A Trigger Tool to Detect Harm in Pediatric Inpatient Settings

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abstract

OBJECTIVES: An efficient and reliable process for measuring harm due to medical care is needed to advance pediatric patient safety. Several pediatric studies have assessed the use of trigger tools in varying inpatient environments. Using the Institute for Healthcare Improvement's adult-focused Global Trigger Tool as a model, we developed and pilot tested a trigger tool that would identify the most common causes of harm in pediatric inpatient environments.

METHODS: After formal training, 6 academic children's hospitals used this novel pediatric trigger tool to review 100 randomly selected inpatient records per site from patients discharged during the month of February 2012.

RESULTS: From the 600 patient charts evaluated, 240 harmful events ("harms") were identified, resulting in a rate of 40 harms per 100 patients admitted and 54.9 harms per 1000 patient days across the 6 hospitals. At least 1 harm was identified in 146 patients (24.3% of patients). Of the 240 total events, 108 (45.0%) were assessed to have been potentially or definitely preventable. The most common patient harms were intravenous catheter infiltrations/burns, respiratory distress, constipation, pain, and surgical complications.

CONCLUSIONS: Consistent with earlier rates of all-cause harm in adult hospitals, harm occurs at high rates in hospitalized children. Availability and use of an all-cause harm identification tool will establish the epidemiology of harm and will provide a consistent approach to assessing the effect of interventions on harms in hospitalized children.

WHAT'S KNOWN ON THIS SUBJECT: Harm occurs at a high rate in adult inpatient populations. One single-center study, applying an adult-based surveillance tool, suggests that a pediatric inpatient population also has a high rate of harm.

WHAT THIS STUDY ADDS: Harm occurred frequently in 6 freestanding children's hospitals. Identification and understanding of the harm is the first step to making necessary improvements and to preventing future harm.

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Despite the increased attention paid to patient safety over the past 15 years since the publication of "To Err Is Human," harm rates for hospitalized patients remain high.[1,2] Advanced harm detection techniques suggest that national rates of harm resulting in death among hospitalized patients are >4 times higher than originally reported. These rates suggest that almost half a million people die in the United States per year as a result of hospital-associated harm.[3] This estimate would place patient harm as the third leading overall cause of death behind heart disease and cancer.[4]

Consistent and accurate detection of patient harm remains a challenge for most organizations. Although voluntary reports have been shown to capture only 2% to 8% of all harms, they remain the mainstay of harm detection in most hospitals.[5] The Institute of Healthcare Improvement (IHI) noted recently that "public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients."[6] Noting this gap, efforts to improve harm detection have accelerated, with the most visible perhaps being the development, testing, and dissemination of the adult-focused IHI Global Trigger Tool (GTT). A "trigger" is a medical record-based "hint" (such as the use of the antidote naloxone) that "triggers" the search of the medical record to determine whether an adverse event (such as a clinical overdose of an opiate, as opposed to a therapeutic use in response to a nonprescribed opiate use) might have occurred. The GTT, which includes 55 such triggers, has been used in such settings as the North Carolina Patient Safety Study, the Office of the Inspector General of the Centers for Medicare and Medicaid Services report on inpatient harm, and the Office of the Inspector General work in skilled nursing facilities.[2,6–11] These efforts have reinforced the perspective that the trigger tool approach is at present the most reliable and consistent harm detection method.[3,7,10]

