Abstract

- **Objective:** To discuss key issues that emerged during the design and implementation of a Web-based incident reporting system.
- **Setting:** 23 intensive care units in the United States.
- **Project description:** The Web-based reporting form was developed and implemented as part of the Intensive Care Unit Safety Reporting System project funded by the Agency for Healthcare Research and Quality. Unit staff members were trained on the rationale and conceptual basis of the project and the use of the reporting form. They were encouraged to report both adverse events (incidents resulting in patient harm) and near misses (incidents that do not result in patient harm). The first site began reporting in July 2002, with additional sites enrolled sequentially throughout the year.
- **Results:** The experience with this project suggests that 4 areas should be targeted to maximize the success of incident reporting systems: integration with existing reporting structures, promoting incident reporting by staff, coding and analysis of event reports, and use of incident reports to improve patient safety. Multiple reporting systems within a single hospital or health system will not be feasible, and the health care community must consolidate reporting systems and consider how to share data from a single system that is useful to multiple stakeholders.

The problem of adverse events represents a significant challenge for U.S. hospitals. Patients in intensive care units (ICUs) especially may be at risk for exposure to an adverse event because of the complexity of their illnesses and care. It has been estimated that each patient admitted to an ICU is at risk for exposure to 1.7 errors per day of admission [1]. Following publication of the Institute of Medicine’s report *To Err Is Human*, interest in the development and use of incident reporting systems as a means to address the problem of adverse events has grown [2].

We developed and implemented a Web-based incident reporting system as part of an Agency for Healthcare Research and Quality (AHRQ) demonstration project designed to gather and report medical error data. The aim of the Intensive Care Unit Safety Reporting System (ICUSRS) project is to understand the system factors associated with the occurrence of adverse events, both events that result in patient harm and “near misses” in which harm was avoided. From our experience with the ICUSRS, we believe that there are 4 key areas that should be targeted to maximize the success of incident reporting systems: integration with existing reporting structures, promoting incident reporting by staff, coding and analysis of event reports, and use of incident reports to fix what is broken in health care delivery. We discuss each of these topics as it relates to our experience with the ICUSRS.

Background

The project’s leadership and coordinating center is located at the Johns Hopkins University School of Medicine and Bloomberg School of Public Health. ICUs participating in the project were initially selected from among the membership of the Society of Critical Care Medicine (SCCM). News of the project spread through word of mouth, and directors of...
other ICUs contacted us regarding participation in the project. These additional ICUs were invited, and altogether 23 ICUs are participating. Each ICU was required to obtain institutional review board approval for the project.

Prior to initiation of the project, the principal investigator at each ICU assembled a 4-person team of professionals from within the ICU to serve as leaders for the project. In addition to the principal investigator, who was generally the physician ICU director, the teams included nurse managers, nurse educators, risk managers, critical care pharmacists, and others. Unit staff members were trained on the rationale and conceptual basis of the project and the use of the reporting form. The reporting form may be viewed at https://www.icusrs.org/reportingform/train. This training occurred during a site visit by members of the study team from the project’s coordinating center. Unit staff members were encouraged to report both adverse events (incidents resulting in patient harm) and near misses (incidents that do not result in patient harm). The site visit also included a meeting between Johns Hopkins team members and project leadership within the ICU and a representative of risk management. The first site began reporting in July 2002, with additional sites enrolled sequentially throughout the year. AHRQ funding for the ICUSRS project began in October 2001 and continues through August 2004.

Integration with Existing Reporting Systems

The majority of hospitals participating in the ICUSRS had existing incident/adverse event reporting structures at the time the project was introduced. Most hospitals had only one internal reporting mechanism (within their organization) while a few had both internal and external reporting requirements. Commonly, these external mechanisms were state-mandated reporting systems. The variations in organization that we encountered while implementing the ICUSRS required flexibility and sensitivity to the needs of hospital risk management as well as to the workload of the intensive care providers who would be using the ICUSRS. Incident reporting to the ICUSRS was generally organized in 1 of 3 ways: the ICUSRS substituted for the existing reporting form, adverse events and near misses were reported to both systems, or near misses were reported to the ICUSRS with back entry of adverse events to the ICUSRS from reporting forms for the existing system. Where possible, we attempted to organize reporting to the ICUSRS to minimize duplicate reporting by staff. However, the manner in which the ICUSRS would be used at a particular site was decided with input from the staff of the coordinating center, study leadership within the ICU, and representatives of hospital risk management and/or quality improvement departments. We found that integrating the various reporting systems worked best when representatives of risk management or quality improvement were engaged early in the process of onsite study organization. Early contact allowed all members of the team to voice concerns they had regarding conduct of the study and provided adequate time to thoroughly consider alternative methods of organization.

Given the political pressure for error reporting from the federal and state governments, accreditors, professional societies, and hospitals, the burden of multiple reporting systems will likely grow. However, it is not likely that multiple reporting systems within a single hospital or health system will be feasible. Systems that require duplicate error reporting will likely fail. For this reason, hospitals, state government, and professional societies will need to partner to ensure a single front end for reporting. The health care community must begin to consolidate reporting systems and consider how to share data from a single system that is useful to multiple stakeholders. For example, in the ICUSRS, we collect data on incidents involving devices and send de-identified data to the U.S. Food and Drug Administration.

Overcoming Barriers to Incident Reporting

A number of studies have reported barriers to incident reporting, including fear of disciplinary or legal action resulting from the report, perceived lack of value, failure to recognize that a reportable incident has occurred, and time and effort associated with reporting. Our awareness of these issues had a direct effect on the development of the reporting form, the training materials used during site visits, and the development of mechanisms for providing feedback to the ICU leadership and staff.

The Web-based form is both anonymous and confidential. Care was taken to ensure that the form and database are compliant with Health Insurance Portability and Accountability Act (HIPAA) standards and regulations. For instance, we collect only partial information on dates, and no patient or provider identifiers are collected. Where demographic data are collected (eg, time of incident), the form provides response choices in broad categories rather than narrow discrete units. At the data coordination site, the text boxes included on the form are reviewed daily for new reports, and identifying information that is inadvertently reported is removed and replaced with Xs. Thus, the form and database meet the definition of a limited data set under HIPAA.

The reporting form was developed not only to allow for a thorough description of the incident but also to facilitate ease of use in reporting. Text boxes were kept to a minimum, with the majority of questions designed as check boxes. The form also incorporates skip patterns to minimize the number of screens the reporter is asked to complete. During training, we stress the blame-free nature of the project and data collection. Reason’s Swiss cheese model (Figure 1) is used to highlight the role of system failures rather than individual
actions in the occurrence of adverse events [5]. In addition, we highlight the anonymity, confidentiality, and security features of the database and present examples of reportable incidents. A current topic of research is exploration of ICU staff attitudes and beliefs about the use of reporting systems. We believe this endeavor will assist us in further developing methods to overcome barriers and increase reporting.

In a recent paper on incident reporting systems, Leape states that timely analysis and feedback are imperative to encourage ongoing incident reporting, to invest the users in the incident reporting system, and to allow interventions when serious risks are identified [6]. The ICUSRS provides monthly ICU-specific feedback as well as case summaries of illustrative or common adverse events and near misses reported to the database (Figure 2). The reports help project leaders in the participating ICUs to identify organizational hazards and to obtain ideas for improving patient safety. The ICUSRS also includes a data analysis “wizard,” which provides the capability for local study team members to search, examine, and categorize incidents reported from their ICU. With this tool, the sites have ready access to the data and can analyze cases when they want. In addition, we generate a quarterly newsletter that is distributed to the staff of each participating ICU. The newsletter provides updates on study progress and examples of lessons learned from the database and features staff members from among the participating ICUs.

**Coding and Analysis**

To increase the utility of adverse event and near miss reports filed with the ICUSRS, each report is reviewed and coded to indicate the type of incident reported. The coding scheme is designed to be clinically relevant and includes the following broad categories of event types: clinical process; airway management; lines, tubes, drains; equipment/medical device; medication and therapeutics; unit management; communication; information technology/computerized physician order entry; institutional management; and falls. The Table provides an example of each event type. These coding methods allow us to summarize reports filed with the ICUSRS for use in both data analysis and reporting data back to the sites. However, coding and analysis methods are evolving. There is debate regarding the most appropriate and useful coding system for medical incidents, and further research is needed to develop a common taxonomy [7]. The value of a taxonomy should be measured in terms of its usefulness to caregivers for improving patient safety. As such, the taxonomy should evolve from the types of data analysis and feedback the consumer of the data finds useful. This development of a taxonomy will likely be an iterative process. The federal government could work to create a uniform taxonomy so that data could be shared among various reporting systems.

The Web-based ICUSRS reporting form utilizes both free text and check boxes for data entry. Text boxes are provided to allow the reporter to describe the incident in his or her own words and to provide clarification for key data elements (eg, system factors contributing to an incident) when check boxes alone may not be adequate. However, there is debate about the relative value of reporting in free text or check boxes. Although text can provide context regarding
the event, our ability to analyze text is limited. As the number of cases reported to any system grows, the effort and cost required to glean lessons from text data increases as does the effort and time need to manage the sheer volume of reports. The large volumes of reports filed with state or federal mandatory incident reporting systems will place increasing demands on data coding activities, which in turn will limit their ability to provide timely feedback to hospitals and other providers. Research efforts that focus on developing a common taxonomy, analyzing test data, and automating coding of text-based incident reports are sorely needed.

**Using Data to Guide Change**

It is not enough to collect the data and feed it back to a health care organization. The ultimate test of a reporting system's usefulness is whether the data gathered are used to improve...
patient safety. As noted above, the leaders from each participating ICU have 2 avenues by which they can learn about what could be improved in their ICUs: a monthly report of cases and the wizard tool. For instance, the director of one participating ICU used the software wizard to explore the distribution of number and types of events based on day of the week. He learned that the majority of medication events occurred on Thursdays. By examining the organization of care in the ICU, he found that the ICU’s point-of-care pharmacist was not in the ICU on Thursdays. He is now working with hospital leadership to address this problem. In addition to making changes within their ICUs, team leaders are encouraged to share data summaries with leaders from their hospitals through such channels as morbidity and mortality conferences, patient safety committees, hospital risk management, and hospital quality improvement.

Among the ongoing challenges for the ICUSRS is identifying activities in the participating ICUs where data collected by the system have been used to make care safer. Team leaders in the participating ICUs are queried regularly regarding how ICUSRS data are being used to improve care in their ICUs. These lessons and tips are then disseminated among the participating teams so that all members of the ICUSRS project may learn how other teams address system

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Example</th>
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<tbody>
<tr>
<td>General clinical management</td>
<td>Patient self-extubated while RN was away from bedside. Initially O₂ saturations fell to 40% and patient became bradycardic. The patient responded well to bagging with 100% O₂ and was reintubated nasally.</td>
</tr>
<tr>
<td>Clinical process</td>
<td>Guidewire was lost while house officer was placing arterial line in femoral artery and was discovered by nurse when catheter was not functioning and removed. Patient was sent to interventional radiology and wire was successfully retrieved.</td>
</tr>
<tr>
<td>Airway management</td>
<td>Verbal order for ETT advancement 2 cm was given with ventilator changes after turning patient supine from prone position and reading morning chest radiograph. Three hours later patient was advanced during esophagogastrodoudenoscopy procedure with loss of tidal volumes, requiring reintubation/ETT exchange. ETT had not been advanced before the procedure.</td>
</tr>
<tr>
<td>Line, tubes, drain</td>
<td>Upon turning patient the nurse became aware that the transvenous pacemaker was dislodged and completely out of the sheath. House staff were notified. A new transvenous pacemaker was placed after a delay related to the availability of comparable equipment.</td>
</tr>
<tr>
<td>Equipment/medical device</td>
<td>Trauma/neurosurgical patient with elevated intracranial pressure was being cooled with cooling blanket. Cooling blanket became nonfunctional during night shift. Call was made for replacement, but none could be found. Patient cooled by other means (ice bags, air flow, etc). Early day shift called again for cooling blanket replacement. None delivered for approximately 4 hours.</td>
</tr>
<tr>
<td>Medication and therapeutics</td>
<td>Upon checking doctor’s medication orders for a newly admitted patient, the nurse discovered that Fioricet 1 tablet q 4–6 h pm was ordered but was written in the medication administration record as 1–2 tablets q 4–6 h. Pharmacist on duty notified, necessary changes made, wrong dose administration prevented.</td>
</tr>
<tr>
<td>Unit management</td>
<td>Patient identification labels from previous patient not removed from bedside. Patient labels are used for blood draws, orders, etc.</td>
</tr>
<tr>
<td>Communication</td>
<td>Tracheostomy was placed at bedside on patient who was recently heparinized for deep vein thrombosis. Surgery team was not aware that patient was fully heparinized. Procedure resulted in bleeding that needed to be reversed with Protamine.</td>
</tr>
<tr>
<td>Information technology/computerized physician order entry</td>
<td>Digoxin order entered by pharmacy to be given to patient at 21:00 and 3:00, but the doses did not appear on the nurse’s print out sheet to be administered. Bedside nurse noticed the mistake on Siemens Medical Systems printout papers and patient received the doses at the correct time.</td>
</tr>
<tr>
<td>Institutional management</td>
<td>Patient had blood draw for measurement of CK, CK-MB, and troponin due at 23:00. Phlebotomy was called at 23:30 because blood had not been drawn. Phlebotomy was called again at 00:30 because blood had not been drawn. Phlebotomy reported that only one lab technician was making rounds, thus the delay.</td>
</tr>
<tr>
<td>Integumentary</td>
<td>X-ray technician placed x-ray plate under patient and when the plate was removed the patient’s skin tore approximately a dime size with minimal blood loss. The site was cleansed and DuoDerm applied. Patient medicated with 3 mg of Ativan for agitation as result of the incident.</td>
</tr>
<tr>
<td>Patient testing</td>
<td>Gram stain of cerebrospinal fluid was read as negative by blood bank technician, reread by microbiology lab as positive for Streptococcus pneumoniae.</td>
</tr>
<tr>
<td>Patient fall</td>
<td>Patient became confused when he woke up at 05:30 needing to void. Patient fell out of bed when he attempted to climb out over the side rails. Patient was uninjured. RN was at the other patient’s bedside.</td>
</tr>
</tbody>
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CK = creatine kinase; ETT = endotracheal tube.
failures and other problems in ICU care. A meeting of the teams from participating ICUs is held annually. Among the activities included in these meetings is a forum where team leaders share improvement activities resulting from incidents identified by the ICUSRS. Finally, an additional avenue by which the project shares lessons is through partnership with the SCCM. Throughout the life of the project, we have worked with SCCM to ensure that the ICUSRS addresses the needs of the critical care community. Through the SCCM’s Patient Safety Advisory Committee, events reported to ICUSRS are reviewed by an interdisciplinary panel of ICU caregivers, and illustrative cases are summarized and disseminated through the internet and society publications to ensure broad learning from mistakes. We believe that partnership with the SCCM has been crucial to the success of this project.

Conclusion

We have successfully implemented a voluntary, anonymous, nonpunitive incident reporting system in a cohort of ICUs. Through the use of multidisciplinary teams within each ICU, we have worked to ensure that the reporting system is integrated with the other reporting mechanisms that may be in place. We are working at identifying and overcoming barriers to reporting that exist within the ICUs. Through our efforts at developing a coding and reporting structure, we have learned that considerably more research is needed to better understand how to code, analyze, and report incidents so that caregivers and leaders use the information to improve patient safety. We have generated as many questions as we have answered. Nevertheless, many states, and potentially the federal government, are pushing ahead with mandating error reporting, even though many questions remain.

Perhaps most important, we have learned that reporting systems should be designed as communities of learning. Dissemination of any external reporting mechanism requires awareness of and responsiveness to the needs of the member organizations. By working through professional organizations as well as at the ICU level, we have created a system that allows us to learn what is broken in ICU care, disseminate that information to leaders across ICUs, and use the information to improve patient safety in the ICU.

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References