

## Error Reporting Systems

Although the previous chapter talked about creating and disseminating new knowledge to prevent errors from ever happening, this chapter looks at what happens after an error occurs and how to learn from errors and prevent their recurrence. One way to learn from errors is to establish a reporting system. Reporting systems have the potential to serve two important functions. They can hold providers accountable for performance or, alternatively, they can provide information that leads to improved safety. Conceptually, these purposes are not incompatible, but in reality, they can prove difficult to satisfy simultaneously.

Reporting systems whose primary purpose is to hold providers accountable are "mandatory reporting systems." Reporting focuses on errors associated with serious injuries or death. Most mandatory reporting systems are operated by state regulatory programs that have the authority to investigate specific cases and issue penalties or fines for wrong-doing. These systems serve three purposes. First, they provide the public with a minimum level of protection by assuring that the most serious errors are reported and investigated and appropriate follow up action is taken. Second, they provide an incentive to health care organizations to improve patient safety in order to avoid the potential penalties and public exposure. Third, they require all health care organizations to make some level of investment in patient safety, thus creating a more level playing field. While safety experts recognize that errors resulting in serious harm are the "tip of the iceberg," they represent the small subset of errors that signal major system breakdowns with grave consequences for patients.

Reporting systems that focus on safety improvement are "voluntary reporting systems." The focus of voluntary systems is usually on errors that resulted in no harm (sometimes referred to as "near misses") or very minimal patient harm. Reports are usually submitted in confidence outside of the public arena and no penalties or fines are issued around a specific case. When voluntary systems

focus on the analysis of "near misses," their aim is to identify and remedy vulnerabilities in systems before the occurrence of harm. Voluntary reporting systems are particularly useful for identifying types of errors that occur too infrequently for an individual health care organization to readily detect based on their own data, and patterns of errors that point to systemic issues affecting all health care organizations.

The committee believes that there is a need for both mandatory and voluntary reporting systems and that they should be operated separately. Mandatory reporting systems should focus on detection of errors that result in serious patient harm or death (i.e., preventable adverse events). Adequate attention and resources must be devoted to analyzing reports and taking appropriate follow-up action to hold health care organizations accountable. The results of analyses of individual reports should be made available to the public.

The continued development of voluntary reporting efforts should also be encouraged. As discussed in Chapter 6, reports submitted to voluntary reporting systems should be afforded legal protections from data discoverability. Health care organizations should be encouraged to participate in voluntary reporting systems as an important component of their patient safety programs.

For either type of reporting program, implementation without adequate resources for analysis and follow-up will not be useful. Receiving reports is only the first step in the process of reducing errors. Sufficient attention must be devoted to analyzing and understanding the causes of errors in order to make improvements.

## RECOMMENDATIONS

**RECOMMENDATION 5.1** A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should

- designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
- require all health care organizations to report standardized information on a defined list of adverse events;
- provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state

**choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and designate the Center for Patient Safety to:**

**(1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and**

**(2) receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).**

Mandatory reporting systems should focus on the identification of serious adverse events attributable to error. Adverse events are deaths or serious injuries resulting from a medical intervention.<sup>1</sup> Not all, but many, adverse events result from errors. Mandatory reporting systems generally require health care organizations to submit reports on all serious adverse events for two reasons: they are easy to identify and hard to conceal. But it is only after careful analysis that the subset of reports of particular interest, namely those attributable to error, are identified and follow up action can be taken.

The committee also believes that the focus of mandatory reporting system should be narrowly defined. There are significant costs associated with reporting systems, both costs to health care organizations and the cost of operating the oversight program. Furthermore, reporting is useful only if it includes analysis and follow-up of reported events. A more narrowly defined program has a better chance of being successful.

A standardized reporting format is needed to define what ought to be reported and how it should be reported. There are three purposes to having a standardized format. First, a standardized format permits data to be combined and tracked over time. Unless there are consistent definitions and methods for data collection across organizations, the data cannot be aggregated. Second, a standardized format lessens the burden on health care organizations that operate in multiple states or are subject to reporting requirements of by multiple agencies and/or private oversight processes and group purchasers. Third, a standardized format facilitates communication with consumers and purchasers about patient safety.

The recently established Forum for Health Care Quality Measurement and Reporting is well positioned to play a lead role in promulgating standardized reporting formats, including a nomenclature and taxonomy for reporting. The Forum is a public/private partnership charged with developing a comprehensive quality measurement and public reporting strategy. The existing reporting systems (i.e., national and state programs, public and private sector programs) also

represent a growing body of expertise on how to collect and analyze information about errors, and should be consulted during this process.<sup>2</sup>

**RECOMMENDATION 5.2** The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

- describe and disseminate information on existing voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
- convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
- periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
- fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

Voluntary reporting systems are an important part of an overall program for improving patient safety and should be encouraged. Accrediting bodies and group purchasers should recognize and reward health care organizations that participate in voluntary reporting systems.

The existing voluntary systems vary in scope, type of information collected, confidentiality provisions, how feedback to reporters is fashioned, and what is done with the information received in the reports. Although one of the voluntary medication error reporting systems has been in operation for 25 years, others have evolved in just the past six years. A concerted analysis should assess which features make the reporting system most useful, and how the systems can be made more effective and complementary.

The remainder of this chapter contains a discussion of existing error reporting systems, both within health care and other industries, and a discussion of the committee's recommendations.

## **REVIEW OF EXISTING REPORTING SYSTEMS IN HEALTH CARE**

There are a number of reporting systems in health care and other industries. The existing programs vary according to a number of design features. Some programs mandate reporting, whereas others are voluntary. Some programs receive reports from individuals, while others receive reports from organizations. The advantage of receiving reports from organizations is that it signifies that the

institution has some commitment to making corrective system changes. The advantage of receiving reports from individuals is the opportunity for input from frontline practitioners. Reporting systems can also vary in their scope. Those that currently exist in health care tend to be more narrow in focus (e.g., medication-related error), but there are examples outside health care of very comprehensive systems.

There appear to be three general approaches taken in the existing reporting systems. One approach involves mandatory reporting to an external entity. This is the approach is typically employed by states that require reporting by health care organizations for purposes of accountability. A second approach is voluntary, confidential reporting to an external group for purposes of quality improvement (the first model may also use the information for quality improvement, but that is not its main purpose). There are medication reporting programs that fall into this category. Voluntary reporting systems are also used extensively in other industries such as aviation. The third approach is mandatory internal reporting with audit. For example, the Occupational Safety and Health Administration (OSHA) requires organizations to keep data internally according to a standardized format and to make the data available during on-site inspections. The data maintained internally are not routinely submitted, but may be submitted if the organization is selected in the sample of an annual survey.

The following sections provide an overview of existing health care reporting systems in these categories. They also include two examples from areas outside health care. The Aviation Safety Reporting System is discussed because it represents the most sophisticated and long-standing voluntary external reporting system. It differs from the voluntary external reporting systems in health care because of its comprehensive scope. Since there are currently no examples of mandatory internal reporting with audit, the characteristics of the OSHA approach are described.

## **Mandatory External Reporting**

### **State Adverse Event Tracking**

In a recent survey of states conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), it was found that at least one-third of states have some form of adverse event reporting system.<sup>3</sup> It is likely that the actual percentage is higher because not all states responded to the survey and some of the nonrespondents may have reporting requirements. During the development of this report, the Institute of Medicine (IOM) interviewed 13 states with reporting systems to learn more about the scope and operation of their programs. The remainder of this section relates to information provided to the IOM. Appendix D summarizes selected characteristics of the reporting systems in these states, and includes information on what is reported to the state, who is required to submit reports, the number of reports received in the most

recent year available, when the program began, who has access to the information collected and how the state uses the information that is obtained. This is not intended as a comprehensive review, but rather, as an overview of how some state reporting systems are designed.

States have generally focused their reporting systems on patient injuries or facility issues (e.g., fire, structural issues). Reports are submitted by health care organizations, mostly hospitals and/or nursing homes, although some states also include ambulatory care centers and other licensed facilities. Although the programs may require reporting from a variety of licensed facilities, nursing homes often consume a great deal of state regulatory attention. In Connecticut, 14,000 of almost 15,000 reports received in 1996 were from nursing homes.

Several of the programs have been in place for ten years or longer, although they have undergone revisions since their inception. For example, New York State's program has been in place since 1985, but it has been reworked three times, the most recent version having been implemented in 1998 after a three-year pilot test.

Underreporting is believed to plague all programs, especially in their early years of operation. Colorado's program received 17 reports in its first two years of operation,<sup>4</sup> but ten years later, received more than 1000 reports. On the other hand, New York's program receives approximately 20,000 reports annually.

The state programs reported that they protected the confidentiality of certain data, but policies varied. Patient identifiers were never released; practitioner's identity was rarely available. States varied in whether or not the hospital's name was released. For example, Florida is barred from releasing any information with hospital or patient identification; it releases only a statewide summary.

The submission of a report itself did not trigger any public release of information. Some states posted information on the Internet, but only after the health department took official action against the facility. New York has plans to release hospital-specific aggregate information (e.g., how many reports were submitted), but no information on any specific report.

Few states aggregate the data or analyze them to identify general trends. For the most part, analysis and follow-up occurs on a case-by-case basis. For example, in some states, the report alerted the health department to a problem; the department would assess whether or not to conduct a follow-up inspection of the facility. If an inspection was conducted, the department might require corrective action and/or issue a deficiency notice for review during application for relicensure.

Two major impediments to making greater use of the reported data were identified: lack of resources and limitations in data. Many states cited a lack of resources as a reason for conducting only limited analysis of data. Several states had, or were planning to construct a database so that information could be tracked over time but had difficulty getting the resources or expertise to do so. Additionally, several states indicated that the information they received in reports from health care organizations was inadequate and variable. The need for more standardized reporting formats was noted.

