Reporting of medical errors: An intensive care unit experience

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Objective: To determine the occurrence and type of medical errors in an intensive care setting using a voluntary reporting method.

Design: Prospective, single-center, observational study.

Setting: The medical intensive care unit (19 beds) at an urban teaching hospital.

Patients: Adult patients requiring at least 48 hrs of intensive care.

Interventions: Prospective reporting of medical errors.

Measurements and Main Results: During a 6-month period, 232 medical events were reported involving 147 patients. A total of 2598 patient days were surveyed yielding 89.3 medical events reported per 1000 intensive care unit days. The source of the reports included nurses, who reported most of the medical events (59.1%), followed by physicians-in-training (27.2%) and intensive care unit attending physicians (2.6%). One hundred thirty (56.2%) medical events occurred within the intensive care unit and were judged to involve patient careproviders who were working directly in the intensive care unit area. One hundred and two (43.8%) medical events were commissions or omissions that occurred outside of the intensive care unit during patient transports or in the emergency department and hospital floors. Twenty-three (9.9%) medical events leading to a medical error resulted in the need for additional life-sustaining treatment, and seven (3.0%) medical errors may have contributed to patient deaths.

Conclusion: Medical errors appear to be common among patients requiring intensive care. Medical events resulting in an error can result in the need for additional life-sustaining treatments and, in some circumstances, can contribute to patient death. Patient healthcare providers appear to be in a unique position to identify medical errors. Institutions should develop formalized methods for the reporting and analysis of medical errors to improve patient care. (Crit Care Med 2004; 32:727-733) KEY WORDS: errors; intensive care; outcomes; patient care

ntensive care units emerged as a result of the necessity to bring together well-trained medical teams to care for patients with lifethreatening illnesses using sophisticated devices like ventilators and cardiac monitors (1). To increase the safety of the patient care devices used in the intensive care unit setting, alarms are used to alert caregivers to abnormal patient parameters (e.g., apnea, tachycardia, and hypotension). However, intensive care units are still complex environments that may be dangerous not just to the critically ill patient but also to the medical staff exposed to the potentially hazardous surroundings (2). The complexity of intensive care and the medical conditions of patients admitted to intensive care units

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increases the likelihood of medical errors (3).

The importance of medical errors to adverse patient outcomes has been the focus of several reviews and consensus reports. The Institute of Medicine published an extensive report examining the prevalence of medical errors and reviewing potential causes of medical mistakes (4). This report stated that: "The problem is not bad people; the problem is that the system [of medical care] needs to be made safer." More recently, an American Heart Association Scientific Statement acknowledged the occurrence and scope of medical errors in acute cardiac care settings and described the major categories of medical error types (5). More important, this report recognized that improved methods are required for identifying and reporting medical events, especially events such as nonmedication errors that are not readily identified using currently available automated information systems.

We performed this study to examine the yield of a prospective, voluntary, nonpunitive medical event reporting system. This reporting method utilized professional detailing to gain support from the patient care staffs and specially designed cards to be completed by healthcare providers reporting medical events. We established two major goals for this research. First, to describe the frequency and types of reported medical events occurring in an intensive care unit setting. Second, to determine the impact of the reported medical events on patient outcomes. This research was undertaken as part of a larger effort aimed at the systematic prevention of risk and improvement of patient care.

MATERIALS AND METHODS

Study Location and Patients

This study was conducted at a universityaffiliated, urban teaching hospital: Barnes-Jewish Hospital (1,400 beds). During a 6-month period (November 2002 to May 2003), all patients requiring admission to the medical intensive care unit (19 beds) were eligible for this investigation. The medical intensive care unit is a closed unit with a multidisciplinary team providing patient care with the direction of attending physicians who are board certified in critical care medicine. An electronic medical record is used, with bedside terminals available for accessing the medical

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records. This study was approved by the Washington University School of Medicine Human Studies Committee.

