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ARTICLE

Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to Identify Medication-Related Harm in US Children's Hospitals

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What's Known on This Subject

Data using the established Harvard Medical Practice Study methodology revealed a 2.3% rate of adverse drug events (ADEs) in the pediatric inpatient population.

What This Study Adds

A pedatric-focused ADE trigger tool was built and tested. Use of this more sophisticated detection tool identified an 11.1% rate of ADEs in pediatric inpatients.

ABSTRACT

OBJECTIVES. The purposes of this study were to develop a pediatric-focused tool for adverse drug event detection and describe the incidence and characteristics of adverse drug events in children's hospitals identified by this tool.

METHODS. A pediatric-specific trigger tool for adverse drug event detection was developed and tested. Eighty patients from each site were randomly selected for retrospective chart review. All adverse drug events identified using the trigger tool were evaluated for severity, preventability, ability to mitigate, ability to identify the event earlier, and presence of associated occurrence report. Each trigger and the entire tool were evaluated for positive predictive value.

RESULTS. Review of 960 randomly selected charts from 12 children's hospitals revealed 2388 triggers (2.49 per patient) and 107 unique adverse drug events. Mean adverse drug event rates were 11.1 per 100 patients, 15.7 per 1000 patient-days, and 1.23 per 1000 medication doses. The positive predictive value of the trigger tool was 3.7%. Twenty-two percent of all adverse drug events were deemed preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively. Ninety-seven percent of the identified adverse drug events resulted in mild, temporary harm. Only 3.7% of adverse drug events were identified in existing hospital-based occurrence reports. The most common adverse drug events identified were pruritis and nausea, the most common medication classes causing adverse drug events were opioid analgesics and antibiotics, and the most common stages of the medication management process associated with preventable adverse drug events were monitoring and prescribing/ordering.

CONCLUSIONS. Adverse drug event rates in hospitalized children are substantially higher than previously described. Most adverse drug events resulted in temporary harm, and 22% were classified as preventable. Only 3.7% were identified by using traditional voluntary reporting methods. Our pediatric-focused trigger tool is effective at identifying adverse drug events in inpatient pediatric populations.

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Key Words
adverse drug event, trigger tool, pediatrics, harm, patient safety

Abbreviations
AE—adverse event
ADE—adverse drug event
MAR—medication administration record
IHI—Institute for Healthcare Improvement
CHCA—Child Health Corporation of America
PPV—positive predictive value
CI—confidence interval

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In the report *To Err Is Human*,[1] the Institute of Medicine concluded that between 44 000 and 98 000 lives are lost per year in US hospitals as a result of error. This estimate was developed in part from the Harvard Medical Practice Study, which estimated that 3.7% of all hospitalized patients in a New York State cohort experienced an adverse event (AE) related to medical therapy.[2] More recent data from the Harvard group using more sophisticated detection methods revealed a 6.5% rate of adverse drug events (ADEs) alone in the adult inpatient setting, with 33% of these events described as preventable.[3] Application of these methods to a pediatric population revealed a 2.3% ADE rate with 19% described as preventable.[4] Both of these more recent studies[3,4] relied on voluntary and verbally solicited reports from hospital staff, medication administration records (MARs), and nonfocused retrospective chart review to identify medication errors and ADEs. A variety of methods have been used to identify medical errors and ADEs in

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both adult and pediatric patients, including chart review, voluntary reporting by health care providers, direct observation, and review of medical malpractice claims.[4–19]

Recently, a different strategy, known as the trigger method, was shown to be superior to voluntary occurrence reports and conventional unfocused chart review in the identification of AEs in hospitalized adult patients[20–22] and NICU patients.[23] A trigger is defined as an "occurrence, prompt, or flag found on review of the medical chart that 'triggers' further investigation to determine the presence or absence of an adverse event."[20,21] An example of a trigger is the administration of naloxone to a patient, which would prompt a focused chart review for evidence of an opioid-induced AE such as respiratory depression. The use of triggers, therefore, theoretically promotes a more focused and efficient chart review than an unfocused chart review and thus may identify more ADEs. Studies using the trigger method have borne this out,[20–23] identifying AE rates as much as 50 times higher than hospital-based occurrence reporting strategies[21] and identifying AE rates in high-risk populations as high as 112 per 100 patients, with ADE rates of 20 per 100 patients.[22] The only published study to date using a trigger tool in the pediatric population identified an AE rate of 74 per 100 NICU patients when applied to 749 charts from 15 NICUs in North America.[23] Because both the Institute for Healthcare Improvement (IHI) and the Institute of Medicine have recommended a transition from measuring error to that of measuring harm,[20–22,24,25] the trigger method is 1 promising and practical approach for effectively measuring harm associated with hospital-based health care.[20–23]