TABLE 1 PACHMT

	PACHMT Trigger Catalog
	Medical triggers
M1	Neonatal intraventricular hemorrhage grade ≥3
M2	Unplanned endotracheal extubation
M3	Failed endotracheal extubation (reintubation within 24 h of planned extubation)
M4	Total bilirubin >25 mg/dL
M5	Hyperglycemia (14 mmol/L or 250 mg/dL)
M6	Hypernatremia (>160 mEq/L)
M7	Hypoglycemia (2 mmol/L or 40 mg/dL)
M8	Hyponatremia (<125 mEq/L)
M9	Low O_2 saturations
M10	Pain score elevation (≥6 of 10)
	Medication administration triggers
MEDA1	Serum creatinine doubling
MEDA2	Partial thromboplastin time >100 s
MEDA3	Anti Xa >1.5
MEDA4	Warfarin: international normalized ratio >6
MEDA5	Warfarin: vitamin K administration after warfarin administration
MEDA6	Protamine administration
MEDA7	Naloxone administration
MEDA8	Flumazenil administration
MEDA9	Ongoing or intermittent laxative use
MEDA10	Digibind administration
MEDA11	Hyperkalemia (K^+ >6.0 mEq/L) and sodium polystyrene administration
MEDA12	Elevated drug levels (antiepileptics): phenytoin (>30 mcg/mL)
MEDA13	Elevated drug levels (antiepileptics): valproic acid (>170 mcg/mL)
MEDA14	Elevated drug levels (antiepileptics): carbamazepine (>20 mcg/mL)
MEDA15	Elevated drug levels (antiepileptics): oxcarbazepine (>45 mcg/mL)
MEDA16	Elevated drug levels (antiepileptics): Phenobarbital (>30 mcg/mL)
MEDA17	Elevated drug levels (antibiotics): vancomycin (trough >25 mcg/mL)
MEDA18	Elevated drug levels (antibiotics): gentamicin (trough >4 mcg/mL)
MEDA19	Elevated drug levels (antibiotics): tobramycin (trough >4 mcg/mL)
MEDA20	Elevated drug levels (antibiotics): amikacin (trough >20 mcg/mL)
MEDA21	Racemic epinephrine administration (within 24 h after endotracheal extubation)
	Health care–associated infections
HAC1	Positive *Clostridium difficile* test
HAC2	Positive blood culture (only after 48 h from admission)
HAC3	Positive urine culture (only after 48 h from admission)
HAC4	Positive respiratory panel (only after 48 h from admission)
HAC5	Infiltrations: infiltration/phlebitis documentation
HAC6	Infiltrations: hyaluronidase administration
HAC7	Infiltrations: phentolamine administration
HAC8	Pressure ulcer documentation (stage ≥2)
	Perioperative triggers
P1	Abrupt drop of >25% in hemoglobin or hematocrit
P2	Unanticipated insertion of arterial or central venous line during surgery
P3	Intraoperative epinephrine, norepinephrine or phenylephrine (noncardiac patients)
P4	Mechanical ventilation >48 h postoperatively
P5	Operative time >6 h (noncardiac patients)
P6	X-ray intraoperatively or in postanesthesia care unit
	Readmission triggers
R1	Readmission to ICU within 24 h from discharge/transfer
R2	Hospital readmission within 30 d
R3	Readmission to the emergency department within 48 h
	Resuscitation/death triggers
RES1	Any code or arrest, or rapid response team activation
RES2	Transfer to higher level of care
RES3	All inpatient deaths

Although the IHI GTT was designed for the adult population, 1 children's hospital tested it on its pediatric inpatient records and identified

TABLE 2 Harm Classification of Harms Using the NCC MERP (Categories E–I)

Category E	Contributed to or resulted in temporary harm to the patient and required intervention
Category F	Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
Category G	Contributed to or resulted in permanent patient harm
Category H	Required intervention to sustain life
Category I	Contributed to or resulted in the patient's death

NCC MERP, National Coordination Council for Medication Error Reporting and Prevention.

patient harm in more than one-third of admissions.[12] In addition, there have been ongoing efforts to develop trigger tools tailored for pediatric settings. These have included trigger tools for discrete settings (eg, the NICU, PICU, and general pediatric non–intensive care inpatient environment) and specific types of harms (eg, adverse drug events). Such applications of focused trigger tools have identified dramatically higher rates of harm compared with voluntary reports of safety events.[13–17] However, a single, pediatric-specific detection tool that can be applied across all settings, analogous to the IHI's GTT, has not been available. Until a comprehensive standard harm measure is established in pediatrics, improvement efforts will continue to focus on a fraction of the harm that occurs to patients, leaving countless harms within the system unrecognized and unaddressed.[18]