Study Design and Data Collection

General Description. This was an observational study describing a locally developed method for the reporting of medical events and the actual medical events reported. This study was developed after determining the attitudes of patients and physicians regarding the disclosure of medical errors at Barnes-Jewish Hospital (6). The local hospital group organizing the study was the Patient Safety Study Group at Washington University and Barnes-Jewish Hospital. A name was developed for the reporting system using the acronym SAFE (S: Safety, "We are committed to patient safety"; A: Actions, "We take action to eliminate potential risks for medical errors"; F: Focus, "We focus on open communication about errors and safety"; E: Everyone, "Everyone is responsible for ensuring patient safety"). The SAFE acronym was placed on all materials related to this project including error reporting cards, information posters, lapel pins, and letterhead.

The SAFE reporting system was developed by staff from the Patient Safety Study Group based on feedback received during clinical interviews and focus groups. Once developed, physicians and nurses within the critical care areas reviewed the structure of the reporting cards. The objectives of the SAFE reporting system were to provide a mechanism for healthcare providers to report medical events; to address key barriers to the reporting of medical events; to record, compile, and analyze medical event data for selected departments; and to provide knowledge that would guide improvements to patient safety within individual hospital departments and units. The first pilot phase of the SAFE program was carried out in the medical intensive care unit of Barnes-Jewish Hospital.

After a successful trial of this pilot, the SAFE program (with modifications resulting from the pilot experience) was introduced into three other intensive care units, the emergency department, and the recovery areas. The SAFE program was not designed to be a unit-specific method of event reporting. The key element of the program was to identify and report events for analysis to change practices and improve patient care. Therefore, this program was not restricted to events occurring within the borders of the medical intensive care unit, but included any event identified by the staff in the unit as representing a potential medical error.

Pilot Program. The medical event reporting system was designed to be voluntary and nonpunitive. A series of in-services were held for all patient careproviders (physicians, nurses, respiratory therapists, pharmacists, dieticians, and physical therapists) and support staff (unit secretaries, housekeeping, and transport personnel) detailing the SAFE program and its objectives. The key elements of these in-services was to describe the "nonpunitive" nature of the program and to emphasize the importance of reporting all types of medical events, including risky situations, near misses, no-harm events, as well as events resulting in harm. The SAFE program had the support of key leaders (Unit Medical Director, Unit Nurse Manager, Department Chiefs, and Hospital President and Chief Executive Officer) and was not to be used to assign blame or punish individuals for any reported medical events. The system was anonymous so that the reporter could choose whether to include their name on the report form. The professional detailing of all intensive care unit staffs by multiple study representatives, including the Unit Medical Director (M.H.K.) and the unit's clinical nurse specialist (D.P.), was implemented as a key element of this study. Professional detailing has been demonstrated to improve the success of locally implemented protocols and practice changes (7, 8).

The SAFE report form was designed to be simple to capture basic information, trigger appropriate follow-up when necessary, and minimize the time required to fill out the form. The reporting tool consisted of a twosided card (Figs. 1 and 2) that was stored and displayed in dispensers placed in the physician conference room, the cubicles of the two unit secretaries, the charting cart (moved outside

	Print Patient Name and Registration #
Putting Our Patients First	Patient Name
SAFE Reporting	Last First MI
BIC HealthCare"	Pt. Registration #
Patient/Event Information:	
Today's Date: / / Current Time: : Military Time (24 hr dock) hr : min	OR
Date of Event: / / / Time of Event: : Military Time (24 hr clock) hr min	
Location of Event:	Stamp Addressograph Here
DMICU DSICU DCTICU DED	• • • • • • • • • • • • • • • • • • •
(6) Type of Event (Check all that apply)	Medication
Blood Products	
□ Behavioral/Psych. □ IV Complications	□ Test, Treatment, Procedure
Equipment/Product Laboratory	□ Other (specify)
Summarize what happened and what you think caused this event.	What has been done to address or resolve this matter?
➡ Please Complete Reverse Side	-OVER+

Figure 1. Front side of the SAFE medical event reporting card.