Despite the ability of the trigger method to identify harm effectively, there is evidence that 1 generic ADE trigger tool will not work for every environment. For example, when the NICU AE trigger tool was constructed, the authors worked backward from the most frequent and severe AEs in the NICU setting to construct a list of triggers that would most effectively identify these high-frequency, high-severity AEs.[23] This list of AEs and resultant triggers looks substantially different from previously constructed adult-focused trigger tools. Recognizing that pediatric patients likely differ from adult inpatients in regard to relevant ADEs, we embarked on a study to develop and test a pediatric-specific trigger tool to identify ADEs. The aims of this study were

- to develop and test a pediatric population–focused trigger tool, adapted from the existing adult-focused trigger tool,[20] for ADE detection,
- to determine the rate of ADEs in hospitalized children at 12 freestanding children's hospitals in the United States, and
- to identify characteristics of the most frequent ADEs in children's hospitals to provide the basis for developing a cohesive strategy to prevent proactively drug-related harm in inpatient pediatric populations.

METHODS

This study was a cross-sectional one that used retrospective chart review in 12 children's hospitals across the United States (see "Acknowledgments" for participating sites). Patients for phase II were randomly selected from a master list of eligible patients generated at each site. Patients were eligible for phase II of the study when they were in the hospital for a minimum of 2 days and discharged, transferred out, or died between March 18, 2002, and May 28, 2002. Twenty patients were randomly selected from all eligible patients from 4 consecutive successive 2-week blocks beginning March 18, 2002, for a total of 80 patients over the 8-week time frame. Only the first 30 days of hospitalization were included in the review in an effort to maximize the efficiency of the chart review. Patients were excluded when they were in the hospital for <2 days; were in the newborn nursery or admitted through the newborn nursery; were on the obstetrics service; were in the day hospital or observation unit; or were discharged, transferred out, or died before March 18, 2002 or after May 28, 2002.

Intervention

Phase I: Applying the IHI Adult-Focused ADE Trigger Tool to Pediatric Inpatients

A collection of 12 children's hospitals from Child Health Corporation of America (CHCA) evaluated the IHI adult-focused ADE trigger tool[20] in pediatric inpatients. The stated aims of phase I were (1) to adapt an existing adult-focused trigger chart review tool for an inpatient pediatric population, (2) to compare the effectiveness and efficiency of the tool with standard methods of ADE reporting, and (3) to identify new triggers that are unique to the pediatric population. A total of 931 patients who met the inclusion criteria were evaluated retrospectively using the 24-trigger IHI adult-focused ADE trigger tool. Application of the adult-based tool to these 931 pediatric-aged patients identified ADE rates of 9.8 per 100 patients, 13.4 per 1000 patient-days, and 1.38 per 1000 medication doses. On the basis of frequency and efficiency criteria for trigger removal (triggers with a low positive predictive value [PPV], ambiguity, or resulting in extreme inefficiencies during chart review were removed) and trigger addition created a priori, 13 adult-based triggers were removed and 4 pediatric-specific triggers were added to establish the 15-trigger CHCA pediatric-focused ADE trigger tool (Table 1) used in our full study (phase II).

Phase II: Application of the Pediatric-Focused ADE Trigger Tool

Hospitals were recruited from CHCA to participate in the full pediatric-focused ADE trigger tool trial (phase II). A data collection tool and instruction manual with standard processes and detailed definitions for each trigger (eg, hyperglycemia was defined as >150 mg/dL and elevated partial thromboplastin time was defined as >100 seconds) and each associated ADE were then developed. For enhancement of accuracy of ADE identification, each site participated in a face-to-face meeting to discuss the study method; thereafter, a series of conference call–based training exercises consisting of 10 stan-

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TABLE 1 **Final Trigger List Used in the Inpatient Pediatrics ADE Trigger Tool Study**

