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Medical Education Systems, Inc.

Course 704

ETHICS AND MEDICAL ERRORS

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MEDICAL ERRORS AND ETHICS

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MEDICAL ETHICS IN HEALTHCARE

MEDICAL ERRORS

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 the Improving of Health Care Quality

• You will be able to discuss the scope of the problem of medical errors and discuss how they have become a leading cause of death and injury

• You will be able to explain some of the reasons why errors happen, and 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

• You will be able to explain what is meant by "root cause analysis" and identify the key steps in conducting that analysis

• You will be able to explain the JCAHO's role in reducing medical errors and identify some of the key steps they have taken to accomplish that reduction

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. 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.

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. 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). 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. 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 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;

• Feriodically 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

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."

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.

Methodology

To facilitate identification and evaluation of potential patient safety practices, the Editorial Board divided the content for the project into different *domains*. Some cover "content areas," including traditional clinical areas such as adverse drug events, nosocomial infections, and complications of surgery, but also less traditional areas such as fatigue and information transfer. Other domains consist of practices drawn from broad (primarily nonmedical) disciplines likely to contain promising approaches to improving patient safety (e.g., information technology, human factors research, organizational theory). Once this list was created—with significant input from patient safety experts, clinician-researchers, AHRQ, and the NQF Safe Practices Committee—the editors selected teams of authors with expertise in the relevant subject matter and/or familiarity with the techniques of evidence-based review and technology appraisal.

The authors were given explicit instructions regarding search strategies for identifying safety practices for evaluation (including explicit inclusion and exclusion criteria) and criteria for assessing each practice's level of evidence for efficacy or effectiveness in terms of study design and study outcomes. Some safety practices did not meet the inclusion criteria because of the paucity of evidence regarding efficacy or effectiveness but were included in the report because an informed reader might reasonably expect them to be evaluated or because of the depth of public and professional interest in them. For such high profile topics (such as bar coding to prevent misidentifications), the researchers tried to fairly present the practice's background, the experience with the practice thus far, and the evidence (and gaps in the evidence) regarding the practice's value.

For each practice, authors were instructed to research the literature for information on:

- Prevalence of the problem targeted by the practice.
- Severity of the problem targeted by the practice.
- The current utilization of the practice.
- Evidence on efficacy and/or effectiveness of the practice.
- The practice's potential for harm.
- Data on cost, if available.
- Implementation issues.

The report presents the salient elements of each included study (e.g., study design, population/setting, intervention details, results), and highlights any important weaknesses and biases of these studies. Authors were not asked to formally synthesize or combine the evidence across studies (e.g., perform a meta-analysis) as part of their task.

The Editorial Board and the Advisory Panel reviewed the list of domains and practices to identify gaps in coverage. Submitted chapters were reviewed by the Editorial Board and revised by the authors, aided by feedback from the Advisory Panel. Once the content was finalized, the editors analyzed and ranked the practices using a methodology summarized below.

Summarizing the Evidence and Rating the Practices

Because the report is essentially an anthology of a diverse and extensive group of patient safety practices with highly variable relevant evidence, synthesizing the findings was challenging, but necessary to help readers use the information. Two of the most obvious uses for this report are:

1. To inform efforts of providers and health care organizations to improve the safety of the care they provide.
2. To inform AHRQ, other research agencies, and foundations about potential fruitful investments for their research support.

Other uses of the information are likely. In fact, the National Quality Forum plans to use this report to help identify a list of patient safety practices that consumers and others should know about as they choose among the health care provider organizations to which they have access.

In an effort to assist both health care organizations interested in taking substantive actions to improve patient safety and research funders seeking to spend scarce resources wisely, AHRQ asked the EPC to rate the evidence and rank the practices by opportunity for safety improvement and by research priority. This report, therefore, contains two lists.

To create these lists, the editors aimed to separate the practices that are most promising or effective from those that are least so on a range of dimensions, without implying any ability to calibrate a finely gradated scale for those practices in between. The editors also sought to present the ratings in an organized, accessible way while highlighting the limitations inherent in their rating schema. Proper metrics for more precise comparisons (e.g., cost-effectiveness analysis) require more data than are currently available in the literature.

Three major categories of information were gathered to inform the rating exercise:

- **Potential Impact of the Practice.** Based on prevalence and severity of the patient safety target, and current utilization of the practice.
- **Strength of the Evidence Supporting the Practice.** Including an assessment of the relative weight of the evidence, effect size, and need for vigilance to reduce any potential negative collateral effects of the practice.
- **Implementation.** Considering costs, logistical barriers, and policy issues.

For all of these data inputs into the practice ratings, the primary goal was to find the best available evidence from publications and other sources. Because the literature has not been previously organized with an eye toward addressing each of these areas, most of the estimates could be improved with further research, and some are informed by only general and somewhat speculative knowledge. In the summaries, the editors have attempted to highlight those assessments made with limited data.

The four-person editorial team independently rated each of the 79 practices using general scores (e.g., High, Medium, Low) for a number of dimensions, including those italicized in the section above. The editorial team convened for 3 days in June, 2001 to compare scores, discuss disparities, and come to consensus about ratings for each category.

In addition, each member of the team considered the totality of information on potential impact and support for a practice to score each of these factors on a 0 to 10 scale (creating a "Strength of the Evidence" list). For these ratings, the editors took the perspective of a leader of a large health care enterprise (e.g., a hospital or integrated delivery system) and asked the question, "If I wanted to improve patient safety at my institution over the next 3 years and resources were not a significant consideration, how would I grade this practice?" For this rating, the Editorial Board explicitly chose not to formally consider the difficulty or cost of implementation in the rating. Rather, the rating simply reflected the strength of the evidence regarding the effectiveness of the practice and the probable impact of its implementation on reducing adverse events related to health care exposure. If the patient safety target was rated as "High" impact and there was compelling evidence (i.e., "High" relative study strength) that a particular practice could significantly reduce (e.g., "Robust" effect size) the negative consequences of exposure to the health care system (e.g., hospital-acquired infections), raters were likely to score the practice close to 10. If the studies were less convincing, the effect size was less robust, or there was a need for a "Medium" or "High" degree of vigilance because of potential harms, then the rating would be lower.

At the same time, the editors also rated the usefulness of conducting more research on each practice, emphasizing whether there appeared to be questions that a research program might have a reasonable chance of addressing successfully (creating a "Research Priority" list). Here, they asked themselves, "If I were the leader of a large agency or foundation committed to improving patient safety, and were considering allocating funds to promote additional research, how would I grade this practice?" If there was a simple gap in the evidence that could be addressed by a research study or if the practice was multifaceted and implementation could be eased by determining the specific elements that were effective, then the research priority was high. (For this reason, some practices are highly rated on both the "Strength of the Evidence" and "Research Priority" lists.) If the area was one of high potential impact (i.e., large number of patients at risk for morbid or mortal adverse events) and a practice had been inadequately researched, then it would also receive a relatively high rating for research need. Practices might receive low research scores if they held little promise (e.g., relatively few patients are affected by the safety problem addressed by the practice or a significant body of knowledge already demonstrates the practice's lack of utility). Conversely, a practice that was clearly effective, low cost, and easy to implement would not require further research and would also receive low research scores.

In rating both the strength of the evidence and the research priority, the purpose was not to report precise 0 to 10 scores, but to develop general "zones" or practice groupings. This is important because better methods are available for making comparative ratings when the data inputs are available. The relative paucity of the evidence dissuaded the editors from using a more precise, sophisticated, but ultimately unfeasible, approach.

Clear Opportunities for Safety Improvement

The following 11 patient safety practices were the most highly rated (of the 79 practices reviewed in detail) in terms of strength of the evidence supporting more widespread implementation. Practices appear in descending order, with the most highly rated practices listed first. Because of the imprecision of the ratings, the editors did not further divide the practices, nor indicate where there were ties.

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality.
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections.
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections.
- Asking that patients recall and restate what they have been told during the informed consent process.
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia.
- Use of pressure relieving bedding materials to prevent pressure ulcers.
- Use of real-time ultrasound guidance during central line insertion to prevent complications.
- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications.
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

This list is generally weighted toward clinical rather than organizational matters, and toward care of the very, rather than the mildly or chronically ill. Although more than a dozen practices considered were general safety practices that have been the focus of patient safety experts for decades (i.e., computerized physician order entry, simulators, creating a "culture of safety," crew resource management), most research on patient safety has focused on more clinical areas. The potential application of practices drawn from outside health care has excited the patient safety community, and many such practices have apparent validity. However, clinical research has been promoted by the significant resources applied to it through Federal, foundation, and industry support. Since this study went where the evidence took it, more clinical practices rose to the top as potentially ready for implementation.

Clear Opportunities for Research

Until recently, patient safety research has had few champions, and even fewer champions with resources to bring to bear. The recent initiatives from AHRQ and other funders are a promising shift in this historical situation, and should yield important benefits.

In terms of the research agenda for patient safety, the following 12 practices rated most highly, as follows:

- Improved perioperative glucose control to decrease perioperative infections.
- Localizing specific surgeries and procedures to high volume centers.
- Use of supplemental perioperative oxygen to decrease perioperative infections.
- Changes in nursing staffing to decrease overall hospital morbidity and mortality.
- Use of silver alloy-coated urinary catheters to prevent urinary tract infections.
- Computerized physician order entry with computerized decision support systems to decrease medication errors and adverse events primarily due to the drug ordering process.
- Limitations placed on antibiotic use to prevent hospital-acquired infections due to antibiotic-resistant organisms.
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections.
- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and post-surgical patients.
- Use of analgesics in the patient with an acutely painful abdomen without compromising diagnostic accuracy.
- Improved handwashing compliance (via education/behavior change; sink technology and placement; or the use of antimicrobial washing substances).

Of course, the vast majority of the 79 practices covered in this report would benefit from additional research. In particular, some practices with longstanding success outside of medicine (e.g., promoting a culture of safety) deserve further analysis, but were not explicitly ranked due to their unique nature and the present weakness of the evidentiary base in the health care literature.

Conclusions

This report represents a first effort to approach the field of patient safety through the lens of evidence-based medicine. Just as To Err is Human sounded a national alarm regarding patient safety and catalyzed other important commentaries regarding this vital problem, this review seeks to plant a seed for future implementation and research by organizing and evaluating the relevant literature. Although all those involved tried hard to include all relevant practices and to review all pertinent evidence, inevitably some of both were missed. Moreover, the effort to grade and rank practices, many of which have only the beginnings of an evidentiary base, was admittedly ambitious and challenging. It is hoped that this report provides a template for future clinicians, researchers, and policy makers as they extend, and inevitably improve upon, this work.

In the detailed reviews of the practices, the editors have tried to define (to the extent possible from the literature) the associated costs—financial, operational, and political. However, these considerations were not factored into the summary ratings, nor were judgments made regarding the appropriate expenditures to improve safety. Such judgments, which involve complex tradeoffs between public dollars and private ones, and between saving lives by improving patient safety versus doing so by investing in other health care or non-health care practices, will obviously be critical. However, the public reaction to the IOM report, and the media and legislative responses that followed it, seem to indicate that Americans are highly concerned about the risks of medical errors and would welcome public and private investment to decrease them. It seems logical to infer that Americans value safety during a hospitalization just as highly as safety during a transcontinental flight."

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.

Select for Figure 1 (2 KB).

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."

Making Quality Count

Following are examples of AHRQ-supported research now in progress that focuses on improving health care quality.

Bringing evidence-based medicine to the hospital bedside. Researchers at the University of Iowa are carrying out a 3-year randomized study at 12 hospitals in Iowa, Missouri, and Illinois to evaluate the effectiveness and cost-effectiveness of implementing an evidence-based acute pain management guideline for hospitalized elderly hip fracture patients. The intervention targets both nurses and prescribing physicians and includes training, computerized learning modules, the use of opinion leaders, the use of feedback and reminder cards, and system interventions for modifying chart forms and institutional policy. The goals are to determine whether a multidimensional organizational intervention alters nurse and physician behaviors and whether institutional barriers to change are reduced.

Evidence-based reminders in home health care. These researchers are comparing the effectiveness of two alternative information-based strategies intended to improve provider performance and promote adherence to evidence-based guidelines among home health care nurses. The study uses a randomized design that assigns nurses to one of two treatment groups or a control group (usual care).

Nurses in the basic intervention group receive "just in time" E-mail reminders highlighting six condition-specific practices they should follow for patients with either heart failure or cancer pain. Nurses in the augmented intervention group receive the same E-mail reminders along with additional information and consulting services from an expert peer.

Understanding variability in community mammography. This community-based, multicenter observational study involves a unique collaboration among three geographically distinct breast cancer surveillance programs in the States of Washington, New Hampshire, and Colorado. The investigators are collecting breast cancer outcomes and interpretive data on more than 500,000 mammograms from 91 facilities and 279 radiologists. The goal is to identify reasons for variability in the interpretation of mammograms and determine how the quality of mammography can be improved.

Racial and ethnic variation in medical interactions. In this 5-year program, researchers at the Baylor College of Medicine and the Houston VA are developing and testing interventions to improve doctor-patient communication patterns to reduce racial and ethnic disparities in use and outcomes. Both clinicians and patients are participating in the project, which also includes an information dissemination component to translate research findings into practice as rapidly as possible.

Otitis media: Parent education to avoid antibiotic use. Acute otitis media (AOM) continues to be a major child health problem. The average child experiences 2.6 AOM episodes per year in the first 2 years of life. The overuse of antibiotics for AOM has led to the emergence of multi-drug resistant pathogens, even though research has shown that 80 to 90 percent of children with AOM will recover without antibiotics.

This randomized controlled trial is evaluating the safety, efficacy, cost to parent, and acceptability of an intervention consisting of parent education, nonantibiotic symptomatic therapy, and careful followup of children with mild AOM. The goal is to establish the safety of withholding antibiotics from children with mild AOM and change parents' expectations about universal antibiotic treatment of AOM.

Benefits of regionalizing surgery for Medicare patients. In this ongoing study, researchers at Dartmouth Medical School are using Medicare data and data from AHRQ's National Inpatient Sample (NIS) to investigate the potential benefits of regionalizing patients who have certain high-risk procedures.

For example, in the April 11, 2002, issue of the *New England Journal of Medicine*, they reported a 12 percent difference in survival for patients being treated for cancer of the pancreas at high- and low-volume hospitals. Only 4 percent of patients treated at the highest volume hospitals died, compared with 16 percent at the lowest volume hospitals. Indeed, they found that elderly patients undergoing treatment for any 1 of 14 high-risk cardiovascular or cancer operations were more likely to survive if they were treated in high-volume hospitals.

Future Research

Priorities for future research on quality and quality improvement—particularly the overuse, underuse, and misuse of health care services—include:

- Identify which financial and organizational factors promote quality and how different payment methods, financial incentives, and organizational factors affect the behavior of health care organizations, providers, purchasers, and patients.
- Design and implement new care processes that enable patients to act as co-managers of their health care, particularly for chronic illnesses.
- Identify telecommunications applications that will enhance patients' access to information and patient-provider communication.
- Identify effective information technology tools and systems that alert providers in real-time to the critical information they need to provide safer, high quality care.
- Implement and evaluate strategies to improve quality of care for people with disabilities.
- Identify and address factors that promote adoption of promising quality improvement strategies (e.g., patient self-management) by all who would benefit.

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,1 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.2

• 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.3 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.4 Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).5

• 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. 6

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.[7] 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.[8]

• 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,[9,10] in 1993 medication errors are estimated to have accounted for about 7,000 deaths.[11] 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.[12] 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.[13] Numerous studies document errors in prescribing medications,[14,15] dispensing by pharmacists,[16] and unintentional nonadherence on the part of the patient.[17] 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.

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Introduction

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 report, 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).[18]

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."[19] 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).[20]

When a study in the literature has used a definition that deviates from the above definitions, it is noted below.

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.[21,22,23] 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.

Efforts to assess the importance of various types of errors are currently hampered by the lack of a standardized taxonomy for reporting adverse events, errors, and risk factors.[24,25] A limited number of studies focus directly on the causes of adverse events, but attempts to classify adverse events according to "root causes" are complicated by the fact that several interlocking factors often contribute to an error or series of errors that in turn result in an adverse event.[26,27] In recent years, some progress toward a more standardized nomenclature and taxonomy has been made in the medication area, but much work remains to be done.[28]

The following discussion of the literature addresses four questions:

1. How frequently do errors occur?

2. What factors contribute to errors?

3. What are the costs of errors?

4. Are public perceptions of safety in health care consistent with the evidence?

How Frequently do Errors Occur?

For the most part, studies that provide insight into the incidence and prevalence of errors fall into two categories:

1. General studies of patients experiencing adverse events. These are studies of adverse events in general, not studies limited to medication-related events. These studies are limited in number, but some represent large-scale, multi-institutional analyses.

Virtually all studies in this category focus on hospitalized patients. With the exception of medication-related events discussed in the second category, little if any research has focused on errors or adverse events occurring outside of hospital settings, for example, in ambulatory care clinics, surgicenters, office practices, home health, or care administered by patients, their family, and friends at home.

2. Studies of patients experiencing medication-related errors. There is an abundance of studies that fall into this category. Although many focus on errors and adverse events associated with ordering and administering medication to hospitalized patients, some studies focus on patients in ambulatory settings.

Adverse Events

29 Not all, but a sizable proportion of adverse events are the result of errors. Numerous studies have looked at the proportion of adverse events attributable to medical error. Due to methodologic challenges, far fewer studies focus on the full range of error—namely, those that result in injury *and* those that expose the patient to risk but do not result in injury.

The most extensive study of adverse events is the Harvard Medical Practice Study, a study of more than 30,000 randomly selected discharges from 51 randomly selected hospitals in New York State in 1984.30 Adverse events, manifest by prolonged hospitalization or disability at the time of discharge or both, occurred in 3.7 percent of the hospitalizations. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent and the proportion of adverse events due to negligence was 27.6 percent. Although most of these adverse events gave rise to disability lasting less than six months, 13.6 percent resulted in death and 2.6 percent caused permanently disabling injuries. Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).31,32

The findings of the Harvard Medical Practice Study in New York have recently been corroborated by a study of adverse events in Colorado and Utah occurring in 1992.33 This study included the review of medical records pertaining to a random sample of 15,000 discharges from a representative sample of hospitals in the two states. Adverse events occurred in 2.9 percent of hospitalizations in each state. Over four out of five of these adverse events occurred in the hospital, the remaining occurred prior to admission in physicians' offices, patients' homes or other non-hospital settings. The proportion of adverse events due to negligence was 29.2 percent, and the proportion of adverse events that were preventable was 53 percent.34 As was the case in the New York study, over 50 percent of adverse events were minor, temporary injuries. But the study in New York found that 13.6 percent of adverse events led to death, as compared with 6.6 percent in Colorado and Utah. In New York, about one in four negligent adverse events led to death, while in Colorado and Utah, death resulted in about 1 out of every 11 negligent adverse events. Factors that might explain the differences between the two studies include: temporal changes in health care, and differences in the states' patient populations and health care systems.35

Both the study in New York and the study in Colorado and Utah identified a subset of preventable adverse events that also satisfied criteria applied by the legal system in determining negligence. It is important to note that although some of these cases may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.

Extrapolation of the results of the Colorado and Utah study to the over 33.6 million admissions to hospitals in the United States in 1997, implies that at least 44,000 Americans die in hospitals each year as a result of preventable medical errors.[36] Based on the results of the New York study, the number of deaths due to medical error may be as high as 98,000.[37] By way of comparison, the lower estimate is greater than the number of deaths attributable to the 8th-leading cause of death.[38]

Some maintain these extrapolations likely underestimate the occurrence of preventable adverse events because these studies: (1) considered only those patients whose injuries resulted in a specified level of harm; (2) imposed a high threshold to determine whether an adverse event was preventable or negligent (concurrence of two reviewers); and (3) included only errors that are documented in patient records.[39]

Two studies that relied on both medical record abstraction and other information sources, such as provider reports, have found higher rates of adverse events occurring in hospitals. In a study of 815 consecutive patients on a general medical service of a university hospital, it was found that 36 percent had an iatrogenic illness, defined as any illness that resulted from a diagnostic procedure, from any form of therapy, or from a harmful occurrence that was not a natural consequence of the patient's disease.[40] Of the 815 patients, nine percent had an iatrogenic illness that threatened life or produced considerable disability, and for another two percent, iatrogenic illness was believed to contribute to the death of the patient.

In a study of 1,047 patients admitted to two intensive care units and one surgical unit at a large teaching hospital, 480 (45.8 percent) were identified as having had an adverse event, where adverse event was defined as "situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen."[41] For 185 patients (17.7 percent), the adverse event was serious, producing disability or death. The likelihood of experiencing an adverse event increased about six percent for each day of hospital stay.

Some information on errors can also be gleaned from studies that focus on inpatients who died or experienced a myocardial infarction or postsurgical complication. In a study of 182 deaths in 12 hospitals from three conditions (cerebrovascular accident, pneumonia, or myocardial infarction), it was found that at least 14 percent and possibly as many as 27 percent of the deaths might have been prevented.[42] A 1991 analysis of 203 incidents of cardiac arrest at a teaching hospital,[43] found that 14 percent followed an iatrogenic complication and that more than half of these might have been prevented. In a study of 44,603 patients who underwent surgery between 1977 and 1990 at a large medical center, 2,428 patients (5.4 percent) suffered complications and nearly one-half of these complications were attributable to error.[44] Another 749 died during the same hospitalization; 7.5 percent of these deaths were attributed to error.

Patients who died during surgery requiring general anesthesia have been the focus of many studies over the last few decades. Anesthesia is an area in which very impressive improvements in safety have been made. As more and more attention has been focused on understanding the factors that contribute to error and on the design of safer systems, preventable mishaps have declined.[45,46,47,48] Studies, some conducted in Australia, the United Kingdom and other countries, indicate that, today, anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics in the early 1980s.[49] The gains in anesthesia are very impressive and were accomplished through a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches to reducing errors.[50]

Lastly, some studies have relied on incident reporting systems to identify and analyze errors. For example, in Australia, 324 general practitioners participating voluntarily in an incident reporting system reported a total of 805 incidents during October 1993 through June 1995, of which 76 percent were preventable and 27 percent had the potential for severe harm.[51] These studies provide information on the types of errors that occur but are not useful for estimating the incidence of errors, because the population at risk (i.e., the denominator) is generally unknown.

Medication-Related Errors

Even though medication errors that result in death or serious injury occur infrequently, sizable and increasing numbers of people are affected because of the extensive use of drugs in both out-of-hospital and in-hospital settings. In 1998, nearly 2.5 billion prescriptions were dispensed in U.S. pharmacies at an estimated cost of about $92 billion.[52] An estimated 3.75 billion drug administrations were made to patients in hospitals.[53]

In a review of U.S. death certificates between 1983 and 1993, it was found that 7,391 people died in 1993 from medication errors (accidental poisoning by drugs, medicaments, and biologicals that resulted from acknowledged errors by patients or medical personnel), compared with 2,876 people in 1983, representing a 2.57-fold increase.[54] Outpatient deaths due to medication errors rose 8.48-fold during the 10-year period, compared with a 2.37-fold increase in inpatient deaths.

Medication Errors in Hospitals

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.[55] 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 discuss 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.[56] In a review of 4,031 adult admissions to 11 medical and surgical units at two tertiary care hospitals, Bates et al. identified 247 ADEs for an extrapolated event rate of 6.5 ADEs per 100 nonobstetrical admissions, and a mean number per hospital per year of approximately 1,900 ADEs.[57] 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.[58] 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.[59]

Children are at particular risk of medication errors, and as discussed below, this is attributable primarily to incorrect dosages.[60,61] In a study of 101,022 medication orders at two children's teaching hospitals, a total of 479 errant medication orders were identified, of which 27 represented potentially lethal prescribing errors.[62] The frequency of errors was similar at the two institutions, 4.9 and 4.5 errors per 1,000 medication orders. The error rate per 100 patient-days was greater in the pediatric intensive care units (PICUs) than in the pediatric ward or neonatal intensive care units, and the authors attribute this to the greater heterogeneity of patients cared for in PICUs and the broad range of drugs and dosages used. In a four-year prospective quality assurance study, 315 medication errors resulting in injury were reported among the 2,147 neonatal and pediatric intensive care admissions, an error rate of one per 6.8 admissions.[63] The frequency of iatrogenic injury of any sort due to a medication error was 3.1 percent—one injury for each 33 intensive care admissions.

Not surprisingly, the potential for medication-related error increases as the average number of drugs administered increases. In a prospective cohort study of 4,031 adult admissions to 11 medical and surgical units in two tertiary care hospitals (including two medical and three surgical ICUs), the rate of preventable ADEs and preventable potential ADEs in ICUs was 19 events per 1,000 patient-days, nearly twice the rate of non-ICUs.[64] When adjusted for the number of drugs used in the previous 24 hours or ordered since admission, there were no differences in error rates between ICUs and nonICUs.

Current estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported.[65,66,67,68] 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.[69]

Some errors are also difficult to detect in the absence of computerized surveillance systems. In a study of 36,653 hospitalized patients, Classen et al. identified 731 ADEs in 648 patients, but only 92 of these were reported by physicians, pharmacists, and nurses.[70] The remaining 631 were detected from automated signals, the most common of which were diphenhydramine hydrochloride and naloxone hydrochloride use, high serum drug levels, leukopenia, and the use of phytonadione and antidiarrheals.

