NATIONAL QUALITY FORUM

Serious Reportable Events in Healthcare 2006 Update

A CONSENSUS REPORT

Foreword

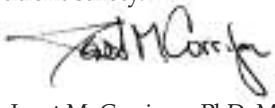
In 2002, the National Quality Forum (NQF) published *Serious Reportable Events in Healthcare: A Consensus Report.* At that time, only a handful of states required the reporting of some types of healthcare errors, and no standardized list of reportable events existed. Today, numerous healthcare reporting systems are in operation, and a sizable number of states and governmental entities—collectively covering about 80 million lives—use the initial NQF-endorsed™ list of 27 serious reportable events as the backbone of their incident reporting systems. With the passage of the Patient Safety and Quality Improvement Act of 2005, there likely will be even greater emphasis in the future on the establishment of reporting systems to enable national learning and patient safety improvement.

This update of that initial list, *Serious Reportable Events in Healthcare—2006 Update: A Consensus Report,* identifies 28 adverse events that are serious, largely preventable, and of concern to healthcare providers, consumers, and all stakeholders. The updated specifications and new event (artificial insemination with the wrong donor sperm or wrong egg) reflect changes in the evidence base, as well as further refinement of the initial list of events based on experience to date. This report also summarizes the progress that has been made in implementing serious reportable event reporting systems and provides guidance to those who will be engaged in implementing such reporting systems in the future.

To further assist healthcare organizations in their efforts to improve safety, NQF has produced a companion report, *Safe Practices for Better Healthcare: A Consensus Report,* which identifies 30 safe practices that should be universally utilized in applicable clinical care settings to reduce the risk of harm to patients. The number of organizations that have implemented all or part of the NQF-endorsed *Safe Practices for Better Healthcare* aimed at preventing adverse events continues to increase. Tens of thousands of lives are forever changed each year as a result of healthcare errors. There is a critical need to enhance health system capacity to provide care that is both safe and effective.

NQF continues to encourage widespread adoption of patient safety reporting systems using the NQF-endorsed list of events and specifications. Standardized event reporting followed by rigorous analysis of the data provides important information that can be used to improve the safety of healthcare.

We thank NQF Members and the Serious Reportable Events Consensus Standards Maintenance Committee for their collective contribution to this work and their dedication to improving patient safety.



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Serious Reportable Events in Healthcare—2006 Update

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Executive Summary

As of November 2006, 25 states required licensed healthcare facilities to report at least some kinds of adverse events related to healthcare. After publication of the 2002 National Quality Forum (NQF) report *Serious Reportable Events in Healthcare*, in 2003 Minnesota became the first state to require reporting of the entire NQF list. It has since been joined by California, Connecticut, Illinois, Indiana, New Jersey, Oregon, Washington, and Wyoming, and a number of other states are considering implementation of the list.

Today, numerous healthcare error reporting systems are in operation. However, systematic, national improvement in patient safety still remains uncoordinated and based on efforts that are driven by individual healthcare organizations, systems, or states, and improvement is not occurring in a unified, national fashion.

Similar to the original 2002 NQF report, this 2006 update reflects consensus on a list of unambiguous, serious, preventable adverse events that concern both the public and healthcare providers and could form the basis for a national reporting system that would lead to substantial improvements in patient safety. The events on the list are identifiable and measurable, and the risk of occurrence of these events is significantly influenced by the policies and procedures of healthcare organizations. This document affirms the ongoing value of the list, updates the original 27 events—with material changes to 3 of the events and to the specifications of 4 events—and adds 1 new event. The report also summarizes the progress that has been made in implementing the list. NQF expects that any of the 28 serious reportable events that occur will be investigated for cause or contributing factors and the findings acted upon to prevent future occurrences. Furthermore, public reporting of these events raises the awareness of all healthcare organizations regarding the potential for such occurrences and should stimulate the critical review of systems for their prevention.

The events remain grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal events. The list of serious reportable events follows.

