Reporting of Perioperative Adverse Events by Pediatric Anesthesiologists at a Tertiary Children’s Hospital: Targeted Interventions to Increase the Rate of Reporting

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**BACKGROUND:** Incident reporting systems (IRSs) are important patient safety tools for identifying risks and opportunities for improvement. A major IRS limitation is underreporting of incidents. Perioperative anesthesia IRSs have been established at multiple pediatric institutions and a national pediatric anesthesia IRS for perioperative serious adverse events (SAEs) is maintained by Wake Up Safe (WUS), a patient safety organization dedicated to pediatric anesthesia quality improvement. A confidential, electronic, perioperative IRS was instituted at our tertiary children’s hospital, which is a WUS member. The primary study aim was to increase the rate of incident reporting by anesthesiologists at our institution through a series of interventions. The secondary aim was to characterize our reporting behavior relative to national practice by referencing SAE data from WUS.

**METHODS:** Perioperative adverse events reported over a 71-month period (November 2010 to September 2016) were categorized and the monthly reporting rates determined. Effects of 6 interventions targeted to increase the reporting rate were analyzed using control charts. Intervention 5 involved interviewing pediatric anesthesiologists to ascertain incident reporting barriers and motivators. A key driver diagram was developed and used to guide an improvement initiative. Incidents that fulfilled WUS criteria for SAEs were identified and categorized. SAE reporting rates over a 27-month period for 12 WUS member institutions were determined.

**RESULTS:** 2689 perioperative adverse events were noted in 1980 of 72,384 anesthetics. Mean monthly adverse event case rate was 273 (95% confidence interval, 250–297) per 10,000 anesthetics. A subgroup involving 54,469 cases had 529 SAEs in 440 anesthetics; a mean monthly SAE case rate of 80 (95% confidence interval, 69–91) per 10,000 anesthetics. Cardiac, respiratory, and airway events predominated. Relative to WUS peer members, our institution is a high-reporting outlier. The rate of incident reporting per 10,000 anesthetics was sustainably increased from 149 ± 35 to 387 ± 73 (mean ± SD) after implementing mandatory IRS data entry and Intervention 5 quality improvement initiative. Barriers to reporting included concern for punitive repercussions, feelings of incompetence, poor education about what constitutes an event, lack of feedback, and the perception that reporting had no value. These were addressed by IRS education, cultivation of a culture of safety where reporting is encouraged, reporter feedback, and better inclusion of anesthesiologists in patient safety work.

**CONCLUSIONS:** Electronic mandatory IRS data entry and an initiative to understand and address reporting barriers and motivators were associated with sustained increases in the adverse event reporting rate. These strategies to minimize underreporting enhance IRS value for learning and may be generalizable. (Anesth Analg 2017;125:1515–23)

For many decades, anesthesiologists have been interested in perioperative safety, including anesthesia-related mortality and adverse events. Adverse events are untoward or unfavorable medical occurrences (incidents). Anesthesiology was the first medical specialty to adopt incident reporting as a safety tool. The goal of reporting is to understand how and why an adverse event occurred and to develop preventative and corrective actions to improve safety. Common events can be tracked and opportunities for improvement identified. Uncommon events can be tracked and knowledge shared with others. The opportunity to report adverse events can influence caregivers’ attitudes and behaviors positively regarding safety.

With the recent emphasis on iatrogenic harm, there is an increased imperative for healthcare organizations to learn from patient safety incidents. However, underreporting remains pervasive and opportunities for preventing patient harm are lost. Wide variations in rate of reporting occur within and between institutions.

**Available Knowledge**

Two years after our institution implemented an electronic information system, a confidential incident reporting system (IRS) was embedded within the electronic anesthetic record.

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Accepted for publication April 7, 2017.

Funding: None.

The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal’s website (www.anesthesia-analgesia.org).

Reprints will not be available from the authors.

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Incidents are voluntarily reported by anesthesiologists and have been collected since November 2010 through to the present time. Reported incidents are reviewed monthly by a Pediatric Anesthesia Safety Committee (PASC) that is responsible for Professional Practice Evaluation (PPE) of all anesthesiologists who provide patient care at the study institution. Causal analysis of adverse events often reveals system or process improvement opportunities that can be addressed using quality improvement (QI) methodology.3,5

Rationale
Integration of PPE and QI activities helped PASC members appreciate the potential value of physician-reported incidents.17 Concern about underreporting arose because there was considerable variation in the monthly incident reporting rates between anesthesiologists with similar procedure and patient care mixes. Therefore, interventions were initiated to increase the rate of incident reporting. These are described, with the desire to contribute to the advancement of pediatric anesthesia safety by openly sharing our experiences.18

Study information is presented using Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines (www.squire-statement.org/guidelines/).