Medication Errors in Ambulatory Settings

There is evidence indicating that ADEs account for a sizable number of admissions to inpatient facilities, but we do not know what proportion of these ADE-related admissions are attributable to errors. One study found that between three and 11 percent of hospital admissions were attributable to ADEs.[71] A review of 14 Australian studies published between 1988 and 1996 reported that 2.4 to 3.6 percent of all hospital admissions were drug related, and between 32 and 69 percent were definitely or possibly preventable. Drug groups most commonly involved were cytotoxics, cardiovascular agents, antihypertensives, anticoagulants, and nonsteroidal anti-inflammatory drugs.[72]

ADEs also result in increased visits to physician offices and emergency departments. In an analysis of 1,000 patients drawn from a community of-rice-based medical practice who were observed for adverse drug reactions, adverse effects were recorded in 42 (4.2 percent), of which 23 were judged to be unnecessary and potentially avoidable.[73] In an analysis of 62,216 visits to an emergency department by patients enrolled in a health maintenance organization (HMO), it was found that 1,074 (1.7 percent) were related to medication noncompliance or inappropriate prescribing.[74]

There is a sizable body of literature to document the incidence of patient noncompliance with medication regimens, but less is known about the proportion of noncompliance attributable to medical error (defined as accidental or unintentional nonadherence to a therapeutic program) as opposed to intentional noncompliance. In a meta-analysis of seven studies, Sullivan et al. estimate that 5.5 percent of admissions can be attributed to drug therapy noncompliance, amounting to 1.94 million admissions and $8.5 billion in hospital expenditures in 1986.[75] Similar results were obtained by Einarson in a meta-analysis of 37 studies published between 1966 and 1989, which found that hospital admissions caused by ADEs, resulting from noncompliance or unintentionally inappropriate drug use, ranged from 0.2 to 21.7 percent with a median of 4.9 percent and a mean of 5.5 percent.[76] Patient noncompliance is clearly an important quality issue, but it should be emphasized that we do not know the extent to which noncompliance is related to errors.

Factors that Contribute to Errors

Studies of Adverse Events

Patient safety problems of many kinds occur during the course of providing health care. They include transfusion errors and adverse drug events; wrong-site surgery and surgical injuries; preventable suicides; restraint-related injuries or death; hospital-acquired or other treatment-related infections; and falls, burns, pressure ulcers, and mistaken identity. Leape et al. have characterized the kinds of errors that resulted in medical injury in the Medical Practice Study as diagnostic, treatment, preventive, or other errors (see Box 2.1).

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 errors (44 percent), diagnosis (17 percent), failure to prevent injury (12 percent) and errors in the use of a drug (10 percent). The contributions of complexity and technology to such error rates is highlighted by the higher rates of events that occur in the highly technical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery. In hospitals, high error rates with serious consequences are most likely in intensive care units, operating rooms and emergency departments.

Thomas et al., in their study of admissions to hospitals in Colorado and Utah experiencing adverse events, found that about 30 percent were attributable to negligence.[77] The hospital location with the highest proportion of negligent adverse events (52.6 percent) was the emergency department. The authors note the complexity inherent in emergency medical care and point to the need to improve teamwork and standardize work procedures.

Other studies have made similar attempts to classify errors. Dubois and Brook studied 49 preventable deaths from 12 hospitals, and found that for those who died of a myocardial infarction, preventable deaths reflected errors in management; for cerebrovascular accident, most deaths reflected errors in diagnosis; and for pneumonia, some deaths reflected errors in management and some reflected errors in diagnosis.[78] In an analysis of 203 cardiac arrests at a teaching hospital, Bedell et al. found that of the half that might have been prevented, the most common causes of potentially preventable arrest were medication errors and toxic effects, and suboptimal response by physicians to clinical signs and symptoms.[79]

BOX 2.1 **Types of Errors**
Diagnostic
Error or delay in diagnosis
Failure to employ indicated tests

Use of outmoded tests or therapy
Failure to act on results of monitoring or testing
Treatment
Error in the performance of an operation, procedure, or test
Error in administering the treatment
Error in the dose or method of using a drug
Avoidable delay in treatment or in responding to an abnormal test
Inappropriate (not indicated) care
Preventive
Failure to provide prophylactic treatment
Inadequate monitoring or follow-up of treatment
Other
Failure of communication
Equipment failure
Other system failure
SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. *Qual Rev Bull*. 19(5):144–149, 1993.

Studies of Medication Errors

Ensuring appropriate medication use is a complex process involving multiple organizations and professionals from various disciplines; knowledge of drugs; timely access to accurate and complete patient information; and a series of interrelated decisions over a period of time. As shown in Box 2.2, errors can creep into this process at various points. Some errors are errors of commission (e.g., administration of improper drug), while others are errors of omission (e.g., failure to administer a drug that was prescribed).

Medication errors are often preventable, although reducing the error rate significantly will require multiple interventions. In the study of prescribing errors conducted by Lesar et al.,[80] the most common factors associated with errors were decline in renal or hepatic function requiring alteration of drug therapy (13.9 percent); patient history of allergy to the same medication class (12.1 percent); using the wrong drug name, dosage form, or abbreviation (11.4 percent for both brand name and generic name orders); incorrect dosage calculations (11.1 percent); and atypical or unusual and critical dosage frequency considerations (10.8 percent). The most common groups of factors associated with errors were those related to knowledge and the application of knowledge regarding drug therapy (30 percent); knowledge and use of knowledge regarding patient factors that affect drug therapy (29.2 percent); use of calculations, decimal points, or unit and rate expression factors (17.5 percent); and nomenclature—for example incorrect drug name, dosage form, or abbreviations (13.4 percent).

Many studies have identified inappropriate prescribing as a particularly important factor in accounting for medication errors. In an analysis of 1987 National Medical Expenditure Survey data, it was found that physicians prescribe potentially inappropriate medications for nearly a quarter of all older people living in the community.[81] In a study of 366 consecutive patients admitted to a department of cardiology, "definite" or "probable" drug events (i.e., adverse drug reactions and dose-related therapeutic failures) accounted for 15 admissions, of which five were judged to be due to error in prescription and another five judged to have been avoidable had appropriate measures been taken by prescribing physicians.[82] In an analysis of 682 children admitted to a Congenital Heart Disease Center at a teaching hospital in the United Kingdom, 441 medication errors were reported by nurses, doctors, and pharmacists, of which prescribing errors accounted for 68 percent, followed by administration errors (25 percent) and supply errors (seven percent).[83] In Burnum's[84] analysis of 1,000 patients drawn from a community office-based medical practice who experienced adverse drug reactions, 23 patients were judged to have experienced an "unnecessary and potentially avoidable" event, 10 of which were due to physician error (i.e., six due to administration of a drug not indicated and four to improper drug administration).

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.[85] 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.[86] Eighty-eight percent of the errors involved giving patients the wrong drug or the wrong strength.

Errors in the ordering and administration of medications are common in hospitals. Bates et al.,[87] in an analysis of more than 4,000 admissions to two tertiary care hospitals, found that about 28 percent of 247 adverse drug events were preventable and most of these resulted from errors that occurred at the stages of ordering and administration.

Davis and Cohen[88] in their review of the literature and other evidence on errors report an error rate of 12 percent to be common in the preparation and administration of medications in hospitals. In a study of medication orders at two children's teaching hospitals, Folli et al.[89] found that errors occurred in almost five out of every 1,000 orders and that the most prevalent error was overdose.

Patients make errors too. With greater emphasis on community-based long-term care, increased ambulatory surgery, shorter hospital lengths of stay, and greater reliance on complex drug therapy, patients play an increasingly important role in the administration of drugs. Greenberg et al.[90] found that 4.3 percent of the elderly enrolled in Medicare social HMOs required assistance with the administration of medications. The inability to manage complex drug therapies explains why some elderly are in institutional rather than community-based long-term-care settings.[91]

Automated information and decision support systems are effective in reducing many types of errors. In an analysis of admissions to 11 medical and surgical units at two tertiary care hospitals, Leape et al.[92] identified 334 errors as the causes of 264 preventable ADEs and potential ADEs. About three out of four errors were caused by one of seven types of systems failures (drug knowledge dissemination, dose and identity checking, patient information availability, order transcription, allergy defense, medication order tracking, and interservice communication), and all could have been improved by better information systems that disseminate knowledge about drugs and make drug and patient information readily accessible at the time it is needed.

Computerized drug order entry systems have much potential to reduce errors. In a study of 379 consecutive admissions to three medical units at an urban tertiary care hospital, 10,070 medication orders were written and 530 medication errors were identified (5.3 errors per 100 orders). More than half of the medication errors involved at least one missing dose of a medication.[93] Of the 530 medication errors, five (0.9 percent) resulted in adverse drug events that were judged preventable, and another 35 represented potential adverse drug events (i.e., medication errors with the potential for injury but in which no injury occurred). Physician computer order entry could have prevented 84 percent missing dose medication errors, 86 percent of potential adverse drug events, and 60 percent of preventable adverse drug events. However, more sophisticated technology is not the only option; involving pharmacists in reviewing drug orders significantly reduced the potential harm resulting from errant medication orders.[94,95]

The Cost of Errors

In addition to the unfortunate health consequences suffered by many as a result of medical error, there are direct and indirect costs borne by society as a whole as a result of medical errors. Direct costs refer to higher health care expenditures, while indirect costs include factors such as lost productivity, disability costs, and personal costs of care.

Based on analysis of 459 adverse events identified by reviewing the medical records of 14,732 randomly selected 1992 discharges from 28 hospitals in Colorado and Utah, Thomas et al. estimated the total costs (lost income, lost household production, disability and health care costs) to be nearly $662 million of which health care costs totaled $348 million.[96]

The total costs associated with the 265 of the 459 adverse events that were found to be preventable were $308 million, of which $159 million represented health care costs. Based on extrapolation to all hospital admissions in the United States, the authors estimate the national costs of adverse events to be $37.6 billion and of preventable adverse events to be $17 billion. The total national costs associated with adverse events was approximately 4 percent 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 AIDS.

It has been estimated that for every dollar spent on ambulatory medications, another dollar is spent to treat new health problems caused by the medication.97 Studies of the direct costs of medication-related errors fall into three categories; (1) population-based studies of patients in a community or health plan; (2) studies of medication-related errors that occur in hospitals; and (3) studies of medication-related errors that occur in nursing homes.

One estimate places the annual national health care cost of drug-related morbidity and mortality in the ambulatory setting as high as $76.6 billion in 1994.98 Not all drug-related morbidity and mortality is preventable, but numerous studies document errors in prescribing,99,100 dispensing by pharmacists,101 and unintentional nonadherence on the part of the patient.102

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.103 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 a matched case-control study of all patients admitted to a large teaching hospital from January 1990 through December 1993, it was found that adverse drug events complicated 2.43 admissions per 100.104 Controls were matched to cases on primary discharge diagnosis related group (DRG), age, sex, acuity, and year of admission. The occurrence of an ADE was associated with an increased length of stay of 1.91 days and an increased cost of $2,262. The increased risk of death among patients experiencing an adverse drug event was 1.88.

Other studies corroborate the high cost of medication-related errors. One study conducted in a university-affiliated medical center hospital estimated that the annual costs of treating the 1,911 medication-related problems identified through the hospital's voluntary reporting system in 1994 totaled slightly less than $1.5 million.105 Bloom has estimated that $3.9 billion was spent in 1983 to manage the preventable gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs.106

Medication-related errors also occur in nursing homes. For every dollar spent on drugs in nursing facilities, $1.33 is consumed in the treatment of drug-related morbidity and mortality, amounting to $7.6 billion for the nation as a whole, of which $3.6 billion has been estimated to be avoidable.107

Public Perceptions of Safety

Although the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, a good deal more public attention has been focused on improving safety in the airline industry than in the health care industry. The likelihood of dying per domestic jet flight is estimated to be one in eight million.[108] Statistically, an average passenger would have to fly around the clock for more than 438 years before being involved in a fatal crash. This compares very favorably with a death risk per domestic flight of one in two million during the decade 1967–1976. Some believe that public concern about airline safety, in response to the impact of news stories, has played an important role in the dramatic improvement in safety in the airline industry.

The American public is aware that health care is less safe than some other environments, but to date, it has made few demands on the health care industry to demonstrate improvement. In a public opinion poll conducted by Louis Harris & Associates for the National Patient Safety Foundation, the health care environment was perceived as "moderately safe" (rated 4.9 on a scale of one through seven where one is not safe at all and seven is very safe).[109] Respondents viewed the health care environment as much safer than nuclear power or food handling, but somewhat less safe than airline travel or the work environment.

Americans have a very limited understanding of health care safety issues. When asked, What comes to mind when you think about patient safety issues in the health care environment? 28 percent of respondents did not mention anything, 20 percent mentioned exposure to infection, 13 percent cited the general level of care patients receive, and 11 percent cited qualifications of health professionals.[110] When asked about the main cause of medical mistakes, respondents most frequently cited carelessness or negligence (29 percent) of health care professionals, who are overworked, worried, or stressed (27 percent).

Most people learn about medical mistakes through anecdotes. More than four out of five respondents have heard about a situation in which a medical mistake was made.[111] When asked how they heard about the most recent medical mistake, 42 percent cited a friend or relative; 39 percent, television, newspaper, or radio; and 12 percent, personal experience.

Most people view medical mistakes as an "individual provider issue" rather than a failure in the process of delivering care in a complex delivery system. When asked about possible solutions to prevent medical mistakes, actions rated very effective by respondents were "keeping health care professionals with bad track records from providing care" (75 percent) and "better training of health care professionals" (69 percent).[112]

There are numerous factors that might contribute to the "disconnect" between public perceptions and actual health care error rates. The various accreditation and licensure programs for health care organizations and providers have been promoted as "Good Housekeeping Seals of Approval," yet they fail to provide adequate assurance of a safe environment. Reducing medical errors and improving patient safety are not an explicit focus of these processes. Even licensed and accredited organizations may have implemented only rudimentary systems and processes to ensure patient safety.

For the most part, media coverage has been limited to occasional reporting of anecdotal cases. The impact of anecdotal information on safety may also be less effective in health care than in the nuclear waste or airline industries, where an individual event often impacts dozens or hundreds of people at a time.

Patient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations."

Why Do Errors Happen?

The report, To Error is Human, then goes on to look at causes of errors. Why do they happen?

"The common initial reaction when is to find and blame an error occurs someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. 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.

This section covers two key areas. First, definitions of several key terms are offered. This is important because there is no agreed-upon terminology for talking about this issue.1 Second, the emphasis in this chapter (and in this report generally) is about how to make systems safer; its primary focus is not on "getting rid of bad apples," or individuals with patterns of poor performance. The underlying assumption is that lasting and broad-based safety improvements in an industry can be brought about through a systems approach.

Finally, it should be noted that although the examples may draw more from inpatient or institutional settings, errors occur in all settings. The concepts presented in this section are just as applicable to ambulatory care, home care, community pharmacies, or any other setting in which health care is delivered.

Here is a case study to illustrate a series of definitions and concepts in patient safety. After presentation of the case study, the chapter will define what comprises a system, how accidents occur, how human error contributes to accidents and how these elements fit into a broader concept of safety. The case study will be referenced to illustrate several of the concepts. The next section will examine whether certain types of systems are more prone to accidents than others. Finally, after a short discussion of the study of human factors, the chapter summarizes what health care can learn from other industries about safety.

Why Do Accidents Happen?

Major accidents, such as Three Mile Island or the *Challenger* accident, grab people's attention and make the front page of newspapers. Because they usually affect only one individual at a time, accidents in health care delivery are less visible and dramatic than those in other industries. Except for celebrated cases, such as Betsy Lehman (the *Boston Globe* reporter who died from an overdose during chemotherapy) or Willie King (who had the wrong leg amputated),[2] they are rarely noticed. However, accidents are a form of information about a system.[3] They represent places in which the system failed and the breakdown resulted in harm.

An Illustrative Case in Patient Safety

Infusion devices are mechanical devices that administer intravenous solutions containing drugs to patients. A patient was undergoing a cardiac procedure. This patient had a tendency toward being hypertensive and this was known to the staff.

As part of the routine set-up for surgery, a nurse assembled three different infusion devices. The nurse was a new member of the team in the operating room; she had just started working at the hospital a few weeks before. The other members of the team had been working together for at least six months. The nurse was being very careful when setting up the devices because one of them was a slightly different model than she had used before.

Each infusion device administered a different medication that would be used during surgery. For each medication, the infusion device had to be programmed according to how much medication would flow into the patient (calculated as "cc's/hour"). The medications had different concentrations and each required calculation of the correct dose for that specific patient. The correct cc's/hour were programmed into the infusion devices.

The anesthesiologist, who monitors and uses the infusion devices during surgery, usually arrived for surgery while the nurse was completing her set-up of the infusion devices and was able to check them over. This particular morning, the anesthesiologist was running behind from a previous surgery. When he arrived in the operating room, the rest of the team was ready to start. The anesthesiologist quickly glanced at the set-up and accepted the report as given to him by the nurse.

One of the infusion devices was started at the beginning of surgery. About halfway through the surgery, the patient's blood pressure began to rise. The anesthesiologist tried to counteract this by starting one of the other infusion devices that had been set up earlier. He checked the drip chamber in the intravenous (IV) tubing and did not see any drips. He checked the IV tubing and found a closed clamp, which he opened. At this point, the second device signaled an occlusion, or blockage, in the tubing by sounding an alarm and flashing an error message. The anesthesiologist found a closed clamp in this tubing as well, opened it, pressed the re-start button and the device resumed pumping without further difficulty. He returned to the first device that he had started and found that there had been a free flow of fluid and medication to the patient, resulting in an overdose. The team responded appropriately and the patient recovered without further incident.

The case was reviewed two weeks later at the hospital's "morbidity and mortality" committee meeting, where the hospital staff reviews cases that encountered a problem to identify what happened and how to avoid a recurrence. The IV tubing had been removed from the device and discarded. The bioengineering service had checked the pump and found it to be functioning accurately. It was not possible to determine whether the tubing had been inserted incorrectly into the device, whether the infusion rate had been set incorrectly or changed while the device was in use, or whether the device had malfunctioned unexpectedly. The anesthesiologist was convinced that the tubing had been inserted incorrectly, so that when the clamp was open the fluid was able to flow freely rather than being controlled by the infusion device. The nurse felt the anesthesiologist had failed to check the infusion system adequately before turning on the devices. Neither knew whether it was possible for an infusion device to have a safety mechansim built into it that would prevent free flows from happening.

Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a centrally owned multihospital system, or a virtual system comprised of many different partners over a wide geographic area. However, an operating room or an obstetrical unit is also a type of system. Furthermore, any element in a system probably belongs to multiple systems. For example, one operating room is part of a surgical department, which is part of a hospital, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand.

When large systems fail, it is due to multiple faults that occur together in an unanticipated interaction,[6] creating a chain of events in which the faults grow and evolve.[7]

Their accumulation results in an accident. *"An accident is an event that involves damage to a defined system that disrupts the ongoing or future output of that system."*[8]

The *Challenger* failed because of a combination of brittle O-ring seals, unexpected cold weather, reliance on the seals in the design of the boosters, and change in the roles of the contractor and NASA. Individually, no one factor caused the event, but when they came together, disaster struck. Perrow uses a DEPOSE (**D**esign, **E**quipment **P**rocedures, **O**perators, **S**upplies and materials, and **E**nvironment) framework to identify the potential sources of failures. In evaluating the environment, some researchers explicitly include organizational design and characteristics.[9]

The complex coincidences that cause systems to fail could rarely have been foreseen by the people involved. As a result, they are reviewed only in hindsight; however, knowing the outcome of an event influences how we assess past events.[10] *Hindsight bias* means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident, highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information,[11] hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.

Although many features of systems and accidents in other industries are also found in health care, there are important differences. In most other industries, when an accident occurs the worker and the company are directly affected. There is a saying that the pilot is always the first at the scene of an airline accident. In health care, the damage happens to a third party; the patient is harmed; the health professional or the organization, only rarely. Furthermore, harm occurs to only one patient at a time; not whole groups of patients, making the accident less visible.*

In any industry, one of the greatest contributors to accidents is human error. Perrow has estimated that, on average, 60–80 percent of accidents involve human error. There is reason to believe that this is equally true in health. An analysis of anesthesia found that human error was involved in 82 percent of preventable incidents; the remainder involved mainly equipment failure.[12] Even when equipment failure occurs, it can be exacerbated by human error.[13] However, saying that an accident is due to human error is not the same as assigning blame. Humans commit errors for a variety of expected and unexpected reasons, which are discussed in more detail in the next two sections.

Understanding Errors

The work of Reason provides a good understanding of errors. He defines an error as the failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.[14] It is important to note the inclusion of "intention."

According to Reason, error is not meaningful without the consideration of intention. That is, it has no meaning when applied to unintentional behaviors because errors depend on two kinds of failure, either actions do not go as intended or the intended action is not the correct one. In the first case, the desired outcome may or may not be achieved; in the second case, the desired outcome cannot be achieved.

Reason differentiates between slips or lapses and mistakes. A slip or lapse occurs when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable and a lapse is not. For example, turning the wrong knob on a piece of equipment would be a slip; not being able to recall something from memory is a lapse.

In a mistake, the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong. The situation might have been assessed incorrectly, and/or there could have been a lack of knowledge of the situation. In a mistake, the original intention is inadequate; a failure of planning is involved.

In medicine, slips, lapses, and mistakes are all serious and can potentially harm patients. For example, in medicine, a slip might be involved if the physician chooses an appropriate medication, writes 10 mg when the intention was to write 1 mg. The original intention is correct (the correct medication was chosen given the patient's condition), but the action did not proceed as planned. On the other hand, a mistake in medicine might involve selecting the wrong drug because the diagnosis is wrong. In this case, the situation was misassessed and the action planned is wrong. If the terms "slip" and "mistake" are used, it is important not to equate slip with "minor." Patients can die from slips as well as mistakes.

For this report, *error is defined as the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning)*. From the patient's perspective, not only should a medical intervention proceed properly and safely, it should be the correct intervention for the particular condition. This report addresses primarily the first concern, errors of execution, since they have their own epidemiology, causes, and remedies that are different from errors in planning. Subsequent reports from the Quality of Health Care in America project will consider the full range of quality-related issues, sometimes classified as overuse, underuse and misuse.[15]

Latent and Active Errors

In considering how humans contribute to error, it is important to distinguish between active and latent errors.[16] *Active errors occur at the level of the frontline operator, and their effects are felt almost immediately*. This is sometimes called the sharp end.[17] *Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations*. These are called the blunt end. The active error is that the pilot crashed the plane. The latent error is that a previously undiscovered design malfunction caused the plane to roll unexpectedly in a way the pilot could not control and the plane crashed.

Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors. Analysis of the *Challenger* accident traced contributing events back nine years.

In the Three Mile Island accident, latent errors were traced back two years.[18] Latent errors can be difficult for the people working in the system to notice since the errors may be hidden in the design of routine processes in computer programs or in the structure or management of the organization. People also become accustomed to design defects and learn to work around them, so they are often not recognized.

In her book about the *Challenger* explosion, Vaughan describes the "normalization of deviance" in which small changes in behavior became the norm and expanded the boundaries so that additional deviations became acceptable.[19] When deviant events become acceptable, the potential for errors is created because signals are overlooked or misinterpreted and accumulate without being noticed.

Current responses to errors tend to focus on the active errors by punishing individuals (e.g., firing or suing them), retraining or other responses aimed at preventing recurrence of the active error. Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence. Because large system failures represent latent failures coming together in unexpected ways, they appear to be unique in retrospect. Since the same mix of factors is unlikely to occur again, efforts to prevent specific active errors are not likely to make the system any safer.[20]

Focusing on active errors lets the latent failures remain in the system, and their accumulation actually makes the system more prone to future failure.[21] Discovering and fixing latent failures, and decreasing their duration, are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur.

Understanding Safety

Most of this chapter thus far has drawn on Perrow's normal accident theory, which believes that accident are inevitable in certain systems. Although they may be rare, accidents are "normal" in complex, high technology industries. In contrast to studying the causes of accident and errors, other researchers have focused on the characteristics that make certain industries, such as military aircraft carriers or chemical processing, highly reliable.[22] High reliability theory believes that accidents can be prevented through good organizational design and management.[23] Characteristics of highly reliable industries include an organizational commitment to safety, high levels of redundancy in personnel and safety measures, and a strong organizational culture for continuous learning and willingness to change.[24] Correct performance and error can be viewed as "two sides of the same coin."[25] Although accidents may occur, systems can be designed to be safer so that accidents are very rare.

The National Patient Safety Foundation has defined patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care.[26] Safety does not reside in a person, device or department, but emerges from the interactions of

components of a system. Others have specifically examined pharmaceutical safety and defined it to include maximizing therapeutic benefit, reducing risk, and eliminating harm.[27] That is, benefit relates to risk. Other experts have also defined safety as a relative concept. Brewer and Colditz suggest that the acceptability of an adverse event depends on the seriousness of the underlying illness and the availability of alternative treatments.[28] The committee's focus, however, was not on the patient's response to a treatment, but rather on the ability of a system to deliver care safely. From this perspective, the committee believes that there is a level of safety that can and should be ensured. Safety is relative only in that it continues to evolve over time and, when risks do become known, they become part of the safety requirements.

Safety is more than just the absence of errors. Safety has multiple dimensions, including the following:

• an outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context;

• A set of processes that identify, evaluate, and minimize hazards and are continuously improving, and

• An outcome that is manifested by fewer medical errors and minimized risk or hazard.[29]

For this report, *safety is defined as freedom from accidental injury*. This simple definition recognizes that from the patient's perspective, the primary safety goal is to prevent accidental injuries. If an environment is safe, the risk of accidents is lower. Making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care.

Are Some Types of Systems More Prone to Accidents?