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8 Risk Management Event/ Incident form completed? If harm occurred, report event to your risk management department			□ Yes	🗆 No	Review at	on generated for purposes of Peer t the request and under the of a BJH Peer Review Committee
Perso	on Reporting (optional)					
9 o	Attending MD	□ Housestaff MD		Nurse		
	Respiratory Therapist	Pharmacist		□ Other _		
	Reporter's Name					
	Reporter's Beeper # / Othe	er Contact Information				
Harn	<u>n Scale</u> (based upon your	best knowledge of inf	ormation a	wailable at the tim	e of this rep	ort)
Whi	ich best describes the event/i	ncident you are reportin	g? (Choose	one answer)		
	No event occurs	red, but a risky situation	n was found	that increased the ri	sk for an even	t to occur
	□ An event occurred, but was caught before affecting/reaching the patient					
	□ An event occurred and reached the patient, but the patient was not harmed					
	An event occurs	red, patient was harmed,	but harm d	id not result in death	(circle A or E	3)
		orary Harm (complete recov			Harm (complete	recovery NOT expected)
	□ An event occurr	red and resulted in death	to the patie	nt		
How	w was the care of the patient	affected? (Choose the b	est answer k	nown at the time of	this report)	
	•	treatment/intervention (i			• •	
	•	ical or surgical treatmen			,	
	Additional testi	ng required (i.e., lab test	s, x-rays)	-		Washington University School of Medicine Patient Safety Project
				660 South Euclid - Box 8051 St. Louis, MO 63110		
	Care was not af	fected				(3 14) 454-8203
Please	Return Card To Nearest SAFE I	<u>Reportina</u> Mailbox.			Thank You F	or Your Participation

Figure 2. Back side of the SAFE medical event reporting card.

of each patient room during morning rounds), and the nursing lounge area. The front side of the card required the patient's name and hospital registration number to be entered along with the date and time the report card was filled out, the date and time of the event, the location of the event (the cards were designed to eventually be used in multiple hospital areas), and the type of event (Table 1). Additional space was provided for the individual reporting the event to describe the event, the perceived cause of the event, and whether any action was taken to remedy the situation. The second side of the card ascertained whether a hospital risk management form was completed, the job description of the person reporting the event, the reporter's contact information (optional), and the Harm Scale used to ascertain the event's potential risk to the patient and how the patient's care was affected by the event.

Two clearly marked, locked, and mounted collection boxes along with instructive posters were available in the medical intensive care unit for staff to deposit their completed SAFE reporting cards. The deposit boxes were emptied every weekday by one of the Patient Safety Study Group coordinators. Data from the reporting cards were entered into a restrictedaccess, password-protected electronic database. Reports were generated on a monthly basis from the accumulated cards and shared with the medical intensive care unit quality improvement committee made up of the Unit Medical Director, the unit nurse manager, nursing and respiratory therapy staff, and the unit pharmacist for the purpose of peer review. Additionally, data from the medical event reports were shared with the hospital's patient safety office and the hospital critical care committee. This was done to verify events and assist in the development of actions and recommendations to improve the hospital's operating system supporting the medical intensive care unit. Any patient or family communications concerning reported medical events were conducted at the discretion of the intensive care unit attending physician.

Analyzing the Event Reports and Assessment of Outcomes

Each SAFE reporting card was initially reviewed by one of two registered nurses serving on the Patient Safety Study Group at Washington University and Barnes-Jewish Hospital. This initial review was to assess entries for harm and potential harm and to determine whether immediate follow-up was necessary. If necessary, events were forwarded to the Office of Risk Management for additional review. A more formal assessment of the potential impact of a reported event on patient outcomes and medical care was conducted by at least two members of the Patient Safety Study Group. Specific interviews were performed to verify the Harm Scale reports when the individual reporting the event was identified and there appeared to be some discrepancy between the described medical event and the effect of the event on subsequent medical care. The medical events were grouped into categories according to consensus between the reviewers. Any differences of opinion about the classification of a medical event were discussed and resolved at the time of the reviews. In addition to the assessment of outcome, the number of events reported with the SAFE program was compared with the preexisting proprietary system used at Barnes-Jewish Hospital called RISKMASTER (Computer Sciences, El Segundo, CA). RISKMASTER is a centralized database accessible through any hospital computer allowing direct entry of patientspecific information concerning a medical event or high-risk situation.

