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Using Voluntary Reporting of Hazards to Improve Patient Safety

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“Given limited resources, institutions might be advised to focus on improving the quality . . . rather than increasing the quantity of reports.”

—Herzer, et al. (p. 346)



Reporting Systems

Patient Safety Reporting Systems: Sustained Quality Improvement Using a Multidisciplinary Team and “Good Catch” Awards

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Twelve years have passed since *To Err Is Human* exposed the shortcomings of the quality and safety of health care in the United States.¹ Hospitals have made substantial commitments to health care quality and patient safety through individual initiatives of executive leadership involvement in quality, investments in safety culture, education and training for medical students and residents in quality and safety, the creation of patient safety committees, and implementation of patient safety reporting systems (PSRSs). Hospital leadership is involved in executive walkarounds,^{2,3} safety culture is measured,⁴ medical students and residents receive education in quality and safety,⁵ hospital departments have patient safety committees and directors of quality and safety,⁶ and PSRSs are widespread.⁷ In this article, we describe how we enhanced a PSRS as part of a comprehensive program to identify and mitigate hazards that could harm patients at the Weinberg Surgical Suite at The Johns Hopkins Hospital (Baltimore), a 16-operating-room (OR) inpatient/outpatient cancer center.

A Multiphase and Multidisciplinary Process for Patient Safety Reporting and Follow-Up

In 2007 we created a framework for maximizing the potential of any PSRS. The goal of this approach was to identify and mitigate hazards using a multidisciplinary team with local oversight of patient safety reporting data coupled with positive public recognition (a “Good Catch” award) for the person or group who initiated the effort to improve safety by reporting the hazard in the PSRS and then liaised with the multidisciplinary team in the process of mitigating it. We defined a *hazard* as any potential source of harm.⁸ This framework consisted of six phases: (1) identify a hazard to patient safety, (2) report the hazard in a patient safety reporting system, (3) analyze the report with a multidisciplinary team, (4) mitigate the hazard and educate practitioners, (5) reward the individual (or group) who reported and helped mitigate the patient safety hazard, and (6) follow up to

Article-at-a-Glance

Background: Since 1999, hospitals have made substantial commitments to health care quality and patient safety through individual initiatives of executive leadership involvement in quality, investments in safety culture, education and training for medical students and residents in quality and safety, the creation of patient safety committees, and implementation of patient safety reporting systems. At the Weinberg Surgical Suite at The Johns Hopkins Hospital (Baltimore), a 16-operating-room inpatient/outpatient cancer center, a patient safety reporting process was developed to maximize the usefulness of the reports and the long-term sustainability of quality improvements arising from them.

Methods: A six-phase framework was created incorporating UHC’s Patient Safety Net® (PSN): Identify, report, analyze, mitigate, reward, and follow up. Unique features of this process included a multidisciplinary team to review reports, mitigate hazards, educate and empower providers, recognize the identifying/reporting individuals or groups with “Good Catch” awards, and follow up to determine if quality improvements were sustained over time.

Results: Good Catch awards have been given in recognition of 29 patient safety hazards identified since 2008; in each of these cases, an initiative was developed to mitigate the original hazard. Twenty-five (86%) of the associated quality improvements have been sustained. Two Good Catch award-winning projects—vials of heparin with an unusually high concentration of the drug that posed a potential overdose hazard and a rapid infusion device that resisted practitioner control—are described in detail.

Conclusion: A multidisciplinary team’s analysis and mitigation of hazards identified in a patient safety reporting process entailed positive recognition with a Good Catch award, education of practitioners, and long-term follow-up.

