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TECHNICAL REPORT

A Review of Current State-Level Adverse Medical Event Reporting Practices

Toward National Standards

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Prepared for the Agency for Healthcare Research and Quality

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SUMMARY

In 2000, the Institute of Medicine (IOM) published *To Err is Human*, which revealed that preventable adverse medical events resulting from human error pose a significant threat to patient safety and cost the healthcare industry millions of dollars. The federal government has a vested interest in improving the safety of healthcare. In keeping with the recommendations presented in *To Err Is Human,* the Agency for Healthcare Research and Quality (AHRQ) is leading the national Patient Safety Initiative to combat medical errors. One component of this initiative involves tracking change over time in the incidence of adverse medical events nationally. Currently, nearly half of states require or request that such events be reported.

A second IOM report, *Patient Safety: Achieving a New Standard of Care* (2004), recommended that efforts to achieve consistent standards for medical error reporting be undertaken. Standardized reporting systems can help to ensure that patient safety data are collected efficiently, used consistently, and shared appropriately across healthcare organizations and regulatory bodies. Used as intended, such systems can increase our understanding of adverse medical events and help us determine how to address them. To support these efforts, AHRQ contracted with RAND to examine several issues related to the design of adverse medical event systems. The research reported here aims to

- describe the adverse medical event reporting systems currently used by states and the accreditation bodies that evaluate healthcare organizations
- prepare a structured compilation of the data elements used in describing adverse events under these systems
- identify similarities and differences across state reporting systems
- determine whether existing methods of coding information regarding health and healthcare for storage and analysis in

electronic systems could be used to characterize adverse medical events

- generate and organize ideas regarding the design and implementation of a nationwide standardized adverse medical events reporting system.

RAND SURVEY OF STATE AGENCIES

Between October and December 2004, we conducted phone surveys of the agencies and departments responsible for hospital licensing and regulation in each of the 50 states. During the phone interview, we determined whether the state had a hospital reporting system for adverse medical events. Our main goal was to identify systems that required reporting of adverse events—singly or in the aggregate—that occur in hospitals and other provider organizations, so long as hospitals were among them. We collected detailed information about reporting systems, including purpose, implementation date, type and format of information collected, how information concerning adverse events is submitted to the state, and what is considered a reportable adverse event.

To determine whether the goals of the systems we identified reflected a concern with patient safety, we examined the system documentation, looking for certain key words. For example, we considered whether the legislation under which the system was enacted or the description of the system developed by regulators used the words "patient safety" or emphasized improving patient care rather than punishing providers or hospitals for mistakes. We also requested all supporting documentation, including codebooks, standard reporting forms, and entity relationship diagrams, which are diagrams or flowcharts that illustrate the structure of the information collected. In many cases, our informants directed us to a Web site that contained much—but not all—of the documentation we requested. In general, these Web sites contained the law governing the system and the standard reporting forms.

With the documentation and other information provided by state informants, we profiled each state system, using as a template to organize our observations the IOM-recommended domains of patient safety reporting. We created analytic files based on these profiles, which we

used to determine what types of information about adverse events states are collecting.

Results

Although we observed considerable variation across states in both the administrative procedures and the substantive aspects of the adverse medical event reporting systems we examined, the most striking result was the extent to which these systems had become more similar since the release of *To Err Is Human* (IOM 2000), a conclusion we reached by comparing the results we obtained with those obtained in prior surveys by the National Academy for State Health Policy (Flowers and Riley, 2000) and IOM (2000).

Administrative Characteristics of Adverse Reporting Systems. Our survey revealed that 24 states have at least one formal adverse medical event reporting system. Twenty of these systems are mandatory, that is, the healthcare organizations covered by the system are required to report certain adverse events to the state. General and acute care hospitals were cited most frequently as the kinds of facilities required to report adverse medical events, followed by ambulatory surgical centers, skilled nursing facilities, and psychiatric hospitals. Few of the states we surveyed were able to readily provide documentation about their electronically stored data (e.g., data dictionary, codebook, and entity relationship diagrams), and we found little agreement about what constitutes a data dictionary and codebook. The absence of formal documentation and definitions suggests a need for clarification and standardization to ensure that the adverse events reported to the system are categorized accurately, which is essential to cross-institutional or cross-jurisdictional comparisons and to efforts to identify trends in the incidence of adverse events.