Accidents are more likely to happen in certain types of systems. When they do occur, they represent failures in the way systems are designed. The primary objective of systems design ought to be to make it difficult for accidents and errors to occur and to minimize damage if they do occur.[30]

Perrow characterizes systems according to two important dimensions: complexity and tight or loose coupling.[31] Systems that are more complex and tightly coupled are more prone to accidents and have to be made more reliable.[32] In Reason's words, complex and tightly coupled systems can "spring nasty surprises."[33]

In complex systems, one component of the system can interact with multiple other components, sometimes in unexpected or invisible ways. Although all systems have many parts that interact, the problem arises when one part serves multiple functions because if this part fails, all of the dependent functions fail as well. Complex systems are characterized by specialization and interdependency.

Complex systems also tend to have multiple feedback loops, and to receive information indirectly, and because of

Specialization, there is little chance of substituting or reassigning personnel or other resources.

In contrast to complex systems, linear systems contain interactions that are expected in the usual and familiar production sequence. One component of the system interacts with the component immediately preceding it in the production process and the component following it. Linear systems tend to have segregated subsystems, few feedback loops, and easy substitutions (less specialization).

An example of complexity is the concern with year 2000 (Y2K) computer problems. A failure in one part of the system can unexpectedly interrupt other parts, and all of the interrelated processes that can be affected are not yet visible. Complexity is also the reason that changes in long-standing production processes must be made cautiously.[34] When tasks are distributed across a team, for example, many interactions that are critical to the process may not be noticed until they are changed or removed.

Coupling is a mechanical term meaning that there is no slack or buffer between two items. Large systems that are tightly coupled have more time-dependent processes and sequences that are more fixed (e.g., *y* depends on *x* having been done). There is often only one way to reach a goal. Compared to tightly coupled systems, loosely coupled systems can tolerate processing delays, can reorder the sequence of production, and can employ alternative methods or resources.

All systems have linear interactions; however, some systems additionally experience greater complexity. Complex interactions contribute to accidents because they can confuse operators. Tight coupling contributes to accidents because things unravel too quickly and prevent errors from being intercepted or prevent speedy recovery from an event.[35] Because of complexity and coupling, small failures can grow into large accidents.

Although there are not firm assignments, Perrow considered nuclear power plants, nuclear weapons handling, and aircraft to be complex, tightly coupled systems.[36] Multiple processes are happening simultaneously, and failure in one area can interrupt another. Dams and rail transportation are considered tightly coupled because the steps in production are closely linked, but linear because there are few unexpected interactions. Universities are considered complex, but loosely coupled, since the impact of a decision in one area can likely be limited to that area.

Perrow did not classify health care as a system, but others have suggested that health care is complex and tightly coupled.[37] The activities in the typical emergency room, surgical suite, or intensive care unit exemplify complex and tightly coupled systems. Therefore, the delivery of health care services may be classified as an industry prone to accidents.[38]

Complex, tightly coupled systems have to be made more reliable.[39] One of the advantages of having systems is that it is possible to build in more defenses against failure.

Systems that are more complex, tightly coupled, and are more prone to accidents can reduce the likelihood of accidents by simplifying and standardizing processes, building in redundancy, developing backup systems, and so forth.

Another aspect of making systems more reliable has to do with organizational design and team performance. Since these are part of activities within organizations, they are discussed in Chapter 8.

Conditions That Create Errors

Factors can intervene between the design of a system and the production process that creates conditions in which errors are more likely to happen. James Reason refers to these factors as psychological precursors or preconditions.[40] Although good managerial decisions are required for safe and efficient production, they are not sufficient. There is also a need to have the right equipment, well-maintained and reliable; a skilled and knowledgeable workforce; reasonable work schedules, well-designed jobs; clear guidance on desired and undesired performance, et cetera. Factors such as these are the precursors or preconditions for safe production processes.

Any given precondition can contribute to a large number of unsafe acts. For example, training deficiencies can show up as high workload, undue time pressure, inappropriate perception of hazards, or motivational difficulties.[41] Preconditions are latent failures embedded in the system. Designing safe systems means taking into account people's psychological limits and either seeking ways to eliminate the preconditions or intervening to minimize their consequences. Job design, equipment selection and use, operational procedures, work schedules, and so forth, are all factors in the production process that can be designed for safety.

One specific type of precondition that receives a lot of attention is technology. The occurrence of human error creates the perception that humans are unreliable and inefficient. One response to this has been to find the unreliable person who committed the error and focus on preventing him or her from doing it again. Another response has been to increase the use of technology to automate processes so as to remove opportunities for humans to make errors. The growth of technology over the past several decades has contributed to system complexity so this particular issue is highlighted here.

Technology changes the tasks that people do by shifting the workload and eliminating human decision making.[42] Where a worker previously may have overseen an entire production process, he or she may intervene now only in the last few steps if the previous steps are automated. For example, flying an aircraft has become more automated, which has helped reduce workload during nonpeak periods. During peak times, such as take-off and landing, there may be more processes to monitor and information to interpret.

Furthermore, the operator must still do things that cannot be automated. This usually involves having to monitor automated systems for rare, abnormal events[43] because machines cannot deal with infrequent events in a constantly changing environment.[44] Fortunately, automated systems rarely fail. Unfortunately, this means that operators do not practice basic skills, so workers lose skills in exactly the activities they need in order to take over when something goes wrong.

Automation makes systems more "opaque" to people who manage, maintain, and operate them.[45] Processes that are automated are less visible because machines intervene between the person and the task. For example, automation means that people have less hands-on contact with processes and are elevated to more supervisory and planning tasks. Direct information is filtered through a machine (e.g., a computer), and operators run the risk of having too much information to interpret or of not getting the right information.

One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone.[46] Good machines can question the actions of operators, offer advice, and examine a range of alternative possibilities that humans cannot possibly remember. In medicine, automated order entry systems or decision support systems have this aim. However, technology can also create new demands on operators. For example, a new piece of equipment may provide more precise measurements, but also demand better precision from the operator for the equipment to work properly.[47] Devices that have not been standardized, or that work and look differently, increase the likelihood of operator errors. Equipment may not be designed using human factors principles to account for the human-machine interface.[48]

Technology also has to be recognized as a "member" of the work team. When technology shifts workloads, it also shifts the interactions between team members. Where processes may have been monitored by several people, technology can permit the task to be accomplished by fewer people. This affects the distributed nature of the job in which tasks are shared among several people and may influence the ability to discover and recover from errors.[49]

In this context, technology does not involve just computers and information technology. It includes "techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered."[50] Additionally, the use of the term technology is not restricted to the technology employed by health care professionals. It can also include people at home of different ages, visual abilities, languages, and so forth, who must use different kinds of medical equipment and devices. As more care shifts to ambulatory and home settings, the use of medical technology by non-health professionals can be expected to take on increasing importance.

Research on Human Factors

Research in the area of human factors is just beginning to be applied to health care. It borrows from the disciplines of industrial engineering and psychology. *Human factors is defined as the study of the interrelationships between humans, the tools they use, and the environment in which they live and work.*[51]

In the context of this report, a human factors approach is used to understand where and why systems or processes break down. This approach examines the process of error, looking at the causes, circumstances, conditions, associated procedures and devices and other factors connected with the event. Studying human performance can result in the creation of safer systems and the reduction of conditions that lead to errors.

However, not all errors are related to human factors. Although equipment and materials should take into account the design of the way people use them, human factors may not resolve instances of equipment breakdown or material failure.

Much of the work in human factors is on improving the human-system interface by designing better systems and processes.52 This might include, for example, simplifying and standardizing procedures, building in redundancy to provide backup and opportunities for recovery, improving communications and coordination within teams, or redesigning equipment to improve the human-machine interface.

Two approaches have typically been used in human factors analysis. The first is critical incident analysis. Critical incident analysis examines a significant or pivotal occurrence to understand where the system broke down, why the incident occurred, and the circumstances surrounding the incident.53 Analyzing critical incidents, whether or not the event actually leads to a bad outcome, provides an understanding of the conditions that produced an actual error or the risk of error and contributing factors.

A critical incident analysis in anesthesia found that human error was involved in 82 percent of preventable incidents. The study identified the most frequent categories of error and the riskiest steps in the process of administering anesthesia. Recommended corrective actions included such things as labeling and packaging strategies to highlight differences among anesthesiologists in the way they prepared their workspace, training issues for residents, work-rest cycles, how relief and replacement processes could be improved, and equipment improvements (e.g., standardizing equipment in terms of the shape of knobs and the direction in which they turn).

Another analytic approach is referred to as "naturalistic decision making."54 This approach examines the way people make decisions in their natural work settings. It considers all of the factors that are typically controlled for in a laboratory-type evaluation, such as time pressure, noise and other distractions, insufficient information, and competing goals. In this method, the researcher goes out with workers in various fields, such as firefighters or nurses, observes them in practice, and then walks them through to reconstruct various incidents. The analysis uncovers the factors weighed and the processes used in making decisions when faced with ambiguous information under time pressure.

In terms of applying human factors research, David Woods of Ohio State University describes a process of reporting, investigation, innovation, and dissemination (David Woods, personal communication, December 17, 1998). Reporting or other means of identifying errors tells people where errors are occurring and where improvements can be made. The investigation stage uses human factors and other analyses to determine the contributing factors and circumstances that created the conditions in which errors could occur. The design of safer systems provides opportunities for innovation and working with early adopters to test out new approaches. Finally, dissemination of innovation throughout the industry shifts the baseline for performance. The experience of the early adopters redefines what is possible and provides models for implementation.

Aviation has long analyzed the role of human factors in performance. The Ames Research Center (part of the National Aeronautics and Space Administration) has examined areas related to information technology, automation, and the use of simulators for training in basic and crisis skills, for example. Other recent projects include detecting and correcting errors in flight; interruptions, distractions and lapses of attention in the cockpit; and designing information displays to assist pilots in maintaining awareness of their situation during flight.[55]

Summary

The following key points can be summarized from this chapter.

1. Some systems are more prone to accidents than others because of the way the components are tied together. Health care services is a complex and technological industry prone to accidents.

2. Much can be done to make systems more reliable and safe. When large systems fail, it is due to multiple faults that occur together.

3. One of the greatest contributors to accidents in any industry including health care, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons.

4. Latent errors or system failures pose the greatest threat to safety in a complex system because they lead to operator errors. They are failures built into the system and present long before the active error. Latent errors are difficult for the people working in the system to see since they may be hidden in computers or layers of management and people become accustomed to working around the problem.

5. Current responses to errors tend to focus on the active errors. Although this may sometimes be appropriate, in many cases it is not an effective way to make systems safer. If latent failures remain unaddressed, their accumulation actually makes the system more prone to future failure. Discovering and fixing latent failures and decreasing their duration are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur.

6. The application of human factors in other industries has successfully reduced errors. Health care has to look at medical error not as a special case of medicine, but as a special case of error, and to apply the theory and approaches already used in other fields to reduce errors and improve reliability.[56]

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38. On the other hand, in some places, the health system may be complex, but loosely coupled. For example, during an emergency, a patient may receive services from a loosely networked set of subsystems—from the ambulance to the emergency room to the outpatient clinic to home care. See Van Cott in Bogner, 1994.

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Root Cause Analysis

According to the President of Stanford Medical School, Dr. Raymond GAETA, in a message entitled “Getting to the Root Cause,” said that: “Most physicians and other health-care professionals realize that medical errors remain an ever-present threat to patients' well-being. To successfully reduce and prevent errors, however, we must learn to view and deal with errors differently. When a patient receives the wrong medication, we know that an error has occurred, but we must recognize that other, less-obvious incidents constitute medical errors as well.

It is all too easy for us to dismiss an error as an isolated event that won't happen again. We rationalize that it was a single individual's mistake that occurred because of an unusual confluence of circumstances. Meanwhile, we never believe it could happen to us.

When we view medical errors in isolation, however, we miss the opportunity to really understand the nature of the problem and we overlook important themes that could help patients and health-care professionals in the future. The process of "root-cause analysis" is the mechanism by which we at Stanford Medical Center - and clinicians at many other medical centers - strive to learn from each event in the name of patient safety.

Rather than view the error as an isolated incident occurring at a single point in time, root-cause analysis expands the timeline and requires us to look further upstream from the event. This approach allows us to identify system problems that individually are not problematic but which, in combination, allow for the "unusual confluence of circumstances" that lead to medical errors.

A root-cause analysis is typically conducted by an interdisciplinary team of the individuals who witnessed or were otherwise involved in the incident. The focus of the analysis is to learn what we can do better next time. Root-cause analyses demonstrate that certain actions, behaviors and attitudes can contribute to catastrophic results under certain conditions. Viewing the problem in this "process flow" manner can reveal a pattern of error that would otherwise be attributed to unconnected events. Such insight can lead to valuable changes in policies and procedures so that no future patients are harmed.

In a case recently cited in the Annals of Internal Medicine, for example, a 67-year-old woman was admitted for cerebral angiography and mistakenly underwent an invasive cardiac electrophysiology study. Through a root-cause analysis, the team identified 17 distinct errors that led to the mix-up. No single error could have caused the event, but in combination with system weaknesses, the wrong patient was taken to the EP lab. The contributing errors included absent or misused protocols for patient identification and informed consent; faulty exchange of information among caregivers; and poorly functioning teams.

Performing a root-cause analysis can also be very beneficial in response to a "near-miss." No error occurred because one of our checks and balances intervened before a critical step. Although we applaud the vigilance that catches such errors in time, this vigilance should be the last level of security because a near-miss indicates that the overall system is not designed optimally.

Reducing the number of near-misses is a key goal of root-cause analyses, and physicians and staff should be encouraged to report near-misses as well as actual errors. Ultimately, each event provides an opportunity to learn and to improve safety for our patients.

Physician participation in this process is crucial. We can learn about the perspective of other health-care providers, and the brainstorming that occurs can lead to profound changes in how we care for our patients. Accordingly, physicians should embrace this type of analysis as a tool that will help ensure the safety of their patients."

Agreeing with the Stanford President, Geoff Mumford, PhD, of the Public Policy Office, wrote regarding the "To Error is Human" report: "On December 7, 1999, the Institute of Medicine (IOM) dropped a bomb during what would have been a quiet congressional recess. The "bomb" was a report entitled "To Err is Human: Building a Safer Health System," identifying medical error as the third leading cause of death in the United States. Fortunately, beyond identifying the problem, the report also made several recommendations to begin addressing the problem. Those recommendations included the creation of a Center for Patient Safety to be housed within the Agency for Health Research Quality (formally, the Agency for Health Care Policy Research) and recommendations to develop both voluntary and mandatory reporting systems to help identify the context in which errors occur.

The report received wide attention from both the Clinton administration and the popular press, and Congress soon followed suit. Sen. Arlen Specter (R-PA) initiated hearings in his Appropriations Subcommittee, which provides federal funding for a variety of public health agencies. Sen. Jim Jeffords (R-VT) began a series of hearings in his Health Education Labor and Pensions Committee, which provides legislative authority for public health programs.

Efforts to Bring Human Factors Expertise to the Table

APA, the Federation of Behavioral, Psychological, and Cognitive Sciences, and the Human Factors and Ergonomics Society (HFES) began a concerted lobbying effort to make sure that the interests and experience of human factors psychologists were brought to bear on the legislative process. As a result, we were invited to participate in congressional staff briefings, and to comment on Sen. Specter's draft legislation "The Medical Error Reduction Act of 2000." We suggested several changes to expand the scope of the bill in the interest of building a culture of safety. In addition, APA and the Federation arranged for experts in the field of patient safety to conduct team briefings for Senate Labor Committee staff and House Commerce Committee staff during the second week of February (see sidebar).

Complexity of Medical Error and Injury Issues

Experts believe that any legislative action should aim to reduce the number of medical errors, and the resulting deaths and injuries, but that success depends on understanding the complex nature of medical error. Measures not designed with respect for that complexity risk being ineffective or even injurious themselves.

Medical error is usually the result of a confluence of circumstances rather than simply one person making a mistake, so reducing medical error and injury cannot be accomplished simply by identifying and punishing individuals who have made errors. Instead, most experts believe that reduction depends on addressing error systemically. That is, it depends on understanding the relationship between proximal and distal causes of error and altering the causal stream, so that errors are not facilitated. Reduction of error and injury also depend on understanding success, since medical-setting studies show that far more accidents are waiting to happen than actually happen.

Given the level of complexity in understanding medical error and injury issues, the task for psychologists entering the debate is to highlight several key points for Congress. First, a convincing case must be made for funding sophisticated data collection and analysis to better understand the nature of error and success in medical settings, and for applying this knowledge to improve medical treatment. As always, there is the danger that Congress may respond to pressure from many constituencies by instituting reporting and investigative procedures that are not empirically supported. Second, any program designed to combat error and injury must obtain cooperation of the stakeholders ? those within the medical system ? in order to be effective. Finally, expertise from a variety of scientific and technical disciplines must be incorporated at all stages of program design and implementation.

Clearly, error in medicine (as in any complex system) involves understanding how people perform, how people think, how people communicate with one another, and how people interact with technology in complex organizational systems. So a systems approach to understanding both safety and error involves multiple domains within scientific psychology, and we look forward to bringing that perspective to light in developing a useful response to the IOM report. If you haven't already reviewed the National Patient Safety Foundation report entitled "A Tale of Two Stories: Contrasting Views of Patient Safety", you can read it on-line at http://www.npsf.org/exec/report.html."

Root Cause Analysis

According to a report written by Heidi Wald, MD, University of Pennsylvania School of Medicine and Kaveh G. Shojania, MD, University of California, San Francisco School of Medicine:

"Historically, medicine has relied heavily on quantitative approaches for quality improvement and error reduction. For instance, the US Food and Drug Administration (FDA) has collected data on major transfusion errors since the mid-1970s. Using the statistical power of these nationwide data, the most common types of errors have been periodically reviewed and systems improvements recommended.

These epidemiologic techniques are suited to complications that occur with reasonable frequency, but not for rare (but nonetheless important) errors. Outside of medicine, high-risk industries have developed techniques to address major accidents. Clearly the nuclear power industry cannot wait for several Three Mile Island-type events to occur in order to conduct valid analyses to determine the likely causes.

A retrospective approach to error analysis, called root cause analysis (RCA), is widely applied to investigate major industrial accidents. RCA has its foundations in industrial psychology and human factors engineering. Many experts have championed it for the investigation of sentinel events in medicine. In 1997, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) mandated the use of RCA in the investigation of sentinel events in accredited hospitals.

The most commonly cited taxonomy of human error in the medical literature is based on the work of James Reason. Reason describes 2 major categories of error: active error, which generally occurs at the point of human interface with a complex system, and latent error, which represents failures of system design. RCA is generally employed to uncover latent errors underlying a sentinel event.

RCA provides a structured and process-focused framework with which to approach sentinel event analysis. Its cardinal tenet is to avoid the pervasive and counterproductive culture of individual blame. Systems and organizational issues can be identified and addressed, and active errors are acknowledged. Systematic application of RCA may uncover common root causes that link a disparate collection of accidents (i.e., a variety of serious adverse events occurring at shift change). Careful analysis may suggest system changes designed to prevent future incidents.

Despite these intriguing qualities, RCA has significant methodologic limitations. RCAs are in essence uncontrolled case studies. As the occurrence of accidents is highly unpredictable, it is impossible to know if the root cause established by the analysis is the cause of the accident. In addition, RCAs may be tainted by hindsight bias. Other biases stem from how deeply the causes are probed and influenced by the prevailing concerns of the day. The fact that technological failures (device malfunction), which previously represented the focus of most accident analyses, have been supplanted by staffing issues, management failures, and information systems problems may be an example of the latter bias. Finally, RCAs are time-consuming and labor intensive.

Despite legitimate concerns about the place of RCA in medical error reduction, the JCAHO mandate ensures that RCA will be widely used to analyze sentinel events. Qualitative methods such as RCA should be used to supplement quantitative methods, to generate new hypotheses, and to examine events not amenable to quantitative methods (for example, those that occur rarely). As such, its credibility as a research tool should be judged by the standards appropriate for qualitative research, not quantitative. Yet, the outcomes and costs associated with RCA are largely unreported. This chapter reviews the small body of published literature regarding the use of RCA in the investigation of medical errors.

Practice Description

To be credible, RCA requires rigorous application of established qualitative techniques. Once a sentinel event has been identified for analysis (egg, a major chemotherapy dosing error, a case of wrong-site surgery, or major ABO incompatible transfusion reaction), a multidisciplinary team is assembled to direct the investigation. The members of this team should be trained in the techniques and goals of RCA, as the tendency to revert to personal biases is strong.

Multiple investigators allow triangulation or corroboration of major findings and increase the validity of the final results. Based on the concepts of active and latent error described above, accident analysis is generally broken down into the following steps:

1. *Data collection*: establishment of what happened through structured interviews, document review, and/or field observation. These data are used to generate a sequence or timeline of events preceeding and following the event.
2. *Data analysis*: an iterative process to examine the sequence of events generated above with the goals of determining the common underlying factors:
    i. Establishment of how the event happened by identification of active failures in the sequence.
    ii. Establishment of why the event happened through identification of latent failures in the sequence which are generalizable.

In order to ensure consideration of all potential root causes of error, one popular conceptual framework for contributing factors has been proposed based on work by Reason. Several other frameworks also exist. The categories of factors influencing clinical practice include institutional/regulatory, organizational/management, work environment, team factors, staff factors, task factors, and patient characteristics. Each category can be expanded to provide more detail. A credible RCA considers root causes in all categories before rejecting a factor or category of factors as non-contributory. A standardized template in the form of a tree (or "Ishikawa") may help direct the process of identifying contributing factors, with such factors leading to the event grouped (on tree "roots") by category. Category labels may vary depending on the setting.

At the conclusion of the RCA, the team summarizes the underlying causes and their relative contributions, and begins to identify administrative and systems problems that might be candidates for redesign.

Prevalence and Severity of the Target Safety Problem

JCAHO's 6-year-old sentinel event database of voluntarily reported incidents (see Chapter 4) has captured a mere 1152 events, of which 62% occurred in general hospitals. Two-thirds of the events were self-reported by institutions, with the remainder coming from patient complaints, media stories and other sources. These statistics are clearly affected by underreporting and consist primarily of serious adverse events (76% of events reported resulted in patient deaths), not near misses. The number of sentinel events appropriate for RCA is likely to be orders of magnitude greater.

The selection of events for RCA may be crucial to its successful implementation on a regular basis. Clearly, it cannot be performed for every medical error. JCAHO provides guidance for hospitals about which events are considered "sentinel," but the decision to conduct RCA is at the discretion of the leadership of the organization.

If the number of events is large and homogeneous, many events can be excluded from analysis. In a transfusion medicine reporting system, all events were screened after initial report and entered in the database, but those not considered sufficiently unique did not undergo RCA.

Opportunities for Impact

While routine RCA of sentinel events is mandated, the degree to which hospitals carry out credible RCAs is unknown. Given the numerous demands on hospital administrators and clinical staff, it is likely that many hospitals fail to give this process a high profile, assigning the task to a few personnel with minimal training in RCA rather than involving trained leaders from all relevant departments. The degree of underreporting to JCAHO suggests that many hospitals are wary of probationary status and the legal implications of disclosure of sentinel events and the results of RCAs.

Study Designs

As RCA is a qualitative technique, most reports in the literature are case studies or case series of its application in medicine. There is little published literature that systematically evaluates the impact of formal RCA on error rates. The most rigorous study comes from a tertiary referral hospital in Texas that systematically applied RCA to all serious adverse drug events (ADEs) considered preventable. The time series contained background data during the initial implementation period of 12 months and a 17-month follow-up phase.

Study Outcomes

Published reports of the application of RCA in medicine generally present incident reporting rates, categories of active errors determined by the RCA, categories of root causes (latent errors) of the events, and suggested systems improvements. While these do not represent clinical outcomes, they are reasonable surrogates for evaluation. For instance, increased incident reporting rates may reflect an institution’s shift toward increased acceptance of quality improvement and organizational change.

Evidence for Effectiveness of the Practice

The Texas study revealed a 45% decrease in the rate of voluntarily reported serious ADEs between the study and follow-up periods (7.2 per 100,000 to 4.0 per 100,000 patient-days, $p<0.001$). Although there were no fatal ADEs in the follow-up period, the small number of mortalities in the baseline period resulted in extremely wide confidence intervals, so that comparing the mortality rates serves little purpose.

The authors of the Texas study attribute the decline in serious ADEs to the implementation of blame-free RCA, which prompted important leadership focus and policy changes related to safety issues. Other changes consisted of improvements in numerous aspects of the medication ordering and distribution processes (egg, the application of "forcing" and "constraining" functions that make it impossible to perform certain common errors), as well as more general changes in organizational features, such as staffing levels.

The significance of the decline in ADEs and its relationship to RCA in the Texas study is unclear. As the study followed a highly publicized, fatal ADE at the hospital, other cultural or systems changes may have contributed to the measured effect. The authors were unable to identify a control group, nor did they report data from serious ADEs in the year preceding the study. Their data may reflect underreporting, as there is no active surveillance for ADEs at the study hospital, leaving the authors to rely on voluntary reports. The decline in reported ADEs may actually call into question the robustness of their reporting system as other studies have found that instituting a blame-free system leads to large increases in event reporting. On the other hand, it seems unlikely that serious ADEs would be missed in a culture of heightened sensitivity to error.

In a separate report, an event reporting system for transfusion medicine was implemented at 2 blood centers and 2 transfusion services. Unique events were subjected to RCA, and all events were classified using a model adapted from the petrochemical industry. There were 503 events reported and 1238 root causes identified. Human failure accounted for 46% of causes, 27% were due to technical failures, and 27% were from organizational failures. This distribution was very similar to that seen in the petrochemical industry, perhaps an indication of the universality of causes of error in complex systems, regardless of industry.

