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## Measuring Harm in Hospitalized Children via a Trigger Tool

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## ABSTRACT

**Background:** The 1999 report *To Err Is Human* published by the Institute of Medicine estimated that between 44,000 and 98,000 deaths occur each year in US hospitals due to medical errors. However, processes to detect medically induced harm remain inaccurate and inconsistent. Hospitalized pediatric patients are at high risk for adverse events, with published rates ranging between 1% and 11% of all hospitalizations.

**Objective:** The study aimed to use the Global Assessment of Pediatric Patient Safety (GAPPS) tool to detect adverse events in a pediatric inpatient setting of an academic medical center children's hospital and compare to internal incident reporting methods.

**Methods:** Nurse reviewers used the GAPPS tool during a retrospective chart review of 100 patients discharged from the children's hospital. Among the total 100 cases, 20 adverse events were discovered with the tool. Adverse events were validated by physician reviewers, and the severity of harm and preventability were assigned. The number of adverse events was then compared to internal incident reporting for the same time frame.

**Results:** The detection rate is 4.87% within 411 patient-days. In contrast, the hospital had only 1.22% incident reports.

**Conclusions:** The GAPPS tool can detect four times more adverse events than the hospital incident reporting system. The results are likely to be replicated for other children's hospitals to increase identification of adverse events and harm to patients.

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## Background

The Institute of Medicine's document, *To Err Is Human*, published by the Institute of Medicine, reports up to 98,000 deaths occur annually in United States (US) hospitals because of medical errors (Kohn, Corrigan, & Donaldson, 1999). Processes to measure medically induced harm remain erroneous. Measures of adverse events (AEs), defined as injuries caused by the use, including non-use, of a drug, test, or medical treatment, are often used to quantify harm (Sharek et al., 2006). Most hospitals rely on voluntary incident reporting to identify AEs; but, evidence suggests that this method captures only a small percentage of AEs

(1%–6%) (Cullen et al., 1995; Classen et al., 2011). Hence the process of chart review has been incorporated into adverse event detection methods used by many hospitals (Brennan et al., 1991; Sari, Sheldon, Cracknell & Turnbull, 2007). This may involve in-depth screening of individual patient records for AEs and can be exhaustive.

Another approach is the use of trigger tools, that can be applied to measure patient safety (Jick, 1974). A trigger is an occurrence or flag found on review of the medical record that prompts additional investigation to determine the presence or absence of an adverse event (Sharek et al., 2006). These triggers are extracted from the medical record, such as pharmacy and clinical laboratory data, or a focused review of the discharge summary and progress notes. Examples of triggers include an administration of an antidote-type medication (e.g., naloxone) or specific laboratory values such as rising creatinine or hyperglycemia (Sharek et al., 2006; Takata et al., 2008). Once a trigger is detected, a more comprehensive review is undertaken to examine the potential for an adverse event (Children's Hospital Association, 2012). By drawing on a randomly selected sample of patient charts, trigger tool methodology allows for faster assessment than exhaustive chart review and higher sensitivity than voluntary reporting (Rozich, Haraden, & Resar, 2003; Resar, Rozich, and Classen, 2003).

**Abbreviations:** AE, adverse event; ADE, adverse drug event; CITI, Collaborative Institutional Training Initiative; IHI, Institute of Healthcare Improvement; AHRQ, Agency for Healthcare Research and Quality; GAPPS, Global Assessment of Pediatric Patient Safety; REDcap, Research Electronic Data Capture; EHR, electronic health record.

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Trigger tools detect AEs in a high percentage of hospitalizations (19%–63%) and have evolved significantly over time (Thomas et al., 2000; Wilson et al., 1995). As trigger tool methodology and evaluation have developed and become more standardized, the Office of the Inspector General commissioned work to investigate the trigger method; this work confirms that the trigger tool method identifies more AEs than voluntary reporting (Office of the Inspector General, 2010). Classen et al. found that the Trigger Tool approach identified ten times more AEs than the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicators, and almost one hundred times more events than voluntary reporting (Classen et al., 2011). It has high specificity, and moderate sensitivity, and favourable intrarater and interrater reliability (Sharek et al., 2011).

The Institute for Healthcare Improvement (IHI) defines harm as “unintended physical injury resulting from or contributed by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death” (Griffin & Resar, 2009, p. 5). There are several categories of harm, which are labelled using the following categories: E, temporary harm with an intervention required; F, temporary harm requiring initial or prolonged hospitalization; G, permanent patient harm; H, harm that requires a life-sustaining intervention; and I, harm contributing to death (National Coordinating Council for Medication Error Reporting and Prevention, 2017).

To reduce AEs in hospitalized children, an efficient and systematic process to identify AEs needs to be established. Pediatric patients are particularly vulnerable to AEs, with published rates as high as to 11% (Stockwell & Slonim, 2006; Woods et al., 2005). Within neonatal and pediatric intensive care units, studies have indicated 74 and 203 AEs, respectively, per 100 patients (Sharek et al., 2006; Takata et al., 2008). Such events are associated with large costs to both patients and hospitals (Bates et al., 1997).