Table 1. An Overview of the Patient Safety Reporting and Follow-Up Process

Process Phases	Activities
1. Identify a hazard to patient safety	<ul style="list-style-type: none"> ■ Determine that an event has occurred that could harm a patient. ■ Clearly communicate the hazard to other members of the patient care team.
2. Report the hazard in a patient safety reporting system.	<ul style="list-style-type: none"> ■ Enter a full report in a patient safety reporting system, documenting the identified hazard. ■ Use SBAR (Situation, Background, Assessment, and Recommendation) to describe the event in the free-text field.
3. Analyze the report with a multidisciplinary team.	<ul style="list-style-type: none"> ■ Form a multidisciplinary team to review the report within the specific unit or patient care unit. ■ Invite the individual who reported the hazard to present it to the team. ■ Identify factors that contributed to the hazard. ■ Determine how the hazard could be prevented from recurring.
4. Mitigate the hazard and educate practitioners.	<ul style="list-style-type: none"> ■ Identify individuals who are responsible for mitigating hazards in their respective domains, determine a plan of action, and agree on a timetable for completion. ■ Engage hospital leadership to support the team's efforts.
5. Reward the individual (or group) who reported and helped mitigate the patient safety hazard.	<ul style="list-style-type: none"> ■ Present the "Good Catch" award to an individual or group, publicly display the award in the patient care unit with a summary of the hazard and what was done to mitigate it, and provide the individual with a certificate signed by hospital leadership to recognize this effort. ■ Educate the department or hospital by discussing the patient safety hazard in grand rounds, mortality and morbidity conferences, or nursing and medical teaching conferences. ■ Track and monitor any patient safety events related to the original hazard.
6. Follow up to verify sustained quality improvement.	<ul style="list-style-type: none"> ■ Follow up to verify sustained quality improvement related to each patient safety hazard.

verify sustained quality improvement, as summarized in Table 1 (above) and now described in detail.

PHASE 1: IDENTIFY A HAZARD TO PATIENT SAFETY

The purpose of this phase was to identify anything that happened in the clinical environment that could threaten the safety of a patient. All members of the patient care team (physicians, nurses, technicians, and other hospital staff) were educated to be responsible for recognizing situations or conditions that could lead to patient harm. The existence of any hazard was to be clearly communicated to other members of the team and entered in the PSRS. These hazards ranged from potentially unsafe conditions to events in which no harm occurred to events in which harm or death occurred.

PHASE 2: REPORT THE HAZARD IN A PATIENT SAFETY REPORTING SYSTEM

Reporting hazards in a PSRS preserves relevant information that is necessary to analyze events after the fact and helps to develop a fact-based, appropriate plan to mitigate the hazards and prevent them from recurring. Many PSRSs have a free-text field in which an individual can enter a structured description of the hazard or event using a simple mnemonic communication tool known as SBAR (Situation, Background, Assessment, and Rec-

ommendation) (Figure 1, page 341).⁹ The SBAR format encourages the individual to organize information about the patient safety hazard into a concise description that includes contributing factors and suggested solutions to address the problem. Reports in the PSRS are sent electronically to a multidisciplinary team of providers and staff as determined by the institution.

PHASE 3: ANALYZE THE REPORT WITH A MULTIDISCIPLINARY TEAM

It is important that a multidisciplinary team of stakeholders (for example, physicians, clinical department administrators, nurses, risk managers, equipment specialists, managers of clinical operations and information technology) already be designated and functional so that it can review the reported hazard and provide feedback to the specific clinical unit or patient care area.¹⁰ All individuals who are familiar with the event context should participate in interpreting the hazard (that is, those who can tease out the various human and organizational factors involved).¹¹ A diverse team can offer a comprehensive knowledge base.¹² For example, explanations given by risk managers on the multidisciplinary team can help practitioners understand the process of prospective risk mitigation as well as the legal considerations involved in risk analysis.¹³ This level of on-site management also cultivates expertise and leadership at the level of the

What Is SBAR?

Situation:

- State what is happening at the present time that has warranted the communication.
- Identify the patient, his or her symptoms, and the procedure.
- Discuss what was supposed to happen (for example, what drugs were supposed to be used).
- Discuss what mistake was made.
- State what the final resolution/result was.

Background:

- Explain circumstances leading up to this situation. Put the situation into context for the reader/listener.
- Discuss relevant events that led up to the problem.
- Identify if the same problem has occurred before.

Assessment:

- What do you think the problem is?
- Identify the problem.
- Discuss possible reasons for why the problem occurred.
- If the problem was previously identified, state what was done to try to resolve it.

Recommendation:

- What would you do to try to correct the problem?
- Identify steps necessary to fix the problem.
- Identify the people responsible for those steps.
- Recommend solutions for the prevention of the problem in the future.

Figure 1. *The SBAR format encourages the individual to organize information about the patient safety hazard into a concise description that includes contributing factors and suggested solutions to address the problem. Adapted from Haig KM, Sutton S, Whittington J. SBAR: A shared mental model for improving communication between clinicians. Jt Comm J Qual Patient Saf. 2006; 32(3):167–175. Questions or triggers were added for each of the four steps.*

frontline providers. As such, it is valuable to invite the individual who reported the hazard to present the case. This action sends a clear signal to that individual as well as others working in the clinical unit that timely feedback is a priority and that their input is valued.

