



CHAPTER ONE

PATIENT SAFETY

Crossing the Chasm from Legal and Regulatory Compliance

Fay A. Rozovsky

The concept of *patient safety* caught mainstream attention with the publication of *To Err Is Human: Building a Safer Health System* (Kohn, Corrigan, and Donaldson, 2000). This Institute of Medicine (IOM) report captured worldwide attention with the suggestion that every year, 44,000 to 98,000 Americans lose their lives to medical error, a startling statistic. The data suggested that health care took more lives than those lost to motor vehicle accidents, breast cancer, AIDS, and workplace accidents. The report suggested that these deaths were due largely to bad systems in American health care. Regulatory and market-based strategies were offered in the IOM report, along with a goal of at least a 50 percent reduction in medical errors over a five-year period.

Two major themes emerged in *To Err Is Human*: that medical error is a systemic problem and that concerns about liability make health care systems hesitant to report errors. Yet without such information the health care field cannot learn effectively about mistakes and make positive changes.

Federal agencies responded with a report that delineated a number of recommendations for implementing the strategies discussed in *To Err Is Human*. The Quality Interagency Coordination Task Force report (QuIC, 2000) outlined a number of measures intended to effect positive change. At the state level, a number of jurisdictions have enacted legislation with the goal of improving patient safety. This legislation has taken many forms, from laws about voluntary and mandatory reporting of medical errors and adverse events (for example, in

Florida, New York, and Pennsylvania¹) (Flowers and Riley, 2001) to laws designed to encourage disclosure (for example, in Colorado²) to laws that set nurse-patient ratios (for example, in California³).

Systemic change has also been provoked by private organizations, associations, and accreditation bodies. Medical residency programs must now comply with well-defined parameters for the number of hours of work that program participants may perform.⁴ Patient safety indicators called *never events* have been promoted by the National Quality Forum (NQF).⁵ Additionally, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has put in place a host of standards designed to enhance patient safety along the continuum of care (see, for example, JCAHO, 2004).

Notwithstanding this mosaic of federal and state laws and private initiatives, patient safety seems an elusive goal. That this is the case is reflected in subsequent reports from the IOM, data from other groups that collect information on medication errors, and case law reports. Frustration with persistent patient safety concerns has resulted in some rethinking about what can be done to reduce medical error. Moving from an approach premised on *systemic* change to more individual-based accountability is one step in this regard. Redesigning laws that address evidentiary protection is another area of serious consideration.

Clearly, *patient safety* is an evolving concept in contemporary health care. The terms that define patient safety continue to undergo change. Care providers, lawyers, and public policy professionals grapple with what can be done to bridge the chasm between the goal of patient safety on the one hand and on the other the legal and regulatory environment that must be put in place to promote significant reduction in medical error.

Terms That Define Patient Safety

In its recent report titled *Patient Safety: Achieving a New Standard for Care*, the Institute of Medicine pointed out that the patient safety field needs a standardized terminology to facilitate data aggregation (IOM, 2004). Absent a common taxonomy with terms that all can use, and absent a standardized format for obtaining and reporting data, the field will be hard pressed to learn and to improve systems. The lack of a coherent taxonomy means that health care organizations spend too much effort comparing apples to oranges rather than apples to apples and oranges to oranges. The lack of standardized information sets is ironic in a field driven by data. The reality is that an error barely averted might be a *near miss* at one health care organization and a *good catch* at another facility.

In *Patient Safety*, the IOM calls for a streamlined approach. If this approach is accepted, the health care field would use the HL7 Clinical Document Architecture format, which enables a user to incorporate a narrative section within the framework of a standardized taxonomy of terms. As new terminology is identified, it would be incorporated using the Systemized Nomenclature of Human and Veterinary Medicine or SNOMED CT. To facilitate use of this common ground of patient safety terminology, the National Library of Medicine would be funded to maintain and distribute the taxonomy. The World Health Organization would be encouraged to enhance the International Classification of Diseases (ICD) 9/10-CM E-codes to permit collection of information on adverse events. This would enable international comparisons in the patient safety arena.