A recent study by Landrigan et al. (2016) found that the Global Assessment of Pediatric Patient Safety (GAPPS) tool reliably identifies AEs and can monitor quality improvement efforts (see Fig. 1). The Global Assessment Tool was adapted from the Global Trigger Tool used in the adult patient population by Landrigan et al. (2016) for use with pediatric patients. The initial study was conducted in 2013 and was developed to measure and track AEs. Trigger tools are developed to identify signals that suggest an AE may happen. Most trigger tools are designed for the adult patient population. Landrigan et al. (2016) was the first team to identify triggers to include in a pediatric tool and to test this tool during a nationwide study in 16 academic and community hospitals. This study was to test for validity and reliability of the adapted tool for the pediatric population. The outcome of this field test (primary reviewers and hospital-based secondary reviewers) proved that reviewers agreed that a record did or did not contain a suspected AE 92% of the time ( $k = 0.69$ ) (Landrigan et al., 2016). The secondary physician reviewers agreed on the presence and absence of an AE 92% of the time ( $k = 0.81$ ) (Landrigan et al., 2016). There was a 40% sensitivity and 91% specificity found on the tool (Landrigan et al., 2016). Reliability of the GAPPS tool was measured and the  $k$  point estimated a 95% confidence interval (Landrigan et al., 2016). This tool is more sensitive than a passive voluntary reporting system, making it feasible to monitor patient safety over time. The overall rate of harm has not changed over the last decade (Landrigan et al., 2010). Our aims were to measure the rate of AEs in our general pediatrics department of the children's hospital and compare what was found using the GAPPS tool with our organization's voluntary incident reporting system.

A number of methods have been used to measure AEs in hospitals, including a voluntary reporting system (or incident reports), Agency for Healthcare Research and Quality Patient Safety Indicators, chart reviews, and trigger tools. Each of them has their distinct advantages and disadvantages. Incident reports are the most commonly used strategies to study patient safety in hospitals. They are comparatively easy and inexpensive, but identify less than one-tenth of all AEs (Cullen et al., 1995; Classen et al., 2011). They are usually completed

by nurses and are related to nursing issues (Wild & Bradley, 2005). Incidents are completed voluntarily; therefore, they are sometimes under reported because of lack of time to complete, confusion as to who completes them if working as a team and also fear of punishment because of mistakes. In addition, they may not capture the entire spectrum of harm events (Olsen et al., 2007). Patient Safety Incidents are highly prone to variation in coding practices (Romano et al., 2002). Also, they focus largely on surgical/procedural complications (Naessens et al., 2009). Similarly, retrospective chart reviews are time consuming, resource-intensive, and depend on proper chart documentation (Zhan & Miller, 2003). The trigger tool is a focused chart review, and most AEs can be captured in 20 min (Resar, Rozich & Classen, 2003).

## Design and Methods

### Design

A descriptive design was used to gather preliminary data. A convenience sample of 100 discharges from the children's hospital was chosen. There were no excluded populations within the pediatric discharges. Data collection was via retrospective chart review only.

### Setting

A children's hospital in an academic medical center with 531 registered beds was used for the study. The organization has an electronic health record and uses the Epic software system with bar coding capabilities for medications. The Institutional Review Board (IRB) at the university approved this project as part of the Children's Hospital Quality Improvement Initiatives. Informed consent was not required because no individual patients or providers were identified.

### Methods

Before starting the project, the research group completed the CITI (Collaborative Institutional Training Initiative) course. The research group consisted of a pediatric nurse practitioner, two physicians, and four clinical nurses. The entire group was trained on the GAPPS tool and how to conduct a chart review by the study team coordinator. The training consisted of case studies, PowerPoint presentations, and a sample chart that everyone reviewed with the GAPPS tool. Once training was complete, the four chart reviewers reviewed a total of 100 charts randomly selected from the previous year. The chart review process was a retrospective chart review that was a manual process. Each chart was reviewed independently by two reviewers. The reviewers read the chart independently, limiting the review time to 30 min. The charts were read for the following: coding summary, discharge summary, physician orders, medication administration record, laboratory results, radiology reports, procedure notes, and nursing/multidisciplinary notes. If none of the triggers were identified, then the review was complete for that chart. If there were triggers identified, then the chart was reviewed in depth to investigate if there were any AEs. If there was an AE, then a level of harm was assigned. After independently reviewing the charts, the reviewers then compared notes and discussed discrepancies to reach an agreement on the harm. The physicians reviewed the charts that were flagged as having AEs. The harms were also assessed for preventability. Events where no obvious breach of care occurred and all necessary precautions were taken and no clear alteration in care exists to prevent the AE was classified non-preventable. The event was classified as preventable if precautions were not taken and a breach of standard of care occurred. All results were logged into Research Electronic Data Capture (REDCap). REDCap is a browser-based, metadata-driven software solution and workflow methodology for designing clinical and

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