Specific Aims
The study is a description of all anesthesiologist-reported adverse event rates recorded at our institution during the period from November 1, 2010, to September 30, 2016. The primary aim of the study is to determine whether interventions to increase incident reporting were successful (defined as a 50% increase in the monthly critical incident reporting rate) and sustained (defined as an effect maintained for at least 6 months).

A secondary aim is to characterize our reporting rate relative to national practice by referencing serious adverse event (SAE) data from our institution to the Wake Up Safe (WUS) SAE database.

METHODS

Context
Study subjects were patients undergoing anesthesia at a freestanding tertiary children’s hospital that is affiliated with a university. Anesthesia care was provided by pediatric anesthesiologists who are University Medical School faculty and, with one exception, have completed a pediatric anesthesia fellowship.

Since November 2010, the anesthesiologists have utilized an electronic anesthetic record system containing a confidential IRS that is separate from the medical record. The IRS provides anesthesiologists the choice of “Nothing to report” or a list of 82 different adverse events in 14 different categories, including a free text option. Multiple adverse events can be selected. If the cursor is located over an adverse event checkbox, the definition of that adverse event is displayed. Adverse events eligible for reporting include those that occur during anesthesia care or within 24 hours of the end of anesthesia care. All IRS-related information is secured in confidential, legally protected databases.

WUS is a patient safety organization dedicated to pediatric anesthesia QI and maintains a registry of pediatric SAEs that occur during anesthesia or within 24 hours of the end of anesthesia care. SAEs are defined by WUS as untoward occurrences that result in death, are life threatening, require unplanned or prolongation of hospitalization, or result in disability or incapacity.3,19 Our institution started contributing data to the WUS SAE registry in May 2014.

Intervention and Measures

Incident Reporting (IR) Interventions. From November 2010 until February 2012, the IRS was left unaltered to allow anesthesiologists to become familiar with the system. Incident data were collected and reviewed. With the goal of increasing the rate of incident reporting,20 the following interventions were then sequentially implemented.

(i) Intervention 1: Mandated data entry (March 2012). To finalize the anesthetic record, anesthesiologists were required via a force function to report an incident or attest that no incident occurred.

(ii) Intervention 2: Individual reporting rate feedback (May 2013). Anesthesiologists were shown their reporting rate relative to deidentified peers.

(iii) Intervention 3: Change to different hospital electronic information system (April 2014). The new electronic system necessitated redesign of the IRS user interface and presented an opportunity to enhance the reporting tool.

(iv) Intervention 4: WUS peer visit (September 2014). A WUS representative formally evaluated our institution’s perioperative safety practices.

(v) Intervention 5: QI initiative to increase incident reporting—phase I (January 2015). To identify motivators and barriers to incident reporting, one investigator (M.K.M.) conducted semistructured, confidential in-person interviews with the institution’s full-time pediatric anesthesiologists over a 3-week period. The reporting behavior of all anesthesiologists eligible for interview was categorized by using incident reporting frequency quartiles. Interview conduct and methodology were designed to encourage respondents to speak candidly. The 20- to 40-minute interviews included open-ended questions that explored reporting motivators and barriers. Qualitative answers were transcribed verbatim by the interviewer into a secure database and were reviewed by the respondent to confirm accuracy. Thematic analysis was used to identify the motivator and barrier themes of incident reporting within the transcribed interview responses.21,22 Saturation, indicated by redundancy and the fact that no new themes emerged, was reached at the end of the 12th interview. M.K.M. continued interviewing anesthesiologists until the conclusion of the study time frame.

To design an intervention intended to reduce barriers and support motivators to reporting, the investigators developed a process improvement map using a key driver diagram.19

(vi) Intervention 6: QI initiative to increase incident reporting—phase II (June 2015).
Measures.

(i) Monthly reported adverse event rates (per 10,000 anesthetics) were calculated using data from the pediatric anesthesia IRS and checked for accuracy against a hospital analytics report that provides total anesthetics performed from billing data.

(ii) All adverse events recorded during the period April 1, 2012, to September 30, 2016, were reviewed to identify those that met WUS criteria for an SAE. SAEs were categorized as primarily, secondarily, or not related to anesthesia care. Monthly SAE rates (per 10,000 anesthetics) were calculated.