Recently, a comprehensive pediatric trigger list for the inpatient environment using a modified Delphi technique was developed. The tool was modeled after the IHI GTT and named the Pediatric All-Cause Harm Measurement Tool (PACHMT).[19] Of note, the PACHMT was developed anticipating future automation to allow integration into electronic health records. Using the PACHMT, we sought to pilot test the tool to estimate harm rates across 6 children's hospitals and to ensure the feasibility and appropriateness of the tool as a way to estimate the rates of all-cause harm in hospitalized children. Although no tool can consistently identify all causes of harm, the PACHMT was designed to identify many of the most common causes of pediatric harm able to be recognized through trigger methodology.

METHODS

Design, Setting, and Patients

As has been done in previous trigger tool studies, we used a cross-sectional study design, using retrospective chart review in 6 academic freestanding children's hospitals with previous trigger tool experience from different regions of the country. Patient records were eligible for inpatients who were <22 years of age, had a length of stay between 24 hours and 6 months, and were discharged in February 2012.[20] Any patients who were admitted for rehabilitation, to the normal newborn nursery, to day treatment areas, or with a primary discharge diagnosis related to psychiatric or obstetric care were excluded as is consistent with earlier study designs.[12–17] A random sample of 100 patients who met the inclusion criteria was selected from each site for review. Institutional review board waiver or approval for this study was granted at each site.

Intervention

The list of pediatric-specific triggers from the PACHMT was created via a modified Delphi process described previously.[19] The PACHMT trigger list (Table 1), an instruction manual containing detailed definitions of triggers, a list of likely associated predefined harm events and case examples, and data collection forms were distributed to each hospital. Each site identified at least 1 nonphysician clinical reviewer, either a nurse or pharmacist, as well as 1 physician reviewer. All clinical reviewers and physician reviewers from each site completed standard training on trigger tool chart review methods incorporating the PACHMT and based on previous work by the Children's Hospital Association and IHI.[6,13,14,17] Training was taught by IHI GTT expert educators and consisted of 3 interactive educational webinars. During these sessions, these experts described trigger detection, introduced the PACHMT trigger list, presented the process for the standard application of the tool, reviewed examples, and facilitated active dialogue. The site reviewers independently completed standard case studies for detecting triggers, harm identification, and harm classification that were reviewed during training sessions. Calibration exercises, such as extensive case reviews and group review of event and harm classifications, during training assisted in promoting consistency in the use of the tool and study definitions.

The reviewer-physician team at each site then applied the standard trigger tool review method to review their 100 charts. There were no limits placed on the review time per chart. Once a trigger was identified, the reviewer would determine if there was harm. Harm was defined as an "unintended physical injury (resulting from or contributed to) by medical

TABLE 3 Patient Lengths of Stay and Age

Characteristic	Mean (95% CI)	Median [IQR]
Length of stay (d)	7.3 (6.2–8.3)	4 (3–7)
Length of stay when >30 d (n = 16, 2.7% of total)	68.8 (46.7–90.8)	55.5 (39.5–76)
Patient age (y)	6.2 (5.7–6.7)	4 (0.5–12.0)

TABLE 4 Harms by Frequency (N = 240)

Harm	Total, n (%)
Intravenous catheter infiltration/burn	46 (19.2)
Respiratory distress	18 (7.5)
Constipation	14 (5.8)
Pain	14 (5.8)
Surgical complications	14 (5.8)
Skin rash, bruising or burn	11 (4.6)
Electrolyte disorders (eg, Na+, K+, Ca2+)	9 (3.8)
Oxygen desaturation	9 (3.8)
Respiratory depression/apnea	9 (3.8)
Mental status changes	8 (3.3)
Allergic reaction/ hypersensitivity reaction	7 (2.9)
Hypotension	7 (2.9)
Emesis/vomiting	6 (2.5)
Hemorrhage/bleeding	5 (2.1)
Hypoglycemia	5 (2.1)
Central line–associated blood stream infection	4 (1.7)
Cardiac rhythm derangements (eg, bradycardia, tachycardia, other arrhythmias)	4 (1.7)
Hematologic derangement (eg, anemia, neutropenia, thrombocytopenia)	4 (1.7)
Nosocomial infections (gastrointestinal or respiratory)	4 (1.7)
Unplanned extubation	4 (1.7)
Unplanned surgical procedures	4 (1.7)
Wound infection	4 (1.7)
Catheter-associated urinary tract infection	4 (1.7)
Other	26 (10.8)