Designation	Description
T_1	Diphenhydramine use
T_2	Vitamin K use
T_3	Flumazenil use
T_4	Antiemetic use[a]
T_5	Naloxone use
T_7	Sodium polystyrene use
T_{10}	PTT >100 s
T_{16}	Rising serum creatinine[b]
T_{21}	Oversedation/lethargy/fall/hypotension
T_{22}	Rash
T_{23}	Abrupt medication stop
T_{25}	Serum glucose >150 mg/dL
T_{26}	Hyperkalemia[c]
T_{27}	Called codes
T_{28}	Laxative or stool softener use

Detailed definitions of these triggers, as well as associated adverse drug events, are available at www.chca.com. Triggers T_1 to T_{23} are from the IHI adult-focused trigger tool. Triggers T_{25} to T_{28} were added on the basis of phase 1 test findings. PTT indicates partial thromboplastin time.

[a] Antiemetics, laxatives, and stool softeners were specified according to each hospital's formulary.

[b] Rising serum creatinine was defined as a serum creatinine that becomes elevated relative to age-specific normal values or as an increase in serum creatinine of ≥0.4 mg/dL.

[c] Hyperkalemia was defined according to each hospital's range of reference values.

TABLE 2 **Severity Categories of ADEs Based on the System Used for Classifying Medication Errors by the National Coordinating Council for Medication Error Reporting and Prevention[28]**

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

dardized scenarios was undertaken. The final pediatric ADE trigger tool and a detailed standardized instruction manual were used for guidance in the test scenario evaluation. Additional contact between participating sites and the principal investigator facilitated discussions of results of the exercise, clarified definitions, allowed refinement of the instruction manual, and promoted discussion of strategies to make the chart review more efficient for the full trial. All 12 sites participated in the face-to-face meeting and training exercises.

The full pediatric-focused ADE trigger tool trial (phase II) was launched with a Webcast in May 2002. The final ADE trigger tool, an instruction manual with definitions, a chart audit tool, and instructions for using a standard random selection strategy to identify patients were sent to each site. Specifically, all eligible patients at each site were included in a master list from which 20 patients per 2-week period were randomly selected using the randomization function in Excel (Microsoft Inc, Redmond, WA). We defined an ADE as "an injury, large or small, caused by the use (including nonuse) of a drug."[20–23,26] Preventability was defined on the basis of the initial reviewer's interpretation and the second reviewer's confirmation of whether the ADE could have been prevented.

A physician, nurse, or pharmacist who was trained in chart review methods was designated locally to be the site's initial chart reviewer. We encouraged the use of senior physicians, nurses, or pharmacists who were experienced in chart review to carry out the initial chart review, although no formal criteria were established. Conference calls, e-mail, and telephone access to the investigators were provided to the chart reviewers to promote a more clear understanding of the definitions and methods. Selected charts were reviewed locally for the presence or absence of each of the 15 triggers. Each trigger identified prompted an in-depth review for the presence of an associated ADE. In addition, the chart reviewer was instructed to identify any ADE that was not associated with a trigger. Each identified trigger and any ADE (regardless of whether it was associated with a trigger) were recorded in a customized personal digital assistant with screens based on a standard data collection sheet. Sections of the charts were reviewed in the following order: discharge summary, *International Classification of Diseases, Ninth Revision* codes (if available in the chart), laboratory reports, physician orders and MAR, nursing flow sheets, and nursing/multidisciplinary progress notes. All ADEs were evaluated for severity using categories based on the system used for classifying medication errors by the National Coordinating Council for Medication Error Reporting and Prevention (Table 2).[27] All ADEs were evaluated by the local chart reviewer using local definitions to determine whether these ADEs could have been prevented, identified earlier, or mitigated more effectively and whether an associated occurrence report was filed. In addition, each ADE was evaluated for the stages of the medication process in which a medication error occurred (for preventable ADEs), medication class, the principle diagnosis at discharge of the patient who incurred the ADE, and the hospital location of the event. Each ADE and associated characteristics identified by the primary chart reviewer were then reviewed for accuracy by a local physician (secondary reviewer), who was provided a summary of the event and any relevant clinical information that would allow him or her to confirm (or reject) that an ADE occurred. In case of discrepancy, the second reviewer's interpretations of the preventability, earlier identification, more effective mitigation, medication stages, medication class, principle diagnosis at discharge, and location of event were considered final.