From a legal and regulatory standpoint the 2004 IOM report portends new legal concerns. It includes suggestions about delineating omissions and commissions in medical error. It suggests employing both *primary* and *secondary* event types. The latter could be significant in litigation. Depending on the infrastructure of the taxonomy and the way in which these terms are used in a legal setting, these primary and secondary event types might translate into contributory negligence or comparative negligence if part of the accountability for an adverse event is ascribed to the patient or family caregiver. At a more fundamental legal level the taxonomy might also be used out of context by lawyers representing aggrieved patients. Terms like *near miss*, *risk assessment index*, and *omission* and *commission* could be portrayed in an electronic display before a jury and make more difficult for the defense the task of presenting factual information about what transpired in the occurrence.

There is a need for a consistent taxonomy of terms in the patient safety arena. There is a concomitant need for standardized data sets and other information with which to develop practical methods for error reduction. Using SNOMED CT and refreshing the content of ICD-9/10-CM E-codes are good starts. However, the developmental phase of the process needs to be schooled by an understanding of the ways the taxonomy and data may be used for other purposes. Medical malpractice litigation is but one example. The taxonomy and data might also be used in terminations of agreements between health care facilities and health plans, professional licensure proceedings, and regulatory inquiries by federal funding sources. If the terminology can be easily taken out of context and used for other purposes, the recoil may be a reluctance to use it. These concerns can be avoided. In developing the taxonomy and the data sets, several steps can be taken to ensure proper use:

- The passage of legislation and regulations defining specific and limited uses of the taxonomy for purposes of patient safety and medical error reduction
- The involvement of risk management professionals and health care attorneys in the process of developing a coherent, neutral taxonomy of terms

- The inclusion of data weighting and stratification to ensure accurate use of the information and apple-to-apple comparisons
- Restrictions on using data gathered in the reporting process as evidence in certain circumstances, including litigation
- The education of the public and the media on how to interpret the results of data gleaned from the process

Whether or not these strategies are implemented, health care organizations can take positive steps to limit potential harm from embracing a standardized taxonomy of terms and data aggregation for patient safety. Working with legal counsel, risk management, and health information professionals, senior leadership can implement safeguards with respect to

- Collecting data
- Applying terminology
- Using and explaining information in reports
- Educating staff
- Educating media
- Explaining information to the community

By taking such steps, health care facilities can preempt out-of-context reports or other information use. Staff will know what the data and reports mean within the framework of the health care organization. Legal counsel defending the organization will have a solid foundation from which to respond to out-of-context use of the data by plaintiffs' counsel or those representing the government in an adjudicatory proceeding. The following example demonstrates this approach:

A hospital CEO learns that a patient safety report has received notoriety in the local press. The headline reads, "Falls out of control at local hospital." The article describes the findings of a patient safety project focused on medical-surgical falls. It highlights the fact that some 10 patients suffered injuries in postsurgical falls. What the article does not include are some very important data: the 10 falls occurred among a patient population of 5,500 identified as "at risk" for postsurgical falls. All the injuries involved bruises and contusions. There were no fractured limbs or internal injuries. Rather than a project that portrayed a disaster in patient care, the study was the culmination of a patient safety program for those at risk of falling in the twenty-four hours following inpatient surgery. The study had been conducted after the environment of care had been revamped and staff educated on fall avoidance. The number of falls had been reduced from 105 for a similar cohort a year earlier, when 3 patients had suffered pelvic and wrist fractures and 2 had sustained concussions. Instead of a hospital "out of control" on falls, the study revealed a major victory in patient safety.

Although the CEO has the public relations officer do some damage control, the public is irate. When confronted with the truth, the newspaper apologizes and promises to help unwind the false impression it created in its headline and story. The newspaper editor says that a reporter saw a storyboard on the study on a hospital bulletin board and misunderstood the information.