Potential for Harm

The potential for harm with the use of RCA has received only passing mention in the literature, but might result from flawed analyses. The costs of pursuing absolute safety may be the implementation of increasingly complex and expensive safeguards, which in themselves are prone to systems failures. Ill-conceived RCAs which result in little effective systems improvement could also dampen enthusiasm for the entire quality improvement process. Arguably the harm caused by pursuit of incorrect root causes must be offset by the costs of not pursuing them at all.

Costs and Implementation

No estimates of costs of RCA have appeared in the literature, but as it is a labor-intensive process they are likely significant. Counterproductive cultural norms and medico-legal concerns similar to those seen in incident reporting may hinder implementation of RCA. The authors of the Texas study note the importance of clear expressions of administrative support for the process of blame-free RCA. Other studies note the receptiveness of respondents to blame-free investigation in the name of quality improvement, with one health system reporting a sustained 10-fold increase in reporting.

Comment

Root cause analyses systematically search out latent or system failures that underlie adverse events or near misses. They are limited by their retrospective and inherently speculative nature. There is insufficient evidence in the medical literature to support RCA as a proven patient safety practice, however it may represent an important qualitative tool that is complementary to other techniques employed in error reduction.

When applied appropriately, RCA may illuminate targets for change, and, in certain healthcare contexts, may generate testable hypotheses. The use of RCA merits more consideration, as it lends a formal structure to efforts to learn from past mistakes."

Theory behind RCA

According to a report entitled "Theory, Philosophy & Justification for Root Cause Analysis in Healthcare Organizations; *Why Bother*?"

The move to conduct root cause analysis is largely motivated by a growing recognition that the complexity of health care and health care delivery drives the incidence of adverse events uncomfortably and unacceptably high (Brennan *et al*, 1991). It has been estimated that adverse events occur in nearly 4% of hospitalizations, and that 16% of these lead to permanently disabling injuries or death, *e.g.*, sentinel events (Leape *et al*, 1991). It has been strongly argued that systems should be designed and health care professionals trained in methods that can improve patient safety by reducing hazards in health care (Cook and Woods, 1994). These issues combine to the extent that the JCAHO sentinel event policy has been described as a "lawsuit kit for attorneys" (Healthcare Risk Management, 1998). Consistent with this, the National Patient Safety Foundation (NPSF) maintains as its philosophy that most errors result from faulty systems rather than human error, *e.g.*, poorly designed processes that putting people in situations where errors are more likely to be made, those people are in essence "setup" to make errors for which they are not truly responsible.

Root cause analysis is a set of processes by which the underlying causes of adverse outcomes may be identified, with the goal in mind of preventing the reoccurrence of such events. The JCAHO has been explicit in defining the circumstances under which it requires that an root cause analysis be performed. We have, however, expanded that requirement within our practice to include a much broader scope of application. As an example, just within one large department for which we consulted, of the eight root cause analyses performed in 1998, only one was required by the current, published JCAHO Sentinel Event Policy. It is interesting to note that in terms of impact both on patient care and risk reduction (medical and economic), the root cause analysis required by JCAHO policy was among the least important. Needless to say, in order to resource and justify this expanded role of such analyses, it has become critical to identify an analytic process which is both efficient and effective. There have been several iterations of this process in our practice.

There are many different processes by which root cause analyses are performed; the engineering and industrial risk management literature is rife with arguments for and against the different approaches. It is not the purpose of this current writing to explore those differences. Comments pertinent to root cause analyses performed outside the health care industry will not distinguish among such approaches, but will address as much as possible those areas of commonality.

Root Cause Analysis in Health Care. One area of undisputed agreement is the observation that without strong support by upper management, root cause analyses will be performed in a perfunctory manner, with the singular purpose of meeting JCAHO regulatory requirements. In order to be effective, it must be accepted throughout the organization that the result of any given root cause analysis will be for improvement purposes, not for assignation of blame. This is in keeping with basic philosophy and tenet of continuous improvement in any area of endeavor. Because, however, root cause analysis has been accepted for some two decades in industries other than health care, the level of acceptance by management and personnel is much greater in those industries than can be reasonably expected in health care organizations. Similarly, the value in this analytic procedure is already accepted in other industries and government, being part and parcel of policies pertinent to Departments of Energy and Transportation, Nuclear Regulatory Commission, etc.

In the health care industry, root cause analysis is for the most part still viewed as yet another regulatory requirement which is neither value-added nor inexpensive. As a consequence, there is resistance to the performance of root cause analyses, resistance to learning about their performance, and lack of support at all levels for their effective usage. Lack of familiarity with pertinent literature from other industries compounds this systemic and generally passive-aggressive though at times actively aggressive attitude against root cause analysis in all its aspects. Regrettably, a passing familiarity with such literature will in fact increase the above resistance for two reasons.

Among health care administrators, the fact that it is not uncommon to spend substantial sums of money on a single root cause analysis raises the question of cost-effectiveness. Among health care providers the emphasis on human error in the root cause analysis literature of other industries raises the specter of blame, personal financial liability and the National Practitioner Databank, the last having no equivalent in other industries. Non-practitioners appear to have a tendency to underestimate the real impact of Databank reporting, as well as practitioners' emotional reactions to possibility of such reporting.

In sum, even if the risk manager and/or continuous improvement personnel at a given health care facility is convinced of the value of appropriately performed root cause analyses, there are very difficult obstacles to their effective and acceptable performance. Clearly, education throughout the health care organization is the optimal means by which to address these problems. Unfortunately, a few days of training is not sufficient to allow the attendees to become effective analysis team leaders or facilitators.

Books and manuals are not "living" guides, and with their use, translation to novel circumstance is extraordinarily difficult at best. Even if the analysis is conducted well, there are no standards for reporting, excepting perhaps the JCAHO form ("A Framework for Conducting a Root Cause Analysis In Response to a Sentinel Event"), which has been denigrated by every non-health care root cause analysis consultant with whom we have spoken, though for reasons remarkable for their inconsistency. Philosophy. There are critical philosophical differences in error reduction in other industries versus the health care industry.

These differences are not universal, but are very common. It has been our experience in discussions with root caused analysis experts in other industries that these differences are usually not appreciated, and in fact are at times considered to be antithetical to understanding of how an effective root cause analyses should be approached and conducted.

Significantly and similarly, we have seen no awareness of these differences in the literature pertaining to medical applications of root cause analysis. These philosophical differences have impact upon both the process and outcome of root cause analyses. We have identified three basic philosophical differences: issues of (1) blame, responsibility, and emphasis upon human error, (2) contributing versus causative factors, and, (3) degree of efficacy of corrective action or solutions. It is significant to note at this juncture that the experts with whom we spent the greatest amount of time discussing these and related issues were representatives of firms offering software designed to facilitate the root cause analysis process. It is largely their responses which are reflected in the following paragraphs, when expert's opinions are reported.

Regarding the first of these, we offer an assertion made by a prominent expert in root cause analysis outside of the health care arena, *"All sentinel events are the result of human errors that queue up in a particular sequence."* This writer has just guaranteed that any health care provider who reads this line will adamantly oppose any efforts to institute root cause analytic processes, and has therefore devastated any provider, any hospital counsel and any risk manager who is trying to gain the trust of his or her provider staff in such an endeavor. That the above quotation may or may not be accurate is irrelevant of the fact of its extremely negative emotional impact. That such comments are not uncommon in the root cause analysis literature means that very careful educational groundwork must be established prior to even encouraging health care personnel to read such literature; reality is not necessarily good if the recipient has not been adequately prepared to deal with it.

Going further, litigation for sentinel events may result from the root cause analysis in any industry if a plaintiff secures the product of such an analysis. Personal liability, however, is a far greater risk in the health care industry than in other industries. Issues of personal fear are correspondingly more prominent. Regarding the validity of the above assertion, it is interesting to note that Lucian L. Leape, MD, one of the foremost proponents of root cause analysis in medicine articulates his views thusly, *"Errors must be accepted as evidence of systems flaws, not character flaws"* (Leape, 1994, 1997). In the area of risk management in general (not limited to health care), James Reason asserts, "Indeed it could be argued that for certain complex, automated, well-defended systems, such as nuclear power plants, chemical process plants, modern commercial aircraft and various medical activities (emphasis added), organizational accidents are really the only kind left to happen. Such systems are largely proof against single failures, either human or technical.

Perhaps the greatest risk to these high technology systems is the insidious accumulation of latent failures, hidden behind computerized, "intelligent" interfaces, obscured by layers of management, or lost in the interstices between various specialized departments" (Reason, 1994).

Cook and Woods (1994) present four distinct reasons that failures or accidents are attributed to human error, especially in "complex systems" when in fact this largely constitutes a mis-attribution. Moray (1994) asserts that, *"...the systems of which humans are a part call forth errors from humans, not the other way around."* The foremost experts in risk management both within and without the health care industry emphasize system failures and system-driven errors over direct human error, and the philosophy guiding the process of root cause analysis, be it manual or automated, should reflect this emphasis.

Fears of criminal prosecution within the medical community are not without foundation. For example, in California, there are a handful of physicians facing second degree murder charges. "We need to make sure we find a way to prevent criminal prosecution of doctors from becoming a trend" says a California emergency physician is acquitted of murder charges and the possibility of 15 years to life in prison stemming from clinical decisions. Another doctor is standing trial for the death of a patient whose uterus he perforated during an abortion. (Prager, 1998). These are extreme examples of how a sentinel event with a tragically poor outcome can affect physicians. These are also examples of how the health care provider can be crushed by a system that points to human error without regard for considering systems and process deficiencies which can likely be identified and corrected with a thorough and credible root cause analysis (JCAHO, 1996).

In our research into root cause analysis in aviation, aerospace, transportation, electronics, security and energy industries, we found a nearly ubiquitous underlying assumption that causative factors had to be (1) necessary and sufficient, (2) necessary but not sufficient, or (3) irrelevant. The notion that a factor could be neither necessary nor sufficient to cause an adverse event but could still be of critical importance, seemed to be for the most part an alien and totally unacceptable concept. Even after presenting several actual circumstances in which several factors combined to contribute to a sentinel event, the concept of contributing but non-causative factors was rejected by several of the consultants with whom we spoke.

In fairness, however, this orientation was held most firmly by those practitioners who worked primarily within the confines of mathematical modeling as applied to root cause analysis. These tended to be those experts who were most data bound in their considerations, and their approaches emphasized the use of factor weighting, cut scores, etc. While their approaches have substantial advantage in terms of mathematical objectivity, flexibility in application to medical circumstance appeared to us to be limited. Of note is the fact that such rigidity in the rejection of contributing factors is directly contrary to views expressed by the most recognized experts in the fields of human behavior and risk management (Grandjean, 1980; Norman, 1981, 1988; Reason, 1990). As Reason eloquently describes, "... a detailed examination of the causes of these accidents reveals the insidious concatenation of often relatively banal factors, hardly significant in themselves, but devastating in their combination" (Reason, 1994).

Even less acceptable was the idea that a partial solution to an identified root cause was worth consideration and implementation. It appears to be assumed that any root cause can be either "corrected" or is "non-correctable," though the exact terminology varied with different consultant writers. Not only would we challenge this assumption in the health care arena, but we would likewise challenge the assumption in all areas of application. The difficulty appears to reside with the recognized requirement to monitor the results of any corrective action implemented.

With sentinel events, we are generally discussing very low frequency occurrences, which means rate of occurrence may be a relatively meaningless metric.

Every occurrence is critical, is sentinel, and anything less than a complete correction is less than adequate, *e.g.*, is perceived by certain of these consultants and possibly by both internal and external customers to be a failure. This perception belies, however, the underlying philosophy and guiding principles of continuous improvement; improvements are incremental and ongoing; perfection is targeted, but not attained. Regrettably, sentinel events occur with certain "acceptable" levels of incidence, though for most sentinel events which result in an actual adverse outcome, even one instance is indeed unacceptable. It is our goal to progressively reduce the frequency of all classes of adverse events, knowing that many will not be eliminated. This does not necessarily define a failure. We would argue that this applies within and outside the health care industry."

JCAHO on RCA

In a report entitled "Conducting a Cost-Effective Root Cause Analysis," the JCAHO indicates: "**Prelude:** If you have a sentinel event, and if you don't have a formal process already in place, you've essentially lost this battle already, because you're in the position of crisis functioning. Recoup by bearing in mind that the JCAHO is expecting a gradual development of processes for conducting root cause analyses, and is likely to be quite lenient in terms of the very short time parameter (45 days) which has been established in which to complete a "thorough and credible" root cause analysis. If you do not now have a sentinel event which you must investigate, establish your processes now, so that you are not functioning in a crisis mode when a sentinel or other adverse event occurs. As you do so you must keep in mind all the rather vague terms by which the JCAHO will judge the quality of your analyses. The JCAHO has not yet clearly articulated the criteria by which compliance with the Standards will be measured; this will be an iterative and evolutionary process, as with most JCAHO Standards. Do your practice root cause analyses on non-sentinel events; we conducted a root cause analysis for training purposes on a simple patient fall, with no real adverse outcome, but which ended saving the involved hospital approximately **$525,000 in direct costs**, and an unknown amount in prevented litigation incidents.

You should also be aware that the JCAHO Sentinel Event Policy has been labeled "a lawsuit kit for attorneys" (Healthcare Risk Management, July 1998)

We wish first to offer two descriptions of sentinel events.

The first is by a prominent software developer who is now marketing his non-medically oriented root cause analysis software to the health care industry: *"All sentinel events are the result of human errors that queue up in a particular sequence."*

The second is by Lucian Leape, an internationally known expert in quality management: ***"Errors must be accepted as system flaws, not character flaws."***

Clearly the philosophy articulated by the first of these is not consistent with performance improvement thinking in the health care arena. The root cause analysis methodology chosen must be carefully selected to reflect the philosophy espoused by the organization conducting the analysis.

In the remainder of this article, we offer a simplified representation of the process we use and teach in conducting root cause analyses. Our experience has been that following this process leads to effective problem identification and effective system improvements, with a much reduced resource expenditure. Our data indicates that using this process costs approximately that of other processes, with no apparent decrement in the "thoroughness and credibility" or value of the analysis.

If you are unclear about any of the steps outlined in the following, please do not hesitate to contact us via email.

Identify that an adverse event has occurred. You must have defined and disseminated information throughout your organization as to what constitutes both a sentinel event and an adverse event (yes, we advocate conducting root cause analyses on non-sentinel events) about which you wish to be notified, and you must designate who is to be notified and how. Make the notification simple. Use common sense. You want people to report to you, not to the newspaper or the JCAHO. THANK them for reporting the incident, make it easy to do, and make damned certain that they are included for feedback when the final results are announced.

By having a reporting process established, you also have defined to whom those reports go. That office, typically the office of the risk manager, then must determine *expeditiously* whether or not a root cause analysis is needed. This may involve a decision by a Risk Management Advisory Board or equivalent. That body can't just meet monthly....

If a root cause analysis is deemed appropriate:

- Appoint an RCA facilitator and an RCA team leader -- you need both

  Facilitator: the process expert on conducting a root cause analysis

  Team Leader: the content matter expert pertaining to the event

  Who's in charge? *The Facilitator*

- The team leader and facilitator sit down and identify:

  What data has to be acquired and/or safeguarded, who should do it and how: medical records, statements from personnel, maintenance records, instruction manuals, policy manuals, literature, etc.

  Who should be on the team? It is far better to be over-inclusive than under-inclusive. In point of fact, in our consultations we invite every person in the involved department(s) to every root cause analysis irrelevant of their involvement with the incident under analysis. There are two reasons:

  Everyone learns the process, and,

Some of the best ideas come from those not involved in the event.

- Notify each invited person to bring with them a written (preferably on disk) sequence of everything that they observed, every idea which has occurred to them.

- Establish the first meeting date and time. This is where we break with the JCAHO. The JCAHO manual suggests that everything gets done by the root cause analysis team. Our studies have shown that this will virtually guarantee your facility going into receivership; it simply costs too much. Therefore what is outlined here is the model which we use, teach and advocate. It should be mentioned at this juncture that the feedback received from JCAHO reviewers on the root cause analyses conducted using this approach have been very well received. The fact that facilities with which we consulted presented root cause analyses which were conducted on non-sentinel events amazed the reviewers. That they were done well impressed them even more.

This is our format. We feel that three and occasionally four meetings of no longer than two hours each are sufficient for a worthwhile root cause analysis, excluding additional time spent between those meetings. Schedule two hours each, the third may well be less and the fourth may not be needed, but typically allow a week between meetings.

- Start the first meeting; we prefer an active interplay between the facilitator and the team leader. Allow for brief introductions if there is anyone unknown. Always have a recorder to take notes (preferably not an active participant in the analysis). Always have one or more "white boards" and if possible have a computer with projector.

  Tell everyone why the group is meeting. "We are here to find out all we can about such and such an event; how it happened, how it might be prevented in the future." Emphasize that the purpose is not to find fault, but to prevent future mishaps. There will be some initial disbelief here -- tell the group that you expect that, and you just hope that they will come to trust the team and the process. We frequently give examples of RCA's in which it initially appeared that specific persons were at fault but that the analytic outcome demonstrated a series of system failures which were corrected without action against any person. We will commonly repeat the National Patient Safety Foundation's philosophy that *"...most errors result from faulty systems rather than human error ... that people are in essence 'set up' to make errors for which they are not truly responsible."* You want an example -- an incorrect medication order by a resident who has been on duty for 36 hours, to a nurse who is just finishing a double shift. Who's at fault? The exhausted resident and nurse? Or the system parameters, the process, which assigned those work schedules? Now we're looking at the distinction between a proximal cause and a root cause (or as we prefer, *root contributor* or *contributory factor*).

  Block off a part of the board as a 'parking lot' in which to write items that don't apply now, but which should not be forgotten.

Start by generating the sequence of events. In the event of an injection of KCl that sequence might cover only several hours, while with an inpatient suicide it might be months. Type this via computer projector on the screen so that it can be easily seen and modified. During this time, people will start suggesting causes, solutions, etc. Write them down in the parking lot, avoiding discussion of anything but the event sequence for now. Make the sequence detailed and complete, and continue until everyone is satisfied. This will typically take about one hour. Save it to disk.

Identify the immediate corrective actions which were taken at or near the time of the event. Save it to disk.

Now take a break -- though some teams will prefer to drive on, which should be allowed if that feeling is unanimous.

Have the team look at the sequence of events and mark every item which might in some way have contributed to the adverse event. If just one person thinks it should be marked, mark it.

Now go to traditional brainstorming with the marked items from the event sequence serving as a starting point, letting the group come up with any and all ideas about events, conditions or whatever which might in some way have contributed to (not caused) the adverse event under analysis. Use the parking lot when appropriate, to record ideas that are solutions, or incidental but interesting thoughts. We advise verbal brainstorming, since we have found that people tend to stimulate others' thoughts. Review the JCAHO manual (***"Conducting a Root Cause Analysis in Response to a Sentinel Event"***) wherein among other things you will find a list of possible contributors common in medically-related sentinel events. Use such items as prompts to stimulate the team's brainstorming efforts.

Use Barrier Identification (a simplified variant of barrier analysis) to identify those barriers which either failed to function or did not exist. Add these to the list of potentially contributory factors developed by brainstorming.

Now affinitize. Let the team eliminate duplications, combine items, and then form logical clusters from the brainstorm items. When everyone is reasonably satisfied with the affinitization or clustering process, the first meeting ends, with the second meeting typically scheduled for one week later.

- *During the intervening week*, the team leader and facilitator meet together and attempt to develop a "Contributory Factor Diagram" from the material generated by the team. This term does not appear in the literature -- but there are lots of terms that do. We use this label to emphasize that we wish to identify not just causes, but contributors to an adverse event. The diagram is nothing but a flowchart with all the lines eventually leading upwards to the adverse event. That's the top of the diagram. The second level is the names assigned to each cluster from the affinitization process your team went through. Under each cluster name, in parallel so that equal weighting is implied, lies every member of that cluster. Move clusters around, see if one subsumes another, etc. Play with the diagram. Needless to say, good flowcharting software is a great assist here (We use allCLEAR 4.5 by SPSS). Even try to re-affinitize the items, so long as you also retain an original version as your team left it. Take a look at each of those third tier items and ask the question "WHY?" or "HOW?" You may identify areas of insufficient data, or you may be able to place new items at the fourth, fifth or even sixth level.

Your goal is to go as far as possible with the facilitator and team leader asking the question "Why?" until it can no longer be meaningfully asked. Do this for every third tier item. Code each of the bottom items of every branch as "Insufficient Data", "Non-Contributory", or "Contributory Factor" and color/shape code those three categories.

Assign persons to get the missing data before the next team meeting.

- Start your next meeting, and ask for the team's input on your "Contributory Factor Diagram or Tree." Let them check for omissions, better organization and more logical flow. Let them generate alternatives. Have the team verify or dispute your categorization; see if they can ask the question "Why?" more or in different ways. Reach a consensus on the diagram. This will typically take approximately one hour. By the end of this time, there should be few or no Insufficient Data labels. Make certain that every factor labeled "Non-Correctable" is in fact so. Every "Contributory Factor" which has no lower-level derivatives is a root cause -- we just avoid that terminology for psychological and legal purposes.

  Examine the items you have identified as "Non-Contributory." In the most formal quality improvement sense, such items should not appear in your root cause analysis, since they are, as indicated, "Non-Contributory." In point of fact, certain of these items will be of such high visibility that you must mention them just so that reviewers, either internal or external (like JCAHO) know that they were considered. Prepare a list of such items. We frequently go so far as to retain them on the Contributory Factor Diagram labeled as "High-Visibility, Non-Contributory Factors."

You have just completed the root cause analysis proper -- Now for the action plan.

Have the team generate at least one corrective action or improvement for each "Contributory Factor." In some cases that action will be to recommend that hospital administration designate a working group to address a specific issue. But every "Contributory Factor" must have some corrective action associated with it.

Develop a root cause analysis reporting table or grid with columns for:

Contributory Factor,

Corrective Action,

Person(s) Responsible,

Action Due Date,

Measurement Technique,

Person(s) Responsible, and,

Follow-up Date.

The team may not be able to complete this grid in this meeting. If not, it becomes the task of the team facilitator and leader to do so to the best of their abilities, before the third meeting, one week hence, for review and further elaboration by the team.

- You are now ready for the third, and typically final meeting of the root cause analysis team.

  Present to the team the:

  Event Sequence,

  Contributory Factor Diagram, and,

  Root Cause Analysis Reporting Grid.

  Ask for feedback and changes, especially in the area of additional opportunities for improvement. Identify as a team who should receive copies of the entire work, and who is responsible to distributing those copies (typically the facilitator and team leader). At a minimum the communication in whole or part should include the heads of involved departments, all involved persons, the office of risk management and the office of continuous performance improvement (change names to suit your agency). Don't forget to at least discuss the findings with the person who reported the event.

  Address parking lot items if not already done. Terminate the team.

- It becomes the obligation of the continuous improvement office within each facility to monitor progress made in the corrective actions proposed, and in evaluating the measurements used to evaluate those improvements. That office must have established suitable processes to ensure that there is appropriate follow-through in accordance with the action plan.

Tool to Assist Organizations in the Completion of the Framework for Conducting a Root Cause Analysis

The JCAHO has published the following to help healthcare organizations conduct Root Cause Analysis (RCA):
"*Please note that the root cause analysis and action plan must show evidence of an analysis within the key components as outlined on the root cause analysis matrix for the specific type of event. An area on the matrix that may not have an identified process breakdown should still be summarized to determine that the component was evaluated.*

Brief description of event

Briefly summarize the circumstances surrounding the occurrence including the patient outcome (egg, death, loss of function).

Example: A thirty-six year old male admitted for left hernia repair on May 3, 2002. A right hernia incision was made when the surgeon realized the left side was to be performed. The right side was closed and the left hernia repair was completed.

Who participated in the analysis?

Please include a list of all team members that participated in the analysis by position and title. Please DO NOT include any names!

Example: Orthopedic Surgeon, Preadmission Nurse, Surgical Nurse, OR Technician, Medical-Surgical Nurse, etc.

When did the event occur?

Include the date and time the event took place.

Example: May 3, 2002 at 1:30 pm.

What area/service was impacted?

Include the full variety of services impacted by the event.

Example: This might include Operating Room, Nursing, Medical Staff, Recovery Room, and Preadmission Testing.

What are the steps in the process, as designed? (A Flow Diagram(s))
The organization may provide a Flow Diagram(s) of the steps in the process involving the occurrence. The organization may also list the key steps involved in the specific processes relating to the event.

Ask yourself, are all issues in the flow addressed? Suggestions are outlined below.

- Flow-chart the process as designed.
- Flow-chart the process as it is usually done.
- Flow-chart the process as it was done when the sentinel event occurred.
- Identify risk points and their contribution to the event.
- Flowchart the process with improvements.

Example: For wrong site surgery you may list specific steps within key processes such as Preadmission Assessment and Verification of Site, Site Verification and Assessment by Surgeon, Preanesthesia Assessment, Surgical Preparation and Verification of Site, etc.

What human factors were relevant to the event?

Evaluating the role of human performance factors that may have contributed to an error.

> **Example**: Fatigue of staff involved, personal problems where staff was not focused on job tasks, complex critical thinking requiring knowledge based decisions, not following documented policy and procedure, substance abuse, stress, boredom or staff rushing to complete the task.

How could equipment performance affect the outcome?