Once completed, the data were sent electronically, without patient identifiers, to the central data repository at CHCA. Data were reviewed for completeness and consistency, and all discrepancies or questions were referred to the chart reviewer at the appropriate site for resolution. Institutional review board approval or waiver was obtained by all participating sites.

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TABLE 3 **Patient Characteristics**

Characteristic	Average	Median	Semi-Interquartile Range
Age, y	5.9	3.9	1.8–7.1
Length of stay, d	7.1	4.0	3.0–5.0
Medications per patient	14.3	10.0	8.0–14.0
Doses per patient	90.5	39.0	29.0–55.0

Outcomes

Analysis of outcomes included the following:

- ADEs per 100 patients, per 1000 patient-days, and per 1000 medication doses;
- triggers per patient;
- trigger PPVs (defined as the number of times a specific trigger independently identified an ADE divided by the number of times a trigger was identified) individually and for the trigger tool in total; an ADE could have been identified by ≥1 trigger;
- severity of ADEs (defined as the highest level of harm applicable using the National Coordinating Council for Medication Error Reporting and Prevention severity scale)[27];
- percentage of ADEs that were preventable, could have been identified earlier, could have been mitigated more effectively, or were associated with a hospital occurrence report;
- stages (ordering, transcribing, dispensing, administering, or monitoring) of the medication management process during which the medication error (for preventable ADEs only) was believed to occur;
- class of medication resulting in the ADE;
- principle diagnosis of patient on discharge;
- hospital unit where the ADE occurred.

Statistical Analysis

Descriptive statistics, including 95th percentile confidence intervals (CIs), were calculated for patient and hospitalization characteristics as appropriate. The exact binomial distribution was used for proportions, and the Poisson distribution was used for rates. Statistical analysis was performed by using Stata 9.0 (Stata Corp LP, College Station, TX).

RESULTS

Aggregate Data

A total of 960 randomly selected charts from 12 children's hospitals reflecting a total of 6806 patient-days were evaluated. Relevant patient and hospital characteristics for the study population are listed in Table 3. The mean length of stay was 7.1 days with a median length of stay of 4 days. Thirty (3.1%) of the 960 charts represented admissions that lasted >30 days (range: 31–160 days). A total of 2388 triggers were detected, resulting in a mean rate of 2.49 triggers per patient (95% CI: 2.39–2.59). A total of 107 ADEs were identified, resulting in a mean rate of 11.1 ADEs per 100 patients (range: 0–45; 95% CI: 9.13–13.5; Table 4), 15.7 ADEs per 1000 patient-days (range: 0–55; 95% CI; 12.9–19.0), and 1.23 ADEs per 1000 medication doses (range: 0–8.3; 95% CI: 1.01–1.49). Eight (7.5%) of these 107 ADEs were determined to be the result of a medication's being omitted (order omission: 5; dose omission: 3). A total of 70 patients (7.29%; 95% CI: 5.73%–9.12%) had ≥1 ADEs during their hospitalization. The mean PPV of the trigger tool overall was 3.7% (range of PPVs for each individual independent trigger: 0–20; Table 5).

ADE Characteristics

Of the 107 ADEs identified in this study, 104 (97.2%; 95% CI: 92.0%–99.4%) were classified into category E (defined as contributed to or resulted in temporary harm to the patient and required intervention; Table 2), whereas only 3 (2.8%; 95% CI: 0.6%–8%) of ADEs were classified into category F (defined as contributed to or resulted in temporary harm to the patients and required initial or prolonged hospitalization).[27] Twenty-two percent were deemed preventable, 17.8% could have been identified earlier, 16.8% could have been mitigated more effectively, and only 3.7% ($n = 4$) had a voluntary hospital occurrence report associated with the event. All 4 ADEs identified by occurrence reports were also identified by the pediatric-focused ADE trigger tool.