PHASE 4: MITIGATE THE HAZARD AND EDUCATE PRACTITIONERS

Correcting of the hazards identified by clinicians can take many forms. Some hazards may require design-oriented corrections, such as those involving physical changes to the clinical environment (for example, use of a different medical device or repair of a code cart). Other corrections may entail altering existing policies and procedures, training or credentialing individuals, standardizing communication, or purchasing equipment and drugs. Depending on which form of correction is needed, the required resources, staff time, and financial expenditure may vary widely. For example, while changes to policies and procedures may not be financially costly but may consume staff time,

changes to the physical infrastructure can be costly but would not be time intensive for clinicians. Regardless, hospital leadership should be engaged and supportive of multidisciplinary team efforts and participate in activities such as executive partnerships and facility walkarounds.¹⁴ Leadership's involvement in mitigating the hazard can help garner additional resources should they be needed. It is essential in this phase that the multidisciplinary team identify all individuals who are responsible for mitigating hazards in their respective domains, determine a plan of action, and agree on a timetable for completion.

Grand rounds, morbidity and mortality conferences, and other quality assurance meetings run by either the department or multiple departments are appropriate forums for disseminating information about the hazard and the steps taken to mitigate it. Electronic communication such as e-mail, bulletins, and other hospitalwide announcements can also be used to generate awareness among practitioners. In addition, the department or hospital staff is educated about the hazard, so that similar patient safety events can be identified in an effort to continuously improve care.

PHASE 5: REWARD THE INDIVIDUAL (OR GROUP) WHO REPORTED AND HELPED MITIGATE THE PATIENT SAFETY HAZARD

In this phase, on the basis of the consensus of the multidisciplinary team, an individual or group is acknowledged with the positive public recognition of a Good Catch award. The main criterion for receipt of this award is that the individual or group who originally identified and reported the patient safety hazard also liaised with the multidisciplinary team and participated in its efforts to analyze the hazard and implement a plan to address it. This award is not given to an individual or group for simply recognizing and reporting a near-miss (or *close-call*) incident, which does not in and of itself change practice. Involvement of the reporting individual or group in the activities of the multidisciplinary team creates an understanding that patient safety is everyone's continuing responsibility—a responsibility that is not finished just because a hazard was reported or because a team held a weekly meeting.

PHASE 6: FOLLOW UP TO VERIFY SUSTAINED QUALITY IMPROVEMENT

After the patient safety hazard has been mitigated, it is equally important to revisit the issue at regular intervals to verify that the quality improvement has been sustained during the intervening time. Rectifying a patient safety hazard at a particular point in time with a particular group of people without provid-

ing continuing, ongoing communication and verification cannot guarantee that the issue remains resolved. If it does not remain resolved, it reverts to being a patient safety hazard again.

Methods

SETTING

We began this project in the Weinberg Surgical Suite at The Johns Hopkins Hospital in June 2007. The Weinberg Surgical Suite is an inpatient/outpatient cancer center that contains 16 ORs, an associated preoperative unit and preoperative evaluation center, a 21-bed postanesthesia care unit, and a 20-bed surgical intensive care unit, in which approximately 6,500 high-risk procedures are performed annually. This surgical suite has the Weinberg Perioperative Clinical Services Team (WPCST), a multidisciplinary team composed of physicians, nurses, risk managers, human factors engineers, administrators, and support staff. The WPCST meets weekly to address perioperative issues related to safety, quality, efficiency, teamwork, and development of new surgical services.¹⁰

PATIENT SAFETY REPORTING SYSTEM

The Johns Hopkins Hospital uses UHC's Patient Safety Net[®] (PSN) as its PSRS.¹⁵ Patient safety reports specific to the Weinberg Surgical Suite are gathered from the PSN on a weekly basis. The director of the WPCST [L.J.M.] selects significant reports (often based on severity) that are added to the agenda for WPCST's weekly one-hour meeting. The clinician who reported the patient safety hazard is sometimes invited to present the report to the team but is always involved with the activities of the team in analyzing and mitigating the hazard.

IMPLEMENTATION

The multidisciplinary WPCST plans and implements Phases 3 and 4 of the process during its weekly meeting. Factors contributing to the hazard are identified and analyzed, and preventive approaches are discussed. Weighted-priority-score calculations using a tool developed by the team are used to rank hazards so that the team can most efficiently use limited resources.¹⁰ At the conclusion of the meeting, specific action items, and a timetable are agreed on. Follow-up dates are set to discuss progress at the next WPCST weekly meeting.

