

Chapter 26

Patient Safety and Health Care Quality

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Patient Safety: Preventing Adverse Events
Health Care Quality: Achieving Effectiveness

Roles and Resources in Safety and Quality

The constituents of the health care system have been called to make a commitment to accept an explicit purpose: “to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States.”¹ Achieving this goal implies two things: first, changing the health care culture to one that values the importance of recognizing and preventing medical injuries; second, changing the health care environment to one that looks beyond concepts of error and error prevention, and focuses on the determinants of health care quality and how quality can be achieved.

PATIENT SAFETY: PREVENTING ADVERSE EVENTS

Persons who receive health care are subject to adverse *outcomes*, defined broadly, from death to dissatisfaction and destitution. On the other hand, adverse *events*, the subject of the patient safety movement, are more narrowly focused: the avoiding of injuries to patients from the care that is intended to help them. The process of identifying and avoiding medical injuries requires determining the nature and extent of these injuries and this involves finding their cause.

Medical Injury

Defining

To define preventable medical injury is problematic. Doing so involves using terms of art, that is, words that have a specialized meaning in a particular field, different or more precise than its customary meaning. “Error,” “mistake,” “accident,” “medical misadventure” are all terms of art that have been used to describe medical injuries that are preventable. Not only are there numerous terms that can be used, but the terms themselves carry different meanings and may be perceived differently by the various constituents of health care. The polarity that exists when characterizing the most significant of preventable medical injuries, those that result in death, is illustrated by the way that the media presented the results of a landmark study that predicted its prevalence (emphasis added):

- “The results of the New York study suggest the number [of deaths] may be as high as 98,000.”—The Institute of Medicine, *To Err Is Human* (1999).²
- “Doctors deadly mistakes: Medical errors *kill** up to 98,000 Americans yearly.”—Magazine headline, *Time*, Dec. 13, 1999. (***Kill**, *v.* To deprive of life; to destroy the life of an animal or person.—*Black’s Law Dictionary* (1990).)

Causation

The traditional focus of interest relating to causation in medical error is one that is both retrospective, which introduces an element of “hindsight bias,” and varies according to the interests (which are powerful) of those parties who seek to frame the debate, inevitably of assigning blame or finding liability, to suit their narrow agenda.

Scope

In 1999 the Institute of Medicine published *To Err Is Human: Building a Safer Health System*. Considered the most influential health care publication in the past two decades,³ it reported that as many as 98,000 Americans die each year as a result of preventable medical errors. And although there has been significant debate about the accuracy of this number—some arguing that it is significantly overestimated⁴—it is still frequently used to describe the scope of the problem. Adding even further to the complexity of the notion of preventable medical injury is the presence of much speculation as to the number of “near misses” in the health care system, that is, the number of injuries that, only by chance, did not occur.

Risk

To appreciate how patients may be exposed to preventable medical injury involves understanding that the risk of injury can be described as a “calculus of risk,” whereby it is a function of three things: (1) patterns of illness and injury; (2) diagnostic testing; and (3) treatment. It is with a pattern of illness or injury—manifesting in their signs and symptoms, their history, and the results of a health care provider’s initial examination—that persons enter the health care system.

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Risk as a function of *patterns of illness and injury* generally culminates in harm by way of a provider's failure to make a proper diagnosis; for example, meningitis in febrile infants and children, subarachnoid hemorrhage in patients with headache, and unstable spine fractures in patients who have fallen or been involved in motor vehicle collisions.

Risk as a function of *diagnostic testing* generally manifests in a failure of providers to properly communicate important information. For example, a radiologist may interpret a study as having evidence of serious disease but the patient's primary care provider does not receive this information.

Risk as a function of *treatment* generally occurs by way of errors in the ordering or administration of medications. For example, a physician's written medication order may be illegible, or a provider may administer a medication in a toxic dose, e.g., concentrated potassium and chemotherapeutic agents.

Errors in Medicine

In studying human error, regardless of the setting in which the error occurs, one can use either the "person" approach or the "system" approach.⁵ Although each model gives rise to different philosophies, both seek to answer the same general question: how is it that people, when working in a complex environment, fail when solving problems, performing tasks, interacting with each other, and using devices? Newer disciplines, such as human factors engineering, organizational psychology, and informatics, can help to answer this question. They provide insight into the *context* and *nature* of error, and into its *culmination*, that is, harm.