Serious Reportable Events in Healthcare[1]

1. SURGICAL EVENTS
- A. Surgery performed on the wrong body part
- B. Surgery performed on the wrong patient
- C. Wrong surgical procedure performed on a patient
- D. Unintended retention of a foreign object in a patient after surgery or other procedure
- E. Intraoperative or immediately postoperative death in an ASA Class I patient

2. PRODUCT OR DEVICE EVENTS
- A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. PATIENT PROTECTION EVENTS
- A. Infant discharged to the wrong person
- B. Patient death or serious disability associated with patient elopement (disappearance)
- C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare 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)
- B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-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 healthcare facility
- D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- G. Patient death or serious disability due to spinal manipulative therapy
- H. Artificial insemination with the wrong donor sperm or wrong egg

5. ENVIRONMENTAL EVENTS
- A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- 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 healthcare facility
- D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

6. CRIMINAL EVENTS
- A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- B. Abduction of a patient of any age
- C. Sexual assault on a patient within or on the grounds of a healthcare 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 a healthcare facility

[1]See the full report for applicable care settings for each event, detailed specifications, and additional background and reference material.

Serious Reportable Events in Healthcare—2006 Update

Introduction

As of November 2006, 25 states required licensed healthcare facilities to report at least some kinds of adverse events related to healthcare.[1] Numerous healthcare error reporting systems are in operation, and there is growing evidence that these efforts have been bringing positive change to the quality of care delivered.[2] However, systematic, national improvement in patient safety still remains uncoordinated and based on efforts that are driven by individual healthcare organizations, systems, or states. Improvement is not occurring in a unified, national fashion.

When the National Quality Forum's (NQF's) initial list of serious events that should be publicly reported was published in 2002, healthcare quality and safety in the United States presented a paradox—it still does. In some ways American healthcare is the envy of the world, offering millions of patients ready access to highly skilled, committed professionals working in state-of-the-art healthcare institutions, with all the advantages of the latest innovations in biomedical research, technology, and treatment. At the same time, the "system" is fragmented, often difficult to access, expensive, and suffering from serious and pervasive deficiencies in quality.[3]

[1]National Academy for State Health Policy, *Quality and Patient Safety: State Adverse Event Reporting Rules and Statutes;* December 2005. Available at www.nashp.org/_docdisp_page.cfm?LID=672A5638-A3E7-46D9-AC1F8D151B197AF0. Last accessed July 2006.

[2]Leape LL, Berwick DM, Five years after *To Err Is Human:* what have we learned? *J Am Med Assoc,* 2005;293:2384-2390.

[3]Schuster MA, McGlynn EA, Brook RH, How good is the quality of health care in the United States? *Milbank Q,* 1998;76(4):517-563.

The 2002 NQF-endorsed™ *Serious Reportable Events in Healthcare*[4] was groundbreaking. It reflected consensus on a list of serious, preventable adverse events that could form the basis for a national reporting system and lead to substantial improvements in patient safety. This document affirms the ongoing value of the list, adds 1 event, "artificial insemination with the wrong donor sperm or wrong egg," and updates the original 27 events. In updating the list, material changes were made to three of the events and to specifications of four events (see appendix D). The report also summarizes the progress that has been made in implementing the list.

The events remain grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal events. This NQF report reiterates the importance of the consensus arrived at by consumers, providers, purchasers, researchers, and other healthcare stakeholders about preventable adverse events, and it expands on the earlier report by including implementation guidance to facilitate consistent reporting. Where appropriate, additional specifications and definitions have been included.

As with the original list, NQF expects that any of the 28 serious reportable events that occur will be investigated for cause or contributing factors and that the findings will be acted upon to prevent future occurrences. Furthermore, public reporting of the events raises the awareness of all healthcare organizations regarding the potential for such occurrences and should stimulate the critical review of systems for their prevention.

