Serious Reportable Adverse Events in Health Care

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Abstract

Health care errors resulting in patient harm are a leading cause of morbidity and mortality in the United States, although there is no national reporting of such occurrences. A number of States require reporting of at least some types of these adverse events; however, it is widely agreed that, even where there is required reporting, such events are grossly underreported, due in part to ambiguity about what is to be reported. In 1999, the Institute of Medicine (IOM) recommended that health care errors and adverse events be reported in a systematic manner. The Federal Government's Quality Interagency Coordination Committee concurred with the IOM's recommendation for greater health care error and adverse event reporting, and the National Quality Forum (NQF) was asked to identify a standardized list of preventable, serious adverse events that would facilitate reporting of such occurrences. This article presents the NQF-endorsed consensus list of 27 serious reportable events in health care, along with a discussion of the criteria used in selecting the list and various issues related to implementing reporting of these events. Since the NQF promulgated this list of serious reportable events in 2002, several States and other entities have enacted legislation or taken administrative action to require reporting of these "never events."

Introduction

Lapses in patient safety are a major health care quality problem, and the occurrence of patient harm due to such lapses is remarkably common, causing tens of thousands of deaths each year in the United States.[1, 2] A large majority of these lapses are preventable and are the unintended consequences of a highly complex and imperfect health care delivery system, in which individual minor mishaps sometimes combine to cause harmful—or even disastrous—results. Few of these adverse events are related to negligence or professional misconduct.

Identifying where and when in the care process mishaps occur, and changing processes of care to reduce the chance of harm, requires reliable data about the occurrence of preventable adverse events. However, few such data exist, as there is no standardized national reporting system to provide information on the number and type of even the most serious preventable adverse events. A number of States require reporting of some types of adverse events, from at least some health care settings; however, it is widely agreed that even in States where there is mandatory reporting, these events are grossly underreported, due at least in part to uncertainty about what has to be reported.

As part of a comprehensive approach to improving patient safety, the Institute of Medicine (IOM) has recommended that health care errors and adverse events be reported in a systematic manner.[1] The Federal Government's Quality Interagency Coordination Committee (QuIC) concurred with the IOM's recommendation for greater health care error and adverse event reporting and recommended that the National Quality Forum (NQF) "identify a set of patient safety measurements that should be a basic component of any medical errors reporting system" (and thereby standardize data collection and reporting by States) in January 2000.[3] President Clinton officially endorsed this and the QuIC's other patient safety recommendations, on February 22, 2000. The NQF was jointly asked by the Agency for Healthcare Research and Quality (AHRQ) and the then Health Care Finance Administration (now the Centers for Medicare and Medicaid Services) to undertake this work on March 23, 2000. A contract to execute this work was finalized by the Federal Government in December 2000, and the NQF formally endorsed a list of *Serious Reportable Events* in health care that should never occur—what has been commonly referred to as the "never events"—in early 2002.[4]

Methods

About the National Quality Forum

Originally conceptualized by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry,[5] the National Quality Forum was established as a nonprofit, public benefit corporation and a unique public-private collaborative venture in 1999.[6, 7] It became operational in February 2000.

The NQF's mission is to improve American health care through the endorsement of consensus-based national standards for the measurement and public reporting of health care performance data that provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable, and efficient. The NQF is a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A-119.[8, 9] It has a formal process by which it achieves consensus and endorses standards.[10] This process meets the requirements of the NTTAA, and, therefore, the NQF-endorsed consensus standards enjoy a consequent legal status. In particular, the NTTAA specifies that when a Federal Government agency establishes standards in an area it is obligated to "use voluntary consensus standards in lieu of government unique standards except where inconsistent with law or otherwise impractical."[8]

In addition to endorsing voluntary consensus standards, the NQF also functions as an "honest broker" for health care quality improvement, convening health care's many stakeholders to focus on specific quality-related issues, as well as engaging in other activities aimed at promoting the use of standards, linking

quality measurement to strategies for quality improvement, providing leadership, disseminating information, and exchanging knowledge and ideas. The NQF is the nexus where health care's many divergent stakeholders can come together to find a common approach to foster system-wide improvements in patient safety and quality improvement.