Minutes recorded by an administrative assistant are distributed by e-mail to the entire team following the meeting. Before the next meeting, team members work on their respective action items. Mitigating the hazard at times requires the involvement of and further assessment of the hazard by other stakeholders, such as a human factors engineer, risk manager, or facilities staff member.

EDUCATION OF PRACTITIONERS AND OTHERS

To educate practitioners in the department or in the hospital as a whole, patient safety hazards addressed by the WPCST are presented at departmental grand rounds and morbidity and mortality conferences, as well as at nursing and medical teaching conferences. We educate providers using an adaptation of an SBAR report.⁹ This SBAR format has been adopted as the standard approach for presenting at morbidity and mortality conferences, which are now routinely used as forums for discussing improvements in safety and educating providers about changes in policies or practices.¹⁶

Selected cases associated with Good Catch awards become Web-based educational tools in the form of accessible presentations and knowledge assessment exercises, as well as components of faculty and staff competencies. In our experience, these have been useful venues for disseminating pertinent information about a patient safety hazard, how it was mitigated, and who was responsible for leading the effort. Anesthesiology residents use the process in a practice-based learning course. Resident education, dictated by the Accreditation Council for Graduate Medical Education (ACGME), specifies six core competencies, two of which are practice-based learning and improvement and systems-based practices.¹⁷ We now link each Good Catch award to an ACGME competency and educate residents about the systems defect(s) that prompted that award. The strength of this process is that it can be adapted to meet the needs of virtually any group (from undergraduates to cleaning staff) that needs to learn about patient safety hazards.

The Johns Hopkins University undergraduate students provide support for this six-phase process. They collect data on patient safety hazards by reviewing the literature and analyzing previous reports from the hospital's PSN, assist the multidisciplinary team in investigating patient safety hazards by teasing apart those elements in a system that could contribute to patient harm, draft Good Catch awards, and maintain the Good Catch award bulletin board in the Weinberg Surgical Suite.

THE GOOD CATCH AWARD

To date, 29 Good Catch awards have been given to an individual or group responsible for reporting and helping to mitigate patient safety hazards. These patient safety hazards are detailed in Table 2 (page 343). Individuals honored with a Good Catch award have their photographs displayed beside the award on a bulletin board. In the Weinberg Surgical Suite, this board is affixed to the wall immediately inside the operating suite, where it is readily seen by all OR staff. In addition, award recipients are given a certificate signed by the executive leadership of The