A focus group was convened with representatives from approximately 20 states at the 12th Annual conference of the National Academy of State Health Policy (August 2, 1999). This discussion reinforced the concerns heard in IOM's telephone interviews. Resource constraints were identified, as well as the need for tools, methods, and protocols to constructively address the issue. The group also identified the need for mechanisms to improve the flow of information between the state, consumers, and providers to encourage safety and quality improvements. The need for collaboration across states to identify and promote best practices was also highlighted. Finally, the group emphasized the need to create greater awareness of the problem of patient safety and errors in health care among the general public and among health care professionals as well.

In summary, the state programs appear to provide a public response for investigation of specific events,<sup>5</sup> but are less successful in synthesizing information to analyze where broad system improvements might take place or in communicating alerts and concerns to other institutions. Resource constraints and, in some cases, poorly specified reporting requirements contribute to the inability to have as great an impact as desired.

#### **Food and Drug Administration (FDA)**

Reports submitted to FDA are one part of the surveillance system for monitoring adverse events associated with medical products after their approval (referred to as postmarketing surveillance).<sup>6</sup> Reports may be submitted directly to FDA or through MedWatch, FDA's reporting program. For medical devices, manufacturers are required to report deaths, serious injuries, and malfunctions to FDA. User facilities (hospitals, nursing homes) are required to report deaths to the manufacturer and FDA and to report serious injuries to the manufacturer. For suspected adverse events associated with drugs, reporting is mandatory for manufacturers and voluntary for physicians, consumers, and others. FDA activities are discussed in greater detail in Chapter 7.

#### **Voluntary External Reporting**

##### **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**

JCAHO initiated a sentinel event reporting system for hospitals in 1996 (see chapter 7 for a discussion on JCAHO activities related to accreditation). For its program, a sentinel event is defined as an "unexpected occurrence or variation involving death or serious physical or psychological injury or the risk thereof." Sentinel events subject to reporting are those that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition, or an event that meets one of the

following criteria (even if the outcome was not death or major permanent loss of function): suicide of a patient in a setting where the patient receives around-the-clock care; infant abduction or discharge to the wrong facility; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; or surgery on the wrong patient or wrong body part.<sup>7</sup>

The Joint Commission requires that an organization experiencing a sentinel event conduct a root cause analysis, a process for identifying the basic or causal factors of the event. A hospital may voluntarily report an incident to JCAHO and submit their root cause analysis (including actions for improvement). If an organization experiences a sentinel event but does not voluntarily report it and JCAHO discovers the event (e.g., from the media, patient report, employee report), the organization is still required to prepare an acceptable root cause analysis and action plan. If the root cause analysis and action plan are not acceptable, the organization may be placed on accreditation watch until an acceptable plan is prepared. Root cause analyses and action plans are confidential; they are destroyed after required data elements have been entered into a JCAHO database to be used for tracking and sharing risk reduction strategies.

JCAHO encountered some resistance from hospitals when it introduced the sentinel event reporting program and is still working through the issues today. Since the initiation of the program in 1996, JCAHO has changed the definition of a sentinel event to add more detail, instituted procedural revisions on reporting, authorized on-site review of root cause analyses to minimize risk of additional liability exposure, and altered the procedures for affecting a facility's accreditation status (and disclosing this change to the public) while an event is being investigated.<sup>8</sup> However, concerns remain regarding the confidentiality of data reported to JCAHO and the extent to which the information on a sentinel event is no longer protected under peer review if it is shared with JCAHO (these issues are discussed in Chapter 6).

There is the potential for cooperation between the JCAHO sentinel event program and state adverse event tracking programs. For example, JCAHO is currently working with New York State so that hospitals that report to the state's program are considered to be in compliance with JCAHO's sentinel events program.<sup>9</sup> This will reduce the need for hospitals to report to multiple groups with different requirements for each. The state and JCAHO are also seeking to improve communications between the two organizations before and after hospitals are surveyed for accreditation.

### **Medication Errors Reporting (MER) Program**

The MER program is a voluntary medication error reporting system originated by the Institute for Safe Medication Practice (ISMP) in 1975 and administered today by U.S. Pharmacopeia (USP). The MER program receives reports from frontline practitioners via mail, telephone, or the Internet. Information is

also shared with the FDA and the pharmaceutical companies mentioned in the reports. ISMP also publishes error reports received from USP in 16 publications every month and produces a biweekly publication and periodic special alerts that go to all hospitals in the United States. The MER program has received approximately 3,000 reports since 1993, primarily identifying new and emerging problems based on reports from people on the frontline.

#### **MedMARx from the U.S. Pharmacopoeia**

In August 1998, U.S. Pharmacopoeia initiated the MedMARx program, an Internet-based, anonymous, voluntary system for hospitals to report medication errors. Hospitals subscribe to the program. Hospital employees may then report a medication error anonymously to MedMARx by completing a standardized report. Hospital management is then able to retrieve compiled data on its own facility and also obtain nonidentified comparative information on other participating hospitals. All information reported to MedMARx remains anonymous. All data and correspondence are tied to a confidential facility identification number. Information is not shared with FDA at this time. The JCAHO framework for conducting a root cause analysis is on the system for the convenience of reporters to download the forms, but the programs are not integrated.

#### **Aviation Safety Reporting System at NASA**

The three voluntary reporting systems described above represent focused initiatives that apply to a particular type of organization (e.g., hospital) or particular type of error (e.g., medication error). The Aviation Safety Reporting System (ASRS) is a voluntary, confidential incident reporting system used to identify hazards and latent system deficiencies in order to eliminate or mitigate them.<sup>10</sup> ASRS is described as an example of a comprehensive voluntary reporting system.

ASRS receives "incident" reports, defined as an occurrence associated with the operation of an aircraft that affects or could affect the safety of operations. Reports into ASRS are submitted by individuals confidentially. After any additional information is obtained through follow-up with reporters, the information is maintained anonymously in a database (reports submitted anonymously are not accepted). ASRS is designed to capture near misses, which are seen as fruitful areas for designing solutions to prevent future accidents.

The National Transportation Safety Board (NTSB) investigates aviation accidents. An "accident" is defined as an occurrence that results in death or serious injury or in which the aircraft receives substantial damage. NTSB was formed in 1967 and ASRS in 1976. The investigation of accidents thus preceded attention to near misses.

ASRS operates independently from the Federal Aviation Administration (FAA). It was originally formed under FAA, but operations were shifted to the National Aeronautics and Space Administration (NASA) because of the reluctance of pilots to report incidents (as differentiated from accidents) to a regulatory authority. FAA funds the ASRS, but NASA administers and manages the program independently. ASRS has no regulatory or enforcement powers over civil aviation.

ASRS issues alerts to the industry on hazards it identifies as needed (e.g., ASRS does not go through a regulatory agency to issue an alert or other communication; Linda Connell, Director of ASRS, personal communication, May 20, 1999). If a situation is very serious, it may issue an alert after only one incident. Often, ASRS has received multiple reports and noted a pattern. The purpose of ASRS alerts and other communications is to notify others of problems. Alerts may be disseminated throughout the industry and may also be communicated to the FAA to notify them about areas that may require action. ASRS does not propose or advocate specific solutions because it believes this would interfere with its role as an "honest broker" for reporters. As a result, although some reported problems may be acted upon, others are not. For example, ASRS has been notifying FAA and the industry about problems that have persisted throughout its 23-year history, such as problems with call signs. To date, no agency has been able to find a permanent solution. However, ASRS continues to issue alerts about the problem to remind people that the problem has not been solved.

ASRS maintains a database on reported incidents, identifies hazards and patterns in the data, conducts analyses on types of incidents, and interviews reporters when indicated. It sends out alert messages, publishes a monthly safety bulletin that is distributed to 85,000 readers and produces a semi-annual safety topics publication targeted to the operators and flight crews of complex aircraft. Quick-response studies may be conducted for NTSB and FAA as needed (e.g., if an accident occurred, they may look for similar incidents). ASRS receives over 30,000 reports annually and has an operating budget of approximately \$2 million.<sup>11</sup>

A more recent program is the Aviation Safety Action Programs. The de-identification of reports submitted to ASRS means that organizations do not have access to reports that identify problems in their own operations. In 1997, FAA established a demonstration program for the creation of Aviation Safety Action Programs (ASAP).<sup>12</sup> Under ASAP, an employee may submit a report on a serious incident that does not meet the threshold of an accident to the airline and the FAA with pilot and flight identification. Reports are reviewed at a regular meeting of an event review committee that includes representatives from the employee group, FAA and the airline. Corrective actions are identified as needed.

## **Mandatory Internal Reporting with Audit**

### **Occupational Safety and Health Administration**

OSHA uses a different approach for reporting than the systems already described. It requires companies to keep internal records of injury and illness, but does not require that the data be routinely submitted. The records must be made available during on-site inspections and may be required if the company is included in an annual survey of a sample of companies.<sup>13</sup> OSHA and the Bureau of Labor Statistics both conduct sample surveys and collect the routine data maintained by the companies. These agencies conduct surveys to construct incidence rates on worksite illness and injury that are tracked over time or to examine particular issues of concern, such as a certain activity.

Employers with 11 or more employees must routinely maintain records of occupational injury and illness as they occur. Employees have access to a summary log of the injury and illness reports, and to copies of any citations issued by OSHA. Citations must be posted for three days or until the problem is corrected, whichever is longer. Companies with ten or fewer employees are exempt from keeping such records unless they are selected for an annual survey and are required to report for that period. Some industries, although required to comply with OSHA rules, are not subject to record-keeping requirements (including some retail, trade, insurance, real estate, and services). However, they must still report the most serious accidents (defined as an accident that results in at least one death or five or more hospitalizations).

