Medical Education Systems, Inc.

MEDICAL ERRORS

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Learning Objectives

Upon successful completion of this course, you will be able to:

- You will be able to explain the significance of the To Error is Human Report, and identify its highlights

- You will be able to list and discuss key steps that can be taken in preventing medical errors

- You will be able to discuss the scope of the problem of medical errors and discuss it has become a leading cause of death and injury

- You will be able to identify some of the reasons why errors happen, and discuss what can be done to minimize their occurrence

- You will be able to discuss what types of errors can occur and where they tend to occur

Introduction

Most Americans have grown up having the utmost respect for the medical profession and what it has accomplished over the decades. The family doctor who could fix anything became a fixture in our society. If "doc" said you needed something, then that is what you got. People not only didn't worry about the their healthcare, they didn't think about it! The physician became almost "infallible" in his or her opinions or actions. It was almost like the situation seen in the film "The Wizard of Oz." What the Wizard ordered was to be done. The system seemed to work just fine. Then came along Dorothy and her darling doggie Toto.

During their visit to the Wizard's place of wizardry, Toto's curiosity drove him to pull back the curtain, revealing the Wizard as just an ordinary, albeit educated, man whose views and opinions were not always infallible. In the case of the medical profession, the pulling back of "the curtain" has not been such a rapid and shocking event. It has taken place over time.

To Error is Human: The Report

The exposing of flaws in our health care system began in the media. Sensational medical errors were splattered all over the popular media, and eventually healthcare organizations and government agencies began to investigate. The results of these investigations, as reported in the Executive Summary of an Institute of Medicine report entitled "To Err Is Human: Building a Safer Health System" (2000) proved to be just as shocking as Toto's pulling back of the curtain:

"It was reported that 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.

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. In Colorado and Utah hospitals, 6.6 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.3 The results of the New York Study suggest the number may be as high as 98,000. Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th-leading cause of death. 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).

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.

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. Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.

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. 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 co-payments 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 billions 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.

The decentralized and fragmented nature of the health care delivery system (some would say "nonsystem") also contributes to unsafe conditions for patients, 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. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer. 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. 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.

According to the report, its goal of this report was 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. 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 the 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). 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). 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. 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. 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. Studies have characterized the kinds of errors that resulted in medical injury in the Medical Practice Study as diagnostic, treatment, preventive, or other errors. More than two-thirds (70 percent) of the adverse events found in this study were thought to be preventable, with the most common types of preventable errors being technical. 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. The report referred to in this course 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 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 Healthcare Research and Quality. 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.

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 Healthcare Research and Quality 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 National 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 National 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 patient 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

The 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."

This landmark report ("To Err Is Human: Building a Safer Health System") shook the very foundations of the American health care system. After its publication, the Agency for Healthcare Research and Quality's Quality Interagency Coordination Task Force (QuIC) issued a report entitled "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." In its executive summary, it indicated that:

"Patient safety has become a major concern of the general public and of policymakers at the State and Federal levels. This interest has been fueled, in part, by news coverage of individuals who were the victims of serious medical errors and by the publication in 1999 of the Institute of Medicine's (IOM's) report To Err is Human: Building a Safer Health System. In its report, the IOM highlighted the risks of medical care in the United States and shocked the sensibilities of many Americans, in large part through its estimates of the magnitude of medical-errors-related deaths (44,000 to 98,000 deaths per year) and other serious adverse events.

The report prompted a number of legislative and regulatory initiatives designed to document errors and begin the search for solutions. But Americans, who now wondered whether their next doctor's or hospital visit might harm rather than help them, began to demand concerted action.

Three months after publication of the IOM report, an interagency Federal government group, the Quality Interagency Coordination Task Force (QuIC), released its response, Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact. That report, prepared at the President's request, both inventoried ongoing Federal actions to reduce medical errors and listed more than 100 action items to be undertaken by Federal agencies.