Table 2. “Good Catch” Awards Given to Date*

“Good Catch” Award	System Changes Implemented	QI Sustained?
1. Insulin. No standard infusion concentrations	Standardize pharmacy order sheet institutionwide	Yes
2. Heliox. Delayed delivery to OR	On-site OR Heliox	Yes
3. Liposuction. OR personnel unfamiliar with new equipment	New staff in-service	Yes
4. Modified Surgical Stapler. Surgical stapler needed to be modified for innovative surgery	MedSun and FDA report; stapler modification; modified surgical informed consent	Yes
5. Jet Ventilation. Inadequately maintained OR equipment	Daily equipment check	Yes
6. Latex. Outdated latex-free/safe inventory in Weinberg Surgical Suite	Latex-free/safe environment	No
7. CO ₂ Laser. OR personnel unfamiliar with new equipment	Manufacturer representatives on site whenever device used	Yes
8. Hysteroscopy. OR personnel unfamiliar with new equipment	Specialty nursing and physician in-service	Yes
9. Methemoglobinemia. Topical anesthetic spray (benzocaine)-induced methemoglobinemia	Limited pharmacy distribution of benzocaine	Yes
10. Heparin. Ordering and distribution of 10,000 units/mL throughout institution	Removal of heparin 10,000 units/mL from institution	Yes
11. 180° Table Turn. 180° table turn for surgical site access delayed reestablishing physiologic monitoring	Safety check initiated by surgeon following table turn	No
12. Vecuronium. Neuromuscular blockade drug look-alike error with antibiotic drug	FDA recall of improperly labeled neuromuscular blockade drug	Yes See No. 18
13. Informed Consent. Multisurgeon procedure but only one consent obtained	Individual consent by each surgical service	Yes
14. Rapid Infuser. Resisted practitioner control with unintended alteration of transfusion rate	MedSun and FDA report; institution-initiated equipment change	Yes
15. Supraglottic Airway Device. Replaced the previously used double-lumen airway in prehospital airway management without informing all providers	MIEMSS updates to inform practitioners; MedSun recommendations with manufacturer input (device lacked identification features for providers)	Yes
16. Double-Lumen Endotracheal Tube. Requested for use in a nonapproved patient care unit	Updated policy regarding which patient care units are permitted to use the tube	Yes
17. Transaxillary Robotic Thyroidectomy. Unsafe conditions in new surgical procedure identified	Patient position modified; neuromonitoring recommended with modified surgical informed consent	Yes
18. Vecuronium II. Drug labels noncompliant, but pharmacy continues to order because of shortage of properly labeled drugs	FDA notified of noncompliant labels; increased practitioner awareness	Yes See No. 12
19. Manufacturer-Packaged Cardiac Resuscitation Drugs. Look-alike error	Additional color-labeling for these medications when taken out of manufacturer's boxes	Yes
20. Labels on Endotracheal Tubes. Labels are not standardized	Recommended consistent labels; MedSun recommendation to manufacturer (pending)	No
21. Malfunctioning Bed. For patients with BMI > 45	MedSun report submitted	Yes
22. Central Venous Catheter Infiltrate. Resulted in hematoma	Risk management review of peripheral versus central vascular access	No
23. Trauma Surgery 911. Difficulty mobilizing surgical attending support during unexpected surgical events	Trauma surgery consulted for OR catastrophes	Yes
24. Intraoperative Blood Cell Salvage for Massive Transfusion Hyperkalemia	Perfusionists wash RBCs for massive transfusion hyperkalemia	Yes
25. Glass Ampules Shattered	Appropriate storage of emergency glass ampule drugs	Yes
26. Lack of IV Tubing Backflow Device. Patient did not receive medication	IV tubing backcheck valve is the standard	Yes
27. Access Jackson Table. Modified by surgeon without risk management knowledge	Risk Management Device Subcommittee formed	Yes
28. Latex Discovered in Simulation Center	Presence of latex documented; simulation center leadership developed protocol for removal and replacement of latex products; temporary signs posted to warn users of specific latex-containing equipment	Ongoing
29. LVAD Patient Harm due to Blood Pressure Measurement Limitations Using Automated Cuffs	Multidisciplinary investigation led to new protocol requiring manual cuff and Doppler being purchased; education of providers about change in practice	Ongoing

* QI, quality improvement; OR, operating room; MedSun, Medical Product Safety Network; FDA, US Food and Drug Administration; MIEMSS, Maryland Institute for Emergency Medical Services. Systems; BMI, body mass index; RBC, red blood cell; IV, intravenous; LVAD, left ventricular assist device.

Johns Hopkins Hospital. This certificate becomes a permanent record in each employee's file.

SUSTAINED QUALITY IMPROVEMENT

The sustainability of patient safety quality improvements made during this process was tracked over time through ongoing review of all PSRS reports by the multidisciplinary team or by an institutional patient safety committee. Quality improvements associated with 86% (25) of the 29 Good Catch awards have been sustained since they were first implemented. Some quality improvements have been sustained since 2008 when the process began, while others were initiated more recently but continue to be sustained as of the date of this article. Quality improvements associated with the remaining 14% (4) of the Good Catch awards were not sustained, although, to our knowledge, there have not been any recurrences of those patient safety hazards.

Case Examples of Good Catch Awards

This section describes in detail two of the cases that resulted in a Good Catch award and whose patient safety hazards were addressed using the multiphase and multidisciplinary process described previously.

HIGH-CONCENTRATION HEPARIN

Phase 1. Vials of high-concentration heparin (10,000 units/mL) were found in the Weinberg Surgical Suite satellite pharmacy in a labeled bin containing stocked items. An attending anesthesiologist noted that the vials were substantially more concentrated than the 1,000 units/mL and 5,000 units/mL vials typically used at our institution.

Phase 2. The high-concentration heparin vials were brought to the attention of our institution's perioperative safety officer for removal and follow-up. The event was reported in the PSN.