TABLE 4 **ADE Statistics**

Measure	Result			
	Total	Trigger Tool[a]	Incident Report[a]	Chart Review Only[b]
No. of ADEs	107	89	4	18
ADEs per 100 patients (95% CI)	11.10 (9.13–13.50)	9.27 (7.45–11.40)	0.42 (0.11–1.07)	1.88 (1.11–3.00)
ADEs per 1000 patient-days (95% CI)	15.70 (12.90–19.00)	13.10 (10.50–16.10)	0.59 (0.16–1.50)	2.64 (1.57–4.18)
ADEs per 1000 medications (95% CI)	7.79 (6.39–9.42)	6.48 (5.21–7.98)	0.29 (0.08–0.74)	1.31 (0.78–2.07)
ADEs per 1000 doses (95% CI)	1.23 (1.01–1.49)	1.02 (0.82–1.26)	0.05 (0.01–0.12)	0.21 (0.12–0.33)
Patients with ADE				
n, %	70 (7.29)			
95% CI	55 (5.73)–87 (9.12)			

[a] Four ADEs were identified both by the trigger method and voluntary incident report.

[b] All ADEs not associated with a trigger were identified by chart review. Events included hypokalemia (4); tachycardia (3); abdominal pain/nausea/vomiting, altered mental status, anemia, clonus, fever, pruritis, seizures, and stomatitis (1 each); and "other" (3).

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TABLE 5 **PPVs of the Inpatient Pediatrics ADE Trigger Tool**

Trigger ID	Trigger	PPV, % (95% CI)
T_1	Diphenhydramine use	8.44 (5.68–12.00)
T_2	Vitamin K use	1.85 (0.05–9.89)
T_3	Flumazenil use	0.00 (0.00–0.00)
T_4	Antiemetic use	1.55 (0.80–2.69)
T_5	Naloxone use	12.10 (3.40–28.20)
T_7	Sodium polystyrene use	20.00 (0.51–71.60)
T_{10}	PTT of >100 s	16.70 (0.42–64.10)
T_{16}	Rising serum creatinine	3.85 (0.47–13.20)
T_{21}	Oversedation/lethargy/fall/hypotension	14.90 (6.20–28.30)
T_{22}	Rash	12.70 (5.96–22.70)
T_{23}	Abrupt medication stop	19.70 (10.90–31.30)
T_{25}	Serum glucose of >150 mg/dL	0.60 (0.12–1.74)
T_{26}	Hyperkalemia	3.57 (0.74–10.10)
T_{27}	Called codes	14.30 (0.36–57.90)
T_{28}	Laxative or stool softener use	2.82 (1.36–5.13)
Total		3.73 (3.00–4.57)

Eighteen (16.8%) of the 107 ADEs identified did not have an associated trigger (Table 4). The most common stage of the medication management process for a medication error to occur (resulting in a preventable ADE) was the monitoring phase (62.5%; defined as failure to review a prescribed regimen for appropriateness and detection of problems or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy; Fig 1). The medication class that most frequently was associated with an ADE was analgesics/opioids (51%; Fig 2). The diagnostic category (based on principle discharge diagnosis) that most commonly was associated with an ADE was congenital anomalies (14.9%; Fig 3). The hospital location that most frequently was associated with an ADE was hematology/oncology (18.0 per 100 patients; Fig 4). The most frequent type of ADE was pruritis (17.8%; Fig 5).

DISCUSSION

This study, reviewing 960 charts representing a total of 6806 patient-days from 12 children's hospitals, is the largest detailed review of ADEs yet published in pediatrics. These data form the basis for a better understanding of the frequency and type of ADEs, as well as the most common stages of the medication management process in which they occur, the most common medication classes, the diagnostic categories associated with the events witnessed, and the hospital ward locations most frequently associated with these pediatric ADEs. This information should help to identify and guide strategies to reduce drug-related harm to pediatric inpatients.