RESULTS

A total of 728 patients were admitted to the medical intensive care unit during the study period. Two hundred thirty-two medical events were reported using SAFE cards involving 147 different patients, yielding a rate of reported medical events of 31.9 per 100 intensive care unit patient

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1. Test/treatment/procedure: Delays or omission of prescribed treatments (nonmedication treatments), diagnostic tests, or planned procedures.

- 2. Medication: Delays or omission in prescribed medications, administration of nonprescribed medications, or wrong dose or route of medication administration.
- 3. Equipment/product: Failure in patient care equipment due to either mechanical problems or related to lack of familiarity on the part of the intensive care unit staff.
- 4. Blood products: Delays in the administration of blood products, errors in correct patient matching with blood products, or infusion of blood products without appropriate filters and safeguards in place.
- 5. Intravenous complications: Errors related to the administration of incompatible solutions through intravenous catheters, infusion of solutions through inappropriate catheters or catheter locations, or misadventures in the placement of intravascular catheters.
- 6. Behavioral/psychiatric: Inadequate use of chemical or physical restraints, errors in recognition of emergent behavioral/psychiatric issues (e.g., alcohol/narcotic withdrawal), or inappropriate or excessive use of sedation or antipsychotic medications.
- 7. Laboratory: Delays in sending scheduled laboratory specimens, errors in the identification of specimens, or sending the wrong specimens.
- 8. Surgery: Delays in appropriate surgical interventions or errors related to the performance of specific surgical procedures.
- 9. Falls: Patient falls from bed during routine care, physical therapy, or during transports for diagnostic or therapeutic procedures.



Figure 3. Number of medical events reported according to reporter's job description.

admissions. A total of 2598 patient days were surveyed in the medical intensive care unit, yielding 89.3 medical events reported per 1000 intensive care unit days. Nurses reported most of the medical events using SAFE cards (59.1%) followed by physicians-in-training (medical residents and pulmonary/critical care fellows) (27.2%), intensive care unit attending physicians (2.6%), and other intensive care unit staff (pharmacists, unit secretaries, and students) (4.7%) (Fig. 3). Fifteen (6.5%) of the event reports were completely anonymous without any job description of the individual filling out the report. Medical event reporting cards included the names of the individuals filling out the cards on 50% of the cards. Additionally, 217 (93.5%) event reports contained the reporter's current job description (e.g., attending physician, nurse, and pharmacist). Among the reported events, 68.4% were reported during the day shift, and 31.6% were reported during the night shift.

There were 130 (56.2%) medical events that occurred within the physical location of the intensive care unit, and these events were judged to involve patient healthcare providers working directly in the intensive care unit. A total of 102 (43.8%) medical events were commissions or omissions that occurred outside of the intensive care unit and were not directly attributable to patient careproviders working in the medical intensive care unit. The type of medical events reported and the described impact of these events on subsequent patient care are provided in Table 2. The most common medical events reported were delays or omissions of prescribed nonmedication treatments, diagnostic tests, or necessary/planned procedures (36.5%) followed by medication errors (20.2%), errors in equipment function (7.9%), blood product events (2.5%), events related to intravenous catheters or solutions (2.5%), behavioral/psychiatric management events (2.0%), laboratory errors (1.5%), surgery events (1.0%), one patient fall (0.5%), and a miscellaneous category (20.2%). Twenty-three (9.9%) medical events resulted in the need for additional life-sustaining treatment, and seven (3.0%) events resulting in error may have contributed to patient deaths. A description of the medical events associated with the need for life-sustaining treatments is provided in Table 3. Delays or omissions of prescribed nonmedication treatments, diagnostic tests, or necessary planned procedures accounted for most of the medical events associated with the need for life-sustaining treatments (60.9%).