Phase 3. This incident was immediately assessed by the WPCST to determine the reason for the presence of high-concentration heparin and to evaluate the potential safety hazard posed to patients. It was found that heparin is manufactured in vials in low concentrations of 100 units/mL for flushing heparin locks and in higher concentrations of 1,000 units/mL, 5,000 units/mL and 10,000 units/mL, the highest concentration being only for subcutaneous injection. Fatal medication errors have occurred when the 10,000 units/mL heparin was used to flush a heparin lock.¹⁸ According to the Institute for Safe Medication Practices, those errors occurred because nurses were accustomed to finding only the 10 units/mL heparin vials in their bins, and the labels of the two concentrations were similar.¹⁸ Subsequently,

the manufacturer revised the labeling on its heparin vials.¹⁹ Heparin errors had occurred throughout the United States, including at our own institution and in our insurance consortium (MCIC Vermont, Inc., New York City), when 10,000 units/mL vials were inadvertently used for intravenous injection.²⁰ Consequently, The Johns Hopkins Hospital and the other MCIC institutions have banned the use of 10,000 units/mL heparin in their hospitals. However, in 2008, Baxter Healthcare Corporation, which produces the majority of the heparin supply in the United States, issued a Food and Drug Administration (FDA)-mandated recall of 1,000 units/mL heparin vials because of an increase of allergic-type reactions.²¹ As a result, many institutions were able to obtain only the 10,000 units/mL heparin but believed that individual providers could safely dilute and dispense it. However, providers were not consistently or adequately informed of this situation. In our institution, the 10,000 units/mL vials were inadvertently dispensed to the Weinberg satellite pharmacy. The heparin was correctly labeled by the manufacturer, and the pharmacy bins were correctly labeled, but there was no communication, education, or warning given to providers.

Phase 4. The high-concentration heparin vials and labeled drug box were removed from the Weinberg satellite pharmacy. The pharmacist was notified and immediately investigated other Johns Hopkins OR pharmacies. More of the same high-concentration heparin vials were found stocked and were promptly removed. OR leaders were notified and urged to raise awareness among providers and staff. WPCST members communicated with the pharmacy leadership and the director of pharmacies to ensure their full cooperation in creating mechanisms to prevent future entry of high-concentration heparin vials into the pharmacy inventory. The pharmacy staff was reeducated to ensure that 10,000 units/mL heparin vials were not ordered by the institution.

Phase 5. The anesthesiologist who had identified and helped mitigate the heparin patient safety hazard was given a Good Catch award.

Phase 6. Follow-up over a one-year program showed that this quality improvement was sustained in that 10,000 units/mL heparin vials were no longer being ordered or stocked.

RAPID INFUSER RESISTED PRACTITIONER CONTROL

Phases 1 and 2. A rapid infuser was being used for safe, high-volume infusion during liver resections. This device is used to infuse large amounts of blood products over a short period of time, as required during this procedure. The Johns Hopkins Hospital's Clinical Engineering Services (CES) received a report

from the attending anesthesiologist that a rapid infuser was seen to be infusing at a rate of 500 mL/min, when it had been originally set to infuse at a much lower rate. This incident was reported in the PSN.

Phase 3. The WPCST met with CES and sequestered the rapid infuser so it could be tested. They noted that the touch-screen control panel on the infuser allowed rate adjustments by (a) discrete increments, (b) a fixed selection for 500 mL/min, or (c) via bolus. Three options for touch-screen sensitivity were provided, each option requiring a different duration of contact with the screen to initiate a control action. The device in question was set at “medium” sensitivity; however, the touch-screen controls could not be locked to prevent unintended activation.

Testing the device for approximately two hours indicated that it did not change rate autonomously. On the medium-sensitivity setting, brief, accidental contact with the control panel (by tubing, fingers, or other objects) demonstrated the possibility of unintended control input. CES concluded that in a busy operative environment there could be unintended activation of the touch-screen controls by a moving object. In the knowledge that a manufacturer-led initiative and/or modification of this device would be the ideal solution for our institution and others,²² the WPCST and CES first approached the manufacturer. However, the recommendation to revise the touch-screen control panel was not accepted. Subsequently, The Johns Hopkins Hospital submitted a report to MedSun, the Medical Product Safety Network administered by the FDA. The goal of MedSun is to collaborate with the clinical community to identify and solve problems involving the use of medical devices.²³

Phase 4. To address this patient safety hazard, our human factors engineer designed and then added a hinged, clear acrylic cover above the touch-screen control panel. The cover used a sturdy yet flexible plastic tape as a hinge to provide access for cleaning. The cover provided protection against unintended activation while preserving visual access to display information and enabling intentional control inputs. All rapid infusers of this model in the institution were subsequently modified following

this design.