### **Key Points from Existing Reporting Systems**

There are a number of ways that reporting systems can contribute to improving patient safety. Good reporting systems are a tool for gathering sufficient information about errors from multiple reporters to try to understand the factors that contribute to them and subsequently prevent their recurrence throughout the health care system. Feedback and dissemination of information can create an awareness of problems that have been encountered elsewhere and an expectation that errors should be fixed and safety is important. Finally, a larger-scale effort may improve analytic power by increasing the number of "rare" events reported. A serious error may not occur frequently enough in a single entity to be detected as a systematic problem; it is perceived as a random occurrence. On a larger scale, a trend may be easier to detect.

Reporting systems are particularly useful in their ability to detect unusual events or emerging problems.<sup>14</sup> Unusual events are easier to detect and report because they are rare, whereas common events are viewed as part of the "normal" course. For example, a poorly designed medical device that malfunctions routinely becomes viewed as a normal risk and one that practitioners typically find ways to work around. Some common errors may be recognized and re-

ported, but many are not. Reporting systems also potentially allow for a fast response to a problem since reports come in spontaneously as an event occurs and can be reacted to quickly.

Two challenges that confront reporting systems are getting sufficient participation in the programs and building an adequate response system. All reporting programs, whether mandatory or voluntary, are perceived to suffer from underreporting. Indeed, some experts assert that all reporting is fundamentally voluntary since even mandated reporting can be avoided.<sup>15</sup> However, some mandatory programs receive many reports and some voluntary programs receive fewer reports. New York's mandatory program receives an average of 20,000 reports annually, while a leading voluntary program, the MER Program, has received approximately 3,000 reports since 1993. Reporting adverse reactions to medications to FDA is voluntary for practitioners, and they are not subject to FDA regulation (so the report is not going to an authority that can take action against them). Yet, underreporting is still perceived.<sup>16</sup> Of the approximately 235,000 reports received annually at FDA, 90 percent come from manufacturers (although practitioners may report to the manufacturers who report to FDA). Only about 10 percent are reported directly through MedWatch, mainly from practitioners.

The volume of reporting is influenced by more factors than simply whether reporting is mandatory or voluntary. Several reasons have been suggested for underreporting. One factor is related to confidentiality. As already described, many of the states contacted faced concerns about confidentiality, and what information should be released and when. Although patients were never identified, states varied on whether to release the identity of organizations. They were faced with having to balance the concerns of health care organizations to encourage participation in the program and the importance of making information available to protect and inform consumers. Voluntary programs often set up special procedures to protect the confidentiality of the information they receive. The issue of data protection and discoverability is discussed in greater detail in Chapter 6.

Another set of factors that affects the volume of reports relates to reporter perceptions and abilities. Feedback to reporters is believed to influence participation levels.<sup>17</sup> Belief by reporters that the information is actually used assures them that the time taken to file a report is worthwhile. Reporters need to perceive a benefit for reporting. This is true for all reporting systems, whether mandatory or voluntary. Health care organizations that are trained and educated in event recognition are also more likely to report events.<sup>18</sup> Clear standards, definitions, and tools are also believed to influence reporting levels. Clarity and ease helps reporters know what is expected to be reported and when. One experiment tried paying for reporting. This increased reporting while payments were provided, but the volume was not sustained after payments stopped.<sup>19</sup>

Although some reporting systems that focus on adverse events, such as hospital patients experiencing nosocomial infections, are used to develop incidence rates and track changes in these rates over time, caution must be exercised when calculating rates from any type of adverse event reporting system for several

reasons. Reporting systems are considered to be "passive" in that they rely on a report being submitted by someone who has observed the event.<sup>20</sup> "Active" systems work with participating health care organizations to collect complete data on an issue being tracked to determine rates of an adverse event<sup>21</sup> (e.g., the CDC conducted an active surveillance study of vaccine events with four HMOs linking vaccination records with hospital admission records<sup>22</sup>).

The low occurrence of serious errors can also produce wide variations in frequency from year to year. Some organizations and individuals may routinely report more than others, either because they are more safety conscious or because they have better internal systems.<sup>23</sup> Certain characteristics of medical processes may make it difficult to identify an adverse event, which can also lead to variation in reporting. For example, adverse drug events are difficult to detect when they are widely separated in time from the original use of the drug or when the reaction occurs commonly in an unexposed population.<sup>24</sup> These reasons make it difficult to develop reliable rates from reporting systems, although it may be possible to do so in selected cases. However, even without a rate, repetitive reports flag areas of concern that require attention.

It is important to note, however, that the goal of reporting programs is not to count the number of reports. The volume of reports by itself does not indicate the success of a program. Analyzing and using the information they provide and attaching the right tools, expertise and resources to the information contained in the reports helps to correct errors. Medication errors are heavily monitored, by several public and private reporting systems, some of which afford anonymous reporting. It is possible for a practitioner to voluntarily and confidentially report a medication error to the FDA or to private systems (e.g., MER program, MedMARx). Some states with mandatory reporting may also receive reports of medication-related adverse events. Yet, some medication problems continue to occur, such as unexpected deaths from the availability of concentrated potassium chloride on patient care units.<sup>25</sup>

Reporting systems without adequate resources for analysis and follow-up action are not useful. Reporting without analysis or followup may even be counterproductive in that it weakens support for constructive responses and is viewed as a waste of resources. Although exact figures are not available, it is generally believed that the analysis of reports is harder to do, takes longer and costs more than data collection. Being able to conduct good analyses also requires that the information received through reporting systems is adequate. People involved in the operation of reporting systems believe it is better to have good information on fewer cases than poor information on many cases. The perceived value of reports (in any type of reporting system) lies in the narrative that describes the event and the circumstances under which it occurred. Inadequate information provides no benefit to the reporter or the health system.

### DISCUSSION OF COMMITTEE RECOMMENDATIONS

Reporting systems may have a primary focus on accountability or on safety improvement. Design features vary depending on the primary purpose. Accountability systems are mandatory and usually receive reports on errors that resulted in serious harm or death; safety improvement systems are generally voluntary and often receive reports on events resulting in less serious harm or no harm at all. Accountability systems tend to receive reports from organizations; safety improvement systems may receive reports from organizations or frontline practitioners. Accountability systems may release information to the public; safety improvement systems are more likely to be confidential.

Figure 5.1 presents a proposed hierarchy of reporting, sorting potential errors into two categories: (1) errors that result in serious injury or death (i.e., serious preventable adverse events), and (2) lesser injuries or noninjurious events (near-misses).<sup>26</sup> Few errors cause serious harm or death; that is the tip of the triangle. Most errors result in less or no harm, but may represent early warning signs of a system failure with the potential to cause serious harm or death.

The committee believes that the focus of mandatory reporting systems should be on the top tier of the triangle in Figure 5.1. Errors in the lower tier are issues that might be the focus of voluntary external reporting systems, as well as research projects supported by the Center for Patient Safety and internal patient safety programs of health care organizations. The core reporting formats and measures promulgated by the Forum for Health Care Quality and Measurement should focus first on the top tier. Additional standardized formats and measures pertaining to other types of errors might be promulgated in the future to serve as tools to be made available to voluntary reporting systems or health care organizations for quality improvement purposes.

The committee believes there is an important role for both mandatory and voluntary reporting systems. Mandatory reporting of serious adverse events is essential for public accountability and the current practices are too lax, both in

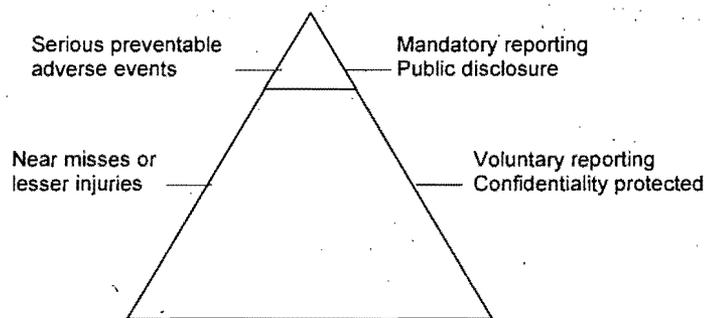


FIGURE 5-1 Hierarchy of reporting.

enforcement of the requirements for reporting and in the regulatory responses to these reports. The public has the right to expect health care organizations to respond to evidence of safety hazards by taking whatever steps are necessary to make it difficult or impossible for a similar event to occur in the future. The public also has the right to be informed about unsafe conditions. Requests by providers for confidentiality and protection from liability seem inappropriate in this context. At the same time, the committee recognizes that appropriately designed voluntary reporting systems have the potential to yield information that will impact significantly on patient safety and can be widely disseminated. The reports and analyses in these reporting systems should be protected from disclosure for legal liability purposes.

### **Mandatory Reporting of Serious Adverse Events**

The committee believes there should be a mandatory reporting program for serious adverse events, implemented nationwide, linked to systems of accountability, and made available to the public. Comparable to aviation "accidents" that are investigated by the National Transportation Safety Board, health care organizations should be required to submit reports on the most serious adverse events using a standard format. The types of adverse events to be reported may include, for example, maternal deaths; deaths or serious injuries associated with the use of a new device, operation or medication; deaths following elective surgery or anesthetic deaths in Class I patients. In light of the sizable number of states that have already established mandatory reporting systems, the committee thinks it would be wise to build on this experience in creating a standardized reporting system that is implemented nationwide.

Within these objectives, however, there should be flexibility in implementation. Flexibility and innovation is important in this stage of development because the existing state programs have used different approaches to implement their programs and a "best practice" or preferred approach is not yet known. The Center for Patient Safety can support states in identifying and communicating best practices. States could choose to collect and analyze such data themselves. Alternatively, they could rely on an accrediting body, such as Joint Commission for Accreditation of Healthcare Organizations or the National Committee for Quality Assurance, to perform the function for them as many states do now for licensing surveys. States could also contract with peer review organizations (PROs) to perform the function. As noted in Chapter 4, the Center for Patient Safety should evaluate the approaches taken by states in implementing reporting programs. States have employed a variety of strategies in their programs, yet few (if any) have been subject to rigorous evaluation. Program features that might be evaluated include: factors that encourage or inhibit reporting, methods of analyzing reports, roles and responsibilities of health care organizations and the state in investigating adverse events, follow up actions taken by states, in-

formation disclosed to the public, and uses of the information by consumers and purchasers.

