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Toward learning from patient safety reporting systems☆

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Abstract

Purpose: To evaluate the frequency and type of factors involved in incidents reported to a patient safety reporting system and answer specific questions to enhance the value of PSRS data to improve patient safety.

Materials and Methods: Prospective cohort study of incidents reported from adult and pediatric intensive care units (ICUs) in the United States to the web-based, voluntary, and anonymous Intensive Care Unit Safety Reporting System. Results from July 1, 2002, to June 30, 2004. Main outcome variables were incidents that could or did lead to patient harm.

Results: Analysis includes 2075 incidents from 23 ICUs. Median number of reports/ICU/month was 3; 5 hospitals submitted 58% of reports. Harm was reported in 42% of incidents with 18 deaths. Common event types: medication/therapeutics (42%) and incorrect/incomplete care delivery (20%); 48% of line/tube/drain incidents led to physical harm. Deficiencies in training/education contributed to 49% of incidents and teamwork issues 32%; 42% of incidents had 2 or more contributing factors. As the number of contributing factors per incident increased, so did risk of harm.

Conclusions: The Intensive Care Unit Safety Reporting System provides a mechanism for multiple ICUs to identify hazards. Data trends show a correlation between multiple contributing factors and higher rates of harm. Further research is needed to help determine how to use PSRS data to improve patient safety.

1. Introduction

Tens of thousands of people are harmed rather than helped by medical care every year [1-3]. In response, the US Congress allocated more than $50 million for patient safety research [4]. The Agency for Healthcare Research and Quality invested some of this money in 16 demonstration projects for patient safety reporting systems (PSRSs) (Marge Keyes, AHRQ, personal communication, 5/10/2005). In addition, Congress passed a bill (HR 663 and S 720) [5] to "improve patient safety and reduce the incidence of events that adversely affect patient safety" [6].

Patient safety reporting systems that identify risks to patients can be used to improve patient safety [2,7].

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Indeed, other high-risk industries, such as commercial aviation, have used reporting systems to improve safety [8]. When an incident occurs in health care, organizations must understand what happened and why, how to reduce the probability of recurrence, and how they know their interventions were effective [9,10]. Patient safety reporting systems typically uncover what happened, whereas investigations such as a root cause analysis explain why the incident occurred and what preventive strategies can be developed and implemented [11,12]. Virtually no research in healthcare has evaluated the effectiveness of interventions in reducing the probability that an event will recur. Offering a PSRS to frontline caregivers may help identify incidents and associated contributing factors and provide information to improve patient safety.

Unlike other high-risk industries, health care has yet to broadly apply incident reporting to improve patient safety [7,13,14]. The specific aims of this study were to evaluate the frequency and type of factors involved in incidents reported to a web-based PSRS and address questions that must be answered to enhance the value of PSRS to improve patient safety.

2. Methods

2.1. Overall design and study population

We developed a voluntary web-based PSRS, the ICU Safety Reporting System (ICUSRS), to collect incidents in ICUs. This was a prospective cohort study in a diverse group of US ICUs. Detailed descriptions of the development and implementation of the ICUSRS have been published [15,16]. This system was informed by the experiences of other researchers [17-20]. All data collected were anonymous to patient and provider. The reporter elected whether to identify their ICU. Data collected were considered a limited data set under HIPAA and, as such, underwent expedited review with waiver of informed consent by the Johns Hopkins University, School of Medicine Institutional Review Board (IRB).

We partnered with the Society for Critical Care Medicine (SCCM) to recruit ICUs and disseminate preliminary findings. Intensive care units were recruited through email solicitation of SCCM membership. We included the first 30 respondents. This number was somewhat arbitrary, balancing the need for adequate sites and incidents to protect anonymity, with operational and financial constraints. The study was described to each ICU director and nurse manager, and they in turn discussed it with their risk managers. If risk managers approved, ICUs submitted the project for internal IRB approval. Intensive care units were enrolled as IRB approval was obtained, with the first site reporting in July 2002. This paper describes incidents submitted from July 1, 2002, through June 30, 2004.

2.2. Definitions

An incident was defined as an event that either could or did lead to patient harm. A no-harm event was called a near miss, and an event that involved harm was called an adverse event. An academic medical center was defined as the main hospital of a medical school; a community teaching hospital employed residents in the ICU but was not the main teaching hospital for a medical school; and a community hospital had no residents in the ICU.

2.3. Data collection and measurement

A training version of the ICUSRS can be found at http://icusrs.org (choose Member Zone). The reporter types in a free-text description of the incident. Check boxes are provided to describe patient demographics (eg, age range, sex), medical therapies (eg, mechanical ventilation, dialysis), surgery, type of providers reporting and participating in the incident, incident location and time frame, degree of patient harm, type of event, and factors contributing to the incident.

The ICUSRS harm measures include death, physiologic changes, physical injury, psychologic distress, discomfort, patient or family dissatisfaction, and anticipated or actual increased length of stay. Contributing factors reported are modified from Charles Vincent's framework and listed in Appendix A [9]. The reporter can select more than 1 contributing factor type and within each factor type select subfactors. For example, subfactors for "Training and Education" are (1) knowledge, skills, and competence; (2) failure to follow an established protocol; and (3) supervision and seeking help.