Relationship to Other NFQ-Endorsed Consensus Standards

The list of 28 serious reportable events is part of a series of NQF-endorsed consensus standards that specifically address healthcare safety. Together with the 30 NQF-endorsed practices in *Safe Practices for Better Healthcare*[5] and the classification

[4] National Quality Forum (NQF), *Serious Reportable Events in Healthcare: A Consensus Report,* Washington, DC: NQF; 2002.

[5] NQF, *Safe Practices for Better Healthcare: A Consensus Report,* NQF: Washington, DC; 2003; NQF, *Safe Practices for Better Healthcare – 2006 Update: A Consensus Report,* Washington, DC: NQF; 2007.

system in *Standardizing a Patient Safety Taxonomy,*[6] a strong array of nationally derived tools for improving, reporting, classifying, and analyzing safety-related healthcare events are offered to enable and facilitate improvements in healthcare safety. Additionally, other NQF-endorsed consensus standards[7] that relate to settings of care such as hospitals and nursing homes, to professional disciplines such as nursing, and to diseases such as cardiac surgery contain patient safety-related standards.

Purpose of the List

As with the 2002 list of events, the primary reason for identifying an unambiguous, standardized list of serious reportable events for mandatory reporting is to facilitate public accountability toward the ultimate goal of systematic learning and improvement in healthcare safety. The list of events recommended in this update enables the standardized data collection and reporting of such events. Public accountability, as used here, is considered to be the duty of individuals and healthcare facilities. This accountability ensures that information about healthcare providers' actions or performance is available to the public directly or through a public agency (or its designee) that has oversight responsibility and is answerable to the general public. How such data might be disclosed to the public (e.g., in a de-identified manner or in aggregated reports) is a policy decision, although public disclosure should occur.

Purpose of the Update

In keeping with the expectations established in the initial report, *Serious Reportable Events in Healthcare* has undergone an update to assure its appropriateness and currency. In fact, the purpose of the update is three-fold: 1) to ensure the continued currency and appropriateness of each item on the list; 2) to ensure that the list remains appropriate for public accountability in light of its implications as voluntary consensus standards under the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41); and 3) to provide the guidance that has been gained from early implementers to those who are just beginning the reporting of these events.

In 2002, when the report was issued, it was determined that pilot testing and implementation of the list should proceed without the complications that could result from the introduction of new definitions or events. It also was determined that, because healthcare measures and standards are useful only as long as they reflect current knowledge and remain appropriate, updating the list would be appropriate in the future. For this reason, NQF established Consensus Standards Maintenance Committees (CSMCs) to review assigned sets of endorsed consensus standards for currency and appropriateness. *Serious Reportable Events* was one of the first groups of NQF-endorsed consensus standards to be reviewed. Moreover, since 2002, in addition to the many new scientific and medical

[6] NQF, *Standardizing A Patient Safety Taxonomy: A Consensus Report,* NQF: Washington, DC; 2006.

[7] NQF, *Compendium 2000 – 2005,* Washington, DC: NQF; 2006.

developments that had occurred, a number of organizations and states had embraced the NQF-endorsed events and had begun reporting, providing the experience the CSMC would need to evaluate the events. A review of this experience, along with a review of the evidence base, has affirmed the continued relevance and importance of the list and in addition has enabled the development of implementation guidance that will assist those who are in the beginning stages of implementation.

Criteria for Inclusion of Events on the List

The criteria for inclusion and the definitions of terms used in the criteria remain unchanged from 2002 (see box A). The list of events described in this report that meet those criteria is not intended to include all events that might possibly be useful to report and they do not include all events that should "never" occur.

Box A – Criteria for Inclusion and Definitions of Terms Used in the Criteria

Criteria

Items included on the list of *Serious Reportable Events in Healthcare* are events that are:

- of concern to both the public and healthcare professionals and providers;
- clearly identifiable and measurable and thus feasible to include in a reporting system; and
- of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.

In addition, to qualify for the list, an event must be unambiguous, usually preventable, serious, and any of the following:

- adverse; and/or
- indicative of a problem in a healthcare facility's safety systems; and/or
- important for public credibility or public accountability.

Definitions of Terms Used in the Criