Chapter 9
Medical Error, Quality Management, and the Evolving Culture of Safety

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Medical Error

Physicians, providers, and other healthcare practitioners are, for the most part, by nature competitive and driven perfectionists. Thus, although most physicians and providers hold themselves to high standards, it is also unfair to hold physicians and providers to a standard of perfection. Where providers practice honestly and diligently and nonetheless commit an error in judgment, which may not in itself rise to the level of medical malpractice or medical negligence, that error may or may not result in harm to a patient. It is likely that the number of unappreciated medical errors that occur each day but remain unrecognized because they do not result in harm is very substantial. In addition, since medical malpractice requires showing of compensable damages, medical errors in themselves are not legally actionable.

In general, medical experience, or knowledge; or, when there is a demonstrable element of carelessness or lack of due diligence. The legal standard for reaching a conclusion that malpractice has occured, is proof that the provider deviated from the generally accepted standards or care. Since medical error generally involves little or no moral or ethical culpability, a punitive legal response, in itself, is most probably unlikely to prevent a recurrence. Rather, a transparent examination of the underlying design, structure, and process failures is perhaps more likely to result in a less error-prone system.

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Historical Perspectives on Medical Errors

Hippocratic writings note that some medical errors arise due to "misfortune" and that "a physician should not be blamed for things that resulted from the nature of the disease and its course" [1]. Furthermore, Hippocrates espoused the principle of *primum non nocere* [2], translated to "first, do no harm" and which has become a pillar of medical ethics now recognized as the principle of nonmaleficence. Sir William Osler (1849–1919), perhaps the greatest contemporary physician, noted that "errors in judgment must occur in the practice of an art which consists largely of balancing probabilities" [3]. In the 1950s, medical errors were described as "diseases of medical progress" [4] and dismissed as "the price we pay for modern diagnosis and therapy" [5]. Schimmel reported that 20% of patients admitted to a university hospital medical service suffered from iatrogenic injury and asserted that the "assessment of all untoward reactions, regardless of severity, is essential to determine their total incidence and to indicate the cumulative risk assumed by the patient exposed to the many drugs and procedures used in his care" and defined the term "noxious episode" as a surrogate term for medical error to encompass all the untoward events, complications, and mishaps that resulted from otherwise acceptable diagnostic or therapeutic measures in a hospital [6].

In the 1990s, a view of medical errors as adverse events *caused by*, rather than being events *incident to*, the process of medical care emerged. The Harvard Medical Practice Study defined medical errors as "unintended injury to patients caused by medical management (rather than the underlying condition of the patient) that results in measurable disability, prolonged hospitalization, or both" [7]. The Institute of Medicine (IOM) in 2000 published *To Err is Human: Building a Safer Health System* in which it purported that medical errors accounted for at least 98,000 inpatient deaths annually, or at least 270 deaths daily.

Nonetheless, physicians and providers remain preoccupied with medical errors; and a substantial body of empirical research on the nature of human error, the cognitive processes by which errors occur, and potential safety models have been published. The design of a medical system in which errors are eliminated is the goal of the patient safety initiative; patients are safer and receive more optimal care in a system in which errors do not occur. It is very likely that medical errors will continue to occur as an inevitable consequence of human fallibility and system complexity.

Definitions of Medical Error

By nature and by definition, an error is unintentional. Nonetheless, there is no standard definition of a "medical error"; instead, studies discuss the conditions under which errors occur and surrogate measures of error that largely depend on the type of adverse patient outcomes or injury caused by errors. Reason has defined medical

errors as "the failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error of planning)" [8]. The "reason" definition has become widely accepted with the caveat that errors of omission may be equally important. The definition of error that reason posited is both process-dependent and outcome-independent. Leape recognized that both acts of commission (action) and acts of omission (inaction) contribute to medical errors. Reason has argued that errors occur from the convergence of multiple and complex contributing factors and has stress the importance of a systems approach to medical error prevention (see Chap. 8). Rasmussen classified human errors as either skill-based, rule-based, or knowledge-based [9, 10].

Legal Implications of Medical Error

Although adverse patient events may occur as a result of medical error, not all medical errors cause adverse events; and not all adverse patient outcomes are the result of error. These concepts are important in arguments of legal syllogism, since persuasion through advocacy can convince triers of fact of negligence, where there is in fact no negligence or malpractice (see Chap. 18). Leape noted in 1994 that "[g]iven the complex nature of medical practice and the multitude of interventions that each patient receives, a high error rate is perhaps not surprising" [11]. Liability risks that stem from new procedures, drugs, and technology impact providers and also researchers, manufacturers, distributors, and those involved in marketing of new technology. These new technologies may allow access to certain elements of care that were previously out of reach for many; these patients may now be candidates for treatment exactly because of new technology. The term "too sick" (or too young or old for surgery) is largely only of historical interest. Nonetheless, with increasing complexity, there comes a smaller margin of error and greater risk of an adverse outcome. The paradox is that technology brings both opportunities for treatment and also risk and litigation. The relevance of such technological risk has a broader social importance since medical innovation is important to individual health, the health of communities, and the economic viability of hospitals and the medical research and innovation pipeline. Moreover, the incidence of malpractice litigation within a cohort is often used a surrogate for quality within medical staff credentialing and in public reporting of the purposes of comparisons.

US Courts have long recognized that the practice of medicine involves drugs and treatments which are "unavoidably unsafe" [12]. The Restatement of Torts discusses unavoidably unsafe products:

> … which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. … Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous…. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of

> ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk.
>
> Restatement of Torts (Second), Section 402A, Comment k

Iatrogenic injury refers to unintentional injuries caused by medical care. Negligent adverse events, caused by a deviation from accepted standards of care, represent a subset of preventable adverse events that may rise to a level of medical negligence. Quality management paradigms stress a definition of quality as a variation or a deviation from standards. Thus, some have argued that variation in medical practice may in itself constitute a subtle form of medical error [13].

Modern medical malpractice liability law is best understood as "regulation by litigation," not merely the private resolution of individual actions [14]. The regulatory role of the tort legal system is thus potentially composed of three independent elements of a "malpractice system" (1): the legal-judicial tort litigation system addresses private controversies regarding quality of care and rules on the validity of the claims; (2) liability insurance indemnifies providers and compensates for victim's injuries; and (3) risk management and providers define new standards and modify behaviors to decrease future risk. An additional well-recognized direct effect of medical malpractice litigation is the notion of defensive medicine; however, the ways in which defensive medicine impacts patient care can be subtle. The most commonly discussed type of defensive medicine is that of providers "overutilizing" services such as laboratory testing, consultations, and imaging [15]. However, there are other insidious types of defensive medicine that can involve "cherry picking" of patients to maximize indicators of outcome and quality or the legitimizing and rationing risky interventions in order to minimize the risk of an apparent error of commission.

In general terms, the goals of medical malpractice tort litigation are based upon the principles of corrective justice, distributive justice, and prevention or deterrence [16]. The intent of the medical liability system is to serve three functions (1): compensate patients injured by negligence, (2) promote corrective justice by providing a mechanism to rectify wrongful losses caused by defendants, and (3) deter negligence [17]. Although deterrence leads to a clinical calibration of safety measures so that the costs do not exceed the benefits, a related phenomenon, defensive medicine, reflects responses that are costly and provide little or no clinical benefit [18]. Mello et al. reviewed 37 studies of malpractice deterrence and found that malpractice liability risk may not be effective in preventing substandard care.

Medical errors have broad sweeping ramifications. The term "error" is associated with a stigma; the term connotes inadequacy and perpetuates a culture of blame [19] (see Chap. 36). An accusation of medical error creates significant emotional distress for physicians, a distress influenced by prior beliefs, perfectionism, and competitiveness engendered by medical training [20].

Responding to an Adverse Event That Causes Patient Harm

In the event that an adverse event occurs that results in patient harm, all involved should be familiar with some model response protocol. Institutions generally lack such protocols. A standardized, or protocolized, response to an adverse event will facilitate after event reviews, system safety initiatives, and potentially help in the defense of a litigation. In general, it is difficult to improve something that is not measured or defined; recollections obtained days or weeks after the event have only limited value in quality and safety improvement. Incident reporting is essential to incident management; likewise, incident analysis is essential to future planning to avoid and better manage similar events in the future.

The US military has developed the "after-action review" (AAR) to support continuous improvement efforts. Learning organizations (see Chap. 8) recognize that "organizational learning requires that teams continuously assess their performance to identify and learn from successes and failures" [21]. The military conducts AARs on successes as well as failures with the intent of identifying both successful strategies and potential pitfalls, or near misses. As is often the case with quality paradigms, the AAR does not extrapolate to the healthcare environment in a perfect fashion; however, the *importance of some model of AAR following a critical incident in healthcare cannot be overstated.*

The Anesthesia Patient Safety Foundation (APSF) has developed an Adverse Event Protocol (AEP) to facilitate an effective, efficient, and coordinated response to a perioperative adverse event. The AEP represents a "standard operating procedure" and a standardized reasonable best practice that eliminates variability through improvisation. The APSF AEP is divided into a series of actions: (1) communication and coordination which is designated to an incident commander who assumes administrative direction and control over the event and coordinates the involvement of consultants and the notification of departmental leadership, administrators, and family members; (2) preservation of evidence which is designed to sequester drugs and equipment to subsequently rule out contamination or malfunction in such a way as to provide credibly unspoiled evidence for later review; (3) debriefing and documentation support which promotes clear, complete, factual, and objective memorialization of the events for the medical record; and (4) subsequent peer review [22].

Numerous methods have been devised by which to analyze a reported incident to reveal the fundamental cause(s) and/or contain potential further adverse effects. Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) represents traditional root cause analysis; it was originally designed for the chemical industry but was effectively applied to incidents arising in healthcare in 1997 [23]. PRISMA, or RCA, develops a causal tree which seeks to work backward from the adverse event to identify a single root cause. One of the limitations of PRISMA, or RCA, in healthcare is that there is rarely one single root cause or latent failure, and thus the RCA can inappropriately assign blame to one of the many potential contributing failures. The "Systemic Incident Reconstruction and

Evaluation" (SIRE) is a Dutch prototype method of root cause analysis that offers multiple modalities for critical incident analysis including reconstructions of timeline, processes, and obstacles. SIRE was developed by the National Center for Patient Safety of the Department of Veterans Affairs. The Ishikawa (fishbone) diagram is also a RCA tool that devises a diagram of the outcome, establishing the key contributing causes and the sub-causes. The functional resonance analysis method (FRAM) represents a more rigid control chart method that looks at variations from standard practices. In general, regardless of the method used to retrospectively analyze the adverse event, it must be contemporaneous, tangible, reliable, evidence-based, and transparent.

The verbal, written, and behavioral responses of involved providers after a perioperative incident have potentially enormous legal ramifications: (1) statements made to peers and support staff are discoverable and may be later admitted into evidence against the provider unless they occur in a protected setting; (2) written documentation which is not objective can later be scrutinized and found to be misleading or self-serving; and (3) "cleaning up" may either result in loss of important evidence (i.e., turning off monitors can wipe temporary electronic memory) or be construed as spoliation (intentional loss or destruction) of evidence [24].

Quality Management

Donabedian, in 1966, published "Evaluating the Quality of Medical Care" as a landmark article in which he divided healthcare quality measures into structure, process, and outcome as a framework for conceptualizing and classifying the matrix of quality inputs which impacted outcome in healthcare. Donabedian considered structure as the sum of available resources including facilities, equipment, and personnel, process as all the supportive and direct activities related to patient care, and outcomes as the end results of care including outcome and also satisfaction [25]. Donabedian divided the available resources into two primary domains: technical and interpersonal. Donabedian further defined "technical care" as the application of science and technology that was necessary to the management of a personal health problem and the "interpersonal" aspect of care as the social and psychological interactions between patient and practitioner. Donabedian's domains have subsequently been referred to as the science and the art of medicine, respectively. The norms of the scientific aspect are governed by the available technical resources, whereas the norms of the personal aspect of medicine are governed by moral and ethical principles of interpersonal relationships or normative behaviors.

In 1974, The Joint Commission first mandated that hospitals implement internal quality audit as a condition of accreditation. Early quality assessment programs were based upon a process of criteria mapping, using implict subjective criteria to review the outcomes stemming from the care rendered to any one particular patient. Service-level quality management programs were largely

physician- or group-focused discussions of outcome and potential changes in approach and/or group educational efforts. This early quality assurance model was that of departmental or hospital-level peer review. In fact, departmental quality assurance programs were often used primarily as a teaching mechanism; this approach led to two potential sub-optimal outcomes (1): powerful figures were not criticized; and (2) quality assurance could be weaponized against less influential peers. Although such peer review was mandated by regulatory bodies, the process was neither standardized, comprehensive, nor data-driven. The widely recognized failure of peer review as an effective quality management tool was highlighted by publications in the lay, legal, and medical literature alleging a medical conspiracy of silence.

Quality management in healthcare underwent a rapid evolution and growth in the 1980s and 1990s with the convergence of innovation in managerial science, organizational culture, social psychology, human factors, and safety science and the demonstrable value of quality management programs imported from the non-healthcare industry sectors. The 1980s were also characterized by concerns regarding cost of care and outcomes. The extrapolation of quality improvement and quality management paradigms from diverse industries to healthcare in the 1990s led to widespread recognition that traditional models of service-level quality measures were largely inadequate. Deming espoused the Plan, Do, Check, Act (PDSA) cycle as a model of continuous quality improvement change implementation [26]. Juran adapted the industrial model of total quality management based on the assumption that quality was an organizational, rather than a personnel, issue [27]. Based upon the pioneering and cumulative works of Donabedian, Deming, and Juran, an emerging consensus formed within healthcare regulation and governance that, in order to implement the empirical, theoretical, and methodological foundations to clinical medicine necessary to advance the study of quality and safety, a multidisciplinary approach, beyond that of clinical medicine, was necessary.