Event types evolved based on emergence of data during the study and encompass 14 classifications (see Table 3 for list). One event type is a hazardous situation, which is defined as an incident in which the health care provider perceived risk of harm above the ICU baseline risk that did not fit into another event type. Incidents could be classified as more than 1 event type.

Each incident is reviewed by either an ICU physician or ICU nurse from the research team to remove patient, provider, unit, or hospital identifiers, and to code incidents into an event type(s). Each ICU receives a monthly report of the incidents identified as originating from its own unit, as well as aggregate comparison data from all other ICUs. The report contains quantitative data for the volume of incidents, types of events and contributing factors, and types of providers filing incidents. Qualitative data include the text description of the incident, and factors contributing to the incident for that month. Case studies were also sent with monthly reports and posted on the SCCM (http://www.sccm.org/professional_resources/quality_corner/, access 05/23/05) and research teams' websites (http://www.safetyresearch.jhu.edu) (Fig. 1). Intensive care units can also access the qualitative data through the ICUSRS website in real time. Intensive care unit teams (ICU

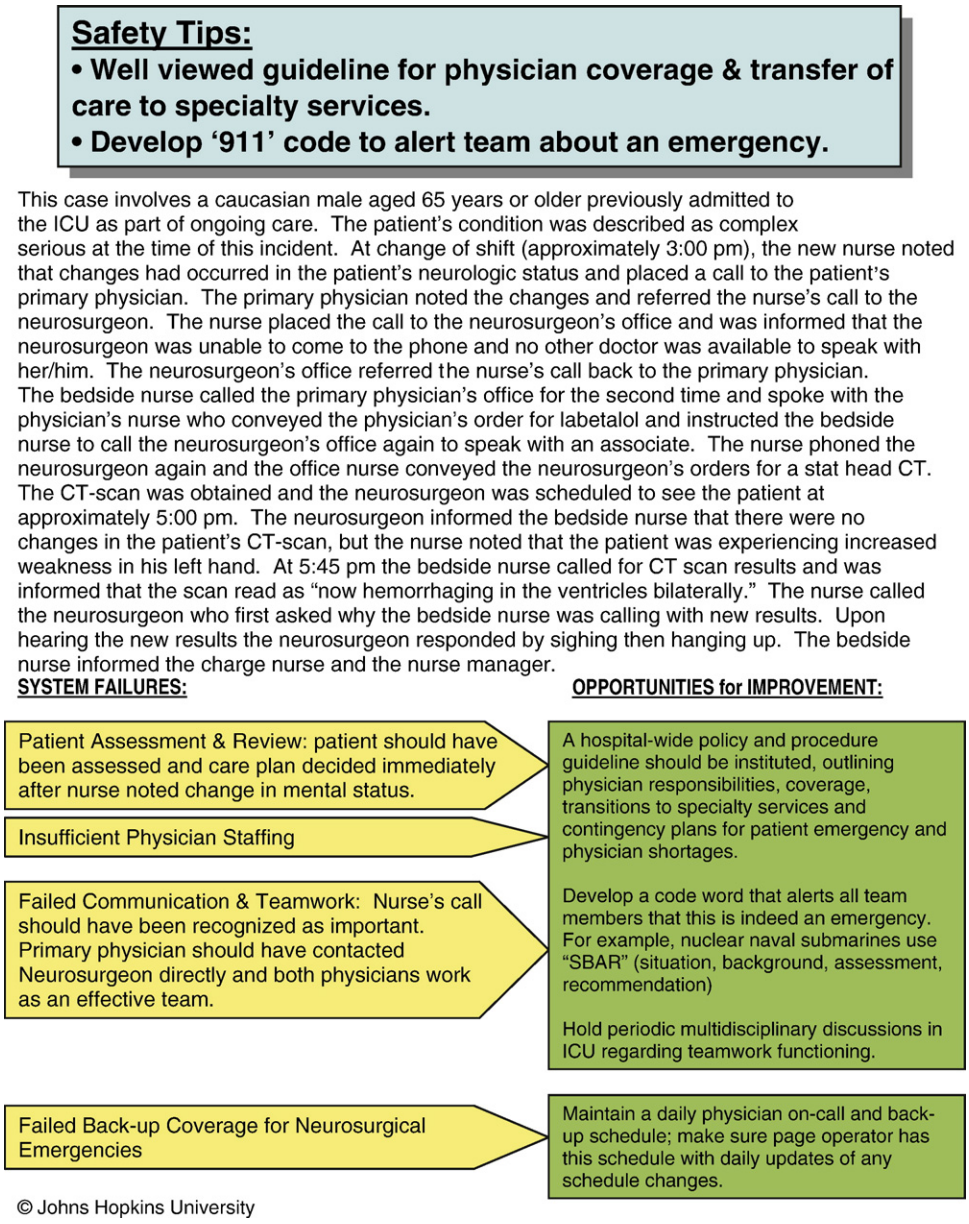

Fig. 1 Example of a case summary from an incident submitted to the ICUSRS.

director, nurse manager, nurse educator) were encouraged to share the monthly reports with staff and post case study summaries on a staff bulletin board. Data from the reports helped one site recognize the need for a pharmacist on daily rounds and another site identify problems with a new computerized physician order entry (CPOE) system. In addition, a quarterly ICUSRS newsletter was distributed to all staff at each site. The feature article was an interview with a staff member at a participating ICU site that actively participated in safety. For example, one nurse saved a child from hypoglycemia or worse when she caught a medication dispensing error (500 U of heparin mixed 500 mL .9 saline ordered, 50 U heparin mixed 500 mL .9 saline dispensed).