Our study of ADE rates in inpatient pediatric populations is consistent with recent studies concluding that the trigger tool methods seem to be more robust than the traditional methods of occurrence reports,[7,20–23,28] nontriggered chart review,[2–4,16] and administrative data analysis.[5,6] For example, the 2 most frequently cited previously published estimates of ADE rates in pediatrics[4,19] used unfocused (ie, nontrigger focused) chart review methods to identify ADEs. Kaushal et al[4] used a combination of "voluntary and verbally solicited reports from house officers, nurses and pharmacists and by medication order sheet, medication administration records and chart review of all hospitalized patients" to identify ADE rates, whereas Holdsworth et al[19] used a clinical pharmacist to "search each medical chart for evidence of ADEs and potential ADEs by reviewing physician and nursing notes, pharmacy records, medication administration records, and laboratory data." In the first study, Kaushal et al[4] reported ADE rates in children on the inpatient wards at 2 urban teaching hospitals to be 2.3 per 100 admissions (26 events), with an additional potential ADE rate of 10 per 100 admissions (115 events). Of the 26 true ADEs, 5 (19%) were determined to be preventable. In the second study, Holdsworth et al reported an ADE rate in pediatric inpatients (PICU and general care unit at a university hospital) of 6 per 100 admissions (76 events), with 61% judged as preventable, and a potential ADE rate of 8.0 per 100 patient-days (94 events).[19] Our data, using the trigger tool method, identified 11.1 ADEs per 100 admissions, thus identifying between 1.8 and 4.8 times more ADEs per discharge than the estimates of Kaushal et al[4] and Holdsworth et al.[19] Similarly, when comparing the pediatric ADE trigger tool method with occurrence reports, our study showed that only 4 of the identified 107 ADEs were identified by the occurrence report system. Although the trigger tool specifically identified only 89 of the 107 total ADEs in this study, it did identify all 4 found via occurrence reporting. Thus, the trigger tool method identified 22 times more ADEs than the frequently used but flawed occurrence report methods.[28] These findings are consistent with other trigger tool occurrence report comparisons as well.[7,20–23] The higher

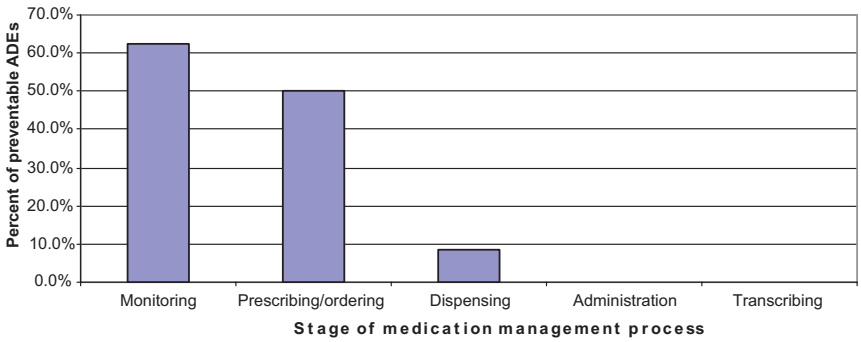

FIGURE 1
Stage of the medication management process in which a medication error occurred (preventable ADEs only; $n = 24$). Note that >1 stage could be identified for each preventable ADE.

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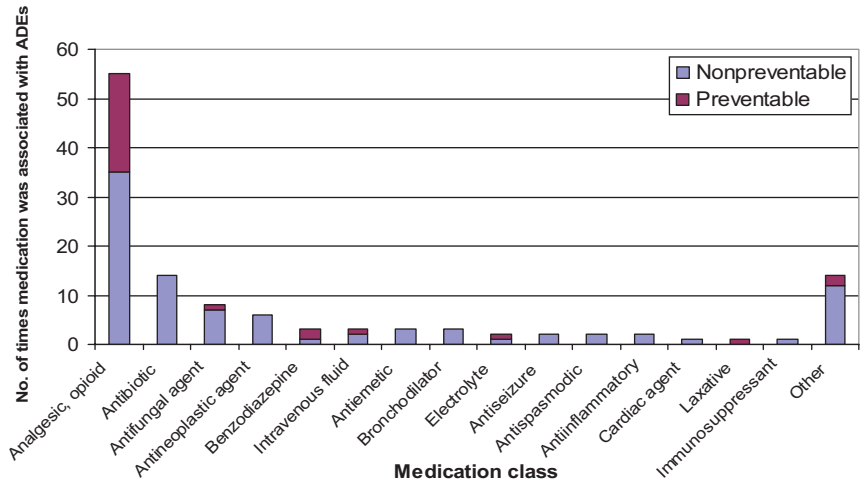

FIGURE 2
Medication classes associated with identified ADEs (n = 107 total ADEs).

rate identified by the trigger tool is likely attributable to the ability of the tool to direct focus on specific circumstances associated with ADEs, on specific chart elements, and on specific ADE types identified a priori to be of interest.