Despite this lack of clarity, we were able to characterize the systems we identified in several important ways. First, nearly all of the systems we identified were oriented toward improving patient safety rather than disciplining misconduct. Second, although variations remain, states are moving toward the use of standardized methods of collecting and managing adverse event reports. For instance, most

states require facilities to submit their reports using a statewide standard reporting form. Further, although most states currently permit multiple modes of submission (usually fax or mail), several states have adopted Web-based systems that demand more uniformity, and this approach appears to be growing. Regardless of how reports of adverse medical events are submitted, most states regularly store them in an electronic format of some sort, which, again, will facilitate comparative and longitudinal analyses. Only two states permit reporting of aggregate counts of events. The others all require reporting of each event defined as a reportable adverse event, another procedure that increases the feasibility of analyzing patient safety data to identify the frequency of various types of adverse events and the circumstances associated with them.

Finally, states are beginning to develop independent or semi-independent agencies to house the organizations concerned with collecting and managing patient safety data. For example, in Pennsylvania, the use of an independent agency has led to a very comprehensive patient safety reporting system. There are, however, some costs associated with this approach related to privity of contract concerns between the state and its vendors. For this investigation, these concerns meant that we were unable to obtain critical details regarding the system, including its data dictionary, codebook, and entity relationship diagrams. If it becomes apparent that systems housed in entities independent of the state are desirable for fiscal, procedural, or political reasons, it may be useful to determine whether there are ways to set up these systems that would permit analysts to have access to the data describing their components, configuration, and contents. Making this information available would help to promote transparency in efforts to monitor adverse events and would facilitate analyses of progress on patient safety concerns.

Procedures for Identifying and Describing Reportable Events. As with administrative procedures, our survey reveals increasing commonality across states in terms of the substantive information required by current adverse event reporting systems. Across systems, requirements concerning what events must be reported and what

information about them must be included have converged. Even without a federal mandate to do so, most states have developed lists of reportable adverse medical events based fully or, more often, in part, on the 27 "never events" defined by the National Quality Forum (NQF),[1] the list of reviewable sentinel events identified by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or a combination of the two. Since 2002, the number of states that require reporting of an NQF never event has increased for 23 of the 27 never events.

The most commonly included NQF never events are

- patient death or serious disability associated with a medication error
- wrong-site surgery
- infant discharge to wrong person
- wrong-patient surgery
- wrong-procedure surgery
- retention of a foreign object

The most commonly included JCAHO reviewable sentinel events are

- surgery performed on wrong patient or wrong body part
- hemolytic transfusion reaction
- rape.

The most common elements collected by state systems about reportable events are

- a narrative of the event
- information on corrective actions taken
- when the event occurred
- patient information.

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[1] *Never events* are adverse medical events that, in a well-managed healthcare institution, should never occur.

ASSESSMENT OF THE UTILITY OF EXISTING MEDICAL STANDARDS FOR CODING ADVERSE MEDICAL EVENTS

A system for recording information regarding adverse medical events requires a coding system to capture information regarding the kind of event, where and when it occurred, who was involved, and so on. Thus, we set out to assess the extent to which existing standards for reporting health information in other contexts—that is, outside the context of patient safety—could be used to code the information in adverse medical event reports. More specifically, we attempted to determine whether existing health information standards could be applied to each of the IOM-recommended data elements for adverse medical event reporting.

We based our assessment on a review of the 27 standards identified by the Consolidated Health Informatics (CHI) initiative. Conducted under the leadership of the U.S. Office of Management and Budget, CHI is an effort to identify a portfolio of interoperability standards for health information. Our analysis suggests that efforts to develop standards for reporting adverse medical events can build on the CHI standards. Existing standards can be used to code much of the IOM-recommended information regarding adverse medical events. Many of the detailed standards already exist for particular data elements, such as patient and product information. Standards for other elements can be developed in the context of existing standards, such as the Systematized Nomenclature of Medicine (SNOMED) and the Logical Observation Identifier Names and Codes (LOINC), or through the efforts of such groups as HL7, which is a standards developing organization dedicated to providing a comprehensive framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information.

Thus, it should not be necessary to develop special standards for coding information about adverse medical events. Such standards already exist or are being developed within the existing framework of other standardization efforts.

PROMULGATING NATIONAL PATIENT SAFETY STANDARDS

As part of our investigation, we convened an expert panel to discuss issues involved in developing and implementing a national

adverse event reporting system. Panel members generally agreed that such a system should be simple, focused on adverse events that cause harm to patients (as opposed to capturing all medical errors), and administered by an organization that is not part of an entity that either provides or pays for healthcare. This last provision is important because, the panelists argued, ensuring the independence of a patient safety data collection and management organization would be essential to obtaining the cooperation of healthcare organizations and personnel.

A number of suggestions concerning the implementation of adverse medical event reporting systems were also offered. Perhaps the most important of these was that the skills of the people who would actually carry out the reporting need to be taken into account. Responsibility for reporting the details of adverse medical events is commonly assigned to healthcare personnel who have limited training, even though determining that a patient-harming adverse event has occurred may require interpreting complex medical data. To deal with this potential mismatch between task requirements and the skills of the relevant personnel, panelists suggested that, whenever possible, state adverse medical event reporting systems use predetermined menus to ensure that all of the essential details are reported using the correct terminology. Panelists also suggested that consideration be given to developing and using a set of "global triggers" that will automatically prompt healthcare personnel who are qualified to determine whether a serious adverse medical event occurred to review the relevant records.

The panelists also emphasized that employees must be assured that the information they provide will be handled confidentially and that the information will be used primarily to improve institutional practices.

Panelists noted, too, that rather than relying solely on incident reports to obtain information on adverse medical events, healthcare facilities should also audit patient records regularly to identify anomalous events, which can then be further investigated to determine whether a serious adverse medical event has indeed occurred.

RECOMMENDATIONS FOR ESTABLISHING A NATIONAL REPOSITORY OF PATIENT SAFETY INFORMATION

Our analysis of current adverse reporting systems, the existing procedures for coding information related to health and healthcare, and the views offered by our panelists lead to the recommendations below, which we believe will provide useful direction in the event that AHRQ moves to establish a national repository of state-provided standard patient safety information.

- **Create and maintain a database containing the information needed to track system characteristics over time.**
  Such a database should contain information concerning characteristics of the system, including the date it was implemented, when it was last modified, names of informants, their titles, and contact information.

- **Provide guidance to states regarding the supporting documentation for adverse event reporting systems.**
  To facilitate coordination and comparison across states, system characteristics and requirements must be documented. The federal government or another entity with experience in creating such documentation will likely need to provide guidance to states as to the types and formats of the materials needed and the format in which the data should be reported. In addition, as states move toward Web-based systems, additional guidance may be needed to develop database documentation that captures the characteristics of an electronic system.

- **In future research, determine how variations in definitions of reportable events affect cross-state comparisons of patient safety outcomes.**
  Many comparisons, and related validity studies, are needed to determine how particular variations in definitions of reportable events affect the assessment of patient safety outcomes. For example, researchers might compare adverse event rates under a system that requires that an event be reported only if it results in severe patient injury or death with the

rates under a system that requires the reporting of any incident regardless of patient harm. Given the variety of ways in which event definitions might differ, considerable research will be needed to settle on a set of definitions that can be used to reliable capture patient safety outcomes.

FINAL OBSERVATIONS

Although the *Patient Safety and Quality Improvement Act of 2005* (Public Law 109-41) may increase the likelihood that states and healthcare systems will focus on the development and implementation of adverse medical event reporting systems, we believe that a national adverse event reporting system with "teeth" will require federal guidance. Even if mandatory state-level reporting systems are implemented, it is unlikely that the states will achieve the level of uniformity in their adverse medical event reporting systems required to monitor the occurrence of such events nationally without such guidance.

The federal government could facilitate such a system by sponsoring workshops to help the states develop a common set of standards for tracking the safety of patients in healthcare facilities. The government could also give grants to cover the costs of implementing these standards. To reinforce the importance of maintaining these systems, the federal government, in collaboration with the states, could amend the Medicare claims processes to require that all healthcare facilities receiving payments from CMS and having the agreed-upon patient safety systems in place receive bonus payments. Concomitantly, a dedicated unit within AHRQ could be established to assemble, analyze, and report on the information provided to patient safety tracking systems of all the states. This approach to standardizing the patient safety tracking systems across the nation will undoubtedly take some time to accomplish, but collaborating with the states in this effort should help to ensure that all states buy into it.

There are two alternatives to a state-federal collaborative model. The first—federal inaction and autonomous action by individual states—will only produce newer versions of the varying outcomes documented in this report. States will adopt and adapt guidelines being

promulgated by various entities, such as NQF and JCAHO, or they will adopt their own idiosyncratic list. There will be considerable variation in how information is collected, transmitted, and stored, thereby making it nearly impossible to develop a national repository of patient safety reports that could be used as a basis for monitoring progress and formulating policy.

The second alternative is direct federal intervention and control. This approach would require establishing yet another reporting system beyond those currently required by the states, the risk management systems implemented by individual institutions, and any other systems facilities may be required to participate in. In addition to imposing additional burdens on facilities (and thereby risking their support for such a system), direct federal intervention would be more costly and less efficient than collaborating with states. The results of our survey show that states have been quick to adopt or adapt reporting systems that incorporate recommendations made in *To Err Is Human* (IOM, 2000), suggesting that federal directives may not be necessary. It is possible, however, that states that have not yet modified their systems may be unwilling to do so in the absence of federal intervention.