2.4. Statistical analysis

The primary analyses are descriptive and presented as proportions. Because an incident can have more than 1 event type or contributing factor, percentages may exceed 100%. We evaluated the association between contributing factors and harm using the χ^2 test. For these analyses, we modeled harm as 2 separate dichotomous variables; physical injury vs no physical injury, and any harm. Any harm was defined as an incident report with any harm variable checked off, vs no harm.

Multiple staff could report on the same incident. We identified potential duplicate reports by matching on ICU; event time frame, day, month, and location; surgical

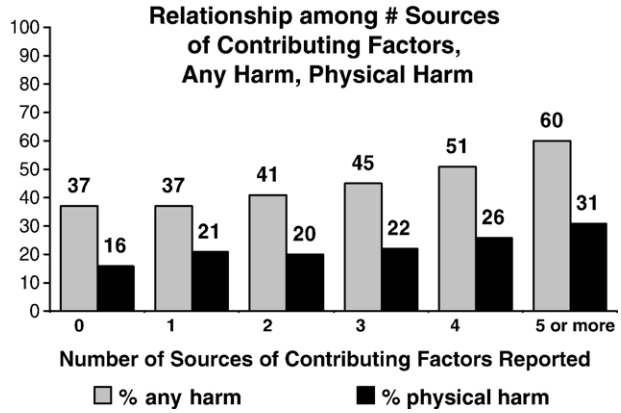

Fig. 2 Relationship between number of types of contributing factors, percent of reports with any patient harm, and percent of reports with physical harm (Because we had too few cases with 6 or more contributing factors, we combined them with incidents involving 5 factors. Sample size = 2075).

procedure; patient age category and sex; and by reviewing the text description of the incident. One percent of incidents (n = 21) were identified as likely reported by more than 1 individual. Because different types of caregivers may view incidents differently, we included potential duplicates in our analysis. Our results did not change when we excluded the potentially duplicative incidents.

3. Results

Of the original 30 ICUs recruited, risk managers declined participation in 7, ICU directors declined participation in 2, and 3 never requested IRB approval. Five additional ICUs were recruited or requested participation; 23 ICUs were actively reporting at the time of this analysis. As of June 30, 2004, 2075 reports were submitted to the ICUSRS.

Table 1 describes volume of reporting per month by ICU. Overall median number of reports per month was 3 (range, 0-18). The largest number of reports by any unit in a given month was 41. The top 5 ICUs accounted for 1213 (58%) of 2075 reports and all 5 incorporated reporting into daily rounds.

Thirteen ICUs (57%) were academic medical centers, 9 (39%) community teaching, and 1 (4%) community hospital. Three of 23 (13%) were pediatric ICUs, and 20 (87%) were adult. Of the 20 adult ICUs, 7 (35%) were surgical, 3 (15%) medical, 6 (30%) mixed medical and surgical, 3 (15%) cardiac surgical, and 1 (5%) coronary care unit. The ICUSRS replaced existing reporting forms in 3 ICUs (13%). In 18 ICUs (78%), staff completed the ICUSRS and a preexisting hospital reporting system, and in 2 (9%) staff completed the preexisting reporting system and the nurse manager back entered data into the ICUSRS.

Table 1 Incident reporting by ICU and month

Participating ICU number	Months reporting	Total reports	Report range/mo	Report median/mo
01	24	110	0-12	4.0
02	24	25	0-4	0.0
03	24	79	0-15	2.5
04	23	423	3-41	18.0
05	22	30	0-4	1.0
06	22	48	0-9	1.0
07	21	32	0-6	1.0
08	21	302	1-37	13.0
09	20	28	0-7	0.0
10	20	53	0-7	2.5
11	20	236	3-23	11.5
12	20	42	0-6	2.0
13	19	85	0-13	3.0
14	19	142	2-15	7.0
15	19	16	0-3	1.0
16	17	35	0-6	2.0
17	16	62	0-10	3.0
18	14	83	0-18	6.0
19	12	78	1-12	6.5
20	11	24	0-5	2.0
21	8	36	0-10	4.5
22	8	57	3-13	6.0
23	7	20	0-5	4.0

Nurses submitted 1370 (69%) reports, with bedside nurses submitting 805 (40%) and charge nurses 565 (28%); physicians, 211 (11%), and pharmacists, 75 (4%) reports. Fifty-nine percent of incidents occurred between 7 AM and 7 PM, 10% occurred each weekend day (Saturday and Sunday), and 14% to 17% reported each weekday.