"Other" includes the following: diarrhea (n = 3); hyperthermia/fever (n = 3); intubation complications/postextubation stridor (n = 3); cardiac arrest (n = 2); decubitus ulcers (n = 2); dehydration (n = 2); gastrointestinal bleed (n = 2); insulin use complication or misuse (n = 2); iatrogenic renal injury, renal failure, renal dysfunction (n = 2); other (n = 2); death (n = 1); seizures (n = 1); and weakness/loss of strength (n = 1).

care that required additional monitoring, treatment, or hospitalization, or that resulted in death."[7] This definition is consistent with the Centers for Medicare and Medicaid Services, Office of the Inspector General, and the Agency for Healthcare Research and Quality's definition of harm.[7,11,21] Once harm was identified, its level of severity was assigned on the basis of the National Coordination Council for Medication Error Reporting and Prevention classification approach (Table 2).[22]

After harm identification and classification, reviewers were asked to assign a level of preventability or nonpreventability. Each harm was assigned as "definitely preventable," "probably preventable," "probably not preventable," or "definitely not preventable." Preventable events were defined as "events where definite breach of standard professional behavior or technique was identified; necessary precautions were not taken; event was preventable by modification of behavior, technique or care."[2] All other harms were considered not preventable.

After the reviewer's assessment of a chart and PACHMT trigger application, physician reviewers reviewed a summary of the harm and either confirmed or modified the primary reviewer's assessment. The physician reviewer's assessment and scoring of the case was considered final.

Outcomes

The primary outcomes of this study were harms per patient and harms per 1000 patient days. Secondary outcomes of interest were (1) triggers per patient,(2) trigger-positive predictive values (defined as the number of times a specific trigger independently identified harm divided by the number of times a trigger was identified) individually and for PACHMT in total,(3) harm severity,(4) percentage of harms that were preventable, percentage of harms that were also identified in local occurrence reports, and median time for chart review.

Statistical Analysis

Patient characteristics were described with means and 95% confidence intervals (CIs), as well as medians with interquartile ranges (IQRs). We summarized harms with frequencies and percentages, and computed rates with 95% Poisson CIs. Finally, for each trigger, we report positive predictive values with exact binomial 95% confidence intervals (CI). All analyses were performed with SAS v.9.3 (SAS, Cary, NC), and $P < .05$ were considered statistically significant.

RESULTS

The median age of patients whose chart was in the study was 4 years (IQR: 0.5–12.0), and 287 (47.8%) were female. The median length of stay was 4 days (IQR: 3–7), and 2.7% of patients had a length of stay >30 days (Table 3).

There were 1093 triggers detected resulting in identification of 204 (85.0%) of the total harms identified. The remaining 36 harms were identified during the chart review process but were not linked to any specific trigger. The positive predictive value of the aggregate PACHMT trigger list was 22.0% (95% CI: 19.0–25.1).

A total of 240 harms were identified from the 600 total patient records reviewed resulting in a rate of 40 harms per 100 patients admitted (95% CI: 35.2–45.4) and 54.9 harms per 1000 patient days (95% CI: 48.3–62.3). At least 1 harm was

TABLE 5 Harm Count and Percent of Total Harms by Harm and Preventability

NCC MERP Harm Category	Total Harms by Category, n (%)	Definitely Preventable, n (%)	Probably Preventable, n (%)	Definitely Not Preventable, n (%)	Probably Not Preventable, n (%)
E	165 (68.5)	26 (10.8)	46 (19.2)	14 (5.8)	79 (32.9)
F	49 (20.4)	8 (3.3)	19 (7.9)	3 (1.3)	19 (7.9)
G	1 (0.4)	1 (0.4)	0	0	0
H	24 (10.0)	3 (1.3)	5 (2.1)	6 (2.5)	10 (4.2)
I	1 (0.4)	0	0	1 (0.4)	0
Totals	240	38 (15.8)	70 (21.2)	24 (10.0)	108 (45.0)

NCC MERP, National Coordination Council for Medication Error Reporting and Prevention.

identified in 146 patients; thus, 24.3% of all patients experienced ≥1 harms. Fifty-one patients (8.5% of the total) had multiple harms. One hundred and eight harms (45.0%) were documented as either probably preventable or definitely preventable.