Although states should have flexibility in how they choose to implement the reporting program, all state programs should require reporting for a standardized core set of adverse events that result in death or serious injury, and the information reported should also be standardized.

The committee believes that these standardized reporting formats should be developed by an organization with the following characteristics. First, it should be a public-private partnership, to reflect the need for involvement by both sectors and the potential use of the reporting format by both the public and the private sectors. Second, it should be broadly representative, to reflect the input from many different stakeholders that have an interest in patient safety. Third, it should be able to gather the expertise needed for the task. This requires adequate financial resources, as well as sufficient standing to involve the leading experts. Enabling legislation can support all three objectives.

The Forum for Health Care Quality Measurement and Reporting meets these criteria. The purpose of this public-private partnership (formed in May, 1999) is to develop a comprehensive quality measurement and public reporting strategy that addresses priorities for quality measurement for all stakeholders consistent with national aims for quality improvement in health care. It is to develop a plan for implementing quality measurement, data collection and reporting standards; identify core sets of measures; and promote standardized measurement specifications. One of its specific tasks should relate to patient safety.

The advantage of using the Forum is that its goal already is to develop a measurement framework for quality generally. A focus on safety would ensure that safety gets built into a broader quality agenda. A public-private partnership would also be able to convene the mix of stakeholders who, it is hoped, would subsequently adopt the standards and standardized reporting recommendations of the Forum. However, the Forum is a new organization that is just starting to come together; undoubtedly some time will be required to build the organization and set its agenda.

Federal enabling legislation and support will be required to direct the Forum for Health Care Quality Measurement and Reporting to promulgate standardized reporting requirements for serious adverse events and encourage all states to implement the minimum reporting requirements. Such federal legislation pertaining to state roles may be modeled after the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA provides three options for implementing a program: (1) states may pass laws congruent with or stronger than the federal floor and enforce them using state agencies; (2) they may create an acceptable alternative mechanism and enforce it with state agencies; or finally, (3) they may decline to pass new laws or modify existing ones and leave enforcement of HIPAA to the federal government.<sup>27</sup> OSHA is similarly designed in that states may develop their own OSHA program with matching funds from the federal government; the federal OSHA program is employed in states that have not formed a state-level program.

### Voluntary Reporting Systems

The committee believes that voluntary reporting systems play a valuable role in encouraging improvements in patient safety and are a complement to mandatory reporting systems. The committee considered whether a national voluntary reporting system should be established similar to the Aviation Safety Reporting System. Compared to mandatory reporting, voluntary reporting systems usually receive reports from frontline practitioners who can report hazardous conditions that may or may not have resulted in patient harm. The aim is to learn about these potential precursors to errors and try to prevent a tragedy from occurring.

The committee does not propose a national voluntary reporting system for several reasons. First, there are already a number of good efforts, particularly in the area of medications. Three complementary national reporting systems are focused on medication errors: FDA, the Institute for Safe Medication Practice, and U.S. Pharmacopeia. The JCAHO sentinel events program is another existing national reporting program for hospitals that will also receive reports on medication and other errors. These reporting systems should be encouraged and promoted within health care organizations, and better use should be made of available information being reported to them.

Second, there are several options available about how to design such a voluntary reporting system. Better information is needed on what would be the best approach. At least three different approaches were identified. One is a universal, voluntary reporting system, modeled after ASRS. The concern with this approach is the potential volume of reports that might come forward when such a system is applied to health care. Another concern is that any single group is unlikely to have the expertise needed to analyze and interpret the diverse set of issues raised in health care. The experience of ASRS has shown that the analysts reviewing incoming reports must be content experts who can understand and interpret these reports.<sup>28</sup> In health care, different expertise is likely needed to analyze, for example, medication errors, equipment problems, problems in the intensive care unit (ICU), pediatric problems, and home care problems.

Another approach is to develop focused "mini-systems" that are targeted toward selected areas (e.g., those that exist for medications) rather than a single voluntary program. This approach would manage the potential volume of reports and match the expertise to the problems. It is possible that there should be different mini-systems for different issues such as medications, surgery, pediatrics, and so forth. If such mini-systems are formed, there should be a mechanism for sharing information across them since a report to one system may have relevance for another (e.g., surgical events that also involve medications).

A third possibility is to use a sampling approach. For example, in its post-marketing surveillance of medical devices, FDA is moving away from a universal reporting system for hospitals and nursing homes to one in which a representative sample of hospitals and nursing homes keeps complete data. Its pilot test found that both the quantity and the quality of reports improved when FDA

worked with a sample of hospitals who were trained in error identification and reporting and could receive feedback quickly. By periodically renewing the sample, the burden on any organization is limited (although participation in the sample may have the side benefit of helping interested organizations build their internal systems and train practitioners in error detection).

Lastly, establishing a comprehensive voluntary reporting system modeled after ASRS would require an enormous investment of time and resources. The committee believes that recommending such an investment would be premature in light of the many questions still surrounding this issue.

The committee does believe that voluntary reporting systems have a very important role to play in enhancing understanding of the factors that contribute to errors. When properly structured, voluntary systems can help to keep participating health care organizations focused on patient safety issues through frequent communication about emerging concerns and potential safety improvement strategies. Voluntary systems can provide much-needed expertise and information to health care organizations and providers.

The continued development of voluntary reporting efforts should be encouraged. Through its various outreach activities, the Center for Patient Safety should describe and disseminate information on voluntary reporting programs throughout the health care industry and should periodically convene sponsors and users of voluntary reporting systems to discuss ways in which these systems can be made more effective. As a part of developing the national research agenda for safety, the Center for Patient Safety should consider projects that might lead to the development of knowledge and tools that would enhance the effectiveness of voluntary reporting programs. The Center should also periodically assess whether there are gaps in the current complement of voluntary reporting programs and should consider funding pilot projects.

In summary, this chapter and the previous chapter outlining the proposed Center for Patient Safety together describe a comprehensive approach for improving the availability of information about medical errors and using the information to design systems that are safer for patients. Although this chapter focuses on using reporting systems to learn about and learn from errors that have already occurred, Chapter 4 focused on how to create and disseminate new knowledge for building safer delivery systems. Both of these strategies should work together to make health care safer for patients.

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## Executive Summary

The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during "minor" surgery due to a drug mix-up.<sup>1</sup>

These horrific cases that make the headlines are just the tip of the iceberg. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.<sup>2</sup> In Colorado and Utah hospitals, 8.8 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.

When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.<sup>3</sup> The results of the New York Study suggest the number may be as high as 98,000.<sup>4</sup> Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8<sup>th</sup> leading cause of death.<sup>5</sup> More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).<sup>6</sup>

Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one-half.<sup>7</sup>

In terms of lives lost, patient safety is as important an issue as worker safety. Every year, over 6,000 Americans die from workplace injuries.<sup>8</sup> Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.<sup>9</sup>

Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly. One recent study conducted at two prestigious teaching hospitals, found that about two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of \$4,700 per admission or about \$2.8 million annually for a 700-bed teaching hospital.<sup>10</sup> If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about \$2 billion for the nation as a whole.

These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total costs. More care and increasingly complex care is provided in ambulatory settings. Outpatient surgical centers, physician offices and clinics serve thousands of patients daily. Home care requires patients and their families to use complicated equipment and perform follow-up care. Retail pharmacies play a major role in filling prescriptions for patients and educating them about their use. Other institutional settings, such as nursing homes, provide a broad array of services to vulnerable populations. Although many of the available studies have focused on the hospital setting, medical errors present a problem in any setting, not just hospitals.

Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided. It is impossible for the nation to achieve the greatest value possible from the hundreds of millions of dollars spent on medical care if the care contains errors.

But not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

Yet silence surrounds this issue. For the most part, consumers believe they are protected. Media coverage has been limited to reporting of anecdotal cases. Licensure and accreditation confer, in the eyes of the public, a "Good Housekeeping Seal of Approval." Yet, licensing and accreditation processes have focused only limited attention on the issue, and even these minimal efforts have confronted some resistance from health care organizations and providers. Providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors.<sup>11</sup>

The decentralized and fragmented nature of the health care delivery system (some would say "nonsystem") also contributes to unsafe conditions for pa-

tients, and serves as an impediment to efforts to improve safety. Even within hospitals and large medical groups, there are rigidly-defined areas of specialization and influence. For example, when patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrong than when care is better coordinated. At the same time, the provision of care to patients by a collection of loosely affiliated organizations and providers makes it difficult to implement improved clinical information systems capable of providing timely access to complete patient information. Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.

Lastly, the context in which health care is purchased further exacerbates these problems. Group purchasers have made few demands for improvements in safety.<sup>12</sup> Most third party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality.

The goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort. "First do no harm" is an often quoted term from Hippocrates.<sup>13</sup> Everyone working in health care is familiar with the term. At a very minimum, the health system needs to offer that assurance and security to the public.

A comprehensive approach to improving patient safety is needed. This approach cannot focus on a single solution since there is no "magic bullet" that will solve this problem, and indeed, no single recommendation in this report should be considered as *the* answer. Rather, large, complex problems require thoughtful, multifaceted responses. The combined goal of the recommendations is for the external environment to create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety. At the same time, there is a need to enhance knowledge and tools to improve safety and break down legal and cultural barriers that impede safety improvement. Given current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years.