Table 2 reports degree and types of harm. Some degree of harm was reported in 42% of incidents, and physical injury reported in 18% including 18 deaths. Table 3 describes event types, frequency, and those resulting in physical harm, with ICUSRS case examples. Forty-two percent of incidents involved medication errors, with 8% physical harm; and 20% incorrect or incomplete patient care delivery, with 19%

Table 2 Reported degree of harm (N = 2075)[a]

Harm	None	Mild	Moderate	Severe	Did not respond[b]
Physiologic	59%	16%	7%	4%	14%
Physical injury	68%	12%	5%	1%	14%
Psychologic distress	68%	9%	4%	1%	18%
Discomfort	62%	13%	7%	2%	16%
Anticipated/actual prolonged stay	73%	7%	3%	1%	16%

[a] As patients may sustain multiple types of harm, each row totals 100%.

[b] Reporter was not forced to check a response.

Table 3 Types of events and resulting physical harm,[a] July 1, 2002–June 30, 2004 (N = 2075 reports)

Event type	% of all cases	No. of events	Events with physical harm, n (%)	Examples of direct quotes from submitted reports
Medication and therapeutics	42	864	66 (8)	"Patient on Norcuron drip, ordered at 0.3 mcg/kg/min by attending. On day 3, tests indicated that the patient was too paralyzed. Pharmacy had changed the concentration but neglected to tell the staff, so the drip rate was not changed."
Incorrect/incomplete care delivered	20	416	78 (19)	"Latex allergy patient received fluids and medication prepared by pharmacy in bags for patients without latex allergies. Allergy picked up by pharmacy after doses administered."
Equipment/medical device	15	320	87 (27)	"The proximal hub of a triple lumen catheter is fractured leaving an exposed central line lumen open to the air."
Lines, tubes, and drains	13	268	128 (48)	"Swan-Ganz catheter readings off. Swan needed to be repositioned but resident refused to review the waveforms. Erroneous information received until swan repositioned."
Hazardous situations (not otherwise classified)	11	223	16 (7)	"Newly constructed room for three patients has no phone or intercom system. In an emergency the nurse would have to leave the room and the patient to get help. Also no sink to wash hands before and after care."
Orders not completed/delayed	10	197	16 (8)	"Order written to change Heparin dose. This was not communicated to the nurse or flagged causing a delay in rate change."
Airway management	8	176	39 (22)	"Patient agitated, thrashing, endothracheal tube (ETT) coiled in the patient's mouth, O2 saturation 92% and no breath sounds. M.D. at bedside. ETT pulled, patient ventilated with 100% until a nasal ETT was placed instead of oral ETT."
Assessment and review	7	142	51 (36)	"Resident called and asked to evaluate a patient going into failure. Patient with rales, wheezing, dropping saturations, and decreasing urine output. Resident disagreed and did not come to assess the patient. Attending came in, Lasix given and patient intubated."
Patient testing	6	124	22 (18)	"Toxicology sent to lab with instructions for specimen to go to outside lab. Delay in sending to outside lab."
Skin integrity	5	103	84 (82)	"Pressure ulcers developed secondary to Ted stockings being rolled down creasing her thighs."
Patient identification	3	66	2 (3)	"Resident checked coagulation panel on a patient with liver failure and ordered Hespan. The resident was looking at the wrong patient's coagulation panel."
Patient restraint	2	34	9 (26)	"Patient unrestrained and under the care of Anesthesiology. Upon arrival to ICU from the OR, the patient self extubated."
Patient fall	2	34	14 (41)	"Patient removed sequential compression device, Oxygen, pulse ox, climbed over side rails (all four side rails up) and fell out of bed onto hands and knees."
Information technology[b]	1	19	1 (5)	"Critical Medication "Bactrim" dropped out of active medications in CPOE system unknowingly, Picked up by nurse, could have resulted in opportunistic infection"

[a] Because incidents can be coded into more than 1 event type, percentages total more than 100%.

[b] Information technology was also a contributing factor; cases listed as event type were sole event and could not be coded into another event type.

physical harm. Lines, tubes, or drains accounted for 13% of events, with 48% incurring harm.

Table 4 shows the frequency and percent of contributing factors identified and an ICUSRS case example. Of 2075 incidents, training and education was reported as contributing in 49% of incidents, and team and patient factors each contributed in 32% of incidents. Appendix A shows the complete list of factors (and subfactors) with frequency and percent contributing to all reports. Knowledge, skills, and competence contributed in 32% ($P < .05$) of incidents, failure to follow established protocol in 32%, and patient condition in 29% ($P < .05$). Institutional

Table 4 Frequency of contributing factors reported in 2075 incidents submitted to the ICUSRS from July 1, 2002, to June 30, 2004, with examples[a]