An action promised by the Agency for Healthcare Research and Quality (AHRQ), the Federal agency leading efforts to research and promote patient safety, was "the development and dissemination of evidence-based, best safety practices to provider organizations." To initiate the work to be done in fulfilling this promise, AHRQ commissioned the University of California at San Francisco (UCSF)—Stanford University Evidence-based Practice Center (EPC)—in January 2001 to review the scientific literature regarding safety improvement. To accomplish this, the EPC established an Editorial Board that oversaw development of this report by teams of content experts who served as authors.

Defining Patient Safety Practices

Working closely with AHRQ and the National Forum for Quality Measurement and Reporting (the National Quality Forum, or NQF)—a public-private partnership formed in 1999 to promote a national health care quality agenda—the EPC began its work by defining a *patient safety practice* as:

> **A type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.**

This definition is consistent with the dominant conceptual framework in patient safety, which holds that systemic change will be far more productive in reducing medical errors than will targeting and punishing individual providers. The definition's focus on actions that cut across diseases and procedures also allowed the research team to distinguish patient safety activities from the more targeted quality improvement practices (e.g., practices designed to increase the use of beta-blockers in patients who are admitted to the hospital after having a myocardial infarction). The editors recognize, however, that this distinction is imprecise.

This evidence-based review also focuses on hospital care as a starting point because the risks associated with hospitalization are significant, the strategies for improvement are better documented there than in other health care settings, and the importance of patient trust is paramount. The report, however, also considers evidence regarding other sites of care, such as nursing homes, ambulatory care, and patient self-management.

The results of this EPC study will be used by the NQF to identify a set of proven patient safety practices that should be used by hospitals. Identification of these practices by NQF will allow patients throughout the nation to evaluate the actions their hospitals and/or health care facilities have taken to improve safety.

Reporting the Evidence

As is typical for evidence-based reviews, the goal was to provide a critical appraisal of the evidence on the topic. This information would then be available to others to ensure that no practice unsupported by evidence would be endorsed and that no practice substantiated by a high level of proof would lack endorsement. Readers familiar with the state of the evidence regarding quality improvement in areas of health care where this has been a research priority (e.g., cardiovascular care) may be surprised and even disappointed, by the paucity of high-quality evidence in other areas of health care for many patient safety practices. One reason for this is the relative youth of the field. Just as there had been little public recognition of the risks of health care prior to the first IOM report, there has been relatively little attention paid to such risks—and strategies to mitigate them—among health professionals and researchers.

Moreover, there are a number of methodologic reasons why research in patient safety is particularly challenging. Many practices (e.g., the presence of computerized physician order entry systems, modifying nurse staffing levels) cannot be the subject of double-blind studies because their use is evident to the participants. Second, capturing all relevant outcomes, including "near misses"(such as a nurse catching an excessive dosage of a drug just before it is administered to a patient) and actual harm, is often very difficult. Third, many effective practices are multidimensional, and sorting out precisely which part of the intervention works is often quite challenging. Fourth, many of the patient safety problems that generate the most concern (wrong-site surgery, for example) are uncommon enough that demonstrating the success of a "safety practice" in a statistically meaningful manner with respect to outcomes is all but impossible.

Finally, establishing firm epidemiologic links between presumed (and accepted) causes and adverse events is critical, and frequently difficult. For instance, in studying an intuitively plausible "risk factor" for errors, such as "fatigue," analyses of errors commonly reveal the presence of fatigued providers (because many health care providers work long hours and/or late at night). The question is whether or not fatigue is over-represented among situations that lead to errors. The point is not that the problem of long work-hours should be ignored, but rather that strong epidemiologic methods need to be applied before concluding that an intuitive cause of errors is, in fact, causal.