(iii) Cases with SAEs were grouped based on the American Society of Anesthesiologists Physical Status (ASA PS) category into ASA PS I–II and ASA PS III–V. Emergency status was not used because it was unreliably documented. SAE rates between the 2 groups were compared.

(iv) WUS Research and Communications Committee approved our request for information from the WUS SAE registry and developed study data set inclusion criteria. These were (i) a common time period (ie, cases submitted to WUS between April 1, 2014, and June 30, 2016); (ii) institutions similar in nature to the study institution (ie, academic children’s hospitals); and (iii) data were complete (ie, had required demographic information). The study authors calculated member SAE rates (per 10,000 anesthetics) from the data set provided by WUS.

Analysis

The rates of adverse events per 10,000 anesthetics were calculated and presented in control charts using EXCEL (Microsoft, Redmond, WA). A Pareto chart was used to show the cumulative frequency of the various categories of adverse events. SAEs reported for the 2 ASA PS groups were compared and are presented as relative risk ratios (RRs) with 95% confidence intervals (CIs). These were calculated using Epi Info 7.0 Centers for Disease Control (Atlanta, GA). Statistical significance was defined as \( P < .05 \).

Ethical Issues

The institution’s review board determined that the study fulfilled quality assessment/improvement criteria and was exempt from further review.

RESULTS

QI Initiative to Increase Incident Reporting Rate

There were no significant demographic differences in duration of practice, academic rank, and incident reporting behavior between the interviewees (n = 28) and the entire pediatric anesthesia faculty (n = 37). Identified reporting motivator and barrier themes are listed in Table 1. Guided by these findings, a key driver diagram was used to design interventions intended support motivators of, and decrease barriers to, incident reporting (Figure 1). The key drivers to achieve the SMART aim were as follows: (i) improve anesthesiologist understanding of the IRS and reporting expectations; (ii) foster a culture supportive of incident reporting; and (iii) increase understanding of the benefits of incident reporting by providing anesthesiologists with opportunities to participate in QI initiatives that originate from reported events. Phase 1 and phase II interventions are detailed in Figure 1.

All Adverse Events

During the period from November 2010 to September 2016, an adverse event was anesthesiologist-reported for 1980 (2.7%) of the 72,384 anesthetics administered, a mean monthly case rate of 273 (CI, 250–297) per 10,000 anesthetics. There were 2689 reported adverse events; an average of 1.4 events per anesthetic for those cases with a reported adverse event. The monthly rate of anesthetics with adverse events and the timing of incident reporting interventions are shown in Figure 2. The cumulative frequency of various categories of adverse events is displayed as a Pareto chart (Figure 3).

The statistical process control chart (Figure 2) shows that the adverse event reporting rate was stable before the first intervention. The adverse event reporting rate per 10,000 anesthetics increased after mandatory IRS data entry was implemented (Intervention 1) with a shift in the monthly reporting rate mean from 149 (preintervention) to 267 (postintervention). A notable but nonsignificant temporary decline in reporting rate occurred after transition in April 2014 to a different hospital electronic information system (Intervention 3). After implementation of Phase I of the QI project to increase the incident reporting rate (Intervention 5), mean monthly reporting rate per 10,000 anesthetics shifted from 267 (preintervention) to 387 (postintervention) and the change was sustained for >6 months. Reporting increased for all adverse event categories except “Other.” Interventions 2 and 4 had no apparent effect on the reporting rate. Assessment of Intervention 6 may be premature, but one point is noted to be outside the 3 sigma limits.

Serious Adverse Events

During the period from April 2012 to September 2016, 54,469 anesthetics were administered. Of the 1709 anesthetics with adverse events, SAEs (as per WUS criteria) were judged to have occurred in 440 (25.7%) cases. The monthly rate of anesthetics with reported SAEs is displayed in a control chart (Supplemental Digital Content, Figure, http://links.lww.com/AA/B803). A shift in the mean SAE rate from 54 to 120 per 10,000 anesthetics occurred after the January 2015 QI project (Intervention 5) to increase incident reporting.

Reported SAEs are listed in Table 2 in categories utilized by WUS. A total of 529 SAEs were reported from 440 (95% CI, 0.4.3) cases, yielding an average of 1.2 SAEs per anesthetic with an SAE and a mean monthly SAE case rate of 80 (95% CI, 69–91) per 10,000 anesthetics. Cardiovascular (35%), respiratory (30%), and airway (13%) events were most commonly reported. The incidence of an anesthesia-related SAE was 53.6 per 10,000 anesthetics, anesthesia-related code requiring chest compressions was 5.5 per 10,000 anesthetics, and anesthesia-related perioperative death was 0.6 per...
10,000 anesthetics. ASA PS III–V patients were more likely to have an SAE (RR = 2.4 [CI, 1.9–3.0]) and cardiac arrest (RR = 5.4 [CI, 2.2–13.2]). Patients categorized as ASA PS III–V accounted for 43% of total anesthetics performed, 70% of all SAEs, 89% of all chest compressions, and 100% of all perioperative deaths.