Phase 5. The anesthesiologist who reported and helped mitigate the rapid infuser hazard received a Good Catch award (Figure 2, above).

Phase 6. In follow-up, this case was presented at a mortality and morbidity conference within the Department of Anesthesiology and Critical Care Medicine. For 16 months, there have been no further issues with the touch-screen control panel of the rapid infuser following this intervention; however, the institu-

“Good Catch” Award SBAR Summary for Rapid Infuser

GOOD CATCH AWARD!

Rapid Infuser

PSN Report #xxx/Date xxx Or ACCM QA Encounter Report #xxx

S	SITUATION: During an OR emergency requiring massive blood transfusion, a rapid infuser device was used. Practitioners noted that the flow rates would change suddenly and without active practitioner programming and ranged from 50-500 ml/minute. The device was sequestered.
B	BACKGROUND: The rapid infuser is used in the event of anticipated or emergency massive blood transfusion, more frequently in a different OR suite at our institution. An experienced anesthesia provider noticed that inadvertent contact/bumping of the device seemed to trigger the immediate change in flow rate. This unplanned, acute change in flow rate can compromise patient care significantly.
A	ASSESSMENT: Human Factors and CES conducted an RCA and identified changes to the touch screen sensitivity settings that could be adjusted, violations to human factor design allowing for inadvertent activation of commands not intended by practitioners. The manufacturer was contacted, but declined to change the product. MEDSUN was contacted.
R	RECOMMENDATION: <ol style="list-style-type: none"> 1. Practitioners were inserviced regarding default setting for low, medium, and high touch screen sensitivity. 2. MEDSUN approved Hopkins modification of the device by CES. 3. Plastic touch screen cover with flexible hinge designed and implemented by CES with input from CCTs and Infection Control.

STAFF PROVIDING CARE:

LEARNING AND IMPROVING:
PSN HARM SCORE D
ACGME CORE COMPETENCIES 4 OUT OF 6

Figure 2. The SBAR (Situation, Background, Assessment, Recommendation) for the rapid infuser hazard is shown. PSN, Patient Safety Net; OR, operating room; CES, Clinical Engineering Services; RCA, root cause analysis; CCTs, critical care technicians; ACGME, Accreditation Council for Graduate Medical Education. (Available in color in online appendix.)

tion-designed cover on one rapid infuser was damaged and had to be replaced.

Discussion

This multiphase and multidisciplinary process for patient safety reporting and follow-up, which includes a Good Catch award, has been applied to 29 significant patient safety hazards in the Weinberg Surgical Suite since 2008. The resulting quality improvements included modification of equipment (rapid infuser case example); education of providers across the institution (high-concentration vials of heparin case example); changes in the coordination of care; and other improvements, including an FDA-mandated national recall of a widely used neuromuscular blocking drug. It is important to note that many other issues have also been addressed using this process—issues that did not qualify as hazards but were nevertheless important to improving the efficiency or effectiveness of care delivery.

The patient safety reporting and follow-up process built on previous research aimed at learning from PSRSs. Conceptual models have underscored the importance of four major elements: (1) identification and reporting of events, (2) analysis of the events, (3) analysis of derived results, and (4) development and implementation of process changes.²⁴ This process incorporated these four elements within the setting of a multidisciplinary team that reviewed local events on a frequent basis.¹⁰ At the end of this process, the Good Catch award publicly recognized clinicians for their efforts in reporting hazards and leading initiatives to improve patient safety. Importantly, the Good Catch award was given only if the precipitating event/hazard underwent our process of multidisciplinary team review, involved a range of stakeholders, and resulted in the development of an initiative to mitigate the original hazard. A similar nonmonetary award tied to specific improvement goals implemented by the Veterans Health Administration demonstrated an improvement in the timeliness and quality of root cause analysis (RCA) reports.²⁵ Although more centralized than the unit-based process we describe, both processes fostered a culture that valued reporting and, more importantly, proactively used reports to drive quality improvement.

Although our process did not entail the use of financial incentives, other approaches do, often specifically for medical residents, to influence event reporting.²⁶ Such an approach may also be effective insofar as it compensates the reporter for his or her time and attention to detail and may reduce negative perceptions of reporting errors and near misses. However, patient safety reports, whether financially driven or not, are only as useful as the quality of the information that they contain. Simply increas-

ing the number of reports is not meaningful unless (1) the reports contain high-quality, relevant information, and (2) there is a feedback mechanism in place to use that information toward making sustained quality improvements in patient safety. Closing the feedback loop, which involves informing the reporter of the hazard of subsequent actions and improvements, is one of the most important features of a successful patient safety reporting process.²⁷ We achieved this goal by (1) publicly recognizing an individual (group) for his or her efforts to improve safety, (2) educating the broader clinical community about the hazard and how it was mitigated, and (3) verifying that the quality improvement was sustained over time.