RISKMASTER reported 29 medical events in the medical intensive care unit from January 2002 through October 2002, directly preceding the intervention, yielding an average of 2.9 ± 2.0 reported events per month compared with $2.6 \pm$ 2.0 events per month for the 6 months of the intervention (November 2002 through May 2003) (p = .777). RISK-MASTER reported statistically fewer events during both of these time periods compared with events described by the SAFE program (36.3 \pm 10.5 events per month; p < .001 compared with both RISKMASTER time periods).

DISCUSSION

We demonstrated that a voluntary, nonpunitive, prospective reporting system could identify a large number of medical events involving patients admitted to a medical intensive care unit. Overall, we identified 232 medical events, of

	Resultant Effect on Patient Care, n (%)						
Event Type ^a	Life-Sustaining Treatment	Additional Medical/Surgical Treatment	Additional Testing	Increased Monitoring	Care Not Affected	Other	
Test/treatment/procedure $(n = 74)$ Medication $(n = 41)$ Other $(n = 41)$ Equipment/product $(n = 16)$ Not described $(n = 11)$ Blood products $(n = 5)$ Intravenous complications $(n = 5)$ Behavioral/psychiatric $(n = 4)$ Laboratory $(n = 3)$ Surgery $(n = 2)$	$\begin{array}{c} 7 \ (9.5) \\ 4 \ (9.8) \\ 9 \ (22.0) \\ 1 \ (6.3) \\ 1 \ (9.1) \\ 1 \ (20.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \end{array}$	$\begin{array}{c} 9 \ (12.2) \\ 3 \ (7.3) \\ 4 \ (9.8) \\ 2 \ (12.5) \\ 2 \ (18.2) \\ 0 \ (0.0) \\ 4 \ (80.0) \\ 1 \ (25.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \end{array}$	$\begin{array}{c} 8 \ (10.8) \\ 3 \ (7.3) \\ 4 \ (9.8) \\ 0 \ (0.0) \\ 1 \ (9.1) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 3 \ (100.0) \\ 1 \ (50.0) \end{array}$	$\begin{array}{c} 9 \ (12.2) \\ 6 \ (14.6) \\ 4 \ (9.8) \\ 1 \ (6.3) \\ 1 \ (9.1) \\ 0 \ (0.0) \\ 2 \ (50.0) \\ 0 \ (0.0) \\ 1 \ (50.0) \end{array}$	$\begin{array}{c} 40 \ (54.0) \\ 25 \ (61.0) \\ 20 \ (48.7) \\ 11 \ (68.7) \\ 6 \ (54.5) \\ 4 \ (80.0) \\ 1 \ (20.0) \\ 1 \ (25.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \end{array}$	$\begin{array}{c}1\ (1.3)\\0\ (0.0)\\0\ (0.0)\\1\ (6.3)\\0\ (0.0)\\0\ (0.0)\\0\ (0.0)\\0\ (0.0)\\0\ (0.0)\\0\ (0.0)\\0\ (0.0)\end{array}$	

"Describes 203 (87.5%) medical reports providing sufficient information to classify the effect of the medical event on patient care.