In this report, safety is defined as freedom from accidental injury. This definition recognizes that this is the primary safety goal from the patient's perspective. Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. According to noted expert James Reason, errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct, (an error of planning).<sup>14</sup> Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition

of the patient. While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). For example, if a patient has surgery and dies from pneumonia he or she got postoperatively, it is an adverse event. If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution). But the analysis may conclude that no error occurred and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event).

Much can be learned from the analysis of errors. All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals (some experts, such as Deming, believe improving processes is the *only* way to improve quality<sup>15</sup>). The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems and has been doing so since World War II. Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century.<sup>16</sup> In 1998, there were no deaths in the United States in commercial aviation. In health care, preventable injuries from care have been estimated to affect between three to four percent of hospital patients.<sup>17</sup> Although health care may never achieve aviation's impressive record, there is clearly room for improvement.

To err is human, but errors can be prevented. Safety is a critical first step in improving quality of care. The Harvard Medical Practice Study, a seminal research study on this issue, was published almost ten years ago; other studies have corroborated its findings. Yet few tangible actions to improve patient safety can be found. Must we wait another decade to be safe in our health system?

## RECOMMENDATIONS

The IOM Quality of Health Care in America Committee was formed in June 1998 to develop a strategy that will result in a threshold improvement in quality over the next ten years. This report addresses issues related to patient safety, a subset of overall quality-related concerns, and lays out a national

agenda for reducing errors in health care and improving patient safety. Although it is a national agenda, many activities are aimed at prompting responses at the state and local levels and within health care organizations and professional groups.

The committee believes that although there is still much to learn about the types of errors committed in health care and why they occur, enough is known today to recognize that a serious concern exists for patients. Whether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself. This report is a call to action to make health care safer for patients.

The committee believes that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. But the interaction between factors in the external environment and factors inside health care organizations can also prompt the changes needed to improve patient safety. Factors in the external environment include availability of knowledge and tools to improve safety, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements. Factors inside health care organizations include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

In developing its recommendations, the committee seeks to strike a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations. No single action represents a complete answer, nor can any single group or sector offer a complete fix to the problem. However, different groups can, and should, make significant contributions to the solution. The committee recognizes that a number of groups are already working on improving patient safety, such as the National Patient Safety Foundation and the Anesthesia Patient Safety Foundation.

The recommendations contained in this report lay out a four-tiered approach:

- establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

### Leadership and Knowledge

Other industries that have been successful in improving safety, such as aviation and occupational health, have had the support of a designated agency that sets and communicates priorities, monitors progress in achieving goals, directs resources toward areas of need, and brings visibility to important issues. Although various agencies and organizations in health care may contribute to certain of these activities, there is no focal point for raising and sustaining attention to patient safety. Without it, health care is unlikely to match the safety improvements achieved in other industries.

The growing awareness of the frequency and significance of errors in health care creates an imperative to improve our understanding of the problem and devise workable solutions. For some types of errors, the knowledge of how to prevent them exists today. In these areas, the need is for widespread dissemination of this information. For other areas, however, additional work is needed to develop and apply the knowledge that will make care safer for patients. Resources invested in building the knowledge base and diffusing the expertise throughout the industry can pay large dividends to both patients and the health professionals caring for them and produce savings for the health system.

**RECOMMENDATION 4.1 Congress should create a Center for Patient Safety within the Agency for Health Care Policy and Research. This center should**

- set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
- develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

To make significant improvements in patient safety, a highly visible center is needed, with secure and adequate funding. The Center should establish goals for safety; develop a research agenda; define prototype safety systems; develop and disseminate tools for identifying and analyzing errors and evaluate approaches taken; develop tools and methods for educating consumers about patient safety; issue an annual report on the state of patient safety, and recommend additional improvements as needed.

The committee recommends initial annual funding for the Center of \$30 to \$35 million. This initial funding would permit a center to conduct activities in goal setting, tracking, research and dissemination. Funding should grow over time to at least \$100 million, or approximately 1% of the \$8.8 billion in health care costs attributable to preventable adverse events.<sup>18</sup> This initial level of

funding is modest relative to the resources devoted to other public health issues. The Center for Patient Safety should be created within the Agency for Health Care Policy and Research because the agency is already involved in a broad range of quality and safety issues, and has established the infrastructure and experience to fund research, educational and coordinating activities.

### Identifying and Learning from Errors

Another critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance in the future. External reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them.

Reporting systems can be designed to meet two purposes. They can be designed as part of a public system for holding health care organizations accountable for performance. In this instance, reporting is often mandatory, usually focuses on specific cases that involve serious harm or death, may result in fines or penalties relative to the specific case, and information about the event may become known to the public. Such systems ensure a response to specific reports of serious injury, hold organizations and providers accountable for maintaining safety, respond to the public's right to know, and provide incentives to health care organizations to implement internal safety systems that reduce the likelihood of such events occurring. Currently, at least twenty states have mandatory adverse event reporting systems.

Voluntary, confidential reporting systems can also be part of an overall program for improving patient safety and can be designed to complement the mandatory reporting systems previously described. Voluntary reporting systems, which generally focus on a much broader set of errors and strive to detect system weaknesses before the occurrence of serious harm, can provide rich information to health care organizations in support of their quality improvement efforts.

For either purpose, the goal of reporting systems is to analyze the information they gather and identify ways to prevent future errors from occurring. The goal is *not* data collection. Collecting reports and not doing anything with the information serves no useful purpose. Adequate resources and other support must be provided for analysis and response to critical issues.

**RECOMMENDATION 5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should**

- designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;

- require all health care organizations to report standardized information on a defined list of adverse events;

- provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and

- designate the Center for Patient Safety to:
  - (1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and
  - (2) receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

**RECOMMENDATION 5.2** The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

- describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;

- convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;

- periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and

- fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

The committee believes there is a role both for mandatory, public reporting systems and voluntary, confidential reporting systems. However, because of

their distinct purposes, such systems should be operated and maintained separately. A nationwide mandatory reporting system should be established by building upon the current patchwork of state systems and by standardizing the types of adverse events and information to be reported. The newly established Forum for Health Care Quality Measurement and Reporting, a public/private partnership, should be charged with the establishment of such standards. Voluntary reporting systems should also be promoted and the participation of health care organizations in them should be encouraged by accrediting bodies.

**RECOMMENDATION 6.1** Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

The committee believes that information about the most serious adverse events which result in harm to patients and which are subsequently found to result from errors should not be protected from public disclosure. However, the committee also recognizes that for events not falling under this category, fears about the legal discoverability of information may undercut motivations to detect and analyze errors to improve safety. Unless such data are assured protection, information about errors will continue to be hidden and errors will be repeated. A more conducive environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without threat of litigation and without compromising patients' legal rights.

#### **Setting Performance Standards and Expectations for Safety**

Setting and enforcing explicit standards for safety through regulatory and related mechanisms, such as licensing, certification, and accreditation, can define minimum performance levels for health care organizations and professionals. Additionally, the process of developing and adopting standards helps to form expectations for safety among providers and consumers. However, standards and expectations are not only set through regulations. The actions of purchasers and consumers affect the behaviors of health care organizations, and the values and norms set by health professions influence standards of practice, training and education for providers. Standards for patient safety can be applied to health care professionals, the organizations in which they work, and the tools (drugs and devices) they use to care for patients.

**RECOMMENDATION 7.1** Performance standards and expectations for health care organizations should focus greater attention on patient safety.

- **Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.**
- **Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.**

Health care organizations are currently subject to compliance with licensing and accreditation standards. Although both devote some attention to issues related to patient safety, there is opportunity to strengthen such efforts. Regulators and accreditors have a role in encouraging and supporting actions in health care organizations by holding them accountable for ensuring a safe environment for patients. After a reasonable period of time for health care organizations to develop patient safety programs, regulators and accreditors should require them as a minimum standard.

Purchaser and consumer demands also exert influence on health care organizations. Public and private purchasers should consider safety issues in their contracting decisions and reinforce the importance of patient safety by providing relevant information to their employees or beneficiaries. Purchasers should also communicate concerns about patient safety to accrediting bodies to support stronger oversight for patient safety.

**RECOMMENDATION 7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.**

- **Health professional licensing bodies should**

- (1) **implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and**
- (2) **work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.**

- **Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should**

- (1) **develop a curriculum on patient safety and encourage its adoption into training and certification requirements;**
- (2) **disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;**

(3) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;

(4) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and

(5) collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

Although unsafe practitioners are believed to be few in number, the rapid identification of such practitioners and corrective action are important to a comprehensive safety program. Responsibilities for documenting continuing skills are dispersed among licensing boards, specialty boards and professional groups, and health care organizations with little communication or coordination. In their ongoing assessments, existing licensing, certification and accreditation processes for health professionals should place greater attention on safety and performance skills.

Additionally, professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety. Setting standards, convening and communicating with members about safety, incorporating attention to patient safety into training programs and collaborating across disciplines are all mechanisms that will contribute to creating a culture of safety.

**RECOMMENDATION 7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:**

- develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
- require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
- work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.

The FDA's role is to regulate manufacturers for the safety and effectiveness of their drugs and devices. However, even approved products can present safety problems in practice. For example, different drugs with similar sounding names can create confusion for both patients and providers. Attention to the safety of products in actual use should be increased during approval processes and in

post-marketing monitoring systems. The FDA should also work with drug manufacturers, distributors, pharmacy benefit managers, health plans and other organizations to assist clinicians in identifying and preventing problems in the use of drugs.

### **Implementing Safety Systems in Health Care Organizations**

Experience in other high-risk industries has provided well-understood illustrations that can be used to improve health care safety. However, health care management and professionals have rarely provided specific, clear, high-level, organization-wide incentives to apply what has been learned in other industries about ways to prevent error and reduce harm within their own organizations. Chief Executive Officers and Boards of Trustees should be held accountable for making a serious, visible and on-going commitment to creating safe systems of care.