Researchers now believe that most medical errors cannot be prevented by perfecting the technical work of individual doctors, nurses, or pharmacists. Improving patient safety often involves the coordinated efforts of multiple members of the health care team, who may adopt strategies from outside health care. The report reviews several practices whose evidence came from the domains of commercial aviation, nuclear safety, and aerospace, and the disciplines of human factors engineering and organizational theory. Such practices include root cause analysis, computerized physician order entry and decision support, automated medication dispensing systems, bar coding technology, aviation-style preoperative checklists, promoting a "culture of safety," crew resource management, the use of simulators in training, and integrating human factors theory into the design of medical devices and alarms. In reviewing these practices, the research team sought to be flexible regarding standards of evidence, and included research evidence that would not have been considered for medical interventions. For example, the randomized trial that is appropriately hailed as the "gold standard" in clinical medicine is not used in aviation, as this design would not capture all relevant information. Instead, detailed case studies and industrial engineering research approaches are utilized.

Fact Sheet Improving Health Care Quality

The AHRQ also issued a report which reviewed the facts associated with improving health care quality:

“Quality problems are reflected today in the wide variation in use of health care services, the underuse and overuse of some services, and misuse of others. Improving the quality of health care and reducing medical errors are priorities for the Agency for Healthcare Research and Quality (AHRQ).

Every day, millions of Americans receive high-quality health care that helps to maintain or restore their health and ability to function. However, far too many do not. Quality problems are reflected in a wide variation in the use of health care services, underuse of some services, overuse of other services, and misuse of services, including an unacceptable level of errors. A central goal of health care quality improvement is to maintain what is good about the existing health care system while focusing on the

areas that need improvement. Improving the quality of care and reducing medical errors are priority areas for the Agency for Healthcare Research and Quality (AHRQ).

AHRQ is working to develop and test measures of quality, identify the best ways to collect, compare, and communicate data on quality, and widely disseminate information about the most effective strategies for improving the quality of care.

Evidence of Quality Problems

Several types of quality problems in health care have been documented through peer-reviewed research.

Variation in services. There continues to be a pattern of wide variation in health care practice, including regional variations and small-area variations. This is a clear indicator that health care practice has not kept pace with the evolving science of health care to ensure evidence-based practice in the United States.

Underuse of services. Millions of people do not receive necessary care and suffer needless complications that add to costs and reduce productivity. Each year, an estimated 18,000 people die because they do not receive effective interventions. For example, a study of Medicare patients who had suffered heart attacks found that only 21 percent of eligible patients received beta-blockers. The mortality rate among patients who received beta-blockers was 43 percent lower than it was among nonrecipients.

Another AHRQ-funded study examined the use of beta blockers before heart bypass surgery and found that patients who received beta blocker therapy before surgery had lower rates of death and fewer complications both during and after surgery than patients who did not receive this therapy.

Overuse of services. Each year, millions of Americans receive health care services that are unnecessary, increase costs, and may even endanger their health. Research has shown that this occurs across all populations. For example, an analysis of hysterectomies performed on women in seven health plans found that one in six operations was inappropriate. A study examining the use of antibiotics for treating ear infections in children on Medicaid found that expensive antibiotics were used far more often than indicated. According to the findings, if only half the prescriptions written in 1992 for more expensive antibiotics had been written for amoxicillin, a less expensive but equally effective antibiotic, Colorado's Medicaid program would have saved nearly $400,000 that year.

AHRQ-Supported Research Demonstrates Overuse of Preoperative Testing

A recent study by AHRQ-funded researchers found no differences in outcomes between patients who did and did not undergo routine preoperative testing before cataract surgery. Cataract surgery is the most common operation among the elderly in the United States. In 1996, Medicare beneficiaries had about 1.5 million cataract operations. Routine medical testing before cataract surgery is estimated to cost Medicare $150 million each year.

Cataract surgery is usually an outpatient procedure, and rates of illness and death associated with the procedure are very low. This large randomized study involved nearly 20,000 elective cataract operations in 18,189 patients at nine surgical centers. The overall rate of complications, both during and after surgery, was the same for both groups (31.3 per 1,000 operations). The researchers conclude that routine preoperative testing confers no benefit on patients having cataract surgery.

Misuse of services. Too many Americans are injured during the course of their treatment, and some die prematurely as a result.