Table 3. Medical	events	associated	with	additional	life-sustaining treatment
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Patient No.	Event Description				
1	Unrecognized mechanical failure of mechanical ventilator.				
2^a	>30 hrs in ED with septic shock and inadequate fluid resuscitation.				
3	Phenytoin overdose without cardiac monitoring prior to ICU admit.				
4^a	>24 hrs in ED without appropriate monitoring/resuscitation.				
$\frac{4^a}{5^a}$	Aspiration of feedings administered through the G port of a G-J tube.				
6	Lack of adequate sedation during emergent intubation. ^b				
7^a	Hemorrhagic shock, lost type and cross, delayed transfusion by 4 hrs.				
8	DNR patient underwent inappropriate cardiac resuscitation.				
9	Large PTX missed on two chest radiographs in the surgical recovery room.				
10^a	Ordered HD not performed, which resulted in emergent intubation. ^b				
11^{a}	Untreated yeast and GNB in peritoneal fluid reported for 2 days.				
12	3-hr delay in RBC transfusion for shock due to illegible orders.				
13	Wrong medication given (beta-blocker) resulting in vasopressor need.				
14	2-hr chest radiograph delay for CVC delayed volume resuscitation.				
15	Propofol overdose during intubation resulted in vasopressor need.				
16	CVC in femoral position on floor unmonitored with massive hematoma.				
17	Premature extubation after upper airway edema. ^b				
18	Inadvertent extubation during bronchoscopy. ^b				
19	Free air on ED radiograph not reported to ICU staff.				
20	Inadequate restraints with resultant self-extubation and pulmonary arrest.				
21	Inadequate sedation/restraints pulled out CVC delaying resuscitation.				
22^a	Disconnected BIPAP on floor without monitoring, resulting in arrest.				
22^a	Arrested on floor, ineffective ventilation using Jackson tracheostomy.				

BIPAP, bilevel positive airway pressure; CVC, central venous catheter; DNR, do not resuscitate; ED, emergency department; G, gastric; GNB, Gram-negative bacteria; HD, hemodialysis; ICU, intensive care unit; J, jejeunal; PTX, pneumothorax; RBC, red blood cell.

^{*a*}Medical error potentially contributing to patient death; ^{*b*}prolonged hypoxemia associated with the medical error.

which >40% involved incidents or personnel outside of the medical intensive care unit. Approximately 10% of the reported medical events resulted in the need for additional life-sustaining interventions, and 3.0% of the medical events resulting in errors may have contributed to patient deaths. The SAFE reporting system described statistically more events compared with a hospital-wide computer database for cataloging errors and highrisk events. These findings highlight the common occurrence of medical events resulting in errors in the intensive care unit setting, including events associated with direct patient harm. Additionally, our results suggest that medical events can be prospectively identified and reported by members of the intensive care unit team. The ability to identify medical events in a systematic manner offers the potential for improving patient care by changing medical practices to reduce the future occurrence of such events and thereby decreasing the number of actual medical errors (4).

This study describes a nonpunitive method for the prospective reporting of medical events in the intensive care unit setting. Beckmann et al. (9) previously described a method of medical error reporting in an Australian intensive care unit using anonymous facilitated incident monitoring with a standardized report form. Compared with retrospective medical chart review, these investigators found that an established incident reporting system, enhanced by facilitation of reports at morning rounds by senior staff, identified a larger number of preventable incidents. Our reporting method differs from the one described by Beckmann and co-workers in that we attempted to gather identifying information on the individuals reporting the medical events as well as specific information concerning the impact of the reported events on patient outcomes. This was purposefully done to facilitate the gathering of additional details regarding the reported events and to expedite any improvements in the process of medical care derived from review of these reports. For example, our review of the events occurring with one of the patients described in Table 3 resulted in hospital policy changes regarding the utilization of noninvasive mechanical ventilation on hospital floors.