**RECOMMENDATION 8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should**

- provide strong, clear and visible attention to safety;
- implement non-punitive systems for reporting and analyzing errors within their organizations;
- incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies and processes; and
- establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.

Health care organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal that is demonstrated by the strong direction and involvement of governance, management and clinical leadership. In addition, a meaningful patient safety program should include defined program objectives, personnel, and budget and should be monitored by regular progress reports to governance.

**RECOMMENDATION 8.2 Health care organizations should implement proven medication safety practices.**

A number of practices have been shown to reduce errors in the medication process. Several professional and collaborative organizations interested in pa-

tient safety have developed and published recommendations for safe medication practices, especially for hospitals. Although some of these recommendations have been implemented, none have been universally adopted and some are not yet implemented in a majority of hospitals. Safe medication practices should be implemented in all hospitals and health care organizations in which they are appropriate.

### SUMMARY

This report lays out a comprehensive strategy for addressing a serious problem in health care to which we are all vulnerable. By laying out a concise list of recommendations, the committee does not underestimate the many barriers that must be overcome to accomplish this agenda. Significant changes are required to improve awareness of the problem by the public and health professionals, to align payment systems and the liability system so they encourage safety improvements, to develop training and education programs that emphasize the importance of safety and for chief executive officers and trustees of health care organizations to create a culture of safety and demonstrate it in their daily decisions.

Although no single activity can offer the solution, the combination of activities proposed offers a roadmap toward a safer health system. The proposed program should be evaluated after five years to assess progress in making the health system safer. With adequate leadership, attention and resources, improvements can be made. It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives and meet the challenges ahead.

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# American Medical Association

Physicians dedicated to the health of America



## Statement

FOR IMMEDIATE RELEASE

November 30, 1999

### AMA ON IMPROVING PATIENT SAFETY

Statement attributable to:

Nancy W. Dickey, MD  
AMA Immediate-Past President

"The AMA is pleased the Institute of Medicine is taking a serious look at patient safety and is recommending a plan to improve the best medical care in the world.

"Any error that causes harm to a patient is one error too many. In general, medicine is very safe, but medicine is also very complex and is not without risk.

"While we may never achieve perfection, we must continue to strive for it. In its continuing effort to improve patient care, the AMA and other organizations launched the National Patient Safety Foundation in 1997 to acknowledge and address error in the health care system.

"NPSF is taking a new approach to reducing errors and accidents in health care that emphasizes a systems-learning approach, as opposed to methods that focus only on blame and punishment. The health care system is in place to heal not harm. But when an error occurs, it's important to learn from it so as not to repeat it.

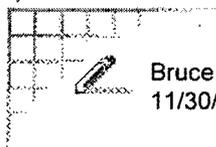
"As the IOM report says, the majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health system is organized.

"Medical science can do more to prevent and cure illness than ever before, but we cannot be satisfied with good when we can do even better. The AMA and the National Patient Safety Foundation will continue to lead the effort to improve patient safety."

#

For more information, please call:

Brenda L. Craine  
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Bruce N. Reed  
11/30/99 11:36:42 AM

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Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Devorah R. Adler/OPD/EOP@EOP

cc:

Subject: ap story

### Clinton Urges War on Medical Errors

By Lauran Neergaard  
AP Medical Writer  
Tuesday, Nov. 30, 1999; 10:28 a.m. EST

WASHINGTON — President Clinton called today for health care providers to work with government and other entities to curb medical errors that a new report says kill thousands of hospital patients each year.

Clinton said he welcomed the report issued Monday by the Institute of Medicine, which quoted studies estimating that at least 44,000 and perhaps as many as 98,000 hospitalized Americans die every year from medical mistakes.

During an Oval Office announcement on parental leave, Clinton told reporters he suggested some sort of partnership to a leading managed care provider on Monday, "and they agreed with that, that we've all got to get together" to resolve the problem.

"No one has an interest in seeing these kinds of mistakes made. And we know that otherwise competent people are making a lot of these mistakes," Clinton said. "We've got to work through how we can use technology, and how we can maybe even slow some of the actions, to make sure that mistakes like this aren't made."

"To err is human" is the report's title, but it stresses that ways exist to prevent many mistakes by anticipating health workers' weaknesses and designing safeguards.

The report recommends major changes to the nation's health care system to set as a minimum goal a 50 percent reduction in medical mistakes within five years.

"Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing," said William Richardson, president of the W.K. Kellogg Foundation, who co-authored the report.

There are constant places for doctors, nurses, pharmacists and other

health workers to trip.

Doctors' notoriously poor handwriting too often leaves pharmacists squinting to decipher a dose – was it 10 milligrams or 10 micrograms? – or even the name of the prescribed drug.

Too many drug names sound confusingly alike. Consider the painkiller Celebrex and the anti-seizure drug Cerebyx; or Narcan, which treats morphine overdoses, and Norcuron, which can paralyze breathing muscles.

Medical knowledge grows so rapidly that it is difficult to stay abreast of the latest treatment or newly discovered danger. Technology poses hazards when device models change from year to year, leaving doctors fumbling for the right switch.

And most health professionals do not have their competence regularly retested after receiving their license to practice, the report said.

In fact, health care is a decade behind other high-risk industries in improving safety, the report said. It pointed to the transportation industry as a model: Just as engineers design cars so they cannot start in reverse, and airlines limit pilots' flying time to keep them rested, so can health care be improved.

Some fixes already are under way: Some hospitals have computerized prescriptions. The Food and Drug Administration is hunting ways to catch sound-alike drugs. Anesthesiologists persuaded many manufacturers to standardize equipment and thus decreased technology-caused errors. Many doctors now literally mark the spot of surgical incisions before patients are put to sleep, so everyone agrees on what will be cut.

But the Institute of Medicine said reducing medical mistakes requires a bigger commitment. It recommended:

–Congress should establish a federal Center for Patient Safety. It would require \$35 million to start and should eventually spend \$100 million a year in safety research. Still, that represents just a fraction of an estimated \$8.8 billion spent yearly as a result of medical mistakes, the report calculated.

–The government should require that hospitals, and eventually other health organizations, report all serious mistakes to state agencies so experts can detect patterns of problems and take action. About 20 states now require error reporting, but how much and what penalties they impose varies widely.

–State licensing boards and medical accreditors should periodically re-examine health practitioners for competence, stressing safety practices. Standardized medical equipment and treatment guidelines can help doctors keep up.

–Change the "culture of secrecy" that surrounds medical mistakes, encouraging doctors to discuss errors as well as near-misses so problems

**THE WHITE HOUSE**  
**Office of the Press Secretary**

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For Immediate Release

Tuesday, November 30,  
1999

**REMARKS BY THE PRESIDENT  
ON PARENTAL LEAVE**

The Oval Office

9:20 A.M. EST

THE PRESIDENT: Hello. Thank you. Good morning, ladies and gentlemen. The people here with me at the podium are, obviously, Secretary Herman, but also Katie and Eric Banks and their son, Collin, of Fairfax, Virginia; Jonathan and Teresa Graham and their two children from Baltimore; Darsie Cahall and James Baker and their three children from Takoma Park, Maryland.

I'll say a little more about them in a moment. You can see this is a family event. (Laughter.) We've orchestrated the children.

Before I leave for the World Trade Organization meeting on the West Coast, I want to talk a little about how we're using the strength of our economy to help strengthen working families.

Yesterday I signed a budget that maintains the fiscal responsibility that has given us what will be in February the longest economic expansion in our history, and at the same time lives up to the values of the American people. We have no higher value than family, but too many of our families are having trouble balancing the demands of home and work. Today I'm using my executive order -- authority -- to give these parents new tools to succeed at home and on the job.

The surging technology and soaring prosperity we currently enjoy are the result of a lot of hard work and very long hours by the American people. In fact, today many working parents are forced to make the unacceptable choice between being good workers and good parents. Too often, in our round-the-world, round-the-clock economy, there just don't seem to be enough hours in the day for parents to do what they need to do. That's why we've worked hard to help parents balance work and family.

Last May I asked Secretary Herman to develop new ways to address this problem. Today I'm announcing a proposed Labor Department rule that lets states use their unemployment insurance to offer paid leave to new parents. This initiative is totally voluntary for states. It helps them empower more working parents, like the ones standing with me today. With this act, the United States joins the rest of the world's advanced economies, all of whom already have some form of paid leave for parents.

When little Collin was born, his mother, Katie, was working as a waitress, his dad was working as a head electrical technician for a small company. Unfortunately, he was born ill and had to be intensive care for several weeks. Katie took unpaid leave and eventually quit

her job to be with her son. Collin's dad, Eric, wanted to take leave, but couldn't afford to do so. Once Collin was well enough, Katie looked for and, fortunately, landed another job. But both Katie and her husband would have, and should have, been able to take paid leave to care for their son. That's what this parental leave initiative is all about.

I believe giving states the flexibility to experiment with paid employment leave is one of the best things we can do to strengthen our families and help new mothers and fathers meet their responsibilities both at home and at work.

State flexibility and the voluntary nature of this effort are key to its success. In our strong economy, we hope states will take advantage of this new option, and we believe those that do will balance this new benefit with the imperative of maintaining a fiscally sound unemployment insurance program.

This effort builds on our commitment to give working families more tools to help them adapt to the new economy, from expanding the earned income tax credit to our welfare-to-work efforts, from increasing funding for child care to HOPE scholarships.

In the budget bill I signed yesterday, we fought for and won a doubling of resources for after-school programs to give young people a safe place to study between the end of their school day and the end of their parents' work day.