**Wake Up Safe**

WUS Research and Communications Committee determined that 14 member institutions qualified for inclusion in the WUS data set provided for this study but recommended that 2 members should excluded because they were “most likely not reliably reporting events” (M. Haché, WUS Research and Communications Committee Chair). SAE rates for the remaining 12 institutions are shown in Figure 4. The study institution is site number 8.

**DISCUSSION**

**Summary**

Mandatory IRS data entry and interventions designed to support motivators of, and reduce barriers to, incident reporting were associated with sustained increases in the reporting of adverse events and SAEs. Analysis of SAE data provided by WUS suggests our institution is a high-reporting outlier relative to peer institutions.

**Interpretation**

**Incident Reporting**. Incident reporting is one component of the framework recommended for measuring and monitoring safety. Analysis of adverse events yields information about incidence and vulnerability to risk, allows identification of improvement opportunities, and enables evaluation of safety interventions. Voluntary incident reporting via an IRS is primarily limited by underreporting. This study suggests that reporting of anesthesia-related adverse events can be sustainably increased. The findings may inform other institutions that encounter IRS underreporting and incident registries such as WUS. Peterfreund et al reported a 92% increase in the incident reporting rate at an adult hospital after the introduction of a force function that mandated quality assurance documentation before finalization of the electronic anesthetic record. We noted a similar rate increase (79%) after using the same strategy at our pediatric hospital. Although structured within different anesthesia information management systems, both IRSs had similar characteristics: mandatory, secure, legally protected, and well-integrated into anesthesiology workflow. Data entry is flexible, easy, and rapid. Quality assurance is enhanced because information is obtained about every anesthetic and incident rates can be determined. While it is practical for WUS to restrict its focus to patient harm,
we perceive value in analyzing all perioperative incidents because events that did not reach the patient (near-miss safety events) or reached the patient but caused minimal or no harm (precursor safety events) may provide an opportunity to proactively address system vulnerabilities that could cause patient harm.\(^{29,30}\)

The findings associated with Phase I of our QI initiative (Intervention 5) may stimulate further research and be generalizable to diverse situations involving underreporting. We add to the body of literature that examines incident underreporting and describe barriers and motivators relevant to pediatric anesthesiologists. The study also demonstrates that supporting motivators and addressing barriers in a systematic way can lead to sustained increases in perioperative incident reporting.

Before Intervention 5, the monthly incident reporting rate was relatively constant despite the provision of reporting rates to individual anesthesiologists (Intervention 2) and an educational peer visit by a senior WUS representative (Intervention 4). In contrast, Vigoda et al\(^{25}\) found individual feedback and educational interventions were effective in the short-term (3-month follow-up) at increasing the rate of voluntary documentation of anesthesia-related quality assurance events. It is possible that Interventions 2 and 4 were ineffective because the root causes for anesthesiologist underreporting were inadequately addressed.

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**Figure 1.** Key driver diagram for incident reporting quality improvement initiative. The SMART Aim is the goal for the project, which is part of the Global Aim to improve perioperative patient safety. A SMART Aim includes Specific, Measurable, Achievable, Relevant, and Time-bound terminology. The key drivers are the factors that contribute directly to achieving the SMART Aim. The Interventions are the actions that are necessary to achieve the key drivers. IRS indicates incident reporting system; M&M, morbidity and mortality; PPE, Professional Practice Evaluation; QI, quality improvement.

**Figure 2.** Control chart for the monthly reporting rate of adverse events per 10,000 anesthetics for the period from November 1, 2010, to September 30, 2016. The timing of 6 interventions is shown. UCL indicates upper control limits; LCL, lower control limits.
Adoption of QI science methodology for Intervention 5 was useful because it compelled us to ascertain and analyze the motivators for and barriers to incident reporting.

Analysis of motivator and barrier themes indicated that anesthesiologists understood the rationale and potential benefits of an IRS. However, they were uncertain what to report, were worried about the personal consequences of reporting, and saw minimal evidence that incident reporting resulted in patient safety improvements.