In endorsing the list of serious reportable events, the NQF convened a broad-based steering committee to oversee the project and a special advisory panel to provide particular input on adoption and implementation of the list by States. The process generally proceeded as specified by the NQF's formal Consensus Development Process.[10]

Purpose of the list of serious reportable events

While it is believed that having reliable information about the occurrence of the most egregious health care errors that cause patient harm will lead to improvements in patient safety, the primary reason for identifying a standardized set of serious reportable events that would be reported on a mandatory basis was to facilitate public accountability for the occurrence of these adverse events in the delivery of health care. Originally, the intention of developing a consensus list of reportable events was to create the core of a national State-based event reporting system that would increase the public accountability of health care.[3]

For purposes of this project, *public accountability* was considered to be the obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public agency (or its designee) that has responsibility for oversight and is answerable to the general public. Reporting in this context is a different matter than whether or how the reported information might be disclosed to the public after being reported to the responsible agency. Reporting and disclosure are often misunderstood as being the same.

The public expects health care providers to take all appropriate measures to ensure that care is safe, and the public looks to government and other oversight bodies to make sure that such actions are taken. The occurrence of a serious preventable adverse event in health care—e.g., operating on the wrong patient or wrong body part or transfusing the wrong type of blood into a patient—suggests (but does not prove) that a flaw exists in the health care organization's efforts to safeguard patients. It is reasonable for the public to expect an oversight body to investigate such occurrences. In many ways, this is analogous to the reporting of airplane crashes, train derailments, and school bus or tractor-trailer truck crashes. When these types of events occur, the public expects that they will be reported to a responsible transportation oversight agency, investigated, and steps taken to eliminate or remedy whatever caused the event to prevent such occurrences from happening in the future. These serious reportable events are health care's equivalent of airplane or other public-transportation crashes.

Accountability entails both an obligation of health care providers to report on their performance and of oversight bodies to investigate specified occurrences and

to enforce compliance with accepted standards of care for ensuring safety. Both parties have a responsibility to use the information to improve public safety. Having a standardized set of reportable adverse events should facilitate fulfillment of this obligation.

Criteria for including events on the list

The core set of adverse events identified by the NQF was not intended to capture all events that might be useful to know about. Rather, the items on the list are events that are (1) clearly identifiable and measurable, and therefore feasible to include in a reporting system; (2) of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the health care facility; and (3) of concern to both health care providers and the public.

To qualify for this core list of serious reportable events, an event had to be unambiguous, usually preventable, serious, and one or more of the following:

- Adverse.
- Indicative of a problem in a health care facility's safety systems.
- Important for public credibility or public accountability.

Requiring that an event be usually preventable recognizes that some of these events are not always avoidable, given the complexity of health care. The presence of an event on the list, therefore, is not an a priori judgment either of a systems failure or lack of due care. Of note, the frequency with which an event occurs was considered, but was not accepted as a criterion for inclusion of events on the list. Many rare, but serious, events are cause for considerable concern when they occur.

Results

List of serious reportable events

Table 1 presents the NQF-endorsed consensus list of 27 serious reportable events that should be reported and investigated by all health care facilities if they occur. The events are organized in six categories—five that relate to the provision of care (i.e., surgical, product or device, patient protection, care management, and environmental) and one category that includes four criminal events. These latter events involve illegal acts, or acts of misconduct, and are included because they could be indicative of an environment that is unsafe for patients. Although health care facilities cannot eliminate all risk of these events, they can take preventive measures to reduce their risk of occurrence.

By intent, this list of serious reportable events is relatively short, based on the belief that a short and clearly defined list is more likely to be understood and widely used. In obtaining consensus on the list there was ever-present tension between adding items to the list to make it more comprehensive, and keeping it relatively short and probably more effective.

Table 1. List of serious reportable events

Event	Additional specifications
1. Surgical events	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. Product or device events	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility	Excludes deaths associated with neurosurgical procedures known to be a high risk of intravascular air embolism.

Table 1. List of serious reportable events, cont.

Event	Additional specifications
3. Patient protection events	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility	Defined as events that result from patient actions after admission to a health care facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the health care facility.
4. Care management events	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	

Table 1. List of serious reportable events, cont.

Event	Additional specifications
5. Environmental events	
A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility	
D. Patient death associated with a fall while being cared for in a health care facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	
6. Criminal events	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of the health care facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the health care facility	

Criteria for inclusion on the serious reportable event list

Essential to compiling this list was the definition of the terms that define the criteria for inclusion. Having standardized terminology is essential if the list is to be implemented consistently. Key terms that were used and their definitions were as follows.

Event means a discrete, auditable, and clearly defined occurrence.

Adverse describes a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

Preventable describes an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

Serious describes an event that results in death or loss of a body part, or disability or loss of bodily function lasting more than 7 days or that is still present at the time of discharge from an inpatient health care facility or, when referring to other than an adverse event, an event whose occurrence is not trivial.

Unambiguous refers to an event that is clearly defined and easily identified.

In compiling the list, three additional terms were used as "terms of art," but a standardized (i.e., consensus) definition for each of these terms was also used.

Associated with means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship

Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

Health care facility means any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other care of human illness or injury, physical or mental, including care during and after pregnancy. Health care facilities include—but are not limited to—hospitals, nursing homes, rehabilitation centers, medical centers or offices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, and ambulatory surgical centers.

For the list to be used for comparative purposes, changes to the definitions of these terms may have a material effect on data collection and make trend analyses difficult or impossible.

In addition to terminology, detailed specifications may need to be developed for some of the events to ensure standardized data collection. Originally, this was to be the focus of pilot implementation projects that were planned to follow compilation of the initial list. Consequent to a change in administration, those pilot implementation projects were never undertaken.

Discussion

The Institute of Medicine recommended a nationwide, mandatory reporting system involving the collection by State Governments of standardized information about adverse events that result in death or serious harm.[1] This recommendation was met with considerable controversy—especially by health care providers—and, while the IOM's recommendation has not been acted upon nationally, a number of States have pursued State-based reporting of the NQF-endorsed list of Serious Reportable Events. (This is in addition to the States that have longstanding adverse event-reporting requirements.)

Since the NQF promulgated this list of serious reportable events in 2002, three States have enacted legislation to require reporting of these adverse events (Minnesota in 2003, Connecticut and New Jersey in 2004). Several other States have similar legislation pending or are considering such action. In addition, the Department of Defense now requires health plans that it contracts with under the TRICARE program to report these events.

A number of issues pertinent to such reporting systems are briefly highlighted below:

Standardization. Accurate assessment of information from medical error-reporting systems within and across States requires that concepts be clearly defined and measures of these events be applied consistently. Since there are currently no nationwide, standardized definitions and measures of serious reportable events, there is no clear agreement on appropriate ways to apply such measures within State-based reporting systems. The NQF's serious reportable events list attempts to remedy this problem by facilitating standardized data collection. This should be an important initial step to addressing these types of health care errors.

The NQF's list does not limit a State's ability to expand the list. However, maintaining the integrity of the definitions and specifications on the consensus list is essential if the reported information is to be comparable within and across States. That is, if an entity wishes to expand an existing event, it should do so by specifying and collecting the additional information as a separate event. Ideally, new events would only be included after a broad-based review and consensus, such as was done to develop this list.

Specification. In developing this initial list, the NQF realized that additional specification of some events on the NQF list may be necessary to ensure consistent implementation and standardized data collection. Without additional specification, the events may be interpreted and reported differently. For example, if a patient were injured from a device malfunction and needed to use crutches at the time of discharge, some States might interpret this to mean "serious disability," whereas other States might not. However, if the event were to be further specified such that serious disability includes all patients discharged on crutches, in a wheelchair, etc., then this would enable more consistent reporting.) It was envisioned that this need would be addressed as part of the pilot testing and refinement process that was originally planned by the Federal Government, in partnership with interested States, as followup to promulgation of the initial list.