I'm especially proud that the first bill I signed as President, in 1993, was the Family and Medical Leave law. Since then, millions of Americans -- we believe well over 20 million -- have used it to take up to 12 weeks of unpaid leave to care for a newborn or sick relative without losing their jobs. The importance of this benefit has been confirmed by the testimony of experts and parents at the first ever White House Conference on Early Childhood Development in 1997, and from groups like the Academy of Pediatrics. They all reinforce what we already know from common sense, giving parents and primary care givers time to bond with children leads to healthy development including boosting critical language and literacy skills.

But the current law meets just a fraction of the need. And the number one reason families give for not taking advantage of Family and Medical Leave is that they simply can't afford to take time off without a paycheck. The actions we take today will go a long way toward alleviating that burden if the states take up the challenge. I believe it will strengthen parents' bonds with both their children and their jobs.

As I've said, on the eve of this new century, we ought to set a goal that all parents can take time they need for their families, without losing the income they need to support them. The new state authority will move us in the right direction and gives another tool in our national efforts to both strengthen our families and reward the dignity of work.

Thank you very much.

Q Mr. President, what do you hope to achieve in Seattle at the WTO?

THE PRESIDENT: Well, I hope we'll get a new round launched that will slash tariffs and other trade barriers in agriculture and other areas. I hope that we will agree to keep e-commerce free of unusual burdens, and that we will lead to more transparent and open rules among nations so that they believe the trading system is fair.

I also strongly, strongly believe that we should open the process up to all those people who are now demonstrating on the outside. They ought to be a part of it. And I think we should strengthen the role and the interests of labor and the environment in our trade negotiations.

This is not going to be easy to do, partly because some nations, particularly a lot of

developing nations, see our concern for the environment and labor standards as a way to sort of keep them down. But that is not true. What we want to do is to make sure that when we open the trading system, that ordinary Americans benefit.

In our country, about 30 percent of our growth has come from expanded trade. We have kept inflation down because we've kept our markets open and other people have been able to sell good quality products at lower prices in our markets. So we've had this huge growth with low inflation. I just want to make sure that ordinary people everywhere are benefitted by the trading system, and that the economy is not damaged by trading rules that could put short-term economic considerations over long-term environmental considerations.

So I'm very sympathetic with a lot of the causes being raised by all the people that are there demonstrating. And since this has now become a global society with global communications, as well as a global economy, I think it was unrealistic to assume that for the next 50 years, trade could be like it's been for the last 50 -- primarily the province of business executives and political leaders. I think more people are going to demand to be heard, and I think that's a good thing.

Q Mr. President, yesterday a report documented the problem of medical mistakes, and said that 44,000 Americans at least are killed every year because of these medical mistakes. What's your reaction to that, and is there anything that your administration is planning to do about it?

THE PRESIDENT: Well, you may remember that we had a task force a couple of years ago, headed by Secretary Herman and Secretary Shalala, which issued -- in fact, two reports -- one of them recommended the patients' bill of rights. The other set up a quality commission to deal with problems like this.

If you looked at it, to me, one of the most interesting things was that a lot of these hospitals, which are very over-crowded and have people coming in all the time, and have doctors seeing all kinds of patients in rapid succession, have people lose their lives because of improper prescriptions of medicine, not knowing about a patient's allergy, or not knowing about what other medication they're taking. That's a -- and I think that we have an opportunity here to work with the public-private partnership which the task force set up to use modern technology, information technology, and to also do some basic old-fashioned changes in procedures that will save a lot of these lives.

I'm convinced we can do that. I talked yesterday, on the patients' bill of rights, to one of the leading managed care providers in the country, and suggested that they ought to be helping, too, and they agreed with that. We've all got to get together. No one has an interest in seeing these kinds of mistakes made. And we know that otherwise competent people are making a lot of these mistakes. So we've got to work through how we can use technology and how we can maybe even slow some of the actions to make sure that mistakes like this aren't made.

But I think we need -- this is a very welcome report; we need to study it very carefully. And in order to get something done on it, it's going to take a partnership of everybody involved in health care.

Q Mr. President, there's been yet another case of espionage from Russia. Are you concerned that there's some sort of epidemic of spying going on? And what does this say about U.S.-Russian relations?

THE PRESIDENT: From where, from Russia? Well, I think what we should do is investigate this like we do all others. But I don't think we should stop our efforts to try to drastically cut nuclear weapons, or end corruption in Russia, or do all the other things we're supporting. I think this shows the importance of our work that the Congress ratified to continue to reduce the nuclear weapons in Russia and the nuclear threat associated with the

decommissioning of nuclear weapons.

And I think that what we have to do is continue -- we have to deal with espionage firmly, but we need to try to reduce the consequences of error and mistakes and wrongdoing.

Q What do you hear about Yeltsin's health?

THE PRESIDENT: I think it's a case of pneumonia. That's what they said. I checked on it yesterday, and they believe that he'll be all right.

Q Mr. President, the Mexican Attorney General is reportedly saying that 22 Americans are among those found in the mass graves. Have you received any official word?

THE PRESIDENT: No. I asked about it just before I came out here, actually, and I haven't. It's a horrible example, apparently, of the excesses of the drug dealing cartels in Mexico, and I think it reenforces the imperative of our not only trying to protect our border, but to work with the Mexican authorities to try to combat these.

You know, we had a lot of success a few years ago in taking down a number of the Colombian drug cartels, and one of the adverse consequences of that was a lot of the operations were moved north into Mexico. And there are organized criminal operations there, and they are particularly vicious. You may remember that in that same area a couple of years ago, an honest and brave Mexican prosecutor was shot over a hundred times in front of his wife and child. So it's a very violent, dangerous thing, and we have to be on top of it.

Thank you.

Q Mr. President, why aren't you going to Panama? I mean, it's a major event in history.

THE PRESIDENT: Well, first of all, I have taken, and may have to take -- I've already taken, I think, a dozen foreign trips this year -- it is a major event; I think my interest in Latin America is well-known -- but I may have to take yet another trip before the end of the year, and about that time, which is why I asked President Carter and Secretary Albright to head our delegation.

I think that President Carter deserves enormous credit for his leadership in getting the Panama Canal Treaty through. It was, at the time, as you remember, very controversial, immensely unpopular. A lot of members in the Senate were -- had their seats put in peril over it. And I think it --

Q So you're not against the turnover?

THE PRESIDENT: Oh, no. I supported it at the time and I still support it. I think it's the right thing to do. I think that the new government of Panama is committed to maintaining the canal in an appropriate way and keeping it open and working with us to do so, and having good relations.

So no one in Panama or anywhere in Latin America should draw any adverse conclusion. We have a lot of things going on in the world now; I've been out of the country a lot; I need to get ready for the new Congress and the new budget, and I may have to take another foreign trip at about the same time, which is why I have not committed to make the trip. But I think --

Q What, which one?

THE PRESIDENT: I can't talk about it. (Laughter.) But I think -- I do think that Jimmy

Carter deserves to lead our delegation down there. He did an historic and great thing in advocating the Panama Canal Treaty. But the people of Panama should know that this President and our government strongly support both the treaty and the event, which will occur in a few days.

Q You're not worried about the Chinese controlling the canal?

THE PRESIDENT: I think the Chinese will, in fact, be bending over backwards to make sure that they run it in an competent and able and fair manner. This is like them, like China coming into the WTO. I think they'll want to demonstrate to a distant part of the world that they can be a responsible partner, and I would be very surprised if any adverse consequences flowed from the Chinese running the canal.

Q When are you going to Ireland?

THE PRESIDENT: I don't know. You know, I'd like to go once a month.

THE PRESS: Thank you.

END 9:35 A.M. EST



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*Bringing lifetimes of experience and leadership to serve all generations.*

June 16, 1998

The Honorable William Jefferson Clinton  
President of the United States  
1600 Pennsylvania Avenue, NW  
Washington, DC 20502

Dear Mr. President:

AARP has historically championed the interests of Americans of all ages with respect to access to affordable, quality healthcare. In recent years, we have intensified our interest in health quality, in terms of both consumer protections and system-wide quality improvement measures and incentives.

Accordingly, we are pleased to support the establishment of the Forum for Health Quality Measurement and Reporting as a mechanism to help strengthen system-wide quality performance. By coordinating the work of private sector organizations involved in health care quality, the Forum will harness the expertise of the private sector, establish the private sector arm of a public-private partnership to improve quality, and strengthen public support for quality improvement through credible and complete reporting.

We look forward to working with the Forum, the Administration and members of Congress on a bipartisan basis to address the need for higher and more consistent quality in all aspects of American health care.

Sincerely,

A handwritten signature in cursive script that reads "John C. Rother".

John C. Rother  
Director, Legislation & Public Policy





American Association of  
**HEALTH PLANS**

*Quality Medical October File*

## Memorandum

**To:** Chris Jennings  
Deputy Assistant to the President

**From:** Carmella Bocchino  
Vice President of Medical Affairs

**Date:** June 16, 1998

**Re:** **AAHP Quality Improvement & Research Initiatives**

Per our discussion this afternoon, following is a summary description of the AAHP quality improvement and research initiatives in which I am currently engaged:

- ▶ Direct collaborative efforts between AAHP, AAHP member plans, and assorted provider groups to assess innovative models of care and best practices and to disseminate this information within the health plan community.
- ▶ Secure and directly oversee more than \$10 million in project grants from philanthropic organizations and federal agencies (CDC, IIRSA & AHCPR) for the analysis and promotion of public health research, educational programming, and studies on special populations (i.e., maternal & child health, women's health, chronic care).
- ▶ Collaborate with employers/benefit managers to design performance measurements to facilitate health plan comparisons and provide additional information for consumers.
- ▶ Lead AAHP working group in discussions with NIH to increase patient participation in clinical trials.
- ▶ AAHP liaison with voluntary accrediting organizations (NCQA, JCAHO, AAHCC/URAC).
- ▶ AAHP representative on the NCQA Committee on Performance Measurements.
- ▶ Assist in the development of HEDIS measures.
- ▶ Member of the Advisory Committee for QISMC (Quality Improvement Standards for Managed Care).
- ▶ Established exemplary practice award within AAHP to recognize and promote best practice models that have been evaluated by experts in the field of quality/clinical care and are external to AAHP.
- ▶ Lead AAHP Consumer Advisory Committee which advises AAHP on the design of projects focused on increasing/improving information to consumers
- ▶ Lead the development and dissemination of a consumer guide to "Choosing a Health Plan" and a consumer video to increase consumer's understanding of integrated delivery systems

**United  
Hospital Fund**

Empire State Building  
350 Fifth Avenue, 23rd Floor  
New York, NY 10018

# FAX COVER PAGE

To: Chris Jennings 202 456-5560		From: Jim Tallon
Fax Number: 202 456-5557		Company: UNITED HOSPITAL FUND
Date: 6/12/98	Total Pages: 2	For Information Call: (212) 494-0777
Subject: June 17		Fax Number: (212) 494-0830

**Notes:**

Here is my draft.