List the various equipment utilized for that patient during the health care stay. To assist in evaluating these processes consider the following:

Were bio-med checks done and up-to-date? Was the equipment where it was supposed to be? Why or why not? Was staff in-serviced on equipment? How long ago? How frequently is the equipment used? Were alarms, displays, and controls identifiable and/or operating properly? Is the equipment set-up and performing in accordance with the manufacturer's recommendations? Were their equipment recalls that were not addressed? Was equipment designed to accomplish its intended purpose? Were equipment parts defective? Was there a report to another agency regarding equipment defect (FDA, etc)?

> Example**: The PCA pump had not had the scheduled preventive maintenance check completed. The equipment was not functioning properly but the policy for marking defective equipment was not followed. The PCA pump was put into the wrong storage area, along with properly functioning equipment, without posting a sign indicating the equipment was broken. The equipment was then accessed for use on the patient.**

What controllable factors directly affected the outcome?
Identify factors that may have contributed to the event that the organization has the ability to change by making process improvement changes.

> Example**: Site was marked and the prep scrub washed off the marking prior to site verification. Site verification did not occur with all involved, per organizational P&P (physician, nurse, anesthesiologist).**

Where there uncontrollable external factors?
Uncontrollable external factors are those factors that the organization cannot change that contribute to a breakdown in internal processes. An organization should not be willing to assign many issues to this category. Although a factor may be beyond the organization's control, the organization may be able to minimize the factor's effect on patients.

Example**: A hospital may not have control or be able to prevent circumstances that cause a power outage such as lightning striking or flooding, but it can plan for these occurrences and be prepared to generate back-up emergency power. Or, a power outage may be due to a car hitting an electrical pole outside the hospital and the organization has placed warning signs with blinking lights, which are located before the pole.**

What other areas or services are impacted?

List all other areas that have the potential for a similar event to occur. This will assist in implementing risk reduction strategies in other pertinent high-risk areas.

Example**: A wrong site surgery occurred in the main Operating Room. A root cause analysis was conducted and various opportunities for improvements were implemented. The Endoscopy area, Emergency room and any other area where a procedure is performed may be able to incorporate the recommendations for improvements to proactively prevent a similar occurrence.**

To what degree is staff properly qualified and currently competent for their responsibilities?

Include all staff present, not just those that were determined to be involved with the event. Do not overlook physicians and allied health practioners/mid levels. Determine if staff was formally trained to perform the specific duties or tasks involved in the event. Was the training adequate? Was staff qualified to use the equipment? Were competencies documented? Had procedures and equipment been reviewed to ensure a good match between people and tasks performed? Was there agency staff that may not have been familiar with procedures/equipment? Was float staff from another area assisting with lack of orientation to the unit they floated to? Was the individual new and performing a function that they were not oriented/trained/competent in performing? Was staff oriented to the organization and department specific policies/procedures?

Surgery – The surgeon had performed 123 of the same type of procedures with a complication rate of .01 in both 2000 and 2001. Board certified. Mentor to six residents within the past two years. The three-year resident had completed five of these procedures under the attending surgeon with no complication rate. The RN who pre-operatively prepped and assessed the patient had five years of surgical experience within the orthopedic unit and twelve years in general surgery. CEUs as required by state (fifteen per year) were completed. Ten CEUs were in the orthopedic arena. Renewed CPR within the last three months, and so on for the other staff present.

Example: Physicians involved were appropriately privileged and credentialed. All required individuals (egg, RNs, RRT, LPN) are licensed and competent based upon previous evaluations and skill requirements. Agency and float staff has been appropriately oriented to the department/organization and do not have any performance issues.

How did actual staffing compare with ideal levels?

Was there appropriate staffing at the time of the event to address the required workload? Keep in mind if it was a weekend, change of shift, holiday, break time.
Document the actual staffing in area of occurrence versus planned staffing according to the staffing model. Explain any variation; higher or lower staffing.

> **Example**: The staffing model for 26 patients required four RNs, one Patient care assistant, and one unit clerk. Actual staffing included four RNs, two Patient Care Assistants and one unit clerk. Actual staffing exceeded the required numbers. However, three of the four RNs were participating in a staff meeting at the time of the event.

What are the plans for dealing with contingencies what would reduce effective staffing levels?

Summarize current plans in place to deal with staffing deficiencies.

> **Example**: Plans are in place to use agency nurses, contact part time staff for extra hours, utilize critical care nurses for overtime. Surgery cancelled all elective procedures and all other procedures are prioritized according to protocol. Beds are closed when there is not enough staff (Military).

How has staff performance in the relevant processes been assessed? When was this last performed?
Consider staff performance relative to the specific processes associated with the event.

> Example**: An agency nurse was assigned to the patient and had not been oriented to the department policy and procedure for marking the correct body site prior to surgery. A locum tenum was assigned to the ER and had not been oriented to the medical staff manual (MS Bylaws - R&Rs). A PA was functioning outside of his/her defined scope of practice. What did the daily assignment reflect? Was staff assigned according to their level of competency?**

How can orientation and in-service training be improved?
Was all staff oriented to the job responsibilities, organization, and policies and procedures regarding safety, security, hazardous materials, emergency, equipment, life-safety, treatments, and procedures? Are policies revised/updated, evidence based, and readily available? Have policies or procedures changed without providing additional training? Was a new policy developed and staff training

conducted? Do float staff or agency staff receives training within the areas they are assigned? Is this documented?

> Example**:** A policy change regarding the requirements for use of the new IVAC pump had been implemented approximately six months prior to the event. A formal in-service training program had not been completed. The policy was posted for all staff to read and sign off. One staff member had not read the policy changes. The company representative left a business card for formal demonstration of the use of equipment but a date had not been secured to provide the demonstration. The skills checklist had not been revised to incorporate the use of this piece of equipment.

To what degree is all information available when needed?
Was information from various patient assessments completed, shared, and accessed by members of the treatment team as required by policy? Was the patient correctly identified? Was the documentation clear and did it provide an adequate summary of the patient's condition, treatment, and response to treatment? Was the level of automation appropriate? Identify what information systems were utilized during patient care.

Examples**:**

- **No instruction for use of neonatal ambu bag available on code cart or med room.**
- **No policy and procedure for pump settings.**
- **Transfer form reported at risk for falls. Notification missing on chart.**
- **No allergies noted on chart.**

To what degree is communication among participants adequate?
Look at this content to cover verbal and lack of verbal/written communication(s).

- Physician to….
- Nurse to….
- Tech to….
- Pharmacist to….
- Hierarchical issues….
- Cultural issues….

And any other combination you can find during your investigation.

> Example**:** Respiratory Therapist did not communicate their unfamiliarity with the equipment to supervisor prior to patient care. Why? Drill down.

Was communication of key information completed in a timely manner? Was there a misunderstanding of information shared based on a language barrier, abbreviations, terminology, etc.? Was shift-to-shift or unit-to-unit communication completed properly? Were there adequate policies and procedures in place to describe what is required?
Is patient/family/significant other involved when needed in communication of information?

Was adequate information communicated when a patient transferred from one area to another and was this communication of essential information documented?(Hemodynamics, orders, medications, labs, etc.)

To what degree was the physical environment appropriate for the processes being carried out?

Look closely at the environment the patient was in or was transferred to/from. Spaces, privacy, safety, and ease of access are a few items to consider. Was work performed under adverse conditions (hot, humid, improper lighting, cramped, noise, construction projects)? Had there been environmental risk assessments conducted? Did the work environment meet current codes, specifications, and regulations? Was the work environment appropriate to support the function it was being used for?

> Example**:** Eight surgical suites have the head of the table facing north and the 9th suite has the head of the bed facing south. Would redesign reduce the risk of wrong side surgery? If a patient committed suicide by hanging a sheet from the top of the bathroom door, do you remove **several inches off** the door? Drill down how did the patient obtain the sheet? Did patients have open access to the sheets?

What emergency and failure mode responses have been planned and tested?
Had appropriate safety evaluations and disaster drills been conducted? Had provisions been planned and available to support a breakdown in operations?

> Example: Emergency generators are routinely tested monthly with a full load. The generators had performed without problem at the most recent check, approximately three weeks prior to the failure. At that point, generator # 2 had recorded just 554 hours of use, in an estimated life of 44,000 hours. It was later identified that firing up the generators for their monthly checks ages them more rapidly than regular use.

To what degree is the culture conducive to risk identification and reduction?

Did the overall culture of the facility encourage or welcome change, suggestions, and warnings from staff regarding risky situations or problematic areas?
Does management establish methods to identify areas of risk or access employee suggestions for change? Are changes implemented in a timely manner?

> Example**: Members of the management team, including the CEO, participate in attending meetings related to serious adverse events. A confidential suggestion box and hotline have been established to report high-risk issues and each of these are read and evaluated by the management team. Actions are taken on a regular basis.**

What are the barriers to communication of potential risk factors?

What is your organization doing to break down barriers to effect change? Has the organization identified barriers to effective communication among caregivers? If there are no barriers, what have you done and how do you know it has been successful? Be specific.

Example**: Nurse may have fear of retribution regarding the severance of their relationship with medical staff if the chain of communication policy was implemented and they follow the next level in command.**

To what degree is the prevention of adverse outcomes communicated as a high priority?
Explain leadership's role and how it is put into practice, provide examples.

Example: Timely response to an adverse outcome is one of the organization's strategic goals. Disclosure of "unanticipated outcomes policy" has been written and the responsible licensed independent practitioner (LIP) or designee informs the patient/family about these outcomes of care.

What can be done to protect against the effects of uncontrollable factors?
When looking at uncontrollable factors review the system the patient went through.

Example**:**

- **Power failure from thunderstorm.**
- **EMTs arrive at the wrong door.**
- **Patient denies substance abuse.**
- **Physician had a flat tire.**

After listing examples, drill down further on each one and determine what action could be put in place to prevent the event or offer other alternative for action.
Was there a literature search done?

List all sources of literature accessed to complete the analysis and action plan. Literature may be accessed to assist in analyzing the event to determine process breakdowns and/or when developing actions once the root causes have been identified to assist in developing best practice recommendations for changing current practice.

NOTE: Getting to the root cause of a sentinel event involves asking "Why?" and then exploring the ramifications of the response.

Action Plan Suggestions
A detailed risk reduction strategy must be stated for each root cause identified. If a risk reduction is not warranted for the identified cause, an explanation is required. A risk reduction plan may also be developed for all other areas identified as opportunities for improvement that were identified in the analysis but may not be considered root causes. The following components must be addressed:

Risk reduction strategy, person responsible for implementation, date of implementation, and measures of effectiveness. The measures of effectiveness are the same as a performance indicator. They should include anticipated outcome and measure whether or not the action taken was effective.

Your organization may use any format to outline the action plan, such as a gantt chart, providing the following elements are addressed.

Example: The action plan can be set up into the following columns to assure covering all components:

Root Cause(s)/Opportunity for Improvement(s)	Risk reduction Strategy	Person(s) Responsible for Implementation	Date of Implementation	Measurement Strategy
Communication Among Staff Members	Revise site verification policy and procedure to include immediate time out verification of site prior to procedure with both attending surgeon and staff participation. 1. Identify all policies and procedures requiring changes and make revisions 2. Present revised policies and procedures for approval to Nursing Policy and Procedure Committee and Department of Surgery Medical Staff Committee 3. Educate staff through OR staff and Medical Staff inservices and communicatio n in Medical Staff bulletin 4. Incorporate education process into both new employee/phys ician and agency orientation 5. Complete data collection monitoring process for minimally six months.	Manager of Operating Room Manager of Operating Room and Chair for Nursing policy and procedure committee. OR Manager/Chair of Dept. of Surgery OR Manager/Chairperson of Dept. of Surgery OR Manager/ Chair of Dept of Surgery OR Manager	Sept 2002 Sept/Oct 2002 Nov 2002 Nov/Dec 2002 Nov/Dec 2002 Jan-June 2002	OR manager or designee will directly observe 30 cases per month to determine compliance with physician and OR staff completing time out verification of site prior to procedure in accordance with policy revisions. 100% compliance in all observed cases is expected. The % compliance will be reported to QI/PI Committee every month and addressed in 6 month written progress report to JCAHO.

Root Cause(s)/Opportunity for Improvement(s):
Highlight and summarize the root cause(s)/ Opportunity for Improvement(s) Issue identified during the root cause analysis.

Risk Reduction Strategy:
Outline in detail the action plan steps taken to promote change. Be specific. If you change a policy and procedure, summarize the change that you are making. Outline how you are going to implement the policy and procedure (e.g., educate staff, perform post test for staff, etc.).

Person(s) Responsible for Implementation:
Identify by title the individual responsible for implementing the particular risk reduction step.

Date of implementation:
Outline the anticipated date of completion of each identified step. Outline the actual completion date for steps already completed.

Measurement Strategies/Measures of Effectiveness:
Outline the plan for measuring the effectiveness of each risk reduction strategy.

- **Indicators must be objective, measurable, and quantifiable. (Use outcome based measurements whenever possible)**
- **Measures of effectiveness need to have the data collection methodology outlined.**
- **Using a random sample? Define random.**
- **Give sample size and method of collecting.**
- **Are you determining effectiveness by observation? Pre-test/post-test? Pilot test? Audit tool? Explain.**
- **Set a target range that reflects the desired range of performance for each indicator**

Examples of Measurement Strategies:

- **Following a policy and procedure change, all nursing staff will demonstrate competency by passing posttest with score of 90% or higher and appropriately demonstrate 1 IV insertion.**
- **Individual physician complication rates for central catheter insertions will be less than 1%.**
- **15 patients per day entering the ER, 3 per shift will be evaluated from time entering facility until time to treatment to determine average ER waiting times. All expected waiting times should be within 5 minutes for emergent patients and less than 3 hours for non-emergent patients. (This example is not based on any national standards).**
- **Falls per 1000 patient days will be less than 2 per month**

- **Patient Satisfaction with pain management will be evidenced by level of 4 or above on Likert scale.**

External comparisons may be used to develop indicator data and target measures. Sources for external comparison data are performance measurement systems, professional organizations or societies and research articles.

All risk reduction measurement strategies will be evaluated and reported in the required 6 month written progress report following the approval of the RCA and action plan. Each organization will provide JCAHO with the actual results of data collection studies planned in the action plan."

Root Cause Analysis Matrix

The JCAHO has also provided organizations with a matrix to assist them in conducting root cause analysis:

"Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events - June 2002

Detailed inquiry into these areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	Suicide (24° care)	Med. Error	Proced. Cmplic.	Wrong site surg.	Treatment delay	Restraint death	Elopement death	Assault / rape/ hom.	Transfusion death	Infant abduction
Behavioral assessment process [1]	X					X	X	X		
Physical assessment process [2]	X		**X**	X	**X**	X	X			
Patient identification process		X		X					X	
Patient observation procedures	X					X	X	X	X	
Care planning process	X		X			X	X			
Continuum of care	**X**				**X**	**X**				
Staffing levels	X	X	X	X	X	X	X	X	X	X
Orientation & training of staff	X	X	X	X	X	X	X	X	X	X
Competency assessment / credentialing	X	X	X		X	X	X	X	X	X
		X	X							

Supervision of staff [3]					x	X			X	
Communication with patient/family	X			X	X	X	X			X
Communication among staff members	X	X	X	X	X	X			X	X
Availability of information	X	X	X	X	X	X			X	
Adequacy of technological support		X	X							
Equipment maintenance / management		X	X			X				
Physical environment [4]	X	X	X				X	X	X	X
Security systems and processes	X						X	X		X
Control of medications: storage/access		X							X	
Labeling of medication		X							X	

Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).

1. Includes search for contraband.
2. Includes supervision of physicians-in-training.
3. Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions."

Forms for RCA

The Commission has also published forms to help organizations conduct root cause analysis:

Level of Analysis		**Questions**	**Findings**	**Root Cause?**	**Ask "Why?"**	**Take Action**
What happened?	Sentinel Event	What are the details of the event? (Brief description)				
		When did the event occur? (Date, day of week, time)				
		What area/service was impacted?				
Why did it happen?	The process or activity in which the event occurred.	What are the steps in the process, as designed? (A flow diagram may be helpful here)				
What were the most proximate factors?		What steps were involved in (contributed to) the event?				
(Typically "special cause" variation)	Human factors	What human factors were relevant to the outcome?				
	Equipment factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors	What factors directly affected the outcome?				
	Uncontrollable external factors	Are they truly beyond the organization's control?				
	Other	Are there any other factors that have directly influenced this outcome?				

		What other areas or services are impacted				

This template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for "root cause" and risk reduction.

As an aid to avoiding "loose ends," the three columns on the right are provided to be checked off for later reference:

- "Root cause?" should be answered "yes" of "No" for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a "Why?" question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
- "Ask 'Why?" should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn't occur when it should have) – in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a "Why?" question. It is expected that any significant findings that are not identified as root causes themselves have "roots".
- "Take action?" should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the "Take Action?" column for each of the findings that requires an action.

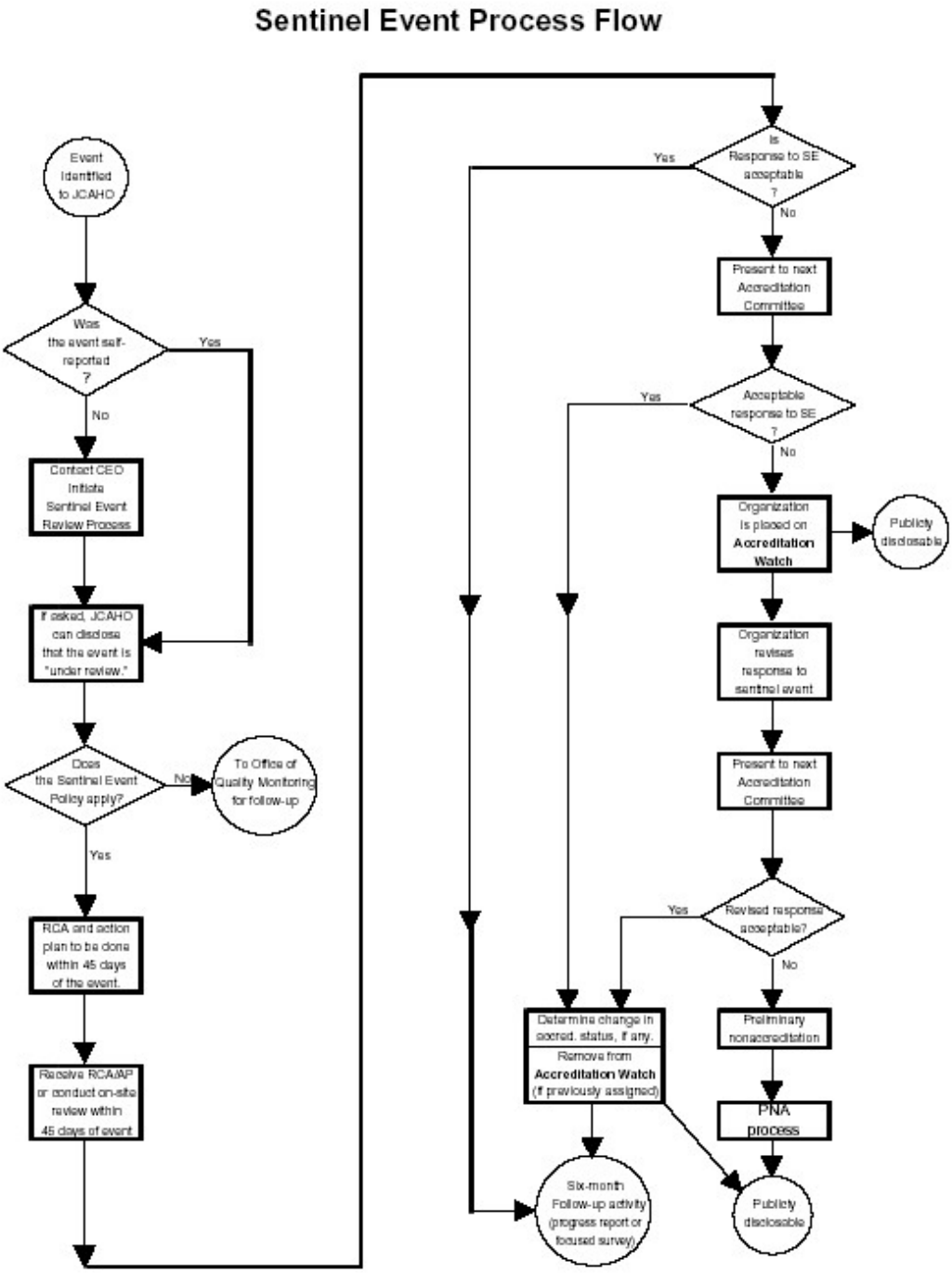
Level of Analysis		**Questions**	**Findings**
Why did that happen? What systems and processes underlie those proximate factors? (Common cause variation here may lead to special cause variation in dependent processes)	Human Resources issues	To what degree are staff properly qualified and currently competent for their responsibilities?	
		How did actual staffing compare with ideal levels?	
		What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?	
		To what degree is staff performance in the operant process(es) addressed?	
Level of Analysis		**Questions**	**Findings**
		How can orientation and in-service training be improved?	
	Information management issues	To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous?	

		To what degree is communication among participants adequate?	
	Environmental management issues	To what degree was the physical environment appropriate for the processes being carried out?	
		What systems are in place to identify environmental risks?	
		What emergency and failure-mode responses have been planned and tested?	
	Leadership issues: - Corporate culture	To what degree is the culture conducive to risk identification and reduction?	
	- Encouragement of communication	What are the barriers to communication of potential risk factors?	
	- Clear communication of priorities	To what degree is the prevention of adverse outcomes communicated as a high priority? How?	
	Uncontrollable factors	What can be done to protect against the effects of these uncontrollable factors?	

Action Plan	**Risk Reduction Strategies**	**Measures of Effectiveness**
For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date and associated measure of effectiveness. OR. …	**Action Item #1:**	
If after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.	**Action Item #2:**	
Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.	**Action Item #3:**	
Consider whether pilot testing of a planned improvement should be conducted.	**Action Item #4:**	
Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.	**Action Item #5:**	
	Action Item #6:	

	Action Item #7:	
	Action Item #8:	
Cite any books or journal articles that were considered in developing this analysis and action plan:		

For dealing with Sentinel events, the commission has published a flow chart:



Summary
We hope you have benefited from this review of what has made the American healthcare system become so focused on preventing/reducing the incidence of medical errors. You should now have a good idea of the scope of the problem, and what can be done to minimize the types of errors that can occur. While W. Edwards Deming's original work was focused on improving performance in "industry," the healthcare field, spearheaded by the JCAHO, has taken giant steps to adopt his principles to caring for patients. We will end this course with a look at just Deming's principles were:

The following is excerpted from Chapter 2 of **Out of the Crisis** by W. Edwards Deming.

1. Create constancy of purpose toward improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.
2. Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.
3. Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
4. End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
6. Institute training on the job.
7. Institute leadership (see Point 12 and Ch. 8). The aim of supervision should be to help people and machines and gadgets to do a better job. Supervision of management is in need of overhaul as well as supervision of production workers.
8. Drive out fear, so that everyone may work effectively for the company (see Ch. 3).
9. Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and in use that may be encountered with the product or service.
10. Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.
11. a. Eliminate work standards (quotas) on the factory floor. Substitute leadership.

    b. Eliminate management by objective. Eliminate management by numbers, numerical goals. Substitute leadership.

12. a. Remove barriers that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality.

b. Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means, *inter alia*, abolishment of the annual merit rating and of management by objective (see Ch. 3).

13. Institute a vigorous program of education and self-improvement.
14. Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job.

Sentinel Event Glossary of Terms

Accreditation Watch An attribute of an organization's Joint Commission accreditation status. A health care organization is placed on Accreditation Watch when a reviewable sentinel event has occurred and has come to the Joint Commission's attention, and a thorough and credible root cause analysis of the sentinel event and action plan have not been completed within a specified time frame.

Action plan The product of the root cause analysis which identifies the strategies that an organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

Active failure An error which is precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses.

Adverse drug event (adverse drug error) Any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (for example, dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.

Adverse drug reaction (ADR) An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.

Adverse event An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.

Aggregate data Data collected and reported by organizations as a sum or total over a given time period, for example, monthly or quarterly.

Barrier analysis The study of the safeguards that can prevent or mitigate (or could have prevented or mitigated) an unwanted event or occurrence. It offers a structured way to visualize the events related to system failure or the creation of a problem.

Benchmarking Continuous measurement of a process, product, or service compared to those of the toughest competitor, to those considered industry leaders, or to similar activities in the organization in order to find and implement ways to improve it. This is one of the foundations of both total quality management and continuous quality improvement. *Internal benchmarking* occurs when similar processes within the same organization are compared. *Competitive benchmarking* occurs when an organization's processes are compared with best practices within the industry. *Functional benchmarking* refers to benchmarking a similar function or process, such as scheduling, in another industry.

Causation The act by which an effect is produced. In epidemiology, the doctrine of causation is used to relate certain factors (predisposing, enabling, precipitating, or reinforcing factors) to disease occurrence. The doctrine of causation is also important in the fields of negligence and criminal law. *Synonym*: causality.

Change analysis A study of the differences between the expected and actual performance of a process. Change analysis involves determining the root cause of an event by examining the effects of change and identifying causes.

Circadian rhythm The rhythmic repetition of certain phenomena in living organisms at about the same time each day. Without cues provided by light, the human circadian cycle lasts 25.9 hours.

Clinical pathway A treatment regime, agreed upon by consensus, that includes all the elements of care, regardless of the effect on patient outcomes. It is a broader look at care and may include tests and x-rays that do not affect patient recovery. *Synonym*: clinical path.

Common-cause variation *See* variation.

Complication A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided. For instance, perforation, hemorrhage, bacteremia, and adverse reactions to medication (particularly in the elderly) are four complications of colonoscopy and its associated anesthesia and sedation. A complication may prolong an inpatient's length of stay or lead to other undesirable outcomes.