To further facilitate consistent reporting, it would be desirable to link the events on the list of adverse events with some type of national, standardized system of codes. Two such commonly used classification systems are the International Classification of Diseases (ICD) and the Current Procedural Terminology (CPT). ICD codes serve as tools for classifying morbidity data for medical records indexing, medical care review, and compilation of health statistics; they are also used in many States to bill for hospital services. CPT codes are used to provide a uniform language that accurately describes medical,

surgical, and diagnostic services, thereby serving as an effective means for reliable, nationwide communication among physicians, patients, and third parties. CPT codes are currently used in Federal programs such as Medicare and Medicaid to code and describe health care services, primarily for billing purposes.[11]

If each event on the list could be linked to an ICD or CPT code, it would represent significant progress toward ensuring that events are consistently reported among States, as well as ease the burden of reporting for health care facilities. However, only about half of the events can be accurately reported using an existing ICD code and even fewer using an existing CPT code.

Of note, in the latter part of 2002, SNOMED® (SNOMED Clinical Terms core terminology provides a common language that enables consistent use of indexing, storing, retrieving and aggregating clinical data across health care specialties and sites) incorporated codes for all of the "never events" into its standardized system of codes.

Reporting. The events described in this list are envisioned as being reportable by all licensed health care facilities in States or other systems that adopt the list as part of an adverse events reporting system. As was already noted, to achieve a national system that yields data comparable within and across States, reporting of the events must be implemented uniformly. Sophisticated information technology systems are not a prerequisite to implementing such reporting, although an interoperable, national health care information infrastructure would significantly ease the burden of reporting on facilities. A number of individual events on this list are elements of other public and private reporting systems, such as the U.S. Food and Drug Administration's MedWatch system for adverse events related to drugs, devices, and biologics, and the U.S. Pharmacopeia's MEDMARX℠ system and National Coordinating Council for Medication Error Reporting and Prevention for drug-related adverse events. Illegal acts are reportable to the criminal justice system, and some criminal events on this list are also reportable to State licensing bodies, yet there is no national consistency in such reporting. By entrusting the reporting of events on this list to a single State agency or State-designated entity, a comprehensive State-based reporting system can evolve that complements the States' public health surveillance role. An additional benefit of a comparable reporting system is that aggregate data may be large enough for statistical analyses of very low incidence events; this would facilitate identifying ways to reduce the occurrence of these adverse events.

Compliance with reporting serious adverse events will depend on how concerns about data discoverability, peer review protections, and legal liability are dealt with. Experience with other reporting systems has made clear the need to avoid punitive systems, as well as the need to ensure privacy protections. Additionally, any reporting system should include feedback to the reporting entity (e.g., the individual practitioners or institutions) and to those designing and implementing findings from root cause analyses and other quality improvement activities. Mere counting of events has no inherent value. Indeed, underlying any reporting system should be both the ability and the intent to improve the effectiveness, efficiency, and quality of health care services.

Reducing the reporting burden

To reduce the reporting burden on health care providers, it would be preferable if States would institute policies that permit facilities to report an event only once to a single State entity. Other relevant state-based reporting systems (e.g., reporting to state health departments) should retrieve reports from the primary receiving entity, not through submission of a duplicate report by the facility. If this is not done, States should, at a minimum, enact policies that allow the same data in the same form to be filed with multiple agencies.

In this same vein, it is recommended that the Federal Government should similarly standardize and coordinate with States. Until a standardized reporting framework is pursued, including coordination with existing voluntary and mandatory systems, the burden on individual health care professionals and-health care facilities to meet the requirements of divergent systems will be an ongoing source of frustration that wastes resources and diminishes the potential for public accountability and quality improvement.

Use of reports based on the list

While the intended use of this consensus list of serious reportable events is to facilitate public accountability, little will be accomplished if the response is merely to record them or if the reports are used to punish the health care organizations. The data should be used in every way possible to actually *improve* patient safety.

Meaningful accountability requires that both health care organizations and oversight agencies use the reports to improve patient safety. There are two main methods by which this can be accomplished.