Previous authors have suggested that healthcare providers would be reluctant to report medical events due to concerns of blame, liability, and estrangement from peers (6, 10, 11). The Institute of Medicine report emphasized the need to develop medical event reporting systems that did not focus blame, but instead fo-

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e demonstrated that medical events resulting in error appear to be common in the intensive care unit setting. Healthcare providers working in the intensive care unit appear to be in a unique position to observe and report such events related to patient care.

cused on the gathering of medical events data to effect useful changes in medical practices (4). Our experience suggests that healthcare providers are willing to identify themselves when reporting medical events to facilitate collection of data surrounding the event. This may be related to preparations before beginning this program that emphasized the nonpunitive nature of the program and the support given to the program by key local opinion leaders. Fostering a cooperative "team" culture appears to be an important element in establishing the success of improvement processes such as those reported in this article (12, 13). The high proportion of reporters willing to identify themselves on the report forms indicated the acceptance of this program by the intensive care unit staff. Most of the medical events were reported by nurses and physicians-in-training. This likely reflects the greater time these individuals spend in direct patient care, which allows them to observe and detect the occurrence of medical events resulting in error.

The medical intensive care unit participating in this project has a history of involvement in quality improvement initiatives, including those sponsored by the Institute of Healthcare Improvement (14). Specific areas targeted for improvement have included the weaning of mechanical ventilation (15), sedation practices (16), end-of-life issues (17), and the prevention of infections (18). Paramount to the performance of these types of initiatives is the ability to ascertain baseline occurrence rates of targeted variables of interest that this study was designed to do. The rate of medical events we observed (89.3 medical events reported per 1000 intensive care unit days) is greater than the rates of hospital-acquired infections described for patients in the intensive care units of Barnes-Jewish Hospital (18, 19). Therefore, based on sheer number of events, the local allocation of resources aimed at reducing the occurrence of medical errors seems justified.

Our study has several limitations. First, it was performed within a single intensive care unit using a locally developed method for the reporting of medical errors. Additionally, this local effort was supported by extramural funds obtained from the federal government as well as local hospital foundation funds. Therefore, our results may not be generalizable to intensive care units and hospitals with different institutional cultures and resource availability. However, the increasing recognition of medical errors, especially in high-volume or high-intensity areas such as intensive care units and emergency departments, suggests that the implementation of similar programs for event detection are likely to be successful (4). Second, we did not have a "gold standard" for the detection of medical events resulting in error available to compare with the results of the program described in this report. Consequently, we cannot determine the success of this program in detecting all relevant events and errors. It is important to recognize that this pilot project is simply the first step in the development of a long-range program aimed at continuously monitoring medical events and improving the process of health care. Effecting change and process improvement based on observations and reported data are the ultimate goal of this program. Simply reporting events without effecting change would be a less worthwhile outcome.

Another potential limitation of our study was that nurses reported most of the events. Therefore, a possible reporting bias of events may have occurred favoring certain types of events or events related to a specific group of medical careproviders. However, we did not find any identifiable pattern of event reporting that differentiated nurses from the other groups examined. Additionally, all events were reported including "near-misses" that resulted in no harm. However, our findings suggest that a reporting bias may have occurred favoring the reporting of events associated with harm or the potential for harm. As a result, we may have underreported the true rate of medical errors. Alternatively, we did not prospectively define the duration of a delay in treatment constituting a medical error. Delays resulting in no harm are usually described as "near-misses," resulting in a possible overestimation of the overall event rate. Nonetheless, 44.6% of the delays or omissions in providing a scheduled treatment or procedure (Table 2) resulted in the need for some additional intervention. This suggests that the reporters describing delays in treatments and procedures were describing clinically important events. Finally, the establishment of the SAFE program may have resulted in a Hawthorne Effect that altered both the care that patients received and the actual reporting of events.

CONCLUSIONS

In summary, we demonstrated that medical events resulting in error appear to be common in the intensive care unit setting. Healthcare providers working in the intensive care unit appear to be in a unique position to observe and report such events related to patient care. The challenge is to develop and implement systematic efforts aimed at improving patient safety by reducing the occurrence of medical errors (20). Our analysis of medical errors involving patients requiring intensive care suggests that these errors are varied in their type and influence on patient outcomes. Therefore, systems developed for the prevention of medical errors need to be broad in scope and address fundamental practices such as communications among healthcare providers and the availability of timely checks and reviews of treatments (4, 5).

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