The lesson learned was this: when dealing with a new initiative (such as a patient safety taxonomy and data aggregation tool), make certain that all consumers of the information understand what they are reading and how to use the information.

The Legal and Regulatory Influences Constraining Patient Safety: Evidentiary Protection

A number of initiatives are underway to encourage the sharing of adverse-event information among health care organizations. The goal is to learn from these situations in order to reduce the likelihood of repetitions that could result in catastrophic injury. Few would dispute the importance of this laudable goal. Avoiding needless patient injuries while improving quality outcomes of care is a common theme found in acute care and other health care facilities. Aside from technical issues such as the taxonomy of terms and standardized data sets, some legal and regulatory constraints exist:

- Legal requirements for confidentiality of data
- Concern that identifying an adverse event will be tantamount to an admission of liability
- Fear that sharing data outside the facility will be seen as a voluntary relinquishment of evidentiary protection under applicable state laws
- Fear that providing data will mean a physician is blamed for the event and will result in corrective action under medical staff bylaws
- Fear that providing data will mean that a nurse or pharmacist is disciplined or fired under the facility's employment requirements

Some may question whether these are substantive legal concerns or merely speculation engendered by a lack of understanding of the law. Addressing each item individually puts these concerns in context.

Legal Requirements for Confidentiality of Data

As is discussed later in this book (Chapter Eleven), there is no uniform legal approach to maintaining confidentiality of adverse-event information. Although

some states provide strong legal protections, others do not do so. Further, the application of state-based confidentiality laws varies within each jurisdiction for hospitals, for long-term care facilities, and for other types of health care organizations.

The absence of confidentiality protection at the federal level also reinforces a concern that adverse-event information could be used for purposes that do not promote patient safety. Indeed, even when adverse-event information is generated under the protection of a state law provision, if those data are then properly obtained by a federal agency as part of a focused review involving patient safety, the information will no longer be cloaked by the state-based confidentiality requirements. This potential reinforces concerns about sharing adverse-event information.

Concern That Identifying an Adverse Event Will Be Tantamount to an Admission of Liability

There are some observers who believe that the mere characterization of an outcome as an adverse event will be interpreted as an admission of culpability for a negligent act. The prospect of this risk serves as a deterrent to reporting of adverse events. Although this risk appears to be remote, it can be addressed with a practical strategy. Statements can be included in the policy and procedure that specify the intent of the adverse-event reporting process. The description of the intent should make it clear that identification of adverse events does not constitute an admission of culpability or constitute a negligent act. And a definition should be included that gives precision to the meaning of *adverse event*. Even if adverse-event data is considered discoverable and admissible as evidence of negligent care, the defense can use the policy and procedure to correct any misunderstandings about the nature and purpose of the information. Implementing this type of strategy can help address the concern that adverse-event data may be seen as evidence of negligence.

Fear That Sharing Data Outside the Facility Will Be Seen as a Voluntary Relinquishment of Evidentiary Protection Under Applicable State Laws

A legitimate concern is that adverse-event data sharing among various health care facilities might abrogate evidentiary protection. This concern is genuine in some states, and the response in those states may be to refrain from sharing adverse-event data.

However, another approach is to explore how certain data elements can be shared with other entities without fear of this type of evidentiary outcome. One

strategy may be to include participants from other health care facilities as members of the peer review or quality improvement process under which the data are generated and evaluated. The review of the data is enriched by including others as members of the protected review process, yet the data remain within the organization rather than migrating. Additional steps are needed to make this a practical option. Legal counsel need to examine carefully the specifics of state law to make certain that this approach will work. Additionally, bylaws, policies, and procedures of the facility may need to be amended to provide for others to participate in the review process. The review will have to be done at the data-generating organization.

Ideally, enhanced peer review and quality improvement laws will remove the need for employing such an option. Nonetheless, for those who want to share adverse-event information to improve patient safety, this may be a practical step.