A fundamental problem with quality improvement is that healthcare, as a system, has yet to define quality in an objective manner. Crude quality-of-care indicators such as mortality, disciplinary actions, malpractice actions or awards, or patient satisfaction may be more situational and less actionable as indicators of quality. For example, mortality needs to be case mix index; malpractice and patient satisfaction may be related to personalities or motivations.

Quality programs continue to evolve and are becoming increasingly complex with advances in the sciences of data analysis and systems engineering. Nonetheless, despite a relatively robust commitment of resources to quality management programs at the institutional, accreditation, and governmental levels, errors continue to occur, and many indicators of quality do not seem to reflect the impact of the resources expended. More recently, healthcare systems are looking at the dollar costs of quality improvement activities in the form of a rerurn on investment (ROI). Costs associated with qality programs include staffing, data collection, and meetings; these may be significant to a healthcare entity and may, in fact, only marginally affect, or reflect, overall clinical outcomes [28].

Patient Safety

The National Patient Safety Foundation (NPSF) notes that "patient safety is related to 'quality of care', but the two concepts are not synonymous. Safety is an important subset of quality" [29]. Patient safety generally relates to the prevention and mitigation of adverse outcomes that stem from the processes of healthcare. The NPSF addresses patient safety in the context of defining characteristics. Patient safety has to do primarily with the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare itself. Thus, the NPSF considers "errors and deviations," "dangerous situations," "near misses," and accidents as elements of patient safety. Nonetheless, patient safety is the result of interactions of the components of the system; it is more than the absence of adverse outcomes and more than the avoidance of identifiable "preventable" errors or occurrences (Table 9.1) [29].

The medical model for team coordination has its origins in the aviation industry which developed the "crew resource management" (CRM) paradigm in 1978 (see Chap. 8). CRM focuses on building and sustaining an organizational culture that encourages all team members to respectfully question authority while preserving authority and chain of command; it encompasses knowledge, skills, and attitudes including communications, situational awareness, problem-solving, decision-making, and teamwork. Thus, there is a general similarity between the Donabedian model of structure, process, and outcome and CRM; the holistic and team approach of CRM seeks to make the best use of all available resources including equipment, procedures, and people in order to promote safety and enhance operational efficiency. CRM has permeated healthcare in the form of a "safety culture" which universally establishes safety as an organizational priority by fostering teamwork, patient involvement, transparency, and accountability. The fundamental importance of teamwork is further exemplified in the high-reliability organization (HRO). A high-reliability organization (HRO) is one that has succeeded in avoiding catastrophes despite a high level of risk and complexity [24]. The optimal approach to patient safety in healthcare remains controversial and uncertain. Chassin and Loeb

Table 9.1 NPSF agenda for patient safety research

Incident reporting system
Medication error
Safety culture
Patient handoffs and discontinuities in care
Missed diagnosis
Misdiagnosis
Medical device design
Coordination of medical work
Understanding of the nature of expertise
Analyses of technical work

[30] determined that the methodology through which HROs generate and maintain high levels of safety cannot be directly extrapolated to the healthcare environment; rather, incremental changes can be identified through which healthcare systems may progress toward high reliability. These incremental changes include (1) a leadership's commitment to zero harm, (2) a functional culture of safety throughout the organization, and (3) the widespread deployment of highly effective process improvement tools. In summary, patient safety is best accomplished through a combination of individual personnel commitment to, and an organizational culture that unconditionally supports, patient safety. It is likely that no single "model" will provide a better solution than a shared commitment to excellence.

Conclusions

Despite the existence of a single American healthcare system, there is extreme variability in the availability and the quality of care within the individual components of that system. Providers have varying levels of skill, experience, and knowledge; and practitioners, as humans, have differing work ethic, priorities, and standards. Similarly, there is a wide variability in the type of services which are available in different office, clinical, and hospital settings; diagnostic and treatment services that are commonplace in a tertiary or quaternary medical center may not even be contemplated in rural community or critical access hospitals. Thus, universal or national constructs of health quality can best be described as efforts to provide the most appropriate, timely, and best care under the circumstances. Similarly, by extrapolation, discussions of access to healthcare are meaningless unless that access refers to a basic but uniform quality of healthcare. Finally, as the cost of healthcare undergoes increasingly greater scrutiny, that care which demonstrably and repeatedly does not conform to quality standards may be classified as waste. The goal of the tort legal system is not the truth but justice; therefore, malpractice litigation is also a suboptimal mechanism to improve the quality of healthcare.

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