Coupled system A system which links two or more activities so that one process is dependent on another for completion. A system can be loosely or tightly coupled.

Error of commission An error which occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched for another patient.

Error of omission An error which occurs as a result of an action not taken, for example, when a delay in performing an indicated cesarean section results in a fetal death, when a nurse omits a dose of a medication that should be administered, or when a patient suicide is associated with a

lapse in carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes.

Fault tree analysis A systematic way of prospectively examining a design for possible ways in which failure can occur. The analysis considers the possible direct proximate causes that could lead to the event and seeks their origins. Once this is accomplished, ways to avoid these origins and causes must be identified.

Flow chart A pictorial summary that shows with symbols and words the steps, sequence, and relationship of the various operations involved in the performance of a function or a process. *Synonym*: flow diagram.

FMECA (failure mode, effect, and criticality analysis) A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur.

Iatrogenic 1. Resulting from the professional activities of physicians, or, more broadly, from the activities of health professionals. Originally applied to disorders induced in the patient by autosuggestion based on a physician's examination, manner, or discussion, the term is currently applied to any undesirable condition in a patient occurring as the result of treatment by a physician (or other health professional), especially to infections acquired by the patient during the course of treatment. **2.** Pertaining to an illness or injury resulting from a procedure, therapy, or other element of care.

Immediate cause *See* proximate cause.

Incident report The documentation for any unusual problem, incident, or other situation that is likely to lead to undesirable effects or that varies from established policies and procedures or practices. *Synonym*: occurrence report.

Indicator 1. A measure used to determine, over time, performance of functions, processes, and outcomes. **2.** A statistical value that provides an indication of the condition or direction over time of performance of a defined process or achievement of a defined outcome.

Latent failure An error which is precipitated by a consequence of management and organizational processes and poses the greatest danger to complex systems. Latent failures cannot be foreseen but, if detected, they can be corrected before they contribute to mishaps.

Local trigger An intrinsic defect or atypical condition that can create failures.

Malpractice Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position; often applied to physicians, dentists, lawyers, and public officers to denote negligent or unskillful performance of duties when professional skills are obligatory. Malpractice is a cause of action for which damages are allowed.

Negligence Failure to use such care as a reasonably prudent and careful person would use under similar circumstances.

Observation method An active method of error surveillance in which a trained observer watches the care delivery process.

Occurrence screening A system for concurrent or retrospective identification of adverse patient occurrences (APOs) through medical chart-based review according to objective screening criteria. Examples of criteria include admission for adverse results of outpatient management, readmission for complications, incomplete management of problems on previous hospitalization, or unplanned removal, injury, or repair of an organ or structure during surgery. Criteria are used organizationwide or adapted for departmental or topic-specific screening. Occurrence screening identifies about 80% to 85% of APOs. It will miss APOs that are not identifiable from the medical record.

Outcome The result of the performance (or nonperformance) of a function(s) or process(es).

Pareto chart A special form of vertical bar graph that displays information in such a way that priorities for process improvement can be established. It shows the relative importance of all the data and is used to direct efforts to the largest improvement opportunity by highlighting the "vital few" in contrast to the "many others."

Plan-do-study-act (PDSA) cycle A four-part method for discovering and correcting assignable causes to improve the quality of processes. *Synonyms*: Deming cycle; Shewhart cycle.

Process A goal-directed, interrelated series of actions, events, mechanisms, or steps.

Proximate cause An act or omission that naturally and directly produces a consequence. It is the superficial or obvious cause for an occurrence. Treating only the "symptoms," or the proximate special cause, may lead to some short-term improvements, but will not prevent the variation from recurring.

Retrospective review 1. A method of determining medical necessity or appropriate billing practice for services that have already been rendered. **2.** In behavioral health, evaluative activities conducted when an individual being served is no longer in active treatment.

Risk containment Immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices.

Risk management Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

Risk points Specific points in a process that are susceptible to error or system breakdown. They generally result from a flaw in the initial process design, a high degree of dependence on communication, non-standardized processes, and failure or absence of backup.

Root cause The most fundamental reason for the failure or inefficiency of a process.

Root cause analysis A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

Sentinel event An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

Special-cause variation *See* variation.

Surveillance Ongoing monitoring using methods distinguished by their practicability, uniformity, and rapidity, rather than by complete accuracy. The purpose of surveillance is to detect changes in trend or distribution to initiate investigative or control measures. *Active surveillance* is systematic and involves review of each case within a defined time frame. *Passive surveillance* is not systematic. Cases may be reported through written incident reports, verbal accounts, electronic transmission, or telephone hotlines, for example.

Underlying cause The systems or process cause that allow for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both.

Variation The differences in results obtained in measuring the same phenomenon more than once. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes. Excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. *Common-cause variation,* also called endogenous cause variation or systemic cause variation, in a process is due to the process itself and is produced by interactions of variables of that process is inherent in all processes, not a disturbance in the process. It can be removed only by making basic changes in the process. *Special-cause variation,* also called exogenous-cause variation or extrasystemic cause variation, in performance results from assignable causes. Special-cause variation is intermittent, unpredictable, and unstable. It is not inherently present in a system; rather, it arises from causes that are not part of the system as designed.

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A Tale of Two Stories: Contrasting Views of Patient Safety, National Health Care Safety Council of the National Patient Safety Foundation at the AMA

To Err Is Human: Building a Safer Health System (2000)
Institute of Medicine (IOM)

Agency for Health Care Research and Quality

Out of the Crisis by W. Edwards Deming

The final report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, 1998

Getting to the root cause, Raymond GAETA, Pres. Stanford Medical School

Tool to Assist Organizations in the Completion of the Framework for Conducting a Root Cause Analysis (JCAHO)

Root Cause Analysis Matrix (JCAHO)

National Rural Bioethics Project

Quality of Care: Patient Safety, WHO, 2001

Erring on the Side of Human Factors for Patient Safety, Geoff Mumford, PhD, Public Policy Office

National Patient Safety Foundation at the AMA

Web Sites for organizations associated with patient safety issues:

AARP
Agency for Healthcare Research and Quality (AHRQ)
American Association for the Advancement of Science (AAAS)
American Hospital Association (AHA)
American Medical Association (AMA)
American Nurses Association (ANA)
American Organization of Nurse Executives (AONE)
American Society for Healthcare Risk Management (ASHRM)
American Society of Health-System Pharmacists (ASHP)
American Society for Quality (ASQ)
Anesthesia Patient Safety Foundation
Annenberg Center for Health Sciences
Association of periOperative Registered Nurses (AORN)

Bridge Medical
Council for Public Interest in Anesthesia of the AANA (CPIA)
Department of Defense
Federation of American Hospitals FAH
FDA - Center for Drug Evaluation and Research (FDA)
Institute for Healthcare Improvement (IHI)
Institute for Safe Medication Practices (ISMP)
Joint Commission Resources (JCR)
Medical College of Wisconsin
Medical Group Management Association (MGMA)
National Association for Healthcare Quality (NAHQ)
National Center for Patient Safety (NCPS)
National Committee for Quality Assurance (NCQA)
National Consumers League (NCL)
National Health Council (NHC)
National Patient Safety Foundation (NPSF)
Patient Safety Officer Society (PSOS)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Physician Insurers Association of America (PIAA)
Premier, Inc
USP Center for the Advancement of Patient Safety
Veterans Health Administration National Center for Patient Safety
VHA Inc.

Examination

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. It has been estimated that for every dollar spent on ambulatory medications, _____ is spent to treat new health problems caused by the medication.

a. 20 cents
b. 50 cents
c. 75 cents
d. another dollar

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. _____ means that things that were not seen or understood at the time of the accident seem obvious in retrospect.

a. Monday morning quarterbacking
b. Mirror vision
c. Hindsight bias
d. The Looking Glass Syndrome

15. _____ occur at the level of the frontline operator, and their effects are felt almost immediately. This is sometimes called the sharp end.

a. Active errors
b. Latent errors
c. Accidents
d. Mistakes

16. _____ tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations.

a. Active errors
b. Latent errors
c. Accidents
d. Mistakes

17. According to the National Patient Safety Foundation, Safety is more than just the absence of errors. Safety has multiple dimensions, including._____

a. an outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context
b. a set of processes that identify, evaluate, and minimize hazards and are continuously improving
c. an outcome that is manifested by fewer medical errors and minimized risk or hazard
d. All of the above

18. _____ is typically conducted by an interdisciplinary team of the individuals who witnessed or were otherwise involved in the incident. The focus of the analysis is to learn what we can do better next time. Root-cause analyses demonstrate that certain actions, behaviors and attitudes can contribute to catastrophic results under certain conditions.

a. A sentinel event review
b. A root-cause analysis
c. A JCAHO case analysis
d. Human Factors analysis

19. _____ to error analysis, called root cause analysis (RCA), is widely applied to investigate major industrial accidents. RCA has its foundations in industrial psychology and human factors engineering. Many experts have championed it for the investigation of sentinel events in medicine.

a. A predictive approach
b. A mega-analysis approach
c. A retrospective approach
d. None of the above

20. To be credible, RCA requires rigorous application of _____. Once a sentinel event has been identified for analysis (egg, a major chemotherapy dosing error, a case of wrong-site surgery, or major ABO incompatible transfusion reaction), a multidisciplinary team is assembled to direct the investigation. The members of this team should be trained in the techniques and goals of RCA, as the tendency to revert to personal biases. is strong.

a. established qualitative techniques
b. new paradigms of quantitative methodologies
c. independent thought processes
d. variable matrix techniques

MEDICAL ETHICS IN HEALTHCARE

Ethics in health Care: Values, Obligations and Rights

In many ways, healthcare is an art and a scientific endeavor. Professionals try to act in ways that promotes the best health of the patient. But it is not always clear what is best for the patient. Thus at times choices have to be made that focus on what is best for the individual or their relatives, what medical records can be disclosed and what must be held in strictest confidentiality.

Healthcare Ethics is the study of moral issues that concern healthcare professionals in medicine, nursing, law, sociology, philosophy, and theology. It deals with healthcare values, obligations, rights and needs. Medical ethics in particular trace its roots to the old Greek Hippocratic Oath, which required physicians above all to "do no harm."

Learning OBJECTIVES

At the conclusion of this course participants will be able to:

1. Define ethics and medical ethics, and explain the sources of these ethics.
2. Identify how medical ethics impact patient care.
3. Recognize new medical ethics issues.
4. Apply ethical principles to help improve patient care.
5. List and explain the four underlying principles of bioethics.
6. Understand the relationship between laws, professional ethics, and professional codes such as the AMA Code of Ethics.

INTRODUCTION

In the last half of this century there have been momentous changes in every aspect of the practice of medicine. Even the very scope of the practice of medicine has been expanded. No longer limited to treatment and cure, advances in technology and pharmacology have brought about a rapidly increasing ability to intervene in life and death situations; to alter the physical and the emotional; and soon, to alter human genetics. As the healthcare professional is constantly being faced with new areas in which appropriate actions have to be defined, medical ethics must now race to keep up with medical advances.

This course is designed to provide an overview of the current state of medical ethics to better enable healthcare professionals to provide the best patient care possible. It will also provide tools for guidance in making ethical decisions regarding patient care and interactions with colleagues and facilities. It is divided into three sections:

1. History and background;
2. Deciding ethical questions;
3. Contemporary issues.

This course does not seek to provide definitive answers to what is and what is not ethical, because too many variables exist, including an individual's own religious and/or moral values. Instead, it provides information and direction so that the healthcare professional can determine his or her own standards of ethical behavior, for it is a determination that will have to be made over and over throughout one's medical career.

HISTORY AND BACKGROUND

Before we can explore medical ethics, we must first define ethics. No easy task, since from the beginning of the written word almost every philosopher who has addressed the topic has had a slightly different perspective on the subject.

According to Plato, ethics deals with the absolute good toward which all human activity should be directed. A couple of thousand years after Plato, Immanuel Kant attempted to separate ethics from the realm of religion with his categorical imperative, which he considered the ultimate moral imperative and the rational basis for all moral behavior. According to Kant, the categorical imperative was the natural law by which one should conduct life, despite personal impulses or desires. The British philosopher Bertrand Russell assumed a more cynical point of view with his definition of ethics:

> *"Ethics is in origin the art of recommending to others the sacrifices required for cooperation with oneself."*

For the physician, perhaps the best definition of ethics comes from the poet, W. H. Auden, who wrote in "A Certain World" in 1970 that: *"In order to be a good doctor a man must also have a good character, that is to say, whatever weaknesses and foibles he may have, he must love his fellow human beings in the concrete and desire their good before his own."*

Agreeing on a definition of ethics, however, is only the beginning of the journey. The next step is to determine what is and is not ethical behavior, which has been another source of discussion for centuries.

The Hippocratic Oath – which even today is revered by physicians – was conceived in about 400 BC. Around 1750 BC the Babylonian King, Hammurabi, established precise laws for how medicine was to be practiced as part of what became known as "The Code of Hammurabi." Ever since, the ethics governing the practice of medicine have continued to evolve.

Ethics vs. Laws

Ethics should not be confused with laws. A code of ethics is based on morality and standards rather than legislation. Black's Law Dictionary offers the following definition of ethics: "What is generally called the ethics of the profession is but a consensus of expert opinion as to the necessity of professional standards."

The Hippocratic Oath concerns ethical behavior. This behavior was considered so sacred, the oath was sworn to the god Apollo, the physician, and it states in part: *"I will follow that system of regimen which, according to my ability and my judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."*

The Code of Hammurabi, on the other hand, is a strict set of laws governing how much a physician will earn for his efforts, and what will happen if he fails. For example:

- **"Law #215:** If a physician make a large incision with an operating knife and cure it, or if he open a tumor (over the eye) with an operating knife, and saves the eye, he shall receive ten shekels in money."

- **"Law #218:** If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off."

It's fairly clear why elements of the Hippocratic Oath survived and Hammurabi's laws didn't.

The struggle to create standards for the practice of medicine has continued throughout the centuries and the lines between ethics and laws often blur.

The Evolution of Medical Ethics in the United States

In 1803, Sir Thomas Purcivel, British physician, philosopher and writer, created a code of ethics that became the foundation for the first American document designed to govern the practice of medicine in the United States. It was published in 1847 by the American Medical Association, which held its first meeting specifically to establish a code of medical ethics, and to create minimum requirements for medical education in training.

Since 1847 the code, which has become known as "The Principles of Medical Ethics," has evolved with the times, but the guiding principles remain the same. In 1957 a shorter version was adopted that eliminated some of the provisions that dealt more with matters of etiquette than matters of principle.

The preamble to the revised AMA Principles makes clear their intent:
"The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self.

The following principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician."

The American Osteopathic Association is also guided by an official Code of Ethics, which was most recently revised in 1985. Complete AMA and AOA codes are included in the appendices.

Most state medical associations, many healthcare facilities and even private practices also have published written codes of ethics, which further underscores how important it is to develop an understanding of at least the basic standards of acceptable conduct.

The World View

There are two important international documents that must be included in any study of medical ethics. The first is the "Declaration of Geneva," which was adopted by the General Assembly of the World Medical Association at a meeting in Geneva, Switzerland in 1948. This declaration, a copy of which is included in the Appendix, begins with the following statement:

> "At the time of being admitted as a member of the medical profession: I solemnly pledge myself to consecrate my life to the service of humanity."

A second crucial document, the "Declaration of Helsinki" was adopted by the World Medical Association in 1964 and sets forth ethical guidelines for human research. Its official title is "Recommendations Guiding Doctors in Clinical Research," and in its introduction it states:

> "Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries."

DECIDING ETHICAL QUESTIONS

The following section provides a model for healthcare professionals to use when faced with difficult ethical questions. At such times, it is appropriate to ask four questions to help determine whether or not an action is ethical, and should be taken. The first three of these questions were published in Kenneth Blanchard and Norman Vincent Peale's book, "The Power of Ethical Management." The fourth question will help healthcare professionals round out their examination of the difficult ethical questions they encounter. These questions should be given very careful consideration, and all four should be answered before any action is taken, because each can have an impact on the other.

The Questions

1. Is it legal?
2. Is it balanced?
3. How will it make me feel about myself?
4. Have my peers determined and published a standard of behavior?

Is it legal?

As we have discussed, being legal is not the same thing as being ethical; however, the consideration of whether or not an action is legal should be one of the first to be addressed. Consider the following situation:

A concerned mother brings her adolescent daughter in to see a plastic surgeon. The young girl has a huge, ugly nose that ruins her looks and is causing her to be teased at school. As a result she has become withdrawn, depressed and has made a serious attempt at suicide. The mother's health
insurer does not cover elective cosmetic surgery, nor does it provide mental health benefits.

Therefore, without a physical reason to do the surgery, the child will not be able to have her nose fixed. The girl does have a mild - very mild - deviated septum. The surgeon decides to "code" the condition so that the health insurer will pay. The young girl has a new, smaller nose and is much more attractive physically. Her confidence is given a giant boost and her self-esteem is on its way to being restored. Her suicidal tendencies have totally been eliminated.

In this situation the surgeon may have committed fraud in a strictly legal sense. At the same time, she has done what is best for her patient and has possibly saved her life. Though the doctor's choice may have been ethical, it could be questioned on legal grounds.

It is equally important to remember that just because an action is legal doesn't mean it's ethical. In some instances, a facility can legally refuse to treat a patient who has no health insurance, but is it ethical to deny treatment to a sick person?

This brings us to the next consideration. Is it balanced?

Is it Balanced?

Before any ethical decision can be made, one must consider both sides of the question. Referring to the rhinoplasty example, the physician weighed all the factors, which were:

- Without the surgery, the child would continue to deteriorate emotionally and mentally, and quite possibly commit suicide;
- The mother was not in a financial position to pay for the surgery;
- The physician was not in a financial position to perform the surgery on a pro bono basis;
- A real physical condition did exist that fell just short of being covered by the insurer.

In this instance, the physician felt that the result of "fudging" her diagnosis just slightly, which meant that the insurer would spend several thousand dollars they shouldn't have had to spend, tilted the balance toward performing the surgery because she truly believed it was a life or death decision.

Even in less grave situations, it is incumbent upon the physician or other healthcare provider to weigh all the options and make sure the final decision reached is fairly balanced. In the case cited, the physician felt her decision was balanced and therefore felt good about it, which is very important and is also the third question that must be considered, "How will it make me feel about myself?"

How Will it Make Me Feel About Myself?

Feeling good about oneself is paramount in all decisions. Not just in the short run, but for the long term. What seems like a good stopgap solution in the present might be setting up future difficulties. Additional considerations in answering this question that must be taken into account are:

- How will it affect my patient?
- How will it affect my peers and co-workers?
- Will it establish a pattern that will be hard to break in the future?
    - How would I feel about someone else who took the action or made the decision I am considering?

One key element to bear in mind when contemplating any situation which falls into a gray area is that you will have to live with whatever decision you make, and the possible ramifications of that decision. If in the rhinoplasty example the physician had not treated the patient, and the patient had subsequently made a successful suicide attempt, could she have had a clear conscience because she had done her job according to a strict application of the insurance company's rules? Instead of assuming the cost of the surgery herself, she passed it on to the insurer. Is being a sort of medical Robin Hood moral? Is it ethical? What about in a less grave situation?

For example, a man wants a complete medical check-up simply as a preventative measure, but his insurer doesn't cover annual medical check-ups for men in their 30's. The man wants to find a way to pass the expense on to his insurer. Would his physician be justified in recording in his medical record that the man came in with unexplained symptoms that required a complete physical? Could his physician feel good about passing along costs to the health insurer that could have been covered by the patient?

Again, these are significant considerations, which lead us to the final question, "Have my peers determined and published a standard of behavior?"

Have My Peers Determined and Published a Standard of Behavior?

Back in the 1800's, when the American Medical Association published its first code of ethics things were much more black and white then they are today. In fact, so many shades of gray now exist in the area of medical ethics that in 1997 the American Medical Association created an independent academy devoted solely to ethics. So, very often the answer to the question of whether or not there is a published standard of behavior is "maybe."

For example, at one time some managed care organizations included in their contracts with physicians either an explicit or implicit "gag" clause. Basically these clauses obligated the physician to withhold information from patients about treatment alternatives not covered by their health
plans. These clauses outraged the AMA. In 1996, its Council on Ethical and Judicial Affairs declared:

> "...the physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's managed care plan. Patients cannot be subject to making decisions with inadequate information. That would be an absolute violation of the informed consent requirements."

Gag clauses were also challenged in the courts and have subsequently started to disappear; however, at the time of their existence they created quite an ethical dilemma. The physician could sign a legally binding contract containing the gag clause, obligating himself to withhold treatment in some cases, or he could refuse and therefore not be able to treat patients covered by managed care providers. That option would limit his patient base, restricting his ability to practice medicine and earn an income. Or he could sign the contract and ignore the clause whenever he felt it necessary. Doing so would put him in legal and probably financial jeopardy, but it was the only way he could do the best for his patient. And the only way he could feel good about himself was to do his best for his patient.

As difficult as the topics explored in this section might seem, they pale in comparison to some of the more complex issues that have arisen as a result of the leaps and bounds made in medical technology in recent years. And for every advance there is an explosion of ethical questions, the answers to which can only be decided on a case-by-case basis.

Contemporary Issues

No area of medicine has been untouched by the swift advances made in this technological age. Diagnostic tools like MRI and the CAT scan enable a physician to make much more precise diagnoses. The laser has made it possible to treat conditions noninvasively that once required major surgery. New drugs with the promise of curing some cancers are on the near horizon.

For the most part, all of these advances have been greeted with enthusiasm. But technology has also created an incredible ethical morass in at least two areas: reproductive medicine, and the ability to sustain human life through artificial means. As technology progresses the questions become more difficult, and no hard and fast "one-size-fits-all" answers can be found.

The effects of technology on medical ethics have been so profound that an entirely new category has been created to encompass them - “Bioethics.”

The Rise of Bioethics

Until the end of the 18th century, when Jenner discovered that a vaccine using cowpox could prevent smallpox, the role of the physician was to ease the pain and suffering of a patient, and hopefully effect a cure. With continued advances in immunization, especially Pasteur’s discovery of
a rabies vaccine, and Salk’s polio vaccine, medicine made a steady march toward another important goal, prevention. These were all hailed as miracles of medicine, and generally received with favor.

Then in the 1950’s medicine took a sharp turn down an uncharted path that some equate with the road to an ethical Pandora’s box - the testing of an oral contraceptive.

The test was successful, and in 1960, Enovid 10 became the first commercially available birth control pill. For the first time in the history of medicine it was possible to artificially control a “natural” bodily function. This breakthrough was not greeted with widespread acceptance. The Roman Catholic Church responded by banning the use of oral contraceptives, a ban that is still in effect.

The moral questions posed by the use of oral contraceptives are definitely food for thought. Does humankind have the right to interfere in the natural order of life? Is the person who is not conceived potentially a genius, or another Ghandi?

The potentiality of “controlling human life” has created an ethical crisis that has yet to be resolved, and also spawned another equally sensitive controversy, “who determines what is natural?” The ethical dilemma of what is natural versus what is unnatural covers not only controlling life, but controlling death, and other debatable aspects of medicine that seem to expand exponentially as technology advances.

Does the medical profession assume the role of final determiner of the norm? Or should it be the general population? Or perhaps a “participatory patient democracy” should be created so that ethical questions regarding a certain area of medicine are decided only by those immediately affected. This is not simply a theoretical question, it is one that is being argued daily. An example is the controversy that has arisen over the use of implants.

Ethical Questions in the Use of Implants

The legal and ethical dispute over the use of silicone breast implants dominated the media during the 1980's. Not just regarding the health risks that seemed to be arising from the implants, but the ethical question of whether or not it was "right" to alter a woman's body by implanting an alien substance just to enhance her physical attributes. That raises another interesting ethical question:

- Should certain medical techniques only be used to correct a medical abnormality?

In other words, is a plastic surgeon being ethical when she performs a breast implant as part of breast reconstruction following a mastectomy, but unethical when she performs elective surgery to increase a patient's bust size? Is it morally right to perform rhinoplasty to repair a broken nose, but wrong to simply shorten a long nose, or remove a bump? And who decides?

Surprisingly, one of the most controversial examples of implant surgery has to do with a small device that was first introduced in the 1970's - the cochlear implant.

Cochlear Implants

The cochlear implant is a device made up of several electrodes that is surgically implanted in the cochlea, then connected to a transmitter coil that is placed under the skin and held in place by a magnet. The device has an earpiece microphone with two wires extending from it that are connected to the coil, and to a signal-processing component that can be worn in a pocket, or attached to a belt.

The implant works differently than a hearing aid, which simply amplifies sounds. It creates a sound, or electric signal, when the electrodes stimulate the cochlea. This signal requires "interpretation" so training and speech therapy are necessary to maximize the benefit of the device.

Proponents of the implant - who explain that the signals allow the user to hear cadence, and therefore learn to speak orally more clearly, and to improve lip-reading skills - believe this is a major step forward in enabling the hearing-impaired to lead more "normal" lives. However, there is a very vocal opposition to the implant, on moral as well as medical grounds. The moral questions are wide and varied, but the most ethically challenging is, "What's wrong with being deaf?"

To those in the hearing world, that may seem a ridiculous question. To never hear music, or birds singing, or another human voice seems cruel. But can one miss something one has never had? And by trying to "fix" a child who is non-hearing to make him/her more able to function in a hearing world, is that child instead being consigned to a sort of limbo? Neither part of the hearing or non-hearing community.

