriptors,^{5-8, 10} with one of these also reporting the specialty in association with where the adverse event occurred.¹⁰ Another study reported high level incident types and specialty (Table 6).⁴ The qualitative approach taken in our study has allowed a more specific characterisation of the types of adverse events experienced by a paediatric population and will permit future focussed analyses to understand their underlying causal mechanisms.^{35, 42}

Strengths and weaknesses

Although there are other studies using the GTT in paediatric care,^{4-10, 13, 15, 48-51} they infrequently focus on characterising the adverse events detected. Generic problems with using the GTT have been identified previously and are pertinent to this study. These include completeness and layout of medical records at different health services, differing interpretations by reviewers, and hindsight bias.² Due to logistical issues, with healthcare providers separated by up to 3,000 kilometres, only one nurse surveyor undertook the medical record reviews in this study.

The cognitive load on the surveyors was high, as they were also reviewing medical records for a parallel study on quality of care.²⁰ Records were then re-reviewed to search for adverse events, using different trigger tools depending on the provider types. This may have contributed to the surveyors inadvertently “missing” adverse events, leading to a lower rate of adverse events detected. On the other hand, reviewing the record a number of times may, in some cases, have increased the surveyor’s level of familiarity with the medical record.

Conclusion

Adverse drug reactions and issues with IV lines or access were frequently identified adverse events in our study. Other adverse events such as those associated with wrong or delayed

diagnoses, overdose, and problems with insulin pumps were also identified. We identified and characterised those adverse events which is the first step in understanding causal mechanisms and developing quality improvements in practice. There may be some adverse event types, such as diagnostic issues, that are more suited to collect by the GTT and other methods rather than incident reporting.

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Competing interests statement

The Authors declare that there are no competing interests.

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The lead author, Peter D. Hibbert guarantees the work. As guarantor, he accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

References

1. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. *New Eng J Med*. 2010;363(22):2124-34.
2. Hibbert PD, Molloy CJ, Hooper TD, et al. The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care*. 2016;Dec 1;28(6):640-9.
3. de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008;17(3):216-23.
4. Matlow AG, Baker GR, Flintoft V, et al. Adverse events among children in Canadian hospitals: the Canadian Paediatric Adverse Events Study. *Can Med Assoc J*. 2012;184(13):30.
5. Matlow AG, Cronin CMG, Flintoft V, et al. Description of the development and validation of the Canadian paediatric trigger tool. *BMJ Qual Saf*. 2011;20(5):416-23.
6. Kirkendall ES, Kloppenborg E, Papp J, et al. Measuring adverse events and levels of harm in pediatric inpatients with the global trigger tool. *Pediatrics*. 2012;130(5):e1206-e14.
7. Chapman SM, Fitzsimons J, Davey N, et al. Prevalence and severity of patient harm in a sample of UK-hospitalised children detected by the Paediatric Trigger Tool. *BMJ Open*. 2014;4:e005066.
8. Unbeck M, Lindemalm S, Nydert P, et al. Validation triggers and development of a pediatric trigger tool to identify adverse events. *BMC Health Serv Res*. 2014;14:655.
9. Stockwell DC, Landrigan CP, Toomey SL, et al. Adverse Events in Hospitalized Pediatric Patients. *Pediatrics*. 2018;142(2).
10. Solevag AL, Nakstad B. Utility of a Paediatric Trigger Tool in a Norwegian department of paediatric and adolescent medicine. *BMJ Open*. 2014;4(5):e005011.
11. Stacey S, Coombes I, Wainwright C, et al. Characteristics of adverse medication events in a children's hospital. *J Paed Child Health*. 50(12):966-71.
12. Griffin FA, Resar RK. IHI Global Trigger Tool for measuring adverse events (second edition). Cambridge, MA: Institute for Healthcare Improvement; 2009.
13. Sharek PJ, Horbar JD, Mason W, et al. Adverse Events in the Neonatal Intensive Care Unit: Development, Testing, and Findings of an NICU-Focused Trigger Tool to Identify Harm in North American NICUs. *Pediatrics*. 2006;118(4):1332-40.
14. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. *Pediatr Crit Care Med*. 2010;11(5):568-78.
15. Lander L, Roberson DW, Plummer KM, et al. A trigger tool fails to identify serious errors and adverse events in pediatric otolaryngology. *Otolaryngol Head Neck Surg*. 2010;143(4):480-6.
16. NHS Institute for Innovation and Improvement. Primary Care Trigger Tool - Introduction. London, UK: NHS; 2013.
17. The Health Foundation. 1000 Lives. Tools for improvement: How to Use Trigger Tools. 2010.
18. Hibbert P, Williams H. The use of a global trigger tool to inform quality and safety in Australian general practice: a pilot study. *Aust Fam Physician*. 2014;43(10):723-6.
19. Landrigan CP, Stockwell D, Toomey SL, et al. Performance of the Global Assessment of Pediatric Patient Safety (GAPPS) Tool. *Pediatrics*. 2016;137(6):e20154076.
20. Braithwaite J, Hibbert PD, Jaffe A, et al. Quality of Health Care for Children in Australia, 2012-2013. *JAMA*. 2018;319(11):1113-24.
21. Britt H, Miller GC, Henderson J, et al. General Practice Activity in Australia 2012-13: BEACH: Bettering the Evaluation and Care of Health: Sydney University Press; 2013.
22. Hiscock H, Roberts G, Efron D, et al. Children Attending Paediatricians Study: a national prospective audit of outpatient practice from the Australian Paediatric Research Network. *Med J Aust*. 2011;194(8):392-7.
23. Begg S, Vos T, Barker B, et al. The burden of disease and injury in Australia 2003. Canberra: AIHW; 2007.
24. Australian Institute of Health and Welfare and Commonwealth Department of Health and Family Services. First report on National Health Priority Areas 1996. Canberra: AIHW & DHFS; 1997.