Contributing factors	Frequency	% of all reports[b]	Case examples
Training and education*	1014	49%	Resident and fellow were rewiring a central line through a bloody field. Although the fellow was uncomfortable, he did ask for help, and in an attempt to make a skin nick on the guidewire, nicked the patient's carotid artery
Team factors	670	32%	Cardiologist on-call accepted critically ill patient, but neglected to inform anyone in the ICU of the impending emergent admission.
Patient factors*	653	32%	Patient's history of medication allergies is unclear because mother does not speak English.
ICU Environment	460	22%	Resident caring for a patient with a large intraventricular bleed attempted to contact neurology and found no one on call and no back-up; patient had to be transferred to another hospital.
Provider factors	419	20%	Resident, while preoccupied with a personal family matter, rushed and pulled a chest tube from the wrong patient.
Institutional environment*	328	16%	Patient needed an emergent blood transfusion. When blood bank was called for cross and match of sample previously sent, lab tech stated that sample could not be run on the 3- to 11-pm shift.
Information technology/ CPOE[c]	222	11%	Dose of piperacillin changed in CPOE system, but system would not drop the old medication dose, resulting in the old medication repeatedly appearing in electronic medical record.
Task factors	199	10%	Patient's lab values were incorrectly entered by hematology lab, resulting in a significant delay in transfusion-patient unstable and in shock.

[a] Eighteen sites reporting in year 1; 23 sites reporting in year 2.
[b] More than 1 contributing factor could be picked within an incident, resulting in percentages that exceed 100%.
[c] Not a checkbox option in year 1 data.
* Significant at $P < .05$.

environment contributed in 16%, provider motivation/attitude in 14%, staffing levels in 7%, skills mix in 6%, physical environment in 5%, and provider physical/mental health in 2%; all were statistically significant ($P < .05$).

Forty-two percent of incidents had 2 or more contributing factors, 27% reported 1, and 16% checked no contributing factor. In 2075 incidents, 3965 total contributing factors were identified; an average of 2.4 contributing factors per incident. Caregivers perceived that provider factors contributed to 1 (20%) out of 5 incidents.

Fig. 2 compares the complexity of an incident, percent of reports with any patient harm, and percent with physical harm. As the number of contributing factors per incident increased, the risk for any harm increased ($\chi_1^2 = 7.50$, $P = .006$), and the risk for physical injury increased ($\chi_1^2 = 6.81$, $P = .009$).

4. Discussion

In this national cohort of ICUs, we found that the ICUSRS can serve as a central mechanism to identify hazards. Staff reported 2 or more contributing factors in 3 quarters of the 2075 incidents. This finding demonstrates in health care what safety theorists like James Reason documented in other high-risk industries; incidents are largely the result of system defects [10]. In fact, a trend in the data suggests that incidents with more than 3 types of contributing factors correlated with higher rates of harm. Indeed, Halford et al [21] state that people have a natural limitation for handling 3 variables at a time.

In addition, incidents involving lines, tubes or drains, and skin integrity had the highest reported physical injury, which is probably related to greater visibility of harm. There is a need to educate providers to identify potential hazards before they reach the patient. One possible method would be to use the learning from defects tool to investigate breakdowns in the organization of care that caused the harm [22]. This tool provides a structured approach to identify what happened and why, what action(s) will be taken to mitigate or prevent this event in the future, and whether this action actually reduced the probability that the event will recur. Reports of the lines, tubes, or drains project have been published [23,24].

We found that training and education, and teamwork failures were major contributing factors. Efforts to improve training should focus on knowledge, skills and competence, and use of established protocols. As such, it may be

that the traditional see one, do one, teach one method of clinical training is inadequate and should be supplemented. Potential solutions could be more hands-on-training for physicians and nurses, potentially through the use of simulators, and a longer, more formalized period for supervising inexperienced providers. Additional training for physicians may prove challenging given the Accreditation Council on Graduate Medical Education restrictions on residency work hours. Indeed, recent studies reveal that residents perceive education and patient care have suffered because of work hour restrictions [25,26]. To increase use of established protocols, we must determine whether staff are aware of the protocol and use it appropriately to improve care. Staff may not be aware of the protocol, which should be an area of focus when training new or inexperienced providers.

Teamwork efforts should focus on communication within the care team. Teamwork training programs that connect the different disciplines in medicine (eg, physicians, nurses, pharmacists) are one suggested method of improving communication and team performance. In fact, in 1999 the Accreditation Council on Graduate Medical Education endorsed inclusion of "interpersonal and communication skills" in their core competencies [27] and the Institute of Medicine recommended that health care organizations "establish interdisciplinary team training programs" [2,p,135]. This recommendation was reiterated by the Joint Commission on the Accreditation of Healthcare Organizations in a June 2003 Senate testimony [28]. In addition, there are tools available that managers and researchers could use to improve communication, such as a daily goals checklist and morning or preprocedure briefings [29-31]. Perhaps most important among the communication and teamwork skills is the ability to speak up when you have concerns and to listen when others raise concerns. Caregivers need to recognize that they are more likely to make wise decisions when they have diverse and independent input [32]. As such, the input of different types of caregivers will help the care team make wise decisions that benefit patients. In addition, we need to recognize that although postgraduate years is an important marker for knowledge, time spent with the patient is also a marker for knowledge. As such, patients and their families, nurses, and physicians in training have important knowledge that can inform clinical decisions.