Fear That Providing Data Will Mean a Physician Is Blamed for the Event and Will Result in Corrective Action Under Medical Staff Bylaws

Many physicians are concerned that adverse-event data may be used to affix blame on them, a concern that is incongruent with the underlying *systems* philosophy of the patient safety movement. Those who share this concern fear that a blaming mentality will have serious repercussions, including corrective action within the health care organization and possible licensure proceedings through the auspices of the state board regulating the practice of medicine.

There is a difference between a punitive approach and an accountability philosophy in patient safety. Assigning responsibility to physicians or blaming physicians for adverse outcomes does not recognize that most untoward events are the culmination of several systemic failures that coalesce in failure. It is easier to point a finger at some physicians than it is to tease out which system components failed and how these problems can be corrected.

Since the late 1990s, efforts have been underway to move from the blaming mentality. This initiative has required health care organizations to change their intrinsic culture and their approach to error prevention and reduction. However, as the notion of blamelessness gained notoriety, it was realized that there still needs to be room for individual responsibility. Although system components may fail and result in patients' receiving the wrong medication, the fact remains that some health care professionals have individual accountability for these adverse outcomes. That hospitals enable clinically incompetent doctors to continue to prescribe wrong medications does not detract from the fact that such care providers bear individual responsibility for their actions. With the evolution of the patient safety movement, two important factors have emerged regarding data and accountability. One is that data are imperative for our understanding of why systems fail and how

improvements can be made to promote safety. The other is that these data can be used not to punish but to foster individual accountability for patient safety.

Data also can lead to the suspension or revocation of physicians' privileges. When this happens, health care organizations reinforce the fear that adverse-event data will be used to punish doctors. In more enlightened health care organizations, adverse-event data drive efforts to help physicians understand where they have deficiencies and to help them achieve quality, safe patient care. This may be accomplished through intense in-service education, clinical coursework at other facilities, or one-to-one mentoring. Achieving and maintaining compliance with established safety parameters introduces an accountability approach. It does not involve the use of a big stick to punish for bad outcomes.

Health care organizations are obliged to report certain types of corrective action to state licensure agencies. Independently, dissatisfied patients may file complaints with these agencies. They may seek sanctions or licensure revocation for some physicians. Adverse-event data could be used to make the case for taking such actions. Given the framework in which licensing bodies must operate, they have limited recourse to avoid such responses. The prospect of such regulatory action reinforces the concern of some physicians about the uses of adverse-outcome data. In reality few types of events trigger reports to licensure agencies. Significant evidence must be presented by aggrieved patients to generate responses from licensure agencies. It also takes a substantial amount of information on serious outcomes to compel the use of corrective actions in health care organizations. Thus, on balance, there is a low risk that collecting and using adverse-event data will result in corrective action or licensure activity against physicians.

Fear That Providing Data Will Mean a Nurse or Pharmacist Is Disciplined or Fired Under the Facility's Employment Requirements

The nursing profession sometimes is labeled as one that will "eat its own" for errors or omissions that result in patient injury. Nurses have been seen as having less tolerance for clinical mistakes than physicians do. In the patient safety arena, nurses and pharmacists share the light of scrutiny with physicians. As the culture of blamelessness emerged, some thought it would work to dispel the idea of severe retribution against nurses for serious errors. The case of Betsy Lehman was emblematic of this approach. In the aftermath of a catastrophic medication error at Dana Farber Cancer Institute, detailed evaluations were conducted by JCAHO and the Massachusetts Department of Health. The facility took responsibility for a series of system failures that culminated in the death of a patient from an overdose of medication. The facility made clear that it did not hold the nurses who cared for the patient accountable for the medication error.

A few years later, however, the fear of retribution for adverse outcomes reemerged when the Board of Registration in Nursing decided to pursue sanctions against eighteen nurses involved in this 1994 event that led to the death of Betsy Lehman. The Massachusetts Nurses Association and the Massachusetts Organization of Nurse Executives took a public stand in the hope of persuading the board not to take action against these nurses: “While we believe nurses should and must be held accountable for the safety of their patients and for the integrity of their practice, no nurse should suffer consequences for systemic failures beyond their control” (Massachusetts Nurses Association, 1999). The point made by the Massachusetts Nurses Association is as compelling for pharmacists and other regulated health care professionals. Accountability and integrity are at the core of patient safety. Systemic failures that they cannot control should not trigger disciplinary action. By creating an institutional culture premised on accountability and individual responsibility, health care organizations can put a framework in place that nurtures adverse-event reporting.