Our IRS is based on self-reporting by anesthesiologists. Physicians have distinct views and beliefs about voluntary incident reporting and report adverse events less frequently than nurses or other hospital employees. There appears to be divergence between physician attitudes and their actual reporting practices; the likelihood of physician reporting increases with severity of patient harm. Incident reporting is influenced by a complex network of intrapersonal, interpersonal, institutional, and societal factors that are challenging to address. At a simplistic and practical level, it is noted that learning from incidents is a powerful motivator. If a strong safety culture exists within a learning environment, barriers focused on self (such as fear of blame, incompetence, career prospects, reputation, litigation) can be overcome by the desire to transform incidents into safety improvements.

The Phase II interventions implemented during Intervention 6 targeted the same Phase I key drivers, but the monthly reporting rate appeared unaffected. We suspect Intervention 6 has increased physician engagement. The proportion of pediatric anesthesiologists involved in patient safety activities has increased. It has been argued that the ultimate measure of IRS success is the amount of harm that could be improved. An option of anonymous reporting is recommended but is not possible with our current system. The reporting rate key drivers we developed (Figure 1) are consistent with literature recommendations. IRS success depends on the strength of the patient safety culture, both at organizational and at local levels. Higher incident reporting rates are associated with a more positive safety culture. Our institution promotes PPE as an engine for learning and system improvement within a just culture. The goal is a transparent PPE process that is constructive, dynamic, linked to QI, and sensitive to the reality that most care is delivered by teams.

It may be that the interview process and subsequent discussions with the entire faculty contributed substantially to the success of the QI initiative. Some investigators postulate that education, training, a supportive environment, and illustrating the advantages of reporting are important but should be integrated into the local cultural milieu. It is suggested that beneficial change is best achieved when group training allows members of the group to express their perspectives and collectively integrate new norms.

The Phase II interventions implemented during Intervention 6 targeted the same Phase I key drivers, but the monthly reporting rate appeared unaffected. We suspect Intervention 6 has increased physician engagement. The proportion of pediatric anesthesiologists involved in patient safety activities has increased. It has been argued that the ultimate measure of IRS success is the amount of harm that could be prevented. In 2015, pediatric anesthesia represented 14%
of the institution’s total PPE case volume, but 51% of total improvement project volume. Presently, PASC has >30 ongoing QI projects prompted by reported incidents. This substantial commitment of voluntary physician effort may be valuable for institutions (such as ours) with limited specialized QI resources.

SAEs and WUS. WUS was founded by the Society for Pediatric Anesthesia in 2008 and, as of July 2016, had 30 North American member institutions. WUS chose perioperative SAEs, irrespective of cause, as their measure of patient harm because it reflects a patient-centric approach. Consistent with WUS data, our most common reported SAEs were cardiovascular, respiratory, and airway events.

One IRS limitation is reporting bias, such as preferentially reporting minor incidents rather than serious incidents. After Intervention 5, the SAE rate increased by 128%, whereas the adverse event rate increased by 47%, suggesting SAEs are substantially represented in the postintervention data. To explore whether underreporting and bias confound interpretation of data, we tested for association between SAE rates and ASA PS and found the expected association between ASA PS III–V and a higher rate of SAEs.

As suggested in Figure 4, national IRS programs also experience the challenges of underreporting and other confounding variables. IRS data have been described as nonrandom samples from an unknown pool of events and are primarily for learning and not suited for measuring safety, comparing institutions, or measuring changes over time.

**Study Limitations**

Our IRS database is an incomplete representation of all the adverse events that occurred because of underreporting. A small number of unreported adverse events were detected by mechanisms other than voluntary self-reporting. These included trigger tools, hospital incident reports, patient/family complaints, and referrals from individuals or committees. We did not utilize other methods of adverse event detection such as automated, active surveillance of data sets, chart abstractions, or direct observations of clinical care. The change in informatic systems prevented retrospective identification of SAEs for incidents that occurred before April 2012. Study results were not adjusted for uncontrolled variables and could be subject to confounding bias.

**CONCLUSIONS**

Mandated IRS data entry and focused QI interventions intended to address motivators of and barriers to, incident reporting can increase perioperative incident reporting and potentially enhance patient safety.
ACKNOWLEDGMENTS
The authors gratefully thank Susan L. Bratton, MD, MPH, Professor of Pediatrics, University of Utah, and Division of Critical Care Medicine, Primary Children’s Medical Center for her assistance with the statistical analysis. They also thank Jake Mickelsen, Quality Improvement Manager, Stanford University Medical Center for his assistance with the control charts.

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REFERENCES