Excessive workload, plus insufficient staffing (18%), and provider fatigue (10%) were also attributed to incidents reported. The shortage of nurses and other ancillary staff is a likely cause of these factors given the shift in staffing patterns to longer work hours for nurses. In fact, the risk of making an error increased significantly when nurses work longer than 12 hours at one time [33]. The impact of reduced residency work hours may also be an issue for workload [34,35] and fatigue issues, and should be explored.

In our efforts to encourage staff to feel comfortable reporting incidents to the ICUSRS, we learned that open discussion within a unit was extremely effective and important. In fact, 22% of the participating ICUs (5/23) submitted 58% of the reports in this study. All 5 ICUs incorporated discussion and reporting of incidents into daily patient rounds. This finding reaffirms that staff respond best when a culture of safety is demonstrated on a local level [36,37].

Perhaps the greatest lesson we learned was how early we are in the process of using PSRSs in health care. Although Congress supports efforts to reduce the incidence of adverse events [6], 3 years of funding for PSRS research is insufficient to gain the knowledge needed to learn how PSRS can improve patient safety. During this study, we were confronted by several fundamental issues: what data should be collected; what is the best method to review, code, and analyze the data; and did sites use the data we reported back to improve patient safety? These questions must be answered if we are to use patient safety reporting systems to improve safety.

There are limitations to this study. First, these results may not be generalizable. Hospitals that volunteered may differ in enthusiasm and leadership from hospitals that did not volunteer. Second, because reporting was anonymous, we could not independently verify the accuracy and sensitivity of the data collected. Nevertheless, principal investigators from each ICU reviewed their data monthly and never challenged its accuracy, and an author (PJP) was able to review and confirm the occurrence of incidents submitted at his hospital. Third, because reporting was voluntary, we did not capture all incidents and do not know the degree of staff underreporting. We believe that as safety culture improves, it is likely that reporting will increase. Although underreporting prevents us from reporting on the epidemiology of events, the incidents received represent clear hazards and opportunities to learn and improve patient safety. Fourth, the association between the number of contributing factors and patient harm (Fig. 2) could be influenced by a more active cognitive search to uncover system factors in cases with more severe harm [38]. Fifth, we did not include a regression analysis to evaluate independent variables as it added very little information, and the science still immature in this area. Finally, thus far, we have limited information to evaluate whether patient safety improved as a result of participating in the ICUSRS.

Although the US Congress allocated $50 million for patient safety research in 2001, approximately half was allocated to PSRS. Yet, future federal funding for PSRSs is uncertain. Given the magnitude of the patient safety problem, the concentrated efforts to identify adverse incidents through PSRSs, and the success of incident reporting to improve safety in other industries, patient safety reporting systems should remain a priority for future research.

Appendix A. Frequency of contributing factors reported in 2075 incidents submitted to the ICUSRS from July 1, 2002 to June 30, 2004, with examples[1]

Contributing factors	Frequency	% of all reports*	Case example
Training and education**	1014	49%	
Knowledge, skills, and competence**	658	32%	Physician and nurse with limited dosing knowledge increased phenylephrine to 10 times the recommended maximum dose.
Failure to follow established protocol	653	32%	Standard policy requires that physicians flag all new written orders and oncoming nurse check order sheet to catch unflagged orders. Neither remembered and the order to reduce hydrocortisone from 100 to 50 mg was missed.
Supervision and seeking help	245	12%	Resident and fellow were rewiring a central line through a bloody field. Although the fellow was uncomfortable, he did ask for help, and in an attempt to make a skin nick on the guidewire, nicked the patient's carotid artery.
Team factors	670	32%	
Verbal or written communication during routine care	386	19%	Order written to change heparin dose not communicated to nurse, causing delay in rate change.
Verbal or written communication during hand off	249	12%	OR staff called for patient scheduled for surgery and gave wrong name; wrong patient sent.
Team structure and leadership	138	7%	During a code, the nursing supervisor was the only person with access to the emergency medication; which was a problem as the supervisor was not in the unit.
Verbal or written communication during crisis	42	2%	Cardiologist on-call accepted critically ill patient but neglected to inform anyone in ICU of impending emergent admission.
Patient factors**	653	32%	
Condition (complexity, agitation)**	596	29%	Trauma patient, who was unstable and deteriorating, develops hypotension refractory to norepinephrine, dobutamine, and fluid resuscitation.
Personality and social factors	86	4%	Patient admitted for drug overdose, awakens and extubates self, despite soft wrist restraints.
Language/communication	69	3%	Patient's history of medication allergies is unclear because mother does not speak English.
ICU Environment	460	22%	
Workload	219	11%	Several nurses sent home sick, resulting in staffing shortage. Charge nurse caring for 2 patients with 31-bed unit full, all of which led to incorrect dose programmed into dobutamine pump.
Staffing levels**	148	7%	Resident caring for a patient with large intraventricular bleed attempted to contact neurology and found no one on call and no back-up; patient had to be transferred to another hospital.
Skills mix**	125	6%	New nurse who recently completed orientation gave wrong concentration of Lasix.

[1] Eighteen sites reporting in year 1; 23 sites reporting in year 2.