Regulatory bodies must respond to their legislative mandates. Public policy changes and legislative reform will be necessary. In the interim the use of internal review mechanisms and external evaluations—like those in the Betsy Lehman case—actually may enhance the framework for adverse-event reporting. That institutions demonstrate that they are accountable and that their employees are held to a similar standard may limit professional disciplinary action by licensing boards to those instances in which such activity is warranted.

Perhaps the most important step for deflecting all the concerns discussed here is the enactment of legislation that fosters data gathering and sharing of adverse-event information. If this legislation is written in a way that creates incentives for reporting and using such information, health care organizations and professionals can glean ideas for reducing and preventing errors. Until that time, practical steps can be taken to address the legitimate concerns of care providers who fear retribution.

The Legal Concepts of Standards of Care and Patient Safety

The law is driven by the concept of standards. Legislation and regulations set minimum requirements for care providers to follow. This does not preclude providers from setting higher standards of performance. Those higher standards might arise from a variety of sources, including learned journals or treatises, position statements from a specialty medical college or nursing organization, or internal policies and procedures developed by health care organizations. Sometimes health care entities transform clinical guidelines developed as a pathway for patient care

into a standard of care. The health care field shares this legal construct with many other professional groups. Plumbers, electricians, and professional engineers, for example, also are expected to conduct themselves in accordance with recognized standards of care. Some of these standards emanate from legislation or regulations. Others are generated by national trade associations.

Standards play a key role in the law. A failure to meet established standards may be the basis for terminating a contract. A failure to meet standards may trigger the withholding of payment for services in industry or in the health care field. It also may be the basis for professional liability claims and, in particular, medical malpractice litigation. Understanding the significance of standards puts into context some of the forces influencing the patient safety movement.

The Legal Concept of Standards

Standards are usually set at a minimal level of performance. Thus, if a nurse holds himself out as a *specialist* in cardiac rehabilitation nursing, he will be expected to live up to the standards of a person with those qualifications. His failure to do so can have serious consequences. His employment may be premised on his meeting the standards for such a nurse specialist. Performance that does not meet that level could result in termination of employment. If the nurse has held himself out to be a specialist and does not perform accordingly, with the result being foreseeable injury to a patient, the situation might lead to a professional liability action. As the bar on standards is raised, the level of expected performance is increased. If this nurse held himself out as a nonspecialist in nursing, there might then be no basis for such a claim. As long as the nurse met the standards for an average, reasonable, prudent nurse in the same or similar circumstance, a plaintiff would be hard pressed to demonstrate all the requisite elements of a claim for professional liability.

For many of the procedures in health care, there are now guidelines, pronouncements, and clinical pathways to drive the performance of individual care providers. For example, there is more than one correct approach to performing gastric bypass, and there are competing dietary regimens for weight reduction. The law has evolved to the point that it will not pick and choose among equally valid standards of care. If the evidence presented suggests that two or more differing methodologies are equally acceptable, it is not for a court to say that one is better than the others. That a patient has sustained a bad outcome as a result of a physician's following one standard of care and not another does not automatically suggest that the doctor was culpable of medical malpractice. As long as it can be shown that the standards of care were comparable, there can be no finding of negligence. Quite a different outcome can occur when a care provider follows a standard that is below the minimum level of expected performance. If,

for example, a surgeon uses a technique long since rejected by the field and as a consequence the patient is harmed, there would be a strong basis for a claim.