The mean time for chart review was 42 minutes with a median of 30 minutes (IQR: 15.5–60.0). Of the 240 harms identified, 22 (9.2%) of these were also identified within the hospital's voluntary reporting system.

The most common harms were intravenous catheter infiltrations/burns, respiratory distress, constipation, pain, surgical complications and skin rash, bruising, or burn. A complete listing of the harms experienced is included in Table 4. Sixty-eight percent of the harms documented were rated as level E on the National Coordination Council for Medication Error Reporting and Prevention harm scale. Table 5 categorizes the identified harms by severity level and preventability as determined by the reviewers.

Thirty-six (70.6%) of the PACHMT triggers were identified at least once during the chart review. Table 6 lists the triggers in order of frequency and lists each trigger's positive predictive value.

TABLE 6 Triggers by Frequency, With Positive Predictive Value

Trigger	*n*	Positive Predictive Value, % (95% CI)
Elevated pain score (≥6 of 10)	179	6.7 (3.5–11.4)
Opiate-related constipation with intermittent laxative use	115	11.3 (6.2–18.6)
Hospital readmission within 30 d	88	19.3 (11.7–29.1)
Infiltrations: infiltration/phlebitis documentation	39	92.3 (79.1–98.4)
Low O_2 saturations[a]	31	35.5 (19.2–54.6)
Any code or arrest	23	60.9 (38.5–80.3)
Transfer to a higher level of care	18	50 (26–74)
Hyperglycemia (14 mmol/L or 250 mg/dL)	17	0
Abrupt drop of >25% in hemoglobin or hematocrit	15	40 (16.3–67.7)
Readmission to the emergency department within 48 h	15	20 (4.3–48.1)
Hypoglycemia (2 mmol/L or 40 mg/dL)	9	55.6 (21.2–86.3)
Serum creatinine doubling	9	22.2 (2.8–60)
Hyperkalemia (potassium >6.0 mEq/L)/sodium polystyrene admin: sodium polystyrene use	8	25 (3.2–65.1)
Health care–associated infections: positive urine culture (only after 48 h from admission)	7	71.4 (29–96.3)
Health care–associated infections: positive respiratory panel (only after 48 h from admission)	7	85.7 (42.1–99.6)
Mechanical ventilation ≥48 h postoperatively	7	42.9 (9.9–81.6)
Unplanned endotracheal extubation	5	80 (28.4–99.5)
Hyponatremia (<125 mEq/L)	5	20 (0.5–71.6)
Partial thromboplastin time >100 s	5	20 (0.5–71.6)
Racemic epinephrine administration (patients mechanically ventilated within past 24 h)	5	40 (5.3–85.3)
Protamine administration	4	0
Naloxone administration	4	50 (6.8–93.2)
Elevated drug levels (antiepileptics): phenobarbital (>30 mcg/mL)	4	25 (0.6–80.6)
Health care–associated infections: positive blood culture (only after 48 h from admission)	4	25 (0.6–80.6)
Operative time >6 h (noncardiac patients)	4	25 (0.6–80.6)
X-ray intraoperatively or in postanesthesia care unit	4	25 (0.6–80.6)
Readmission to ICU within 24 h from discharge/transfer	4	75 (19.4–99.4)
Failed endotracheal extubation (reintubation within 24 h of planned extubation)	3	66.7 (9.4–99.2)
Elevated drug levels (antibiotics): vancomycin (trough >25 mcg/mL)	3	0
Elevated drug levels (antibiotics): tobramycin (trough >4 mcg/mL)	3	0
Pressure ulcer documentation (stage >2)	3	0
All inpatient deaths	3	33.3 (0.8–90.6)
Hypernatremia (>160 mEq/L)	2	0
Health care-associated infections: positive *Clostridium difficile* test	2	0
Neonatal intraventricular hemorrhage grade ≥3	1	0
Intraoperative epinephrine, norepinephrine, or phenylephrine (noncardiac patients)	1	0