Context of Error

The goals of medical decision-making are to arrive at a correct diagnosis, to formulate an accurate prognosis, and to provide appropriate treatment.⁶ Accomplishing this goal involves three stages. In the first stage, data is acquired, primarily by obtaining a history and performing a physical examination. Also in this stage diagnostic tests are chosen and performed. In the second stage, the diagnosis becomes increasingly certain (as other diagnoses are refuted) and then, ideally, is confirmed. Treatment is administered as part of the third stage, and often requires the highest levels of knowledge, procedural skills, and teamwork.

Nature of Error

Errors may occur at any stage in the process of a patient's receiving health care and result from an act either of commission (doing something wrong) or omission (failing to do the right thing). Errors can be categorized in various ways:

1. Learned-Skill Errors There are three domains of learning: cognitive, affective, and psychomotor. Failure to apply these skills appropriately may result in, or contribute to, a preventable medical injury.

- The *cognitive* domain involves factual knowledge and the development of the intellectual skills necessary to understand and use that knowledge.

- The *affective* domain involves attitudes, values, and emotions.
- The *procedural* (psychomotor) domain involves physical movement and coordination.

2. Diagnostic Errors Errors may also be categorized as diagnostic errors:⁷

- No-fault errors are the result of a masked or unusual presentation of disease, or of patient-related error (i.e., because the patient is uncooperative or deceptive).
- System-related errors occur in the presence of technical failure and equipment problems, or organizational flaws.
- Cognitive errors are due to faulty knowledge, data gathering, or synthesis.

3. Data and Reasoning Errors This classification scheme, a subpart of the Diagnostic Errors classification (see above), is frequently applied in the case-based study of preventable medical injuries.

- "Premature closure" occurs when not all of the disease processes that were present were discovered.
- "Wrong synthesis" describes a lack of knowledge of a disease leading to an incorrect conclusion.
- "Inadequate synthesis" occurs when the data do not support the conclusions.
- "Omission" occurs when important information that could have led to a correct diagnosis was not obtained.

4. Behavioral Errors Types of behavior can be used to identify the source of errors that are made by health care providers.⁸

- Skill-based behavior requires little or no conscious attention when performing a task. A "slip" is an error of omission or commission resulting from a lack of concentration and occurs commonly if a task is being performed while on "autopilot."
- Knowledge-based behavior requires that one draw upon the "font of knowledge," which accrues over time.
- Rule-based behavior requires that familiar procedures be applied during decision-making; errors associated with rule-based behavior occur when protocols are either chosen, or applied, incorrectly.

Culmination of Error

Deficiencies in various factors related to either the "system" or the "person" will culminate in harm. To better understand how this occurs, it is useful to apply what is known as the *Swiss cheese model*. James Reason⁵ developed this model to illustrate "how analyses of major accidents and catastrophic system failures tend to reveal that multiple, smaller failures will lead up to the actual hazard."⁹ In this model, each slice of cheese represents a safety barrier or precaution relevant to the particular caution. Despite what may be many layers of safety and precaution, each layer nevertheless has "holes"—hence, the Swiss cheese (but unlike in cheese, the holes may be continually opening, shutting, and changing location). The presence of "holes" in the layers of defensive mechanisms may be the result of various deficiencies: in procedures and administrative

controls; in engineering; and in the performance of people. When the holes align, a hazard is allowed to “make it through the cheese,” and harm will occur.

Preventing Medical Error

Efforts to prevent medical error require thoughtful consideration of the inherent limitations of health care providers, and the limitations of the systems in which health care is provided. These efforts generally focus on medical tasks, and more specifically, on how tasks vary both in their impact (the rate of morbidity and mortality that occurs when the task is performed improperly) and in their frequency of use. Efforts to prevent medical error may be prioritized, so that frequently performed tasks with high impact are given the highest levels of attention, and those that are performed rarely and have low impact are given the least.

Error related to frequently performed tasks includes patient misidentification, medication errors, unsafe use of infusion pumps, and problems with equipment alarms. Consistent primarily with the importance of focusing on tasks that, when performed improperly, have high *impact*, the health care industry has looked to the aviation industry which, in response to what is a high-stress, high-risk environment, has led the way in designing systems whose objective is to prevent error. Aviation’s “cockpit resource management”—adopted by the health care setting and renamed “crew resource management” (CRM)—encompasses a range of approaches to training health care providers to function as teams and takes into account organizational cultures of professions and management styles (Table 26-1). CRM safeguards may be designed or applied at either the provider–provider interface or the provider–device/task interface.

The Provider–Provider Interface

Design safeguards at the provider–provider interface recognize the importance of fostering an environment where persons communicate openly. The central principle of CRM is team-centered decision-making, which allows all members to speak freely with equal acceptance of ideas. This approach recognizes the value of a “flattened” authority structure whereby a number of safeguards can be applied.

Call-Out (or Speak-Up) Used during the performance of tasks, especially those involving high levels of risk, the effect of a call-out is to suspend or limit further activity

Backup systems
Team communication and coordination
Adequate briefings, availability and use of resources
Leadership and adequate supervision
System knowledge
Personal readiness
Planning
Correction of known problems and issues
Management support

Table 26-1 Components of crew resource management

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and both (1) mobilize the resources needed to determine whether the present course of action is proper, and (2) take whatever corrective action is required.

Read-Back (or Hear-Back) The purpose of the read-back is to avoid or limit the possibility of miscommunication when information is conveyed verbally. Miscommunication occurs when information is “misspoken” or “misheard.” In this design safeguard, the listener repeats the key information, followed by confirmation of correctness from the transmitter.⁹

Time-Out The time-out refers to a planned period of quiet and/or interdisciplinary discussion focused on ensuring that key procedural details have been addressed. For instance, protocols for ensuring correct site surgery often recommend a “time-out” to confirm the identification of the patient, the surgical procedure, the site, and other key aspects.

The Provider–Device/Task Interface

When workers perform manual tasks and use technology and devices, there are human limits that must be respected. Tasks should be designed with safety foremost in mind; work processes should be standardized, and processes that are key should be simplified; and workers should not have to rely on memory and vigilance to avoid errors.

An important layer of safety at the device/task interface involves frequent use of “constraints” and “forcing functions.” These guide those who are using a device, or performing a manual task, to what is the next appropriate step in a series of actions or decisions. More specifically, a *constraint* makes it hard to do the wrong thing; a *forcing function* makes it impossible. A classic example of a *forcing function* is that one cannot start a car that is in gear.

Prevention and the Provider

Whether using the “person” or the “system” approach to error prevention, in the end it is generally at the human level—in health care, at the level of the patient—where harm occurs. And it remains up to those working in complex and high-risk environments to properly solve problems, to perform tasks safely, to communicate well with others, and to use devices appropriately. Hence the notion that posits that errors are most readily apparent when they occur at the point of contact between a human and, speaking in the broadest of terms, the system.

These errors, in the context of the health care setting, are referred to as occurring at the “sharp end” of the scalpel; that is, by the person closest to the patient or on the front line, such as the surgeon who operates on the wrong body part, or a nurse who incorrectly programs a drug infusion pump.

HEALTH CARE QUALITY: ACHIEVING EFFECTIVENESS

Despite more than six years having passed since the Institute of Medicine published *To Err Is Human*—a landmark in the patient safety movement—there is little evidence

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that the health care system is safer. Failure to achieve significant improvement may lie in a misplaced emphasis on what is the major focus of the patient safety movement: the notion of accidental death. Success may instead lie in using an evidence-based approach to focus not so much on preventable error, but on improving quality.

The Domains of Quality

Although listed first, that health care be *safe* is only one of six “domains of quality” described by the IOM. As for other domains, health care is to be *effective, patient-centered, timely, efficient, and equitable* (Table 26-2). Given this diversity of the domains of quality, given the inherent limitations of health care providers (e.g., their thought processes and ability to retain skills), and given the limitations of the systems in which health care is provided (i.e., its expansiveness and complexity), choosing where to focus efforts to improve health care quality may be difficult. But it is reasonable that highest priority be given to illnesses or injuries that occur frequently, have high impact, are easily and safely diagnosed, and have treatment options that are safe and effective.

Evidence-Based Medicine

Evidence-based medicine is the use of scientific evidence to make health management decisions. In this way, health care is based on scientific evidence, to the extent that it exists, rather than on the basis of tradition, rational conjecture, or expert opinion.

The process whereby evidence is integrated into the delivery of health care involves a number of stages. Evidence is first generated, often by conducting individual studies. The prospective randomized controlled trial is the gold standard of clinical trials, but even among these, some may be poorly designed, have inadequate numbers, or suffer from other methodological inadequacies. The evidence next is

Safe: Avoiding injuries to patients from the care that is intended to help them.
Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
Patient-centered: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

From Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, Washington, D.C.: National Academy Press, 2001.

Table 26-2 Domains of quality

assessed on the basis of quality, and then is synthesized, in its aggregate, into “indicators of quality of care.” These are then implemented by organizations and health care providers into quality improvement efforts and practice guidelines. In the final stage is the ongoing analysis and synthesis into the delivery of health care. Because of their importance, the stages of assessment, synthesis, and implementation are discussed in greater detail.

Assessing Evidence

In assessing quality of evidence, attention is paid both to study design (among other factors) and to the volume of evidence, in aggregate, as revealed by a *systematic review*. In the systematic review the available literature is used to identify, appraise, select, and synthesize the evidence in reference to a *single* clinical question. The question generally involves a particular medical therapy (outcome studies), but questions may involve the diagnosis, prevention, or prognosis of disease, or they may involve etiology or harm.

There are eight *levels of evidence*, some containing subsets, into which evidence can be stratified according to its quality. Of highest quality, level 1(a), is evidence that is based on systematic reviews (with homogeneity) of randomized control trials. Of lowest quality, level 8, is evidence that is based on (merely) rational conjecture and common sense.

Synthesizing Evidence

As evidence is generated, it provides answers to clinical questions, and so allows measures of outcome and process to be formulated. An *outcome measure* indicates the result of the performance (or nonperformance) of a function or process.¹⁰ A *process measure* focuses on a process that leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.¹⁰

Medical evidence, relative to its quality in aggregate, is applied within the health care setting according to strength of recommendation. When there is sufficient evidence, in the form of outcome and process measures, to suggest that instituting specific therapies and health care-related processes will provide a significant benefit, these “indicators of quality of care” can then be integrated into the health care setting. Integration may occur at the organizational level by way of continual measurement of processes and outcomes, and at the provider level by way of *decision support tools, best practices, design of care processes, benchmarking*, etc. Or, integration may occur in a more formal way, at the patient level, by way of *clinical practice guidelines*, that is, statements used to assist health care providers and patients in making decisions about specific health care problems in specific clinical circumstances.

Indicators of Quality Care

Integrating

Indicators of quality of care, derived from medical evidence and in the form of quality measurements and clinical practice guidelines, may be integrated into a number of areas and entities in the health care system.

Disease Patterns Standardized measure sets of quality indicators are used for a variety of disease patterns, most notably, acute myocardial infarction, heart failure, pneumonia, and sepsis.

Settings Evidence shows improvement in health care quality when quality indicators are integrated in anesthesia, obstetric, and intensive care settings.

Procedures Evidence shows that, for highly complex procedures, in facilities where high volumes of the procedure are performed there is increased quality compared to facilities where lower volumes are performed.

Ensuring Compliance

There may be substantial deficits in adherence to indicators of quality of care. One study determined that patients with common medical conditions receive only 50% to 60% of indicated interventions.¹¹ Various reasons exist for the lack of compliance with the adopting of measures that are known to improve quality of care. For example, providers reluctant to surrender whatever autonomy exists in their decision-making cite both a need to practice the “art” of medicine, and the inappropriateness of practicing “cookbook” medicine.

But even among quality indicators with the best of profiles in safety and efficacy, deficits in adherence may be substantial. Consequently, a number and variety of measures have been developed to ensure that individuals and organizations comply with integration of quality indicators.