However, as described earlier, when a care provider holds herself out as one who performs at a higher level, she will be measured by that standard. For example, a neurosurgeon might hold herself out as an expert in high-risk laminectomies. Relying on this fact, a patient agrees to have the neurosurgeon perform this surgery. The patient sustains a permanent disability as a consequence of the laminectomy, and it is shown that this injury was the result of the neurosurgeon performing in a substandard manner and not at the level of an expert in such high-risk procedures. The result is that the neurosurgeon will be held to the higher standard of care because she clearly presented herself as one who performed at that elevated level of surgical expertise.

Proving which standard is the applicable standard is a function of evidence. Information is drawn from experts. It is drawn from data found in peer-reviewed studies, journals, and books. It also is found in standards from contracts and applicable legislation and regulations.

Standards are applied in the context of a given circumstance. This is a key point in the law. The expected level of care or standard in an emergency department may not be applicable in the context of a train derailment in which dozens of injured passengers need immediate care in an open field. The applicability of the standard is adjusted to the circumstances.

Finally, the law anticipates that standards will change over time. In the context of negligence litigation, however, the standard of care is measured by what was expected at the time of the event. Although today the use of a tourniquet is rejected in first-responder aid for a snakebite, in years past it was the acceptable standard of care. A lawsuit brought in 2003 for alleged negligent use of a tourniquet in 1999 would involve the application of the clinical standards in existence at the time of the snakebite.

These points are of particularly significant in the arena of patient safety. As clinical pathways, guidelines, and statistical process controls (SPCs) emerge to drive clinical care, the connection with standards must be considered from a legal and regulatory perspective.

The Legal Significance of a Standard in Patient Safety

For the plaintiffs' bar, the often-quoted Gertrude Stein phrase "Rose is a rose is a rose is a rose" is particularly relevant with respect to patient safety standards. Legal counsel are adept at convincing juries that what is showcased as a "goal" or a "guideline" is a façade for a standard of care. The task of the defense is to disabuse juries from the idea that this is the case. Sometimes the defense is not successful in doing so.

Everyone shares the hope that the health care field will eliminate patient injuries and deaths from medical error. Public policy makers, leaders in the health care field, and care providers are striving for systems and processes that will reach this level of performance. However, in the drive to accomplish this lofty objective, many practical issues with profound legal ramifications must be considered.

When a state or a national trade association or accrediting body adopts a patient safety goal or standard, that goal or standard is expected to have broad application. The California law requiring certain minimum nurse-patient staffing ratios is a good illustration. Reducing the number of patients for whom a nurse is expected to provide care is seen as reducing the opportunity for errors and increasing safe outcomes. The nurse-patient ratio law has created a patient safety standard. The expectation has been set that health care facilities in California will meet this legal standard of care. The failure to do so can trigger a number of legal consequences. The reality is that health care facilities in California are facing the same nurse shortage as facilities across the rest of the country. Even if the California facilities could afford the staffing increase, finding the qualified personnel is a challenge.

The point is that the downstream consequences of establishing a standard should be considered carefully. The financial, material, and personnel requirements must be contemplated whether the standard is the result of legislation or regulation or of a pronouncement by a voluntary trade association. A more practical approach might be to adopt more than one standard or process for addressing each specific target in patient safety.

Providing latitude in terms of equipment, personnel, medication, and process would give health care organizations and professionals the leeway needed to meet such patient safety targets. The content of disparate standards can be evidence based. Thus what may work for a 350-bed, tertiary, acute care facility may not be the same as what works for a critical access hospital. Along with differing evidence-based criteria, accountability can be built in to measure performance. Outcomes that demonstrate achievement of recognized patient safety targets could become paramount, not a regimented process or standard that does not fit all care settings.

In January 2003, the federal government published a new standard that focused on provider efforts for patient safety. Part of the Conditions of Participation in Medicare and Medicaid for Hospitals, this quality assessment and performance improvement (QAPI) regulation reinforces the point that the notion of patient safety is not only about process. It is also about outcomes involving quality, safe care. As stated in the preamble to the QAPI regulation: “We are requiring that a hospital’s QAPI program be an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors” (68 *Fed. Reg.* 16, 3435–3455, Jan. 24, 2003). The QAPI regulation is premised on accountability. It is also

grounded on the reality that there must be some latitude for achieving and maintaining quality care. Absent is the idea that one size fits all. To this extent the regulation is consistent with the understanding that various approaches can be followed to achieve a common purpose: quality, safe care.

