Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.JournalofSurgicalResearch.com

Are we missing the near misses in the OR?—underreporting of safety incidents in pediatric surgery

Emma C. Hamilton, MD,[a,b] *Dean H. Pham, BA, MPH,*[a] *Andrew N. Minzenmayer, BS,*[a,b] *Mary T. Austin, MD, MPH,*[a,b,c] *Kevin P. Lally, MD, MS,*[a,b,c] *KuoJen Tsao, MD,*[a,b,c] *and Akemi L. Kawaguchi, MD, MS*[a,b,c,*]

[a] *Department of Pediatric Surgery, McGovern Medical School, The University of Texas Health Science Center at Houston, Houston, Texas*

[b] *Center for Surgical Trials and Evidence-Based Practice, McGovern Medical School, The University of Texas Health Science Center at Houston, Houston, Texas*

[c] *Children's Memorial Hermann Hospital, Houston, Texas*

ARTICLE INFO

Article history:
Received 20 March 2017
Received in revised form
28 July 2017
Accepted 1 August 2017
Available online xxx

Keywords:
Near miss
Pediatric surgery
Incident reporting
Adverse event reporting
Patient safety

ABSTRACT

Background: Electronic hospital variance reporting systems used to report near misses and adverse events are plagued by underreporting. The purpose of this study is to prospectively evaluate directly observed variances that occur in our pediatric operating room and to correlate these with the two established variance reporting systems in our hospital.

Materials and methods: Trained individuals directly observed pediatric perioperative patient care for 6 wk to identify near misses and adverse events. These direct observations were compared to the established handwritten perioperative variance cards and the electronic hospital variance reporting system. All observations were analyzed and categorized into an additional six safety domains and five variance categories. The chi-square test was used, and *P*-values < 0.05 were considered statistically significant.

Results: Out of 830 surgical cases, 211 were audited by the safety observers. During this period, 137 (64%) near misses were identified by direct observation, while 57 (7%) handwritten and 8 (1%) electronic variance were reported. Only 1 of 137 observed events was reported in the handwritten variance system. Five directly observed adverse events were not reported in either of the two variance reporting systems. Safety observers were more likely to recognize time-out and equipment variances ($P < 0.001$). Both variance reporting systems and direct observation identified numerous policy and process issues.

Conclusions: Despite multiple reporting systems, near misses and adverse events remain underreported. Identifying near misses may help address system and process issues before an adverse event occurs. Efforts need to be made to lessen barriers to reporting in order to improve patient safety.

* *Corresponding author*. McGovern Medical School, The University of Texas Health Science Center at Houston, 6431 Fannin St, MSB 5.246, Houston, TX 77030. Tel.: +713 500 7278; fax: +713 500 7296.

E-mail address: akemi.kawaguchi@uth.tmc.edu (A.L. Kawaguchi).

0022-4804/$ – see front matter © 2017 Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.jss.2017.08.005

Introduction

Deaths from medical errors are estimated to be the third leading cause of death in the United States.[1] Furthermore, despite initiatives to improve patient safety, there have been no significant reductions in the rate of patient harm.[2,3] Although there has been some improvement in the disclosure and documentation of medical errors, the vast majority remain unreported.[4-6] Insufficient knowledge of what constitutes patient harm, not knowing how to report events, perceived lack of effectiveness, fear of retribution, and competing demands of time have all been cited as reasons why errors go unreported.[5-7]

Variances are defined as an omission or commission of an unintended act with potential negative consequences for the patient, the failure to complete a planned action as intended, or the use of the wrong plan to achieve an aim.[8-10] Adverse events, a type of variance, are defined by the Institute of Medicine as "unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient."[11] Near misses, another type of variance, are events that did not reach the patient because of the active recovery from potential harm by processes already in place or by chance alone.[6] The reporting of near misses is vital to understanding individual and systemic problems that may lead to adverse events.

Although several studies have estimated that the rate of medical errors far exceeds those disclosed by voluntary hospital reporting systems, few studies have estimated the rate of near misses.[3,5,12] We hypothesized that even though we have two variance reporting systems at our institution, near misses remain vastly underreported in our pediatric perioperative environment. To test this hypothesis, we conducted a prospective observational study to evaluate for variances in the operating room.

Methods

The Children's Memorial Hermann Hospital is affiliated with the University of Texas Health Science Center and the McGovern Medical School in Houston. This 278-bed academic children's hospital performs approximately 6500 operations annually.

Two systems exist in our hospital for the self-reporting of variances in the operating room. These systems are intended to be complementary and to increase the capture of variances. The first system is a hospital-wide electronic variance reporting program that is monitored by a pediatric hospital safety group comprised of physicians, nurses, hospital leadership, and risk management. Individuals can submit anonymous or identified reports about safety concerns in multiple categories related to patient care. Hospital policy is for all adverse events to be reported through the electronic variance reporting system by involved hospital staff. These reports are sent electronically to a centralized pediatric risk manager. From there, the electronic variances are categorized into quality review, filter committee review, and other. The quality review is done by nursing leadership, and issues are brought back to the nursing management. More serious, select electronic variances are analyzed at a weekly multidisciplinary filter review committee comprised of physicians, nurses, and hospital leadership. Variances are otherwise directed to various managers who were responsible for implementing change among their staff. There is no formal feedback system, and the perioperative caregivers are not involved in the process.

The second system was developed through a quality improvement initiative that addressed the barriers to variance reporting in the children's operating arena. It is a stakeholder-driven reporting system specifically for the children's perioperative staff and consists of handwritten cards that allow open-ended answers by asking "What happened?" These cards can then be placed in HIPAA-compliant boxes located around the perioperative area. The cards are reviewed on a weekly basis by a multidisciplinary committee consisting of a surgeon, an anesthesiologist, an operating room nurse, a preoperative or recovery room nurse, a surgical technologist, and our clinical coordinator. Identified safety events are sent for review by the surgical safety council, which is a multidisciplinary group represented by surgery, anesthesia, nursing, pediatrics, neonatal intensive care unit, pediatric intensive care unit, pediatric emergency room, and hospital leadership. This safety council is responsible for creating, implementing, and auditing various perioperative patient safety programs. Timely feedback is provided to involved individuals, and monthly reports are distributed to all perioperative staff.

For this observational study, four medical students were trained to be safety observers to identify near misses and adverse events in the pediatric operating room. They underwent formal instruction from three of the authors about the definitions of near misses and adverse events and used a standardized data collection sheet to identify variances. Interrater reliability was confirmed by having these individuals observe five operative cases and comparing their observations of variances. Over a 6-wk period, safety observers randomly selected from noncardiac elective and urgent surgical cases between 7 AM and 5 PM on weekdays for audit. Direct observations were made of operative care, and variances were recorded.

As described in Table 1, variances were categorized into six safety domains (equipment/supplies, knowledge/attitude, policy/process, environment, operations, and unable to categorize) and five variance categories (adverse event, good catch/near miss, safety process issue, indirect safety issue, and indeterminate). One of the authors analyzed and categorized the electronic, handwritten, and directly observed pediatric operative variance reports on a weekly basis. Additionally, all electronic, handwritten, and directly observed reports were directly compared for overlap. Differences between the three reporting systems were compared with chi-square analyses using Stata 13.1 (College Station, Texas) at a $P < 0.05$ level of significance. This study was submitted to the IRB and exempted from IRB review as it was considered a quality improvement project.