Financial Incentives Health care providers generally believe that income is based on productivity and that they actually lose money in providing quality care. This has important implications for any cuts paid to doctors, for example by Medicare, as doctors often respond to cuts by performing more services. However, an increasing trend in health care reimbursement policy is “pay for performance (P4P),” whereby providers and other stakeholders collaborate with payors to ensure that quality indicators are used.

Regulatory Incentives The Center for Medicare and Medicaid Services and the JCAHO “Core Measures” program requires hospitals that are seeking accreditation to collect and submit data on clinical performance in treating acute myocardial infarction, heart failure, and pneumonia, according to standardized, evidence-based measure sets.

Legal Incentives Doctors are reluctant to collect information related to quality, and the vast majority of mistakes go unreported. A component of the “tort reform” legislation may be requirements that providers increase compliance with collection of data on quality measures, and increase reporting of errors.

Patient-Based Incentives To better ensure compliance with the CDC guidelines on the importance of good hand

hygiene in preventing the spread of nosocomial infection, in some health care facilities clinical care providers wear “ASK ME” buttons, worn with the implied expectation that upon a patient’s inquiry as to the button’s meaning, providers will be able to report that they do, and will, wash their hands before and after performing examinations.

ROLES AND RESOURCES IN SAFETY AND QUALITY

As efforts to improve patient safety and to ensure quality of care are both widespread and evolving quickly, it is important to have access to information that is accurate and up to date. The Institute of Medicine and the Agency for Healthcare Research and Quality both play important roles as leading agencies. Further, web-based sites allow for extensive and timely publication of important safety and quality material.

Role of the IOM and the AHRQ

The Institute of Medicine (IOM) has played a central role in the patient safety movement. The IOM (www.iom.edu), part of the National Academies, provides science-based advice on matters of biomedical science, medicine, and health. By working outside the framework of government the IOM ensures scientifically informed analysis and independent guidance. Its mission is to serve as adviser to the nation to improve health and provide unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policymakers, professionals, leaders in every sector of society, and the public at large (www.iom.edu/about.asp).

- *To Err Is Human: Building a Safer Health System* (1999), put the spotlight on how tens of thousands of Americans die each year from medical errors and effectively put the issue of patient safety and quality on the radar screen of public and private policymakers.
- *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) described broad quality issues and defined six domains of quality (see Table 26-2). In addition, it lists 10 rules for care delivery redesign; among these, care is customized according to patient needs and values; the patient is the source of control; and knowledge is shared and information flows freely.
- *Patient Safety: Achieving a New Standard for Care* (2004) detailed a plan to facilitate the development of data standards applicable to the collection, coding, and classification of patient safety information.

The Agency for Healthcare Research and Quality (www.ahrq.gov), part of the U.S. Department of Health and Human Services, is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ’s broad programs of research bring practical, science-based information to medical practitioners and to consumers and other health care purchasers (Box 26-1).

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Box 26-1. Medical-Legal Pearl

The National Patient Safety Network's PSNet site (www.psnet.ahrq.gov/content.aspx?taxonomyID=611) includes an extensive list of articles related to the legal and policy approaches to improving safety, including those related to credentialing, licensure, malpractice litigation, and regulation.

Internet Resources

The National Patient Safety Network (www.psnet.ahrq.gov) The PSNet is a national "one-stop" portal of resources for improving patient safety and preventing medical errors and is intended for use by health care providers, administrators, and consumers. PSNet is sponsored by the Agency for Healthcare Research and Quality (AHRQ).

The National Guidelines Clearinghouse (www.guideline.gov) The NGC, also sponsored by AHRQ, is a comprehensive database of evidence-based clinical practice guidelines and related documents.

The National Quality Measures Clearinghouse (www.qualitymeasures.ahrq.gov) The NQMC, also sponsored by AHRQ, is a database and web site for information on specific evidence-based health care quality measures and measure sets.

The Cochrane Collaboration (www.cochrane.org) The Cochrane Collaboration produces and disseminates systematic reviews of health care interventions and promotes the search for evidence in the form of clinical trials and other

studies of interventions. It is an international nonprofit and independent organization.

The National Quality Forum (www.qualityforum.org) The NQF is a private, not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. The NQF mission is to improve American health care through endorsement of consensus-based national standards for measurement and public reporting of health care performance data.

Endnotes

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