There are several limitations of this study. The most important limitation is the lack of a gold standard for ADE detection with which we can compare our results. We therefore made the assumption that the ADEs identified in this study were the sum total of all ADEs that occurred in these patients. This is the only way that we could calculate a PPV for each of the triggers and the tool itself. Second, the use of the trigger tool, in particular the determination of an event as being an ADE, is subjective and susceptible to certain biases that could affect the outcomes in uncertain ways.[29] For efficiency purposes, we did not require a second primary reviewer or a second secondary reviewer (as used in other trigger tool trials[21,22]); however, we attempted to standardize the use of the tool and the interpretations of the findings by requiring review of 10 standard practice scenarios; discussion of the findings via conference call; clear definitions for triggers, ADEs, and severity ratings; a detailed instruction manual with specific instructions, processes, and definitions; open and frequently used access to the primary investigator for questions; and a local second reviewer to confirm all ADEs. Despite these safeguards, there remains some subjectivity in the identification and interpretation of these triggers and events.[29] Additional studies on the interrater reliability of this and other trigger tools is warranted. Third, the classification of preventability (as well as the ability to identify sooner and ability to mitigate more effectively) of an event is subjective[29] and was left to local sites to determine. Although we suspect substantial variability in a chart reviewers' interpretation of preventability, the assignment of preventability in aggregate remains critical to obtaining buy-in to use of the tool and ultimately toward redesigning systems to minimize risk for ADEs in the future. Fourth, we did not evaluate the time required to review each chart, which would help to determine the efficiency of this method of ADE detection. We purposely limited the chart reviews to the first 30 days of hospitalization as a strategy to enhance efficiency, a strategy different from the IHI's recommendation of 20 minutes maximum per chart review.[20,21] This strategy had little effect in our study, however, because only 30 (3.1%) of the 960 patient charts reviewed had admissions of >30 days. Previous studies consistently found that trigger tool–based chart reviews require between 15 and 20 minutes per chart.[20–23] Finally, we did not evaluate interrater reliability between trigger tool reviewers in this study. This may have particular relevance because we allowed several disciplines, including physicians, nurses, and pharmacists, to function as primary reviewers. At least 1 previous trigger tool in pediatrics, using

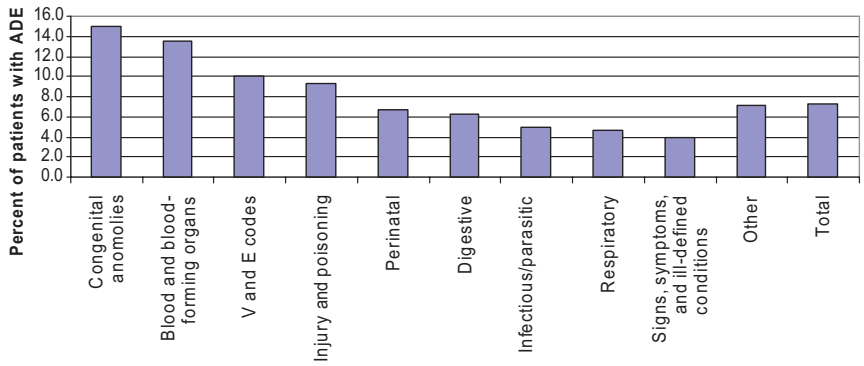

FIGURE 3
Percentage of patients with an ADE according to principle diagnosis category at discharge.

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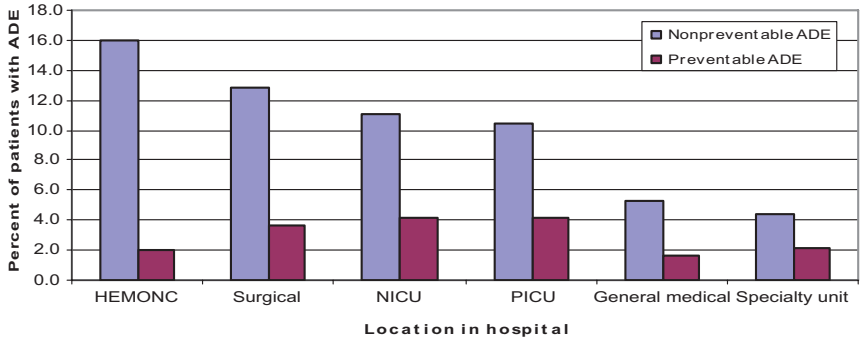

FIGURE 4
Percentage of patients with ADEs according to hospital location. HEMONC indicates hematology/oncology unit.

the same study method as used in this study, showed the reviewers to identify accurately NICU-related triggers 88.8% and NICU-related AEs 92.4% of the time.[23]