There is a very strong, viable non-hearing community which has fought for years against the stereotype of the old "deaf and dumb" label that for so many years created a general feeling that

those who could not hear were somehow less mentally capable—an assumption that has been proven over and over again to be totally without merit.

There is a fully accredited university that is entirely made up of non-hearing students. Non-hearing persons are able to live full, happy lives and to interact successfully in the mainstream of their communities. A few years ago, a deaf woman became Miss America.

The World Federation of the Deaf and other groups who support the existence of a separate Deaf culture maintains that surgically implanting a device into a child automatically labels him/her as "abnormal." Further, they feel it is an example of oppression of a minority by a majority. This is the extreme view, but many clinicians also question the use of the implant in young children, who cannot understand the possible long-term effects. Can a hearing parent understand the impact that the device might have on the child and his/her relationship to the deaf community? Can this device alienate the child from all avenues of "normalcy?" If the device is not implanted until a child is old enough to understand and make the decision personally, has a great disservice been done by slowing down and perhaps permanently retarding his/her ability to learn to speak orally? Just what constitutes "normal" anyway?

Those are all hard questions with no easy answers. As are the ethical questions constantly evolving in another surgical area - transplants.

Transplants

Medical transplants began with corneal transplants. In 1954 a kidney was successfully transplanted from one identical twin to another. The first successful liver transplant was performed by Dr. Thomas Starzel of the University of Colorado in 1967.

None of these important medical milestones was greeted with much negative reaction by the community at large. But in 1967, when another successful transplant was performed, this time by Dr. Christiaan Barnard in South Africa, it was cause for an outcry that in its extreme called Barnard another Dr. Frankenstein. He had transplanted a heart from a dead person into a 55 year old man named Louis Washkansky. Washkansky only lived 18 days, but the deed had been done and the alarm sounded. This was unnatural. This was desecration of the dead. What if a person wasn't really dead when you took the heart? Would doctors and nurses still try to save a patient whose heart could be used for transplant? This could lead us down the path of moral ruin!

Thirty years later, heart transplants are almost routine and commonplace, as are other organ transplantations. Many patients receive more than one organ at a time. Recently there has been a great deal of success transplanting sections of a lung or liver from a living parent into a child. The fears that were raised have mostly proved to have been hysterical reactions to new technology. Of course, there is a persistent "urban legend" surrounding organ transplantations that refuses to die,
perhaps because another technological marvel - the internet and e-mail - work so hard at keeping it alive. An E-mail chain letter surfaces every few months to warn of the horrors of travel,

because you might wake up to find yourself sitting in a tub of ice with one of your kidney's gone.

For the most part, the medical aspects of transplanting organs from one human being to another have become accepted practice, and legislation has been passed to help provide safeguards against abuse:

In 1968 the Uniform Anatomical Gift Act was passed which created the organ donor card, although even if a person signs the donor card the family must be consulted before organs are harvested. This act also prohibited the organ donor's attending physician from participating in the organ removal or transplantation.

In 1984 the National Organ Transplant Act passed. This act prohibited the sale of human organs, and created a national transplant network that would oversee the procurement and distribution of organs. In 1986 The United Network for Organ Sharing was awarded the contract to oversee the national transplant network.

The latest arena for ethical issues in transplantation has risen from a highly controversial area of research, xenografting - the transfer or transplantation of animal tissues and/or organs into a human body. The transplantation of certain cells from animals to humans has garnered some success, for example in the treatment of Parkinson's disease. Again, the ethical question of "what is natural?" surrounds an area of medical advancement. Is it unnatural to implant an organ from a lower species into a human being? Does transplanting an animal organ, or animal tissue, violate certain Judeo-Christian religious ethics? Is the religious ethic the only one that has moral authority?

Among animal rights activists there has been a general hue and cry that this is the greatest form of animal cruelty yet devised by humankind. What right do we have to kill other animals and cut their hearts out? Is human life the only life that has value?

As genetic research advances we will be able to change the genetic makeup of lower species, pigs for example, to make their organs acceptable to the human body. By using genetic manipulation to create animal organs that are more conducive to transplantation into humans, are we violating the natural order of the universe? Are we subverting other species entirely for our own survival?

And what about genetic manipulation in general? This leads us to another very hot topic in modern medical ethics - the Human Genome Project.

The Genome Project

In 1990, the United States Federal Government made three billion dollars available to fund a 15-year research endeavor known as the Human Genome Project. This is an effort to map the entire human genetic code. Since then some commercial companies have entered the race, promising to

create the map quicker and more cheaply. In the early going this vast undertaking produced limited practical applications, but even these have raised a wealth of ethical issues.

For instance, we can now identify genes that cause certain diseases - but we still have no way to cure these diseases. Is there then a benefit to genetic testing of individuals to determine whether or not they or their children are going to develop a certain disease?

One of the most publicized examples relating to genetic testing is Huntington's disease, a hereditary neurological disorder. It is possible to test an individual to determine whether or not they carry the gene for this disease, and whether or not they have the possibility of developing it themselves, or passing it along to their offspring.

Is there any real benefit to knowing that one is going to develop such a dread disease? As of now, there is no cure. In fact, there is no successful treatment. So knowing that one carries the gene only creates a sense of doom and foreboding.

Legally, if one carries the gene does that create what health insurers call "a pre-existing condition?" Is the physician morally obligated to make the results of genetic testing a part of the patient's record, thereby possibly making it impossible for the patient to be insured and receive treatment if/when the disease does develop?

Another ethical knot created by the knowledge that one carries a potentially deadly gene affects the decision of whether or not to have children. At present, it is not possible to remove or correct a defective gene in an embryo, so the only thing a person can do to prevent passing on the gene is to opt not to have children. What impact will that have on the person - and the world at large?

Consider the disease Amyotrophic Lateral Sclerosis (ALS), commonly known as Lou Gehrig's Disease. This is another catastrophic neurological disease for which there is no cure and no effective treatment.

- If gene testing had been available two generations ago, would the sports world have been deprived of baseball great Lou Gehrig?
  - Would the world of science have lost the brilliance of Stephen Hawking?

In this age of ever advancing technology, will there possibly be a cure someday, or will those who carry the ALS gene simply not reproduce and therefore stop the search for a cure, leaving those who develop ALS spontaneously to suffer and die with no hope?

Even if developing a dread disease with an adult onset is inevitable, who is to say that a short life is not worth living? Mozart died in his 30's, yet he was one of the most brilliant and prolific composers in the western world. Did he not merit being given life?

At some point - probably sooner rather than later - it will be possible to test embryos for their genetic make-up, and this will open up another level of ethical nightmares. Will parents want to order a child like they do a new car? Will physicians be faced with a laundry list that says, "Blue eyes, blonde hair, tall, athletic, brilliant?" What happens if during pregnancy something goes

wrong and the child doesn't meet the parents' standards? Do they get a refund? Is the child put up for adoption? If prenatal tests show that there is a perfectly healthy but unfortunately red haired child in the womb, will it be aborted? How much control should we ethically and morally exercise over human reproduction? Are human beings that are less than perfect less valuable? Who determines the standard of acceptability - the physician, the parents, the government?

All of us have heard with horror of the so-called medical experiments made on human beings during the Holocaust in order to create Hitler's "superior race." Doesn't what is happening right now in genetics raise similar ethical questions?

The area of medicine that has made the prenatal manipulation of genes a future probability - reproductive medicine - is another that is rife with conflict and ethical pitfalls.

Reproductive Medicine

One of the most respected physicians of this century, Albert Schweitzer, winner of the Nobel Peace Prize, once wrote:

> *"An absolute ethic calls for the creating of perfection in this life. It cannot be completely achieved; but that fact does not really matter. In this sense reverence for life is an absolute ethic. It makes only the maintenance and promotion of life rank as good. All destruction of and injury to life, under whatever circumstances, it condemns as evil. True, in practice we are forced to choose. At times we have to decide arbitrarily which forms of life, and even which particular individuals, we shall save, and which we shall destroy. But the principle of reverence for life is nonetheless universal and absolute."*

Dr. Schweitzer wrote those words in a magazine article in 1936. Now, more than 60 years later, the ethical question of "...even which particular individuals, we shall save..." is only one life and death decision a physician must grapple with. There is now also the question of who should be born?

The birth control pill was only the beginning of the impact modern medicine has made on human reproduction. Artificial insemination and *in vitro* fertilization have become so much in demand that they have made treating infertility a medical specialty—a specialty full of potential ethical pitfalls.

With the rise of artificial insemination came the unfortunate rise of several sperm banks and specialists who have made headlines for their unethical and illegal actions. One physician was using his own sperm to impregnate women who thought they were selecting a donor from a sperm bank, or being impregnated by sperm from their husbands. This physician not only lied to his patients, he also created the potential for possibly incestuous relationships among persons who were unknowingly half-siblings. This was a morally heinous act, and the physician lost his license and was imprisoned.

Another clear-cut ethical violation was committed by a practice specializing in *in vitro* fertilization. In this case, fertilized embryos were being implanted in the womb of a woman who

was not the egg donor, without her knowledge. Several children were born to parents not their own. Once this became public knowledge it created untold emotional pain for the families involved. Not only for the "birth parents" who discovered that their child was not truly theirs, but for the "genetic parents" who had biological children in the care of total strangers.

DNA testing can answer the biological question of who is biologically related to whom, but the emotional and legal quagmire this situation created will take years to clear up. Should the children be returned to their biological parents? Should the biological parents be forced to contribute to the support of these children? Again, those involved in perpetrating this horrible fraud were jailed.

In these two examples the ethical violations are easy to see, but this isn't always the situation. Other ethical and legal questions have arisen from *in vitro* fertilization.

- Who "owns" the fertilized embryo?
- If a fertilized embryo is not to be implanted, what should be done with it?
- Is it just medical waste to be disposed of?
- Should these embryos be kept viable in a frozen state until technology finds a way to successfully incubate them outside a human womb?

Consider a hypothetical situation:
Two couples come to the same specialist for *in vitro* fertilization. We'll call them couple A and B. The couple A mother is a blue-eyed blonde, the father a brown-eyed brunette. Their procedure is successful and several embryos are fertilized. Couple B has pretty much the same physical characteristics as couple A, but their procedure fails. Then couple A is killed in an auto accident, leaving their fertilized embryos in legal limbo. Instead of destroying the embryos, or putting them into the control of the couple's estate, the physician makes a decision to offer the fertilized embryos to couple B, telling them that they belonged to other parents who are now dead. The implant is successful, and nine months later the mother has a good outcome, delivering a healthy baby. Now this couple who had wanted so desperately to have a child has one, and the child has a loving, supportive family.

Is this legal? Probably not. At least not without going through perhaps years of legal wrangling. Therefore, the physician has made a decision to possibly violate a state statute, but it can be argued that laws were created to serve the best interests of humankind, humankind wasn't created to serve the law. Instead of destroying the potential for human life, the physician has enabled it to have the opportunity to be born. Is that morally wrong? Is that unethical?

These are questions to which there are no definitive answers. They require physicians and other healthcare providers to rely on their own personal ethics and moral standards in making decisions. That same requirement exists in another outgrowth of advancing technology determining who shall die.

Life and Death Decisions

At the end of the 19th century it was very easy to define death. When someone stopped breathing and the heart stopped beating death had occurred. At the end of the 20th century, it's not so simple. Technology has made it possible to keep a human being alive, at least in the technical sense, almost indefinitely. Therefore it was incumbent upon the medical field and society in general to come up with a new definition of death. In the United States this was accomplished in 1978 by passage of the Uniform Brain Death Act, which basically established that for legal purposes, when brain death occurs a person is dead. Unfortunately, defining when death occurs only addresses the tip of the iceberg. Far more complex quandaries lie below the surface.

Life Support Decisions

In common parlance, the decision of when to "pull the plug" on life support equipment has been the subject of much legal and ethical debate. Many hospitals now require that each patient being admitted for even minor surgical procedures must complete a living will. This document requires that the patient or the patient's legal guardian make the choice before surgery of whether or not extraordinary measures will be taken to prolong life, and at what point these measures will be stopped. Legally this protects a physician, but again the line between what is legal and what is ethical blurs.

Does a man or woman 30 years of age entering the hospital for a minor surgical procedure really expect something to go wrong? Even if that person has given his informed consent, did he really understand what might happen? Perhaps not. As medical technology has advanced most patients expect miracles, not problems. Short of creating true terror by describing everything that could possibly go wrong - and pointing out the number of patients who do suffer harm because of medical mishaps - can a physician or other healthcare professional be sure that the patient really wants no extraordinary measures? Again, a tough question. Should the family routinely be consulted about life support decisions even if a living will has been signed? What if there is no family? What if the exact criterion for discontinuing life support is borderline? What if the person is very young and might be able to benefit from future technology?

In emergency situations the question of what to do is sometimes clearer and sometimes more confused. In many emergency rooms life support equipment is routinely used until a determination can be made whether or not a person can be saved. At that point it is up to the chief emergency room physician to make the call. The same is often true in intensive care situations - the physician in charge makes the decision. If continued efforts will prove futile, none are made. Although the term "futile," which is defined as "meaningless, without any hope of a useful result," is now discussed by the medical profession on a regular basis, it too is subject to interpretation.

Sometimes a patient's request to stop life support will be at odds with the physical criteria, and with the physician's point of view. For example, a patient who is mentally aware but must rely totally on life support and feeding tubes for her existence may request that life support be stopped,

which will mean death. There are legal guidelines for dealing with this "right to die" issue, but what about the ethical question? Does the physician have the right to force another human being to live strapped to electronic devices? A human being who is totally dependent and for whom only the most innate human dignity is still possible?

A very famous life support legal case involved a father who wanted the feeding tube that was keeping his daughter alive removed. The young woman had been the victim of an automobile accident and although not brain dead, had no hope of recovery or return to even a semblance of independent life. This became a *cause celebre* for both right-to-die and right to life political forces. Pro-life proponents pointed out that the woman still made sounds, and still made movement. Right to die supporters countered with the fact that these were simply reflexes totally void of cognitive awareness. This case dragged on for years, and went all the way to the Supreme Court. In the end, the father was given custody of his daughter. Her feeding tube was removed and she died shortly thereafter.

Is suicide ever right?

"I have not asked to come into this world, and I don't have a right to make the decision when I am to leave." That is a very common opinion, and it has been prevalent throughout history among most cultures. But for some, the pain of living seems too great. Can a healthcare professional ever go against her vow to do no harm and help a patient to end her life? Another ethical maelstrom has presented itself in the guise of "assisted suicide."

The Supreme Court has ruled that the Constitution does not guarantee a person the right to terminate his/her own life. Therefore if a state wants to pass laws legalizing assisted suicide, they will have to rely on something other than the United States Bill of Rights to defend that legislation. Even if assisted suicide is deemed legal, is it ethical? If suicide, which is self-murder, is declared legal, will broad use of euthanasia follow on its heels? These are the expressed concerns of many religious and ethical groups, as well as many members of the medical profession.

Further, if assisted suicide becomes legal, must a physician working in a public health facility assist in suicide even if it violates his or her own personal or religious ethics?

Perhaps the most emotionally charged field in which life support decisions must be made is that of neonatal intensive care. Thanks to technology, extremely premature infants can now be kept alive.
Babies weighing less than 2 ½ pounds who were given almost no chance of living in the not-too-distant past are now routinely surviving—even those with complex congenital problems.

The question here becomes not can the infant survive, but should the infant survive? Should a child who faces a futile future be kept alive just because we can do it? If a child is doomed to a life of severe mental retardation and multiple physical disabilities, is it ethically appropriate to keep him alive? Conversely, does the physician have the right to play god and decide what

quality of life must be achievable in order for a life to be saved? Who really suffers when a severely retarded infant is saved, the child or the parents?

Some terms from the Death with Dignity National Center:

Advance Directive - a general term that describes two kinds of legal documents, ***living wills*** and ***durable powers of attorney***. These documents allow a person to give instructions about future medical care should he or she be unable to participate in medical decisions due to serious illness or incapacity. Each state regulates the use of advance directives differently.

Aid-in-Dying - a physician's response to a request from a terminally ill, mentally competent adult for the means to hasten death at a time of the patient's own choosing. This usually takes the form of a prescription for lethal medication that the patient may obtain and self-administer. Advocates stress that aid-in-dying should occur only in the context of strict guidelines and safeguards to ensure that reversible causes of despair have been addressed, and that a request is rational, voluntary and enduring.

Comfort Care - an approach to care of the dying that emphasizes the relief of discomfort rather than cure of illness or prolongation of life. Physical, social and emotional needs are the first priority, even when treatment such as high dose pain medication may have the effect of hastening death. Also called ***palliative care.*** Considered legal and ethical in all jurisdictions.

Death with Dignity - A death that is consistent with an individual's personal values and sense of integrity. This may vary considerably between individuals and clinical circumstances. What is tolerable and meaningful for one individual may be unacceptable to another.

Do-Not-Resuscitate Order (DNR) - also called a "no code," a DNR is usually placed on a patient's medical chart to indicate there should be no attempt to restart a failed heartbeat or apply cardiopulmonary resuscitation (CPR) to restore normal breathing. A DNR order can be changed and experts say it should be reviewed regularly. In a DNR situation, a patient is still provided comfort care. Without such an order, emergency medical technicians are legally required to perform CPR.

And another ethical consideration rears its ugly head here - "At what financial cost?"

Shall she have an abortion or not?

One short way to define ethics is to call it the study of right and wrong. Ethics seeks answers to questions like "Is it OK to have an abortion?" "What is usually the right thing to do?"

"I would never have an abortion".....

The outward manifestations of Post Abortion Syndrome can include:

1. Self-destructive behavior, suicidal behavior, drug and alcohol abuse, eating disorders, domestic violence
2. Chronic problems with relationships, marriage and family breakdown, child neglect and abuse

Double Effect - a doctrine established by St. Thomas Aquinas in the 13th Century that an action having two effects: a good one that is intended, and a bad one that is foreseen. The action is acceptable if the actor intends only the good effect. The doctrine is often applied to the use of high doses of morphine and to **terminal sedation**, in which the action is intended to relieve suffering but the predictable effect is to cause death. Sometimes called ***indirect euthanasia***, this practice is considered ethical and legal.

Durable Power of Attorney -a document naming a person to make medical decisions in the event that the individual becomes unable to make those decisions himself or herself. Also called ***healthcare proxy***.

Hospice - an organization offering comfort care for the dying when medical treatment is no longer expected to cure the disease or prolong life. The term may also apply to an insurance benefit that pays the costs of comfort care (usually at home) for patients with a prognosis of six months or less to live.

Life-Sustaining Treatment - any treatment that, if discontinued, would result in death. This includes technological interventions such as dialysis and ventilators, and also simple treatments such as feeding tubes and antibiotics.

Patient Self-Determination Act - a 1991 federal law requiring healthcare facilities that receive Medicare and Medicaid funds to inform patients of their right to execute ***advance*** directives concerning their end-of-life care.

Terminal Sedation - a coma-like state induced when symptoms such as pain, nausea, breathlessness or delirium cannot be controlled while keeping the patient conscious. Patients die after a number of days of the secondary effects of sedation, such as dehydration or pneumonia.

Withholding or Withdrawing - to omit or cease ***life sustaining treatment***, such as a ventilator, feeding tube, or medication that, if used, would prolong the patient's life. Sometimes done upon patient request, but also in accordance with an advance directive or because of judgments of medical futility. Recognized as legal and ethical in every jurisdiction.

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3. Mental health disorders, postnatal depression, depression, anxiety attacks, compulsive disorders and other mental health problems

Abortion is listed as one of the possible precipitating causes of post-traumatic stress disorder in the *Diagnostic and Statistic Manual of Mental Disorder*. Many women suffering abortion trauma are not consciously aware that the abortion is the root cause of their problems. Health professionals are not being trained to identify, treat or prevent Post Abortion Syndrome. Very few counselors or health professionals are prepared to deal with abortion trauma, and even fewer are skilled to do so. Most women seriously damaged by abortion have no access to the professional help they need.

Worldwide studies reveal:

- The suicide rate after aborting is six times the rate after birth.
- The psychiatric admission rate is 53% higher for aborted women than for women who deliver and the rate is *more than twice* that of women in general.
- A computer record link of the whole Danish population (considered to be the best methodological study to date) showed that women who aborted and who were separated,

divorced or widowed were nearly *four* times as likely to be to be admitted to a psychiatric hospital. Teenagers who abort were nearly *twice* as likely compared to those delivering.

- In 1992, the *British Journal of Psychiatry* published a review of over 70 studies which found that psychological or psychiatric disturbances occur in association with abortion and seem marked, severe or persistent in approximately 10% of cases.
- In 1994 a UK Parliamentary Commission of Inquiry into the effects of abortion on women found 87% of women surveyed experienced long-term emotional consequences with 15% actually requesting counseling.
- A recent study in America found that within three to five years after aborting, one in five women met the full diagnostic criteria for Post-Traumatic Stress Disorder.

- **"I had four abortions. What is the big deal?"**

  Description of the Abortion Procedure:
  A surgical abortion is usually given up to anywhere between 7 and 24 weeks of pregnancy. You are numbed by a shot that is given in your cervix, which dulls most of the pain, but not all. Then they dilate you with a metal instrument. A tube is inserted into your vagina and a vacuum sucks the tissues (fetus and placenta) from the uterus. There are other ways of removing the fetus. If you have been pregnant for 7 weeks or less, you may be given a medication to terminate the pregnancy. This sometimes doesn't work and is rarely used. This method takes anywhere from 3 days to 3-4 weeks. Another way is induce early labor. This is usually done after 22 weeks of pregnancy. This could take anywhere from a few minutes to several days.

  After Care:
  Right after the abortion, the woman is observed to see if her blood pressure, heart rate, and bleeding is normal. Before she goes home she may be given an antibiotic, and a 24-hour number to call if any problems occur. For the rest of that same day, it is required for her to keep active. This will reduce the chance of problems. For the next 2-4 weeks, she cant use douche, swim, take tub baths, use tampons, or have intercourse.

  Abortion Post Exam:
  Three weeks after the abortion, it is required that you have an exam with your abortion clinic or with your own healthcare provider. This exam will usually consist of a pregnancy test and cervical check. This is to make sure the abortion is complete and to discover and treat any problems that may have developed.

  Risks:
  Reaction to anesthesia, excessive bleeding, infection, puncture of the uterus (rare), emotional or psychological distress, increase chance of breast cancer

  Cost:
  The cost varies with different surgeons, clinics, how far along the pregnancy is, etc. Normally if you are between 5 and 12 weeks of pregnancy with no health problems, the cost is 400-600 dollars.

Teen Pregnancy and Abortion:
Each year, one million teenagers become pregnant and 85% are unintended. Of all the teenage women who become pregnant, 35% choose to have an abortion. In some states clinics require a legal guardian's permission to have an abortion. But in other states it is strictly confidential.

NOTE:
It is recommended that the woman makes the decision on her own and doesn't have any doubts at all. This is to avoid emotional distress after the abortion. Although it *is normal* for a woman to feel happiness, sadness, relief, anger, gratefulness, disappointment, confidence, fear, loneliness, and guilt. In most clinics counselors will talk to the woman about their decision and all their options that include termination of the pregnancy, to keep the baby, or adoption.

How much does the doctor tell you?

This question does not only deal with physicians, but also with nurses and other healthcare professionals. Generally it is a comfort for patients to know that they can learn what is wrong with them, and that they have control about the passing on of that information. But should the healthcare professional always tell the patient what is going on? And can she pass that information to others?

CHICAGO (Reuters) 12-22-1999-
U.S. physicians rarely fully inform their patients about the caregiving decisions affecting them, a survey of more than 1,000 doctor-patient discussions concluded on Tuesday.

Audiotapes of 1,057 patient visits involving 59 primary care physicians and 65 general and orthopedic surgeons revealed that only 9 percent of 3,552 medical decisions made met the researchers' criteria of complete informed consent.

The criteria for informed decision-making was defined by researchers at the University of Washington, Seattle, as making the patient aware of his or her role in the decision, the nature of the treatment, alternative treatments, the pros and cons of the alternatives, the patient's understanding of the decision, and the patient's preferences.

The physicians were found to be more likely to explain to patients the nature of the planned medical intervention but were unlikely to assess the level of patients' understanding. There are quality-of-care concerns, since there is mounting evidence that inadequate patient involvement may interfere with patient acceptance of treatment and adherence with medical regimens," the report's author, Clarence Braddock III, wrote in the Journal of the American Medical Association. This low level of informed decision-making suggests that physicians' typical practice is out of step with ethical ideals," he wrote. A shortage of time, especially for primary care physicians, is part of the problem.

Ethical principles tend to be established around four basic principles that have served humankind for generations. This is not to say that these principles are the only correct principles, but they are four that have been well accepted and form the basis of many codes of ethics across divergent cultures and organizations.

Respect for Persons

Respect for others relates to how the physician interacts with people. Demonstrating respect for persons depends on the following 4 factors:

1. Autonomy
2. Truth-telling
3. Confidentiality
4. Fidelity

Autonomy

Autonomy states that each patient should be able to determine his or her own affairs. However, the basic principle that underlies informed consent states that for patients to determine their own affairs they must not be coerced. Informed consent requires that patients be provided with a basic understanding of key issues and information necessary to govern their own medical decisions. Informed consent is necessary from the standpoint of medical ethics because ultimately only the patient can give consent to invade the patient's body.

This principle causes ethical dilemmas when family members, the health care team, or an insurance company attempt to make decisions that remain the ethical right of the patient. The issue is complicated by the fact that the patient, by directly or indirectly joining a health insurance plan, gives up certain rights and agrees to abide by the values of the insurance company.