As you see, the first line contains an option. Let me know which you prefer, as well as any other comments you have on the letter.

We are working with your most recent list - but with only a partial list of addresses and telephone numbers. If you have a more complete and/or final list, please fax it to me.

Please call me when you have reviewed the letter.

Thanks.

*Jim Tallon  
just called,  
said you wanted  
to see this  
letter for  
approval  
today*

*Same  
letter!*

# Preventing Fatal Medical Errors

The Institute of Medicine reported this week that between 44,000 and 98,000 hospital patients die each year because of medical mistakes — comparable, says Dr. Lucian Leape of Harvard, a co-author of the report, to having three jumbo jets filled with patients crash every two days.

These frightening numbers have been known by medical researchers for at least a decade. The startling conclusion from the report is how easy it would be to correct many of the fatal errors. The institute, an affiliate of the National Academy of Sciences, has now put its authority behind specific corrective measures.

Dr. Mark Chassin, another of the report's co-authors and a professor of health policy at Mount Sinai Medical Center in New York, says the report shows that hospitals are not as safe as most Americans believe. According to unpublished data from Colorado and Utah in 1992, about 3 percent of patients admitted to hospitals suffered injuries from treatment, of which about 9 percent died. About half of those injuries were preventable.

Dr. Leape says the report's important message is "to stop blaming individuals and focus on hospital systems." Simple redesign of procedures can prevent fatal errors. Pharmacists can prepare and clearly label doses of drugs ahead of time, before doctors or nurses make a mistake in dosage while scrambling to save the life of a heart-attack patient. Computerized systems can identify potentially fatal drug combinations before they are administered, or remind physicians and nurses to take simple pre-

cautions against blood clots in elderly patients.

The report recommends that a center for patient safety be established within the Department of Health and Human Services to collect and distribute information about medical errors and error-prevention systems. The center would be comparable, in many respects, to the federal agencies that monitor safety on the airlines and in the workplace. The report also calls for mandatory reporting of serious injuries and deaths caused by medical mistakes. Until consumers, including large employers, know who makes mistakes, they cannot demand better performance.

The report makes an important distinction, however, in calling for voluntary confidential reporting of less serious errors. The committee recognizes that overzealous reporting of the mistakes of individual doctors and nurses can backfire, driving them to hide mistakes in order to save their careers and financial well-being. Mistakes that are hidden are inevitably mistakes that will be repeated.

Michael Millenson, author of a recent book on medical quality, points out that "the number one cause of medical mistakes is not incompetence but confusion." He says that most treatment-related errors are caused by poorly designed systems that lack "safeguards to protect against anything less than human perfection." The institute report calls for the federal government to help hospitals borrow good ideas that catch mistakes before they cause serious harm. That way hospital care might become as injury-free as airline travel.

## Accountability and Mr. Arafat

Corruption and patronage are serious problems in the West Bank and Gaza Strip territories administered by Yasir Arafat and the Palestinian Authority. But when 20 prominent Palestinian academics and political leaders signed a protest letter accusing Mr. Arafat's administration of "opening the door to opportunists who are spreading corruption throughout Palestinian society," eight were jailed and two more held under house arrest. Eight other signers, who are elected members of the Palestinian Legislative Council, face efforts to strip them of their parliamentary immunity.

The petition also accused Mr. Arafat of ruling tyrannically and yielding too much in negotiations with Israel. But by most accounts, it was the deserved rebuke on corruption that provoked the arrests. Such squelching of needed debate on important but sensitive subjects would be unfortunate at any time. It is especially so as peace talks with Israel accelerate and Palestinian administration in the West Bank and Gaza prepares for more of the responsibilities associated with statehood. The Pal-

estinian political institutions now emerging need to be accountable and democratic enough to inspire confidence at home and abroad.

Since its creation five years ago, the Palestinian Authority has been undermined in effectiveness by the concentration of power in the hands of Mr. Arafat, an abusive security force and a public administration bloated by patronage appointments. Social services and economic development have too often been shaped by the arbitrary decisions of Mr. Arafat's lieutenants. Efforts by the elected legislature to enforce accountability and combat corruption have been ignored. Up to 20 percent of the authority's revenue is excluded from the official budget and spent by Mr. Arafat virtually without oversight.

One of Mr. Arafat's security officials defended the latest arrests by arguing that the middle of final-status negotiations was "not the right time to demand accountability." The truth is just the opposite. Mr. Arafat must learn to listen to his critics instead of jailing them.

The New York Times

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# Must Mistakes Happen?

**T**HE FEAR OF being seriously hurt by some preventable medical mistake—the wrong dose of medicine, a glitch in a machine—has until now been fueled mainly by gory anecdotes about mistaken amputations and other such horrors. Now an alarming report from the prestigious Institute of Medicine suggests that medical errors kill between 44,000 and 98,000 people a year, more than breast cancer, AIDS or traffic accidents. The report is meant as a call to action, a first step to changing a “culture of medicine” that allows most errors to pass unrecorded and fails to look to the underlying systems that make errors likelier. But arriving at this frightening statistic is only the first and easiest part of a huge task.

No one in health care, obviously, wishes patients to die because of mistakes. Factors keeping institutions from focusing on the high rate of preventable error include fear of malpractice liability (which prevents accurate reporting and data-sharing) and a medical culture that, the report says, “creates an expectation of perfection and attributes errors to carelessness or incompetence.”

Previous surges of concern over medical error have failed to make much headway against these systemic barriers. A drive to shorten the brutally long hours of doctors in training, spearheaded by columnist Sidney Zion after his daughter died in circumstances of apparent error, had some limited

effect in New York City. In 1986 Congress created a national database of successful practice actions against doctors, intended to keep practitioners from skipping from state to state without accountability. But concerns about misuse have sharply limited access to those data.

This report takes the different tack of urging that accidents be seen as “a form of information about a system.” It recommends “non-punitive” systems for reporting and analyzing such errors—mandatory for errors resulting in death or serious injury, confidential and voluntary for less serious incidents that could pinpoint lurking risks.

The hurry and stress of the emergency room or intensive care generate avoidable errors. So do long hours or unsafe working conditions for staff. So do the swiftly growing number of new medications, which doctors have been shown to prescribe without, in many cases, checking available information about a patient's other prescriptions. Some suggestions in the report are already being tried, such as a greater Food and Drug Administration role in packaging and drug names. Other steps would require congressional action, such as the creation of a central office to track patient safety.

Errors are, by definition, hard to anticipate. But the sheer scale of this unnecessary loss of life should act as a spur across the system.

## Actions Without Class

**B**ARELY HAD THE ink dried on Judge Thomas Penfield Jackson's findings of fact in the Microsoft antitrust trial when plaintiffs' lawyers began filing class actions against the software giant. One could hardly ask for a better portrait of everything that is predatory about class-action plaintiffs' lawyers. Cases such as these have next to nothing to do with the interests of consumers but are essentially commercial ventures within the judiciary. The purported clients are little more than fictions designed to legitimize the enrichment of their self-appointed representatives.

The Microsoft cases claim to be on behalf of untold numbers of Windows users, whom Judge Jackson determined had paid as much as \$40 more for the product as a result of Microsoft's Windows monopoly than Microsoft needed to charge in order to be profitable. Most of these “clients” presumably don't feel victimized by the company and certainly have not sought to recover that money. Nor do the suits act—as class actions sometimes do—as a check on corporate behavior, since these cases bring nothing new to the table but merely seek to cash in on the findings from preexisting Justice Department litigation. If the company eventually settles such claims, the members of the class—many of whom will not even have known the litigation was taking place—are likely to get some token payment while their self-declared champions get millions of dollars. It is simple buzzardry.

Microsoft has not been the only recent target

of abusive class actions. Last week five of the country's biggest HMOs were sued by lawyers claiming to represent 32 million of their customers. The suit alleges that the HMOs gave bonuses to doctors to restrict patient access to treatments. To the extent this is true and caused damage, it is certainly bad and should be stopped. But it's hard to see these lawyers as legitimate representatives of the downtrodden HMO member. Indeed, the lawyers have been recently peddling their suit around Wall Street in a deliberate attempt to depress the companies' stock value and thereby pressure them to settle. This isn't law. It's an extortion racket.

And it's particularly troubling in cases such as these, in which the plaintiffs' lawyers, who are not elected officials after all, seek to take in their own hands significant public policy questions. The question of HMO behavior, after all, is a legislative issue that should be decided by Congress. And the dispute between the government and Microsoft is ultimately one about the overall shape of the high-tech marketplace, not a question of recovery by individual consumers.

Sometimes, of course, the courts necessarily become an arena of policymaking, and class actions do have a place in our legal system. But where the interests of the consumers are so obviously being subordinated to those of their self-declared lawyers, class actions affect policy with far less democratic legitimacy than even those cases brought by advocacy groups acting on behalf of the public interest as they see it. It is long past time to reform this system.

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PRESERVATION

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