For example, a study of injuries to patients treated in hospitals in New York State found that 3.7 percent experienced adverse events; 13.6 percent of these events led to death, and 2.6 percent led to permanent disability. About one-fourth of these adverse events resulted from negligence. A national study found that over a 10-year period (1983-93), deaths due to medication errors rose more than two-fold, with 7,391 deaths attributed to medication errors in 1993 alone.

Disparities in quality. Although quality problems affect all populations, they may be most marked for members of ethnic and racial minority populations. Researchers at the University of Alabama at Birmingham examined the use of thrombolysis ("clot busters") for patients who had experienced a heart attack and found that while this evidence-based life-saving treatment was underused for all, black Medicare beneficiaries were significantly less likely than whites to receive this treatment.

Findings from Recent Research on Health Care Quality

AHRQ and its predecessor agencies—the Agency for Health Care Research and Quality and the National Center for Health Services Research and Health Care Technology Assessment—have been conducting and supporting research on quality for more than two decades. Following are some examples of findings from recent AHRQ-supported research on quality and quality improvement:

Atrial fibrillation. Thousands of Medicare patients with atrial fibrillation can benefit from a new quality improvement tool developed with support from AHRQ. Researchers found that their new CHADS2 method for predicting risk of stroke in patients with atrial fibrillation is more accurate than existing methods. CHADS2 may be especially helpful for identifying low-risk patients who, by taking aspirin, can avoid the office visits, expense, and side effects associated with warfarin, which carries a risk of bleeding.

Underuse of hip replacement surgery in Hispanic patients. Even when they have insurance, elderly Hispanics undergo far fewer hip replacement operations than elderly non-Hispanic whites. This study of Hispanics aged 65 or older in Texas, New Mexico, Arizona, and Illinois found that they were less than one-third as likely as non-Hispanic whites of the same age to undergo total hip replacement, an operation that can alleviate pain and improve physical function and quality of life in patients with severe osteoarthritis. According to the researchers, underuse of hip replacement surgery by the large and growing U.S. Hispanic population could have important consequences for Medicaid because the resulting excess disability could increase long-term custodial costs.

End-of-life discussions. Findings from this AHRQ study can be used to improve end-of-life care and promote more effective use of health care resources by encouraging discussions between terminally ill HIV patients and their doctors. Half of all HIV-infected people in the United States—especially blacks, Hispanics, injection drug users, and people with low education—never talk about end-of-life care with their doctors. Such discussions could improve physicians' understanding of the care their patients do and do not want when they are very ill and close to death.

New Severity Measure for Hospitalized Pneumonia Patients

Hospitalized pneumonia patients who have abnormal vital signs, mental confusion, or problems with eating or drinking in the 24 hours prior to discharge are more likely than other pneumonia patients not

to be able to resume normal activities on discharge. Also, they face a greater chance of readmission or death.

AHRQ-supported researchers at Mount Sinai School of Medicine developed a simple severity-of-illness measure that can be used by clinicians to judge whether it is safe for a patient to be discharged from the hospital. The measure uses information from the five vital signs that are checked several times a day in hospitalized patients (temperature, heart rate, blood pressure, respiratory rate, and oxygen levels in the blood), as well as assessment of the patient's mental status and ability to eat and drink.

Patients in this study who were discharged with two or more unstable factors had a five-fold greater risk of readmission or death. Using this instrument, the researchers found that one in five of the patients they studied had been discharged "medically unstable."

Errors in Health Care: A Leading Cause of Death and Injury

In the report, *To Error is Human*, it details how Health care is not as safe as it should be. A substantial body of evidence points to medical errors as a leading cause of death and injury:

"• Sizable numbers of Americans are harmed as a result of medical errors. Two studies of large samples of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, found that the proportion of hospital admissions experiencing an adverse event, defined as injuries caused by medical management, were 2.9 and 3.7 percent, respectively. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah.

• Preventable adverse events are a leading cause of death in the United States. When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors. Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death. Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).