Practice Activity

Consider the following scenario.
For three days, a patient in previous good health experiences low back pain without radicular pain following a day of water skiing. She has a friend who had a lumbar laminectomy for herniated disc, and the patient requests an MRI to rule out disc herniation. Your assessment is that there is little likelihood that surgery would remedy the situation, based on the absence of radicular symptoms. Describe the ethical dilemma.

Response: There is a conflict between the physician's respect for patient autonomy (which support the patient's right to make decisions regarding their own welfare) and the physician's respect for beneficence, the desire to do only those things beneficial for the patient. An MRI is likely to show no disc rupture, and thus will not influence the course of therapy. The issue is complicated by the fact that money not spent on this patient may be available to cover the cost of care for another patient.

Truth-telling

Truth telling states that the physician will tell the whole truth, not a half-truth or "white lie." The truth is required even when, in the physician's opinion, it would harm the patient's psychological well being. A dilemma arises when the patient's desires run counter to truth telling. Consider the situation of the unusual patient who says, "I don't want to know any bad news.
Just figure out what is wrong, and treat me as best you can!" You want to respect the patient's request, but you also know that the patient has cancer and will need to make informed decisions about staging and treatments. You know that you cannot make the decisions for the patient because the decisions involve alternative approaches that depend on personal values and goals. You must balance the application of truth telling with the application of autonomy.

Trust—which is built on truth telling, beneficence, and nonmaleficence—has additional implications in the patient-physician relationship. Trust allows for mutual win-win problem solving. It allows a patient to place his or her welfare in the hands of the physician, but also convinces patients that their physician is not directly responsible for sub-optimal medical outcomes.

Practice Activity

Consider the following scenario:
You have been the primary care physician for Mary for many years. Recently, she sought your advice for tiredness. Mary's T4, T3RU, and TSH indicate normal thyroid function. She has a normal thyroid gland by palpation and scan. You advised that the thyroid was not a cause of her tiredness. Nonetheless, she sought advice from another physician who runs a weight loss clinic. He advised weekly tests of thyroid function, and thyroid supplementation. She asks your counsel. You should:

- Terminate the physician-patient relationship, noting that you cannot provide care for her if she is consulting another physician.
- Advise her to follow the recommendations of the other physician.
- Advise her that you see no reason for weekly tests or supplementation, but will continue as her PCP even if she chooses to take advice from another physician.
- Report the other physician to the state medical board for unethical practices.

Response: In this case, autonomy mandates that the patient is the ultimate decision-making authority. Even though you are her PCP, she has the right to seek advice from others. In a disagreement about appropriate treatment you should acknowledge the diversity of opinion in medical issues, but reiterate your position that she does not have a thyroid problem. You should also state that you support her right to obtain second opinions, and your willingness to continue as her advocate and PCP despite the difference of opinion. An ethical issue is involved if the other physician is intentionally giving false advice (as opposed to unintentionally giving bad advice).

Confidentiality

Confidentiality is the third element of Respect for Persons. Physicians are expected to keep confidential what they know about patients. The advent of health insurance, utilization management, and disease management threaten this element. Patients, by virtue of their contracts with insurance companies or their use of legal entitlements, have given up some of their rights in order to get benefits (usually by signing an insurance form).

These agreements allow all diagnoses and clinical information to be shared with insurers, the government, managed care organizations, and numerous others. However, each organization that receives information is expected to maintain the confidentiality so that none except those who need to know are provided with the information.

Practice Activity

Consider the following scenario:

Gary is a 13-year-old boy with abdominal pain, diarrhea, night blindness, and guaiac positive stools. You think the symptoms and signs are likely due to inflammatory bowel disease involving the terminal ileum. You submit to the health plan a request for preauthorized payment for the patient to have an upper GI endoscopy performed by an out-of network gastroenterologist. The request is denied because the gastroenterologist is out- of-network. The employer has called stating their support of the patient's interest, and requests a periodic update. Your office manager asks whether it is ethical and legal to divulge patient-specific data to the health plan without the patient's written consent.

Response:

Patient-specific information can be divulged only with the patient's consent. When the patient signed for health insurance (either directly signing for it or indirectly choosing the insurance from a menu of plans offered by the employer), the patient likely agreed to the insurance company being given medical information for the purpose of utilization review or claims payment. The health plan has a legal right to the medical information. The patient's consent, however, is limited to the health plan. You do not have a legal right, despite good intentions, to divulge the information outside the health plan network of physicians. Specifically, you do not have the right to divulge information to the employer. Doing so will place you in medical-legal liability.

Fidelity

The fourth element of Respect for Persons is fidelity. Fidelity means keeping one's word. Physicians are expected to do what they say they will do with regards to treatment of the patient. Put another way, physicians need to keep their promises.

In summary the four parts of Respect for Persons are:

1. Autonomy
2. Truth telling
3. Confidentiality
4. Fidelity

Practice Activity:

A useful pneumonic to remember the 4 parts of Respect for Persons is:
ACT w/ Fidelity ---

Autonomy
Confidentiality
Truth Telling
Fidelity

Beneficence

Beneficence is acting with charity and kindness. Medical care is intended to benefit the patient. This requires the physician to do all he/she can to aid the patient. Charity is love of one's fellow human being, an act of good will or showing a caring attitude. It is from this principle that many of the not-for-profit charitable health care organizations were formed. The mission of charitable institutions requires that charity care be given even when patients cannot afford to pay for the service. Providing free care in your office is beneficence. Other acts of beneficence include opening the office for a patient who arrives after hours, providing services or advice for a community organization, or providing special services that benefit the community.

Nonmaleficence

The third principle in ethics is nonmaleficence. This principle is similar to the Hippocratic Oath, "First, do no harm." Physicians are expected to undertake those actions that are beneficial to the patient and to avoid those that are harmful to the patient. Though few physicians would disagree with this principle, its complexity is illustrated by situations where the patient may experience pain or potential harm from a treatment. The more dangerous or threatening the treatment, the more nonmaleficence plays a role in decision-making.

Practice Activity:

Consider this scenario:
Besides his clinical practice, Dr Johns serves as director of the local blood bank, for which he receives a fair salary. Because the bank is recognized as an important community resource, Dr Johns has benefited from positive publicity, including a newspaper biography that describes his work for the blood bank as beneficent. Is it?

Response:
Beneficence is characterized by kindness and charity. Beneficence is more a sate of mind, and demonstrated over time, rather than by a single act.
It does not have to involve money. Since he has a salaried position, it is difficult to straightforwardly declare Dr John's work for the bank as beneficent. On the other hand, if the work is in addition to his clinical work, it may cost him more of his most precious commodity: time. The salary may be incidental. If he has given of his time, especially if it affects his personal life, then one could make an argument that his work is beneficent. If he later gives the salary to charity, then both the blood bank work and the cash gift demonstrate beneficence.

Justice

Webster defines justice, the fourth principle, as being righteous, impartial, and fair. Justice is applicable not only to the care of the individual patient, but also in the case of resource allocation decisions now required daily by Medicaid, Medicare, HMOs, insurers, and employers.

Equal treatment is also a concept that falls under justice. Justice requires that all patients with equal health insurance benefit or coverage (or who will pay their own bill) be offered equal treatment, regardless of the source or amount of payment. Justice does not require equal treatment if the patients have different benefits or will not pay their bill. Further, justice does not allow discrimination based on payment. If two patients have similar benefits, but you have contracted to accept different payments, the two patients have a right to equal treatment. Justice, in delivery of contracted health care, depends on the benefit, not on the payment methodology.

The physician is confronted daily with different payers who have various levels of coverage. This results in different expectations on the part of both payer and patient. From the insurer's perspective, as long as the patients under one insurance benefit plan receive equal care, justice has been served for their beneficiaries.

Furthermore, justice does not imply that services should be provided even if the patient is unable to pay the bill directly or via health insurance coverage. Providing services for free would be at the physician's discretion and expense, and would be an example of beneficence. In other words, justice also allows for fairness to the physician. If he/she treated every patient for free, then the clinical practice would probably fail financially. Not only would the physician be harmed, but also his/her services would no longer be available for community benefit.

Practice Activity

Consider this scenario:
Your medical clinic offers the only diabetes education resources within a 75-mile radius. The education service has been losing money since the new director you hired instituted guidelines to

insure that all patients receive fair and equal treatment. You discover that the services are being provided to all patients regardless of their insurance coverage. Your director says she has an ethical responsibility to treat all patients equally, and that you have an ethical responsibility to accept the monetary loss incurred by provision of these services.

Response:
Justice requires that you offer necessary services to all patients who require them. Justice does not require that you deliver the services for free. The director will benefit from education about the ethical principle of justice.

Economic Considerations

In the best of all possible worlds financial cost would never be a consideration in medical treatment. But this is the real world, and economics is increasingly a factor with which all physicians and healthcare providers grapple on a daily basis.

What if a physician wants to order an MRI but the healthcare insurer doesn't think it's necessary. Does the physician tell the patient the healthcare insurer is wrong? Does she challenge the healthcare insurer on behalf of her patient? Does she simply order the test and to hell with the consequences? Someone has to pay for the test, and if not the insurer, who? Is a person to be denied healthcare simply because of economic factors?

Another ethical question that rises from economic factors is, "Should all steps be taken to prolong life even in an elderly person who will probably only survive a few months or years anyway?"

With the pressure on the medical field to cut costs, should we spend hundreds of thousands of dollars to save the life of a person 80 or 90 years old, instead of saving that money to spend on saving the life of people in their 20's or 30's?

The fastest growing segment of our population, statistically, is people over 100 years of age, and it has been estimated that as many as 50% of the baby boom generation will live to be 100, so these are questions that are not going to go away. Who decides how long a life is long enough? Do people lose their basic human rights simply because they live a long time? Again, who decides?

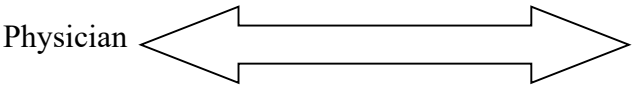
Ethics and Managed Care

As the changes in technology have escalated, so have the costs of medical care. It has become fiscally impossible and irresponsible to continue to offer unlimited services upon demand. This state of affairs has given birth to many changes in medical care, including the emergence of "managed care."

Like any other new endeavor, managed care burst upon the scene with perhaps more speed than planning, and the growing pains have been taking a toll on the practice of medicine ever since, including making it necessary to consider a very fundamental question, which is: Can current medical ethics that apply to individual cases even survive, or must they, like the practice of medicine, become group-based?

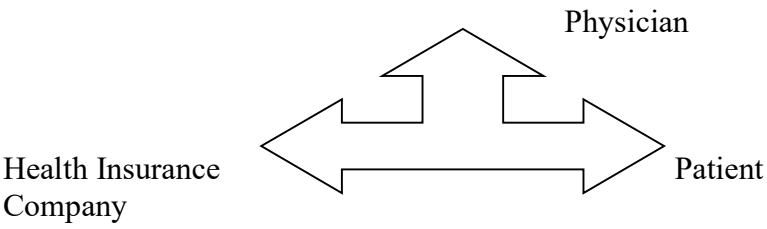
Consider the impact of the changes in the structure of Physician - Patient relationships that have evolved in the 20th century, especially as managed care has become the form of health insurance coverage for the majority of US patients.

One hundred years ago there was a one-to-one relationship in which ethical judgments had to be made.



In most instances the patient sought out a physician, the physician treated the patient, and the patient paid the physician.

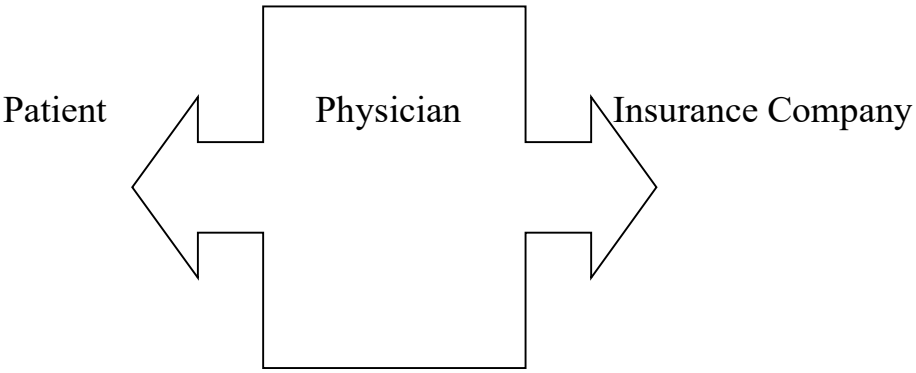
Early on in the 20th century this simple structure was complicated by the addition of another element resulting in a three-part relationship in which ethical judgments had to be made.



In most instances the patient had health insurance, the patient sought out a physician, the physician treated the patient, and the patient's health insurance company paid for all or part of the physician's services. There was no contract regarding care between the physician and the patient's health insurance company, and the physician's ethical choices continued, for the most part, to be steered by her one-on-one relationship with her patient.

With the advent of managed care, things have changed. The physician facing ethical questions has contracts with both her patient and with her patient's health insurance company. Where she

was formerly her own boss regarding patient care decisions, now she has an employment or agency relationship with her patient's health insurance company.



And, as we have discussed, these contracts can create real ethical quagmires for the physician as she has to weigh fiscal as well as physical considerations in her treatment choices.

As physicians have become more vocal in their criticisms of managed care, the medical care world has been responding. Legislation, popularly dubbed "The Patient's Bill of Rights" was introduced in Congress partly in order to "...protect consumers in managed care plans and other healthcare coverage." Individual states have created laws to override some onerous managed care dictates. For instance, the state of New Jersey was among the first to pass a law that requires all healthcare insurers to allow women to stay in the hospital for 48 hours after the vaginal birth of a child, instead of the 24 hours that had become the norm.

Conclusion

Codes of ethics provide guidelines, but each human being must search inside to determine the ethical course of life, both professionally and personally. No one else can do that for you. The Dadaist poet Hugo Ball once said:

> *"Everywhere, the ethical predicament of our time imposes itself with an urgency that suggests that even the question 'Have we anything to eat?' will be answered not in material but in ethical terms."*

The medical field has not yet reached that plateau, but ethical decisions have become an integral part of the everyday practice of medicine.

In the end, the most difficult decisions come down to, "What do you as a human being believe is ethical?" and, "Are you willing to act on that?"

Ultimately, the answers to these questions can be guided by what the Hippocratic oath has urged for all these centuries - putting what is best for the patient first in all ethical considerations.

"The most sublime act is to set another before you."
William Blake, Proverbs of Hell

APPENDIX A

THE AMERICAN MEDICAL ASSOCIATION CODE OF ETHICS

PREAMBLE:
The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self.

The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

1. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.
2. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.
3. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
4. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.
5. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
6. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.
7. A physician shall recognize a responsibility to participate in activities contributing to an improved community.

APPENDIX B

AMERICAN OSTEOPATHIC ASSOCIATION CODE OF ETHICS

Section 1: The physician shall keep in confidence whatever he may learn about a patient in the discharge of professional duties. Information shall be divulged by the physician when required by law or when authorized by the patient.

Section 2: The physician shall give a candid account of the patient's condition to the patient or to those responsible for the patient's care.

Section 3: A physician-patient relationship must be founded on mutual trust, cooperation, and respect. The patient, therefore, must have complete freedom to choose his physician. The physician must have complete freedom to choose patients whom he will serve.

However, the physician should not refuse to accept patients because of the patient's race, creed, color, sex, national origin, or handicap. In emergencies, a physician should make his services available.

Section 4: A physician is never justified in abandoning a patient. The physician shall give due notice to a patient or to those responsible for the patient's care when he withdraws from the case so that another physician may be engaged.

Section 5: A physician shall practice in accordance with the body of systematized and scientific knowledge related to the healing arts. A physician shall maintain competence in such systematized and scientific knowledge through study and clinical applications.

Section 6: The osteopathic profession has an obligation to society to maintain its high standards and, therefore, to continuously regulate itself. A substantial part of such regulation is due to the efforts and influence of the recognized local, state, and national association representing the osteopathic profession. A physician should maintain membership in and actively support such associations and abide by their rules and regulations.

Section 7: Under the law a physician may advertise, but no physician shall advertise or solicit patients directly or indirectly through the use of matters or activities which are false or misleading.

Section 8: A physician shall not hold forth or indicate possession of any degree recognized as the basis for licensure to practice the healing arts unless he is actually licensed on the basis of that degree in the state in which he practices. A physician shall designate his osteopathic school of practice in all professional uses of his name. Indications of specialty practice, membership in professional societies, and related matters shall be governed by rules promulgated by the American Osteopathic Association.

Section 9: A physician shall obtain consultation whenever requested to do so by the patient. A physician should not hesitate to seek consultation whenever he himself believes it advisable.

Section 10: In any dispute between or among physicians involving ethical or organizational matters, the matter in controversy should first be referred to the appropriate arbitrating bodies of the profession.

Section 11: In any dispute between or among physicians regarding the diagnosis and treatment of a patient, the attending physician has the responsibility for final decisions, consistent with any applicable osteopathic hospital rules or regulations.

Section 12: Any fee charged by a physician shall compensate the physician for services actually rendered. There shall be no division of professional fees for referrals of patients.

Section 13: A physician shall respect the law. When necessary a physician shall attempt to help to formulate the law by all proper means in order to improve patient care and public health.

Section 14: In addition to adhering to the foregoing ethical standards, a physician should whenever possible participate in community activities and services.

APPENDIX C

1948 Oath of Geneva

Adopted by the General Assembly of the World Medical Association at Geneva in 1948 and amended by the 22nd World Medical Assembly at Sydney in 1968, the Declaration of Geneva was one of the first and most important actions of the Association. It is a declaration of physicians'
dedication to the humanitarian goals of medicine, a declaration that was especially important in view of the medical crimes which had just been committed in Nazi Germany. The declaration of Geneva was intended to update the Oath of Hippocrates, which was no longer suited to modern conditions.

At the time of being admitted as a member of the medical profession:

- I solemnly pledge myself to consecrate my life to the service of humanity;
- I will give to my teachers the respect and gratitude which is their due;
- I will practice my profession with conscience and dignity;
- The health of my patient will be my first consideration;
- I will respect the secrets which are confided in me, even after the patient has died;
- I will maintain by all the means in my power, the honor and the noble traditions of the medical profession;
- My colleagues will be my brothers;
- I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;
- I will maintain the utmost respect for human life from the time of conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity.
- I make these promises solemnly, freely and upon my honor.

AARC Code of Ethical Behavior for Respiratory Care Practitioner's

AARC Statement of Ethics and Professional Conduct

In the conduct of their professional activities the Respiratory Care Practitioner shall be bound by the following ethical principles. Respiratory Care Practitioners shall.

Actively maintain and continually improve their professional competence, and represent it accurately.

Perform only those procedures or functions in which they are individually competent and which are within the scope of accepted and responsible practice.

Respect and protect the legal and personal rights of patients they treat, including the right to informed consent and refusal of treatment.

Divulge no confidential information regarding any patient or family unless disclosure is required for responsible performance of duty, or required by law.

Provide care without discrimination on any basis, with respect for the rights and dignity of all individuals.

Promote disease prevention and wellness.

Refuse to participate in illegal or unethical acts, and shall refuse to conceal illegal, unethical or incompetent acts of others.

Follow sound scientific procedures and ethical principles in research.

Comply with state or federal laws which govern and relate to their practice.

Avoid any form of conduct that creates a conflict of interest, and shall follow the principles of ethical business behavior.

Promote the positive evolution of the profession, and health care in general, through improvement of the access, efficacy, and cost of patient care.

Refrain from indiscriminate and unnecessary use of resources, both economic and natural, in their practice.

Role Model Statement for Respiratory Care Practitioners

As health care professionals engaged in the performance of cardiopulmonary care, the practitioners of this profession must strive to maintain the highest personal and professional standards. A most important standard in the profession is for that practitioner to serve as a role model in matters concerning health.

In addition to upholding the code of ethics of this profession by continually striving to render the highest quality of patient care possible, the respiratory care practitioner shall serve as a leader and advocate of public respiratory health.

The respiratory care practitioner shall participate in activities leading to awareness of the causes and prevention of pulmonary disease and the problems associated with the cardiopulmonary system.

The respiratory care practitioner shall support the development and promotion of pulmonary disease awareness programs, to include smoking cessation programs, pulmonary function screenings, air pollution monitoring, allergy warnings, and other public education programs.

The respiratory care practitioner shall support research in all areas where efforts could promote improved health and could prevent disease.

The respiratory care practitioner shall provide leadership in determining health promotion and disease prevention activities for students, faculty, practitioners, patients, and the general public.

The respiratory care practitioner shall serve as a physical example of cardiopulmonary health by abstaining from tobacco use and shall make a special personal effort to eliminate smoking and the use of other tobacco products from the home and work environment.

The respiratory care practitioner shall strive to be a model for all members of the health care team by demonstrating responsibility and cooperating with other health care professionals to meet the health needs of the public

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Ethics Examination

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

21. Healthcare Ethics is the study of moral issues that concern healthcare professionals in _____.
a. medicine
b. sociology
c. theology
d. all of the above

22. Medical ethics in particular trace its roots to the old Greek Hippocratic Oath, which required physicians above all to _____.

a. “do what you learned”
b. “obey all laws”
c. “do no harm”
d. none of the above

23. According to _____, ethics deals with the absolute good toward which all human activity should be directed.

a. Hippocrates
b. Plato
c. Aristotle
d. the AMA

24. The British philosopher _____ assumed a more cynical point of view with his definition of ethics:
“Ethics is in origin the art of recommending to others the sacrifices required for cooperation with oneself.”

a. Lord Byron
b. Immanuel Kant
c. Bertrand Russell
d. none of the above

25. _____ Dictionary offers the following definition of ethics: “What is generally called the ethics of the profession is but a consensus of expert opinion as to the necessity of professional standards.”

a. Black’s Law
b. Webster’s
c. Taber’s Medical
d. none of the above

26. The _____, on the other hand, is a strict set of laws governing how much a physician will earn for his efforts, and what will happen if he fails.

a. AMA’s Code of Behavior
b. Code of Hammurabi
c. Hippocratic Oath
d. none of the above

27. In 1803, Sir Thomas Purcivel, British physician, philosopher and writer, created a code of ethics that became the foundation for the first American document designed to govern the practice of medicine in the United States. It was published in 1847 by the _____, which held its first meeting specifically to establish a code of medical ethics

a. American Surgeons’ Society
b. American Hospital Association
c. American Medical Association
d. none of the above

28. So, very often the answer to the question of whether or not there is a published standard of behavior is “_____.”

a. yes
b. no
c. maybe
d. none of the above

29. Surprisingly, one of the most controversial examples of implant surgery has to do with a small device that was first introduced in the 1970’s -.

a. the cochlear implant

b. the breast implant
c. the heart transplant
d. none of the above

30. In 1968 the Uniform Anatomical Gift Act was passed which created the organ donor card, although even if a person signs the donor card the family must be consulted before organs are harvested. This act also prohibited the organ donor's _____ from participating in the organ removal or transplantation.

a. surgeon
b. attending physician
c. family
d. none of the above

31. In 1990, the United States Federal Government made three billion dollars available to fund a 15-year research endeavor known as the _____. This is an effort to map the entire human genetic code.

a. Genetic Research Project
b. Human DNA Universal Coding Project
c. Human Genome Project
d. none of the above

32. One of the most publicized examples relating to genetic testing is_____, a hereditary disorder. It is possible to test an individual to determine whether or not they carry the gene for this disease, and whether or not they have the possibility of developing it themselves, or passing it along to their offspring.

a. Parkinson's disease
b. Huntington's disease
c. Cervical cancer
d. none of the above

33. In the United States this was accomplished in 1978 by passage of the Uniform Brain Death Act, which basically established that for legal purposes, _____.

a. when brain death occurs a person is dead
b. when the heart stops beating, a person is dead

c. when a person stops breathing, a person is dead
d. none of the above

34. In common parlance, the decision of when to "pull the plug" on life support equipment has been the subject of much legal and ethical debate. Many hospitals now require that each patient being admitted for even minor surgical procedures must _____.

a. have signed waivers absolving the hospital and staff of blame for the results of surgery
b. complete a living will
c. have their spouse and/or primary family member sign a document indicating the patient is competent
d. none of the above

35. The Supreme Court has ruled that the Constitution _____ to terminate his/her own life.

a. does not guarantee a person the right
b. allows persons
c. strictly prohibits allowing a person
d. none of the above

36. _____ is listed as one of the possible precipitating causes of post-traumatic stress disorder in the *Diagnostic and Statistic Manual of Mental Disorder*.

a. Attempted suicide
b. Abortion
c. Medical malpractice
d. none of the above

37. The third principle in ethics is _____. This principle is similar to the Hippocratic Oath, "First, do no harm." Physicians are expected to undertake those actions that are beneficial to the patient and to avoid those that are harmful to the patient.

a. malpractice prevention
b. nonmaleficence
c. the good Samaritan principle
d. none of the above

38. The fastest growing segment of our population, statistically, is _____.

a. newborns
b. people over 50 years of age
c. people over 100 years of age
d. none of the above

39. Codes of ethics provide _____, but each human being must search inside to determine the ethical course of life, both professionally and personally. No one else can do that for you.

a. guidelines
b. rules
c. regulations
d. none of the above

40. Adopted by the General Assembly of the World Medical Association at Geneva in 1948 and amended by the 22nd World Medical Assembly at Sydney in 1968, the Declaration of Geneva was one of the first and most important actions of the Association. It is a declaration of physicians' dedication to the humanitarian goals of medicine, a declaration that was especially important in view of the medical crimes which had just been committed in Nazi Germany. The declaration of Geneva was intended to update the Oath of Hippocrates, which was no longer suited to _____.

a. changing society
b. modern laws
c. modern conditions
d. none of the above

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