First, when an event occurs, it should be investigated to determine the underlying system problems and/or failures (e.g., via root cause analysis). The identified problem should then be corrected to prevent recurrence of the event. Prevention strategies can include identifying points in the system of care where protocols should be changed, new or different technologies implemented, training revised, or other processes changed. These activities are the responsibility of the health care organization.

Second, aggregate information about serious reportable events from multiple health care organizations can be used to improve safety if the lessons learned from their investigations of the underlying system problems and/or failures are disseminated to other health care organizations. Such outreach would allow others to take appropriate measures to prevent similar events in their own institutions. Dissemination of this information is possible if the oversight agency or its designee collects information about the adverse events themselves, and information about the findings from the investigations of the events (i.e., from the root cause analyses). The NQF did not get into these details of reporting in its work on developing the list.

Quality improvement organizations

When this list of adverse events is implemented by States, health care facilities have an obligation to report the occurrence of the events. The entities receiving the reports in each State (e.g., public health agencies or State licensing boards) have a reciprocal obligation to ensure that the data provided by the reports are available to the reporting institutions, so that they can be used collectively to both identify problems and explore solutions. These solutions should be focused on systemic prevention strategies as described above. Use of a report to assign responsibility to an individual is rarely justified or successful in preventing future lapses if the same system features remain. Moreover, using reports to perpetuate a culture of blame will assuredly discourage reporting.[12]

Consumers and purchasers

The NQF believes that information based on events that are reported should be made available to consumers and purchasers, as well as providers. Each entity implementing the list should determine its own specifics about how reports are to be analyzed, summarized, and disclosed to the public (i.e., whether institution-specific information versus regional summaries are made public, etc.), but failing to provide a mechanism for public availability is likely to be ill-received by consumers. Of note, State-based reporting, versus a national system, is likely to result in uneven implementation. Such a situation may be problematic for some large purchasers, since many employers operate across State boundaries and health plans.

While public availability of report-related data is important, so too is public education about what the data do, or do not, mean. Because most of the events in the list are likely to be rare, fair comparisons across institutions based on the rate of these events may be impossible based on current risk adjustment and statistical methods. Even multi-year comparisons will most likely not permit fair comparisons. Hence, data derived from reports of events on this list should not be interpreted as meaning an individual institution is of better or lesser quality, nor should it be the sole factor in selecting an institution.

Regional population-based rates are more likely to reflect valid data, particularly for tracking trends over time. States or other reporting entities may wish to collaborate in data analysis efforts so that regional information can be disclosed to consumers and purchasers. Institution-based rates are unlikely to be useful initially, but research to examine the statistical validity of such rates could enhance the future usefulness of the information to consumers, purchasers, and providers.

Unresolved issues and recommendations for research

Considering items that were not included on the list and implementation issues led to the identification of areas for which additional research would be

useful. Among the many issues where research would be helpful, the following were felt to have particular priority:

- What are the most effective mechanisms to collect data and communicate serious reportable events-related data to the public?
- How can data derived from using the NQF list be disclosed in a way that meets the public's needs, yet is balanced with the need for providers to learn from mistakes?
- What is the operational value and utility of including specific events on the list and, in particular, what is the impact of reporting on these events?
- What is the most effective way to code these events, and to review and update the codes?
- What are the preferred methods for risk-adjusting the data when individuals' risks of experiencing the event are so dissimilar?
- To what extent does implementation of the list drive health care quality improvement?

Updating the list

This consensus list of serious reportable events should not be considered static. At the same time, implementation of the list and pilot tests, if they are eventually pursued, should be permitted to proceed for a period of time without being complicated by the introduction of new definitions or events. Currently, it is difficult to project when the list will be updated, but it is recommended that steps be taken to do this in 2005.

Conclusion

The NQF-endorsed list of serious reportable events provides the basis for systematic reporting of at least the most egregious health care errors and associated adverse events. State-based experience with using the list will help identify where it needs more precise specification or definition and other ways it can be improved. Ultimately, collection of these data should both increase public accountability and also lead to improvements in the safety of health care.

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