Despite these design weaknesses, this study reinforces the notion that trigger tools represent the most robust method developed to date to assess ADEs. First, their ability to identify ADEs is substantially greater than previously developed strategies such as administrative database analysis, hospital-based occurrence reports, and nontriggered chart review. The ability to measure harm effectively is becoming increasingly important as the IHI embarks on its 5 Million Lives campaign, a campaign to reduce iatrogenic harm in 5 million inpatients in a 2-year time frame.[25] Trigger tools, a concept established by Roger Resar, MD, and David Classen, MD, both of whom work with the IHI to establish measurement strategies,[20–23,26] are the clear choice for accurately measuring these rates of harm. Second, trigger tools provide a consistent method that allows routine determination of ADE rates over time. The ability to track ADE rates over time in a methodologically consistent manner is critical to quality improvement efforts at a local level. Third, trigger tools are associated with a standardized instruction manual with standard definitions and therefore can potentially be used to identify best practice sites for benchmarking purposes. Finally, trigger tools can potentially be automated, which could allow ADE identification in real time. The heavy weighting of laboratory and medication triggers in the pediatric ADE trigger tool suggests that it could form the basis of an efficient electronic strategy for tracking ADE rates as well as identifying ADEs in real time. This strategy is being explored aggressively at several children's hospitals, with promising results (Brian Jacobs, MD, written personal communication, 2008). Ideally, this real-time identification could be used to mitigate ADEs before they fully evolve. An example of this is identification of a rise in serum creatinine (possibly as a result of a medication error) that is still in the normal creatinine range for age but is flagged automatically by a computer-based preprogrammed "trigger" before extensive renal damage occurs. Several studies successfully used an automated identification system with a trigger tool in the adult setting.[20,30–32] The national movement toward electronic medical charts should enhance this effort.

CONCLUSIONS

This study is the first to develop and evaluate a trigger tool to detect ADEs in an inpatient pediatric population. We identified an ADE rate of 11.1 per 100 admissions (15.7 per 1000 patient-days), the most common stage in the medication management process for a preventable ADE to be the monitoring phase, and the most common class of medications associated with ADEs to be analgesics-opioids (causing 51% of all inpatient ADEs). The unit with the highest ADE rate per patient was the hematology/oncology unit, and the most frequently identified ADE throughout the 12 study hospitals was pruritis. Twenty-two percent of all identified ADEs were classified as preventable, with 2.8% of ADEs falling into

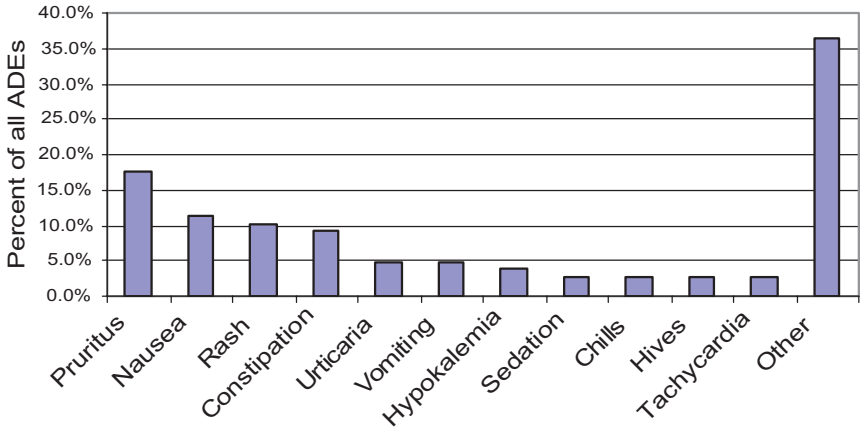

FIGURE 5
Most frequent types of ADEs. "Other" ($n = 39$) was defined as any ADE type with fewer than 3 occurrences.

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the more severe harm categories of F through I. Compared with other detection strategies such as administrative databases, hospital-based occurrence reports, and nontriggered chart review, the trigger method seems superior in identifying ADEs in multiple settings, including an inpatient pediatric population. Our data support this claim, comparing the pediatric-focused ADE trigger tool with occurrence reporting within the inpatient setting. These data should provide the groundwork for aggressive, evidence-based prevention strategies to decrease the substantial risk for medication-related harm to our pediatric inpatient population.

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