• Total national costs (lost income, lost household production, disability, health care costs) are estimated to be between $37.6 billion and $50 billion for adverse events and between $17 billion and $29 billion for preventable adverse events. Health care costs account for over one-half of the total costs. Even when using the lower estimates, the total national costs associated with adverse events and preventable adverse events represent approximately 4 percent and 2 percent, respectively, of national health expenditures in 1996. In 1992, the direct and indirect costs of adverse events were slightly higher than the direct and indirect costs of caring for people with HIV and ADS.

• In terms of lives lost, patient safety is as important an issue as worker safety. Although more than 6,000 Americans die from workplace injuries every year, in 1993 medication errors are estimated to have accounted for about 7,000 deaths. Medication errors account for one out of 131 outpatient deaths and one out of 854 inpatient deaths.

• Medication-related errors occur frequently in hospitals; not all result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two

percent of 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. 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.

• Hospital patients represent only a fraction of the total population at risk of experiencing a medication-related error. In 1998, nearly 2.5 billion prescriptions were dispensed by U.S. pharmacies at a cost of about $92 billion. Numerous studies document errors in prescribing medications, dispensing by pharmacists, and unintentional non-adherence on the part of the patient. Medication errors have the potential to increase as a major contributor to avoidable morbidity and mortality as new medications are introduced for a wider range of indications.

Although the literature pertaining to errors in health care has grown steadily over the last decade and some notable studies are particularly strong methodologically, we do not yet have a complete picture of the epidemiology of errors. Many studies focus on patients experiencing injury and provide valuable insight into the magnitude of harm resulting from errors. Other studies, more limited in number, focus on the occurrence of errors, both those that result in harm and those that do not (sometimes called "near misses"). More is known about errors that occur in hospitals than in other health care delivery settings.

Synthesizing and interpreting the findings in the literature pertaining to errors in health care is complicated due to the absence of standardized nomenclature. For purposes of this course , the terms error and adverse event are defined as follows:

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).

Medication Errors

Medication-related error has been studied extensively for several reasons: it is one of the most common types of error, substantial numbers of individuals are affected, and it accounts for a sizable increase in health care costs. There are also methodologic issues: (1) prescription drugs are widely used, so it is easy to identify an adequate sample of patients who experience adverse drug events; (2) the drug prescribing process provides good documentation of medical decisions, and much of this documentation resides in automated, easily accessible databases; and (3) deaths attributable to medication errors are recorded on death certificates. There are probably other areas of health care delivery that have been studied to a lesser degree but may offer equal or greater opportunity for improvement in safety.

Medication errors occur frequently in hospitals. Numerous studies have assessed the incidence of adverse drug events (ADEs), defined as an injury resulting from medical intervention related to a drug. Not all ADEs are attributable to errors. For example, a patient with no history of allergic reactions to drugs, who experiences an allergic reaction to an antibiotic, has suffered an ADE, but this ADE would not be attributable to error. However, an error would have occurred if an antibiotic was prescribed to a patient with a history of documented allergic reactions, because the medical record was unavailable or

not consulted. We are discussing only those studies of ADEs that identified the subset of ADEs determined to be preventable (i.e., attributable to errors).

In an analysis of 289,411 medication orders written during one year in a tertiary-care teaching hospital, the overall error rate was estimated to be 3.13 errors for each 1,000 orders written and the rate of significant errors to be 1.81 per 1,000 orders. Children are at particular risk of medication errors and this is attributable primarily to incorrect dosages. In a review of 4,031 adult admissions to 11 medical and surgical units at two tertiary care hospitals, researchers identified 247 ADEs for an extrapolated event rate of 6.5 ADEs per 100 no obstetrical admissions, and a mean number per hospital per year of approximately 1,900 ADEs. Twenty-eight percent were judged preventable.

In a study of patients admitted to coronary intensive care, medical, surgical, and obstetric units in an urban tertiary care hospital over a 37-day period, the rate of drug-related incidents was 73 in 2,967 patient-days: 27 incidents were judged ADEs; 34, potential ADEs; and 12, problem orders. Of the 27 ADEs, five were life threatening, nine were serious, and 13 were significant. Of the 27 ADEs, 15(56 percent) were judged definitely or probably preventable. In a study of prescribing errors detected and averted by pharmacists in a 631-bed tertiary care teaching hospital between July 1994 and June 1995, the estimated overall rate of errors was 3.99 per 1,000 medication orders.