A Practical Approach to Dealing with Patient Safety Standards

Health care professionals and facilities face many challenges. Staffing shortages and low reimbursement rates confront those who must decide how to meet demands for technology enhancements and patient safety. Not meeting federal or state requirements is not an option, as that would be clear evidence of standards noncompliance. Within the framework of current resources, there are some practical measures for achieving and maintaining patient safety standards:

1. *Set priorities for patient safety standards.* Work on the key safety areas first.
2. *Set reasonable expectations.* Design standards, goals, and processes that can be achieved within the framework of existing personnel, equipment, and technology.
3. *Conduct failure modes and effects analysis on proposed standards.* Do a 360-degree analysis *before* launching a new standard or process. Take into account budget, equipment, staffing, insurance, and patient needs and complexity as well as other needs in the facility. Address bottlenecks or safety factors that arise from the proposed standard or process.
4. *Field-test the patient safety standard or process.* Pilot the new standard or process to make certain it works within the environment of care. Identify and resolve problem areas.
5. *Educate.* Make certain that all personnel understand how to use the new standard or process. Use competency-based testing for this purpose.
6. *Monitor.* Use a surveillance approach to determine whether the revised process is working as anticipated over time.
7. *Ongoing improvement.* Continuously monitor changes in the field, including evidence-based outcome data that might point to needed changes to the standard or process. Consider as well new staffing initiatives, the introduction of new equipment, and new regulations or medications that might necessitate changes to the standard or process.
8. *Follow a consistent approach.* Use one type of comprehensive analysis to evaluate a patient safety standard or process.
9. *Document the process.* Use a clear, understandable method for recording how the standard or process was developed, implemented, and improved.
10. *Be receptive to multiple standards or processes.* Accommodate different pathways or standards for achieving quality, safe patient care.

Finally, health care organizations need to develop and employ an understandable taxonomy of terms. Universally used definitions are as necessary for such words as *error*, *near miss*, and *adverse event* as they are for such words as *standard*. The glossary found in the 2004 IOM report is a good starting point. Involving legal counsel and the organization's risk management professional in the development of the taxonomy may help to avert potential liability concerns. Ultimately, a consistent methodology and uniform meanings for terms should help propel the development of patient safety standards and measures.

Notes

1. See *Florida Statutes* § 395.0197 (2001) as amended (which requires the timely reporting of events termed *Code 15*); the Medical Care Availability and Reduction of Error (MCARE) Act of 2002, Pennsylvania Public Law 154, No. 13, § 308 *et seq.* (which includes a patient disclosure provision); and New York Patient Occurrence Reporting and Tracking System (NYPORTS), N.Y. Public Health Law § 2805-1 (1998) as amended (which requires hospitals in New York to report certain types of events on an Internet-based system).
2. § 13-25-135 of the *Colorado Revised Statutes* (2003) makes it clear that in a civil proceeding involving an unanticipated outcome of medical care, any apology or expression of sympathy by a health care professional is inadmissible as evidence of admission of liability by the health care professional.
3. The California Business & Professions Act § 2725.3 (effective 2004) and the *California Health Safety Code* § 1276.4 (effective 2004) set minimum staff ratios for nurses in California hospitals.
4. The Residency Review Committee Program of the Accreditation Council for Graduate Medical Education, a private organization that accredits over 7,500 residency education programs, limits resident duty to eighty hours per week (see <http://www.acgme.org>).
5. The National Quality Forum's membership includes a number of well-known organizations, and NQF's list of twenty-seven serious reportable events has been used in legislation. For example, Minnesota has incorporated this list into its Adverse Health Care Events Reporting Law §§ 144.706–144.7069 (2003).

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