25. Australian Institute of Health and Welfare. A picture of Australia's children 2012. Canberra: AIHW; 2012.
26. Marks G, Reddel H, Cooper S, et al. Asthma in Australia 2011. Canberra: AIHW; 2011.
27. Hooper TD, Hibbert PD, Mealing N, et al. CareTrack Kids-part 2. Assessing the appropriateness of the healthcare delivered to Australian children: study protocol for a retrospective medical record review. *BMJ Open*. 2015;5(4):e007749.
28. Wiles LK, Hooper TD, Hibbert PD, et al. CareTrack Kids-part 1. Assessing the appropriateness of healthcare delivered to Australian children: study protocol for clinical indicator development. *BMJ Open*. 2015;5(4):e007748.
29. Hibbert PD, Hallahan AR, Muething SE, et al. CareTrack Kids—part 3. Adverse events in children's healthcare in Australia: study protocol for a retrospective medical record review. *BMJ Open*. 2015;5(4):e007750.
30. Hunt TD, Ramanathan SA, Hannaford NA, et al. CareTrack Australia: assessing the appropriateness of adult healthcare: protocol for a retrospective medical record review. *BMJ Open*. 2012;2:e000665.
31. World Alliance For Patient Safety Drafting G, Sherman H, Castro G, et al. Towards an International Classification for Patient Safety: the conceptual framework. *Int J Qual Health Care*. 2009;21(1):2-8.
32. National Coordination Council for Medication Error Reporting and Prevention. NCC MERP Index for Categorizing Medication Errors 2001.
33. Elo S, Kyngas H. The qualitative content analysis process. *J Adv Nurs*. 2008;62(1):107-15.
34. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245-51.
35. Carson-Stevens A, Hibbert P, Avery A, et al. A cross-sectional mixed methods study protocol to generate learning from patient safety incidents reported from general practice. *BMJ Open*. 2015;5(12):e009079.
36. Good VS, Saldaña M, Gilder R, et al. Large-scale deployment of the Global Trigger Tool across a large hospital system: refinements for the characterisation of adverse events to support patient safety learning opportunities. *BMJ Qual Saf*. 2011;20(1):25-30.
37. Nilsson L, Pihl A, TÅGsjö M, et al. Adverse events are common on the intensive care unit: results from a structured record review. *Acta Anaesthesiol Scand*. 2012;56(8):959-65.
38. Glanzmann C, Frey B, Meier CR, et al. Analysis of medication prescribing errors in critically ill children. *Eur J Pediatr*. 174(10):1347-55.
39. Donaldson LJ, Kelley ET, Dhingra-Kumar N, et al. Medication Without Harm: WHO's Third Global Patient Safety Challenge. *The Lancet*. 2017;389(10080):1680-1.
40. Kaur P, Rickard C, Domer G, et al. Dangers of Peripheral Intravenous Catheterization: The Forgotten Tourniquet and Other Patient Safety Considerations. *Vignettes in Patient Safety*. 2019;4.
41. Sangam SL. Quality improvement measures for early detection of severe intravenous infiltration in infants. 2019;8(2):e000407.
42. Rees P, Edwards A, Powell C, et al. Patient Safety Incidents Involving Sick Children in Primary Care in England and Wales: A Mixed Methods Analysis. *PLoS Med*. 2017;14(1):e1002217.
43. Graber ML, Wachter RM, Cassel CK. Bringing diagnosis into the quality and safety equations. *JAMA*. 2012;308(12):1211-2.
44. Singh H. Diagnostic errors: moving beyond 'no respect' and getting ready for prime time. *BMJ Qual Saf*. 2013;22(10):789-92.
45. Betsy Lehman Center for Patient Safety and Medical Error Reduction. The public's views on medical error in Massachusetts. Cambridge, MA: Harvard School of Public Health; 2014.
46. Sevdalis N, Jacklin R, Arora S, et al. Diagnostic error in a national incident reporting system in the UK. *J Eval Clin Pract*. 2010;16(6):1276-81.
47. National Academies of Sciences E, and Medicine 2015, . Improving Diagnosis in Health Care. Washington, DC: The National Academies Press; 2015.

48. Burch KJ. Using a trigger tool to assess adverse drug events in a children's rehabilitation hospital. *JPPT*. 2011;16(3):204-9.
49. Takata GS, Mason W, Taketomo C, et al. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Pediatrics*. 2008;121(4):e927-35.
50. Larsen G, Donaldson A, Parker H, et al. Preventable harm occurring to critically ill children. *Pediatr Crit Care Med*. 2007;8(4):331-6.
51. Hooper AJ, Tibballs J. Comparison of a Trigger Tool and voluntary reporting to identify adverse events in a paediatric intensive care unit. *Anaesth Intensive Care*. 2014;42(2):199-206.