Physicians do not routinely screen for potential drug interactions, even when medication history information is readily available. In an analysis of 424 randomly selected visits to a hospital emergency department, 47 percent led to added medication, and in 10 percent of the visits in which at least one medication was added, the new medication added a potential adverse interaction. In all cases, a medication history was recorded on the patients and available to the physicians.

Errors can occur in the dispensing of drugs by pharmacists. In a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in Massachusetts. Eighty-eight percent of the errors involved giving patients the wrong drug or the wrong strength.

Medication-related errors occur frequently, most do not result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two percent of admissions experienced a preventable ADE, resulting in an average increased length of stay of 4.6 days and an average increased hospital cost of nearly $4,700 per admission. This amounts to about $2.8 million annually for a 700-bed teaching hospital, and 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.

In conclusion, it should be pointed out that current estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported. For example, in a study of patients admitted to five patient care units at a tertiary care hospital during a six month period in 1993, it was found that incident reports were filed with the hospital's quality assurance program or called into the pharmacy hotline for only three of the 54 people experiencing an adverse drug event.

Post-Test

Select the *best* answer to each of the following items. Mark your responses on the Answer Form.

1. Regarding the scope of the medical errors problem in the United States, medication errors alone, occurring either in or out of the hospital, are estimated to account for _____ deaths annually.

a. nearly 3,000
b. just under 5,000
c. over 7,000
d. approximately 12,000

2. In the "To Error is Human" report, safety is defined as _____.

a. the procedures administered are successful
b. freedom from accidental injury
c. the patient recovers from malady
d. no deaths occur as a result of medical procedures

3. Which of the following were among the recommendations made by that report:

a. establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety
b. identifying and learning from errors through 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
c. 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.
d. All of the above

4. Researchers now believe that most medical errors _____ by perfecting the technical work of individual doctors, nurses, or pharmacists.

a. can be prevented
b. should be prevented
c. cannot be prevented
d. None of the above

5. Which of the following “safety practices” was reported to be most highly rated as being important to patient safety:

a. Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
b. Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.
c. Asking that patients recall and restate what they have been told during the informed consent process.
d. Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

6. Regarding “under-use” of medical services, an estimated _____ people die annually because they do not receive effective interventions.

a. 1,000
b. 5,000
c. 18,000
d. 49, 000

7. Regarding “over-use” of medical services, if only half the prescriptions written in 1992 for more expensive antibiotics had been written for amoxicillin, a less expensive but equally effective antibiotic, Colorado’s Medicaid program would have saved nearly $_____ that year.

a. 10,000
b. 40,000
c. 100,000
d. 400,000

8. In the To Error is Human Report, an error is defined as _____

a. the patient suffered from rather than benefiting from the procedure or medication
b. the patient died
c. the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).
d. the failure of healthcare provider to help the patient

9. According to the Report, a(n) _____ is defined as an injury caused by medical management rather than by the underlying disease or condition of the patient.

a. error
b. adverse event
c. sentinel event
d. a medical mistake

10. Children are at particular risk of medication errors and this is attributable primarily to _____.

a. incorrect dosages
b. mis-labeled drugs
c. wrong medication prescribed
d. All of the above

11. Studies have characterized the kinds of errors that resulted in medical injury in the Medical Practice Study as diagnostic, treatment, preventive, or other errors. More than two-thirds (70 percent) of the adverse events found in this study were thought to be preventable, with the most common types of preventable errors being _____ errors.

a. diagnostic
b. errors in the use of a drug
c. technical
d. failure to prevent injury

12. 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.

a. True
b. False

13. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that _____.

a. management needs to do a better job of coordinating those people
b. the system needs to be made safer
c. there is too little communication among good health care workers
d. al l the above

14. A 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.

a. True
b. False

15. 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.

a. True
b. False

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