We have encountered several challenges in implementing this patient safety reporting and follow-up process. Although it has educated practitioners and staff about patient safety hazards and encouraged reporting, even more work remains to be done to develop lasting system and practice changes. Some of the solutions we devised, particularly equipment modifications, would have been better served by manufacturer-led initiatives, so that individual hospitals do not have to spend resources finding solutions to widespread problems.²² Second, the success of this process is limited by the extent of participation of all members of the health care team and by the sustainability of systems changes. Achieving broad participation and involvement takes commitment and patience. To ensure that the results of the process are sustained over time, it is critical that physicians, nurses, and staff members have access to information about the reported event and the relevant education and operational safety practices initiated to prevent future harm. We have addressed this issue by using various means to disseminate information pertaining to hazards and the actions taken to prevent them, such as grand rounds and other means, as previously described, but additional avenues of communication should also be considered.¹⁶ Third, we have not attempted to use the number of reports submitted to the PSN as a measure of the success of the process because that number is subject to many forces beyond our control, as is to be expected in a busy surgical suite with continually changing staff. Moreover, it is well accepted that PSRSs underrepresent the magnitude of incidents that actually occur and that inferences about change over time based on such data are fraught with inaccuracies.^{1,28} Given limited resources, institutions might be advised to focus on improving the quality—by using tools such as SBAR, as we have described—rather than increasing the quantity of reports. Finally, we did not directly measure the impact of this process on safety culture because of the overlap of other quality improvement initiatives that could have also influenced the data. However, finding ways to correlate

or isolate changes in safety culture with specific quality improvement initiatives is an important area for future research.

Conclusion

Using a six-phase framework, a multidisciplinary team's identification, analysis, and mitigation of patient safety hazards followed by Good Catch awards led to long-term sustained quality improvement initiatives at our institution. It is our hope that clinicians, risk managers, and administrators will find success in applying or expanding on the patient safety reporting and follow-up process described here for protecting patients from harm. **J**

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Online-Only Content



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Figure 2. "Good Catch" Award SBAR Summary for Rapid Infuser (color version)

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Figure 2. “Good Catch” Award SBAR Summary for Rapid Infuser

GOOD CATCH AWARD!

Rapid Infuser

PSN Report #xxx/Date xxx Or ACCM QA Encounter Report #xxx

	<p>SITUATION:</p> <p>During an OR emergency requiring massive blood transfusion, a rapid infuser device was used. Practitioners noted that the flow rates would change suddenly and without active practitioner programming and ranged from 50-500 ml/minute. The device was sequestered.</p>
	<p>BACKGROUND:</p> <p>The rapid infuser is used in the event of anticipated or emergency massive blood transfusion, more frequently in a different OR suite at our institution. An experienced anesthesia provider noticed that inadvertent contact/bumping of the device seemed to trigger the immediate change in flow rate. This unplanned, acute change in flow rate can compromise patient care significantly.</p>
	<p>ASSESSMENT:</p> <p>Human Factors and CES conducted an RCA and identified changes to the touch screen sensitivity settings that could be adjusted, violations to human factor design allowing for inadvertent activation of commands not intended by practitioners. The manufacturer was contacted, but declined to change the product. MEDSUN was contacted.</p>
	<p>RECOMMENDATION:</p> <ol style="list-style-type: none">1. Practitioners were inserviced regarding default setting for low, medium, and high touch screen sensitivity.2. MEDSUN approved Hopkins modification of the device by CES.3. Plastic touch screen cover with flexible hinge designed and implemented by CES with input from CCTs and Infection Control.

STAFF PROVIDING CARE:

LEARNING AND IMPROVING:
PSN HARM SCORE D
ACGME CORE COMPETENCIES 4 OUT OF 6

Figure 2. The SBAR (Situation, Background, Assessment, Recommendation) for the rapid infuser hazard is shown. PSN, Patient Safety Net; OR, operating room; CES, Clinical Engineering Services; RCA, root cause analysis; CCTs, critical care technicians; ACGME, Accreditation Council for Graduate Medical Education.