Appendix A *continued*

Contributing factors	Frequency	% of all reports*	Case example
Physical environment (eg, lack of space, noise level)**	100	5%	Noise on the unit so loud nurse could not hear physician orders.
Availability/maintenance of equipment	76	4%	No intubation trays available in ICU/CCU respiratory closet when patient needed to be emergently intubated; as a result, crash cart had to be opened.
Administrative and managerial support	54	3%	Medication order faxed 2 h late because unit was extremely busy and unit clerk off that day.
Provider factors	419	20%	
Fatigue	210	10%	Fifteen hours into an overtime shift nurse received a new admission, as a result of fatigue antibiotic order was missed and blood cultures drawn in the wrong type of tube.
Motivation/attitude**	288	14%	Resident was called to evaluate a patient thought to be heading into failure; resident refused.
Physical or mental health**	31	2%	Resident while preoccupied with a personal family matter rushed and pulled a chest tube from the wrong patient.
Institutional environment**	328	16%	
Time pressures	158	8%	Patient acuity was high, several patients were in shock, 2 admissions coming from ER and OR, and nurse caring for mentally unstable patient pulled to care for another patient. Mentally unstable patient tried to stand up and fell. The nurse felt the new admissions should have been held in the ER or OR instead of pulling her/him away from patient, but felt she/he would not be supported by leadership or the ER/OR.
Pharmacy—infrastructure, Policy and procedures	84	4%	Pharmacy supplied bag of "replacement" solution labeled as potassium 2 mEq/L (should have been calcium 3 mEq/L)
Pharmacy staffing	44	2%	Clindamycin ordered at 7:30 AM—called Pharmacy at 9:30 AM to notify not here yet. Medication arrived at 11-11:30 AM. First doses of antibiotics should be at bedside within 1 h. Pharmacy staffing shortage.
Pharmacy—inservice education, Change management problems	22	1%	RN gave Botox 195 U IM into right thigh (single injection site). MD's order did not specify MD or NP only to give. Pharmacy dispensed med to unit. Pharmacy did not specify MD or NP to give when protocol is for med to be dispensed to and given by provider. Pharmacy unaware.
Financial resources	20	1%	No hospital resources available to buy new smart pumps.
Laboratory staffing	15	.7%	pt had electrolytes due to be drawn at 1800, still not drawn at 2040 despite 3 phone calls to the lab to expedite the lab draw. Pt on diltiazen drip—was in sinus rhythm, got Lasix, now back in afib. delay in lab draw delaying patient treatment.

(*continued on next page*)

Appendix A *continued*

Contributing factors	Frequency	% of all reports*	Case example
Laboratory—infrastructure, Policy and procedures	14	.7%	Received a fresh open-heart surgery patient who was bleeding extensively from his chest tubes. Stat labs sent at 15:00. Lab values were pertinent to the treatment of this patient were not reported until 17:30. I had called the lab at 17:00 looking for these stat labs and was told I would be called with the results as soon as they were available. Needless to say I was never called.
Laboratory—inservice education, Change management problems	8	.4%	Child with artificial mitral valve impinged upon by clot. . .required thrombolytic therapy. Unable to obtain lab results for stat fibrinogen pretreatment with tpa. Lab still did not run test even after 2 telephone calls. Blood had to be redrawn, 4 hours later, after tpa started. Pretreatment indices thus unavailable in potentially unstable child.
Information technology/CPOE***	252	12%	
User error	175	8%	Consult for speech and language pathologist entered into system on the wrong patient.
Computer software error	51	3%	Meds still showed as active on electronic Medication Administration Record after being discontinued in CPOE system.
Computer malfunction	26	1%	Changed status on patient (from observation to inpatient) resulted in orders vanishing from computerized order entry system.
Task factors	199	10%	
Availability of protocols	137	7%	Patient found with swollen hand and arm due to peripheral IV infiltrating with dopamine—no protocol available noting use of central venous catheters for vasoactive drugs.
Availability of test results**	45	2%	Patient needed an emergent blood transfusion. When blood bank was called for cross and match of sample previously sent, lab tech stated that sample could not be run on the 3-11 pm shift.
Accuracy of test results	32	2%	Patient's lab values were incorrectly entered by hematology lab, resulting in a significant delay in transfusion-patient unstable and in shock.

* More than 1 contributing factor could be picked within an incident, resulting in percentages that exceed 100%.
** Significant at $P < .05$.

References

[1] Leape L, Brennan T, Laird N, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med 1991;324:377-84.

[2] Kohn L, Corrigan J, Donaldson M, editors. Institute of Medicine: creating safety systems in health care organizations. Washington (DC): National Academy Press; 1999. p. 155-202.

[3] Brennan T, Leape L, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. Qual Saf Health Care 2004;13:145-52.

[4] Pronovost P, Wu A, Dorman T, et al. Building safety into ICU care. J Crit Care 2002;17(2):78-85.

[5] Palmisano D. Patient safety legislation-an urgent call to action. http://www.ama-assn.org/amednews/2004/05/17/edca0517.htm.

[6] Patient Safety and Quality Improvement Act of 2005. The Orator.com, Public Law 109-141, 2005, http://www.help.senate.gov/Bills.html.

[7] Leape L. Reporting of adverse events. N Engl J Med 2002; 347(20):1633-8.

[8] Billings C. The NASA Aviation Safety Reporting System: lessons learned from voluntary incident reporting. Chicago: National Patient Safety Foundation; 1999.

[9] Vincent C. Understanding and responding to adverse events. N Engl J Med 2003;348(11):1051-6.

[10] Reason J. Managing the risks of organizational accidents. Burlington (Vt): Ashgate Publishing Company; 2000.

[11] Dekker S. The field guide to human error investigations. Burlington (Vt): Ashgate Publishing Company; 2002.
[12] Latino R, Latino K. Root cause analysis. Improving performance for bottom-line results. Boca Raton (Fla): CRC Press; 2002.
[13] Barach P. Medical errors and patient safety in Massachusetts: what is the role of the commonwealth? Boston: Massachusetts Health Policy Forum; 2000.
[14] Amoore J, Ingram P. Quality improvement report: learning from adverse incidents involving medical devices. BMJ 2002;325(7358): 272-5.
[15] Wu AW, Holzmueller CG, Lubomski L, et al. Development of the ICU Safety Reporting System. J Patient Saf 2005;1(1):23-32.
[16] Holzmueller C, Pronovost P, Dickman F, et al. Creating the web-based Intensive Care Unit Safety Reporting System (ICUSRS). J Am Med Inform Assoc 2005;12(2):130-9.
[17] Beckmann U, West L, Groombridge G, et al. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care. Anaesth Intensive Care 1996;24(3):314-9.
[18] Leape LL. Error in medicine. JAMA 1994;272:1851-7.
[19] Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. BMJ 1998;316:1154-7.
[20] Helmreich R. On error management: lessons from aviation. BMJ 2000;320(7237):781-5.
[21] Halford G, Baker R, McCreeden J, et al. How many variables can humans process? Psychol Sci 2005;16(1):70-6.
[22] Pronovost P, Holzmueller C, Martinez E, et al. A practical tool to learn from defects in patient care. Jt Comm J Qual Pat Saf 2006; 32(2):102-8.
[23] Lubomski L, Pronovost PJ, Thompson D, et al. Building a better incident reporting system: perspectives from a multisite project. J Clin Outcomes Manag 2004;11(5):275-80.
[24] Needham D, Thompson D, Holzmueller C, et al. A system factors analysis of airway events from the Intensive Care Unit Safety Reporting System (ICUSRS). Crit Care Med 2005;33:1701-7.
[25] Byrnes M, Narciso V, Brantley L, et al. Impact or resident work-hour restrictions on trauma care. Am J Surg 2006;191:338-43.
[26] Irani J, Mello M, Ashely S, et al. Surgical residents' perceptions of the effects of the ACGME duty hour requirements 1 year after implementation. Surgery 2005;138:246-53.
[27] ACGME: Outcome Project: General Competencies Vers. 1.3 (9.28.99). Accreditation Council on Graduate Medical Education, 1999, http://www.acgme.org/outcome/comp/compFull.asp#4.
[28] JCAHO: Patient safety: Instilling hospitals with a culture of continuous improvement. Testimony before the Senate committee on Governmental Affairs. JCAHO, 2003, http://www.jointcommission.org/NewsRoom/OnCapitalHill/testimony_061104.htm.
[29] Pronovost P, Berenholtz S, Dorman T, et al. Improving communication in the ICU using daily goals. J Crit Care 2003;18(2):71-5.
[30] Thompson D, Holzmueller C, Hunt D, et al. A morning briefing: setting the stage for a clinically and operationally good day. Jt Comm J Qual Patient Saf 2005;31(8):476-9.
[31] Makary M, Holzmueller C, Thompson D, et al. Operating room briefings: working on the same page. Jt Comm J Qual Saf 2006;32(6):351-5.
[32] Surowiecki J. The wisdom of crowds: why the many are smarter than the few and how collective wisdom shapes business, economics, societies and nations. New York: Random House; 2004.
[33] Rogers A, Hwang W, Scott L, et al. The working hours of hospital staff nurses and patient safety. Health Aff 2004;23(4): 202-12.
[34] Charap M. Reducing resident work hours: unproven assumptions and unforeseen outcomes. Ann Intern Med 2004;140(10):814-5.
[35] Skeff KM, Ezeji-Okoye S, Pompei P, et al. Benefits of resident work hours regulation. Ann Intern Med 2004;140(10):816-7.
[36] Pronovost P, Weast B, Bishop K, et al. Senior executive adopt-a-work unit: a model for safety improvement. Jt Comm J Qual Saf 2004;30(2):59-68.
[37] Odwazny R, Hasler S, Abrams R, et al. Organizational and cultural changes for providing safe patient care. Qual Manag Health Care 2005;14(3):132-43.
[38] Cook R, Woods D. Operating at the sharp end: the complexity of human error. In: Bogner M, editor. Human error in medicine. Hillsdale: Erlbaum; 1994. p. 225-310.