The following triggers were not identified during chart review: total bilirubin >25 mg/dL; Anti Xa >1.5; Warfarin triggers: international normalized ratio >6; Warfarin triggers: vitamin k administration after warfarin, flumazenil administration, Digibind administration; elevated drug levels (antiepileptics): phenytoin (>30 mcg/mL); elevated drug levels (antiepileptics): valproic acid (>170 mcg/mL); elevated drug levels (antiepileptics): carbamazepine (>20 mcg/mL); elevated drug levels (antiepileptics): oxcarbazepine (>45 mcg/mL); elevated drug levels (antibiotics): gentamicin (trough >4 mcg/mL); elevated drug levels (antibiotics): amikacin (trough >20 mcg/mL); infiltrations: hyaluronidase administration; infiltrations: phentolamine administration; unanticipated insertion of arterial or central venous line during surgery.

[a] One minute or more of sustained saturation <75% or >2 spot check saturations <75% in a 24-h period.

DISCUSSION

Using a novel pediatric-specific list of triggers, we found 40 harms per 100 admissions among children hospitalized at 6 large children's hospitals. Consistent with earlier trigger-based harm detection studies, nearly one half of the harm was deemed preventable.[2,13,14] One of every 4 pediatric admissions in our study had at least 1 identified harm. Our detected harm rate is similar to a recent single-site study, which detected a pediatric harm rate of 37 harm events for every 100 admissions using the adult-focused IHI GTT.[12] This is the first multisite study describing all-cause inpatient pediatric harm using a novel pediatric-specific global trigger tool.

Consistent with previous trigger tool efforts, harms were identified substantially more frequently with the PACHMT than with voluntary reporting. Nevertheless, we consider

these 2 approaches to patient safety measurement to be complementary. Although a trigger tool's systematic measurement captures substantially more harm events, voluntary reporting often provides information related to near miss events that are not detected by the trigger tool methodology. We believe a combination of both approaches results in an enhanced understanding of a system's potential fallibilities.[23]

There are several limitations to this study. First, as a pilot, our study had a relatively small sample size and only 1 physician reviewer (rather than the more typical design of 2 physician reviewers) to assess and rate the harms. Second, like adult trigger tool studies,[6,19] our study lacked definitive evidence for which triggers were the best to include, and it does not capture all harms. In an effort to construct a parsimonious list of highly predictive triggers, several potential triggers such as hypocalcemia or hypokalemia were not included in the final trigger tool. Third, we did not undertake inter- or intrarater reliability testing, so we do not yet know the reliability and consistency of this tool between alternative users. Finally, although this was a relatively large, multicenter pilot study, larger studies are needed to better identify rare but clinically important harms, to define the operating characteristics of less common triggers, and to examine how trigger tools work in a more diverse set of hospitals. The federal Pediatric Quality Measures Program is developing such a measure at present, drawing on the work of PACHMT and other trigger tools.

CONCLUSIONS

The application of a novel pediatric global trigger tool identified 40 harms per 100 admissions in 6 freestanding children's hospitals. Despite more than a decade of intense focus, harm continues to occur in large numbers in hospitalized children. The use of the PACHMT trigger tool will provide the foundation to capture harms in a rigorous and systematic way. Use of such trigger tools will lead to a better understanding of the epidemiology of harm in hospitalized children as well as allow tracking of change with patient-safety-focused interventions. Because this work was only intended to be a pilot study, future research should focus on editing the PACHMT to establish the next generation pediatric global trigger tool, conduct a formal study to establish harm rates and epidemiology, and determine the operating characteristics of this tool, with an eye toward integration into the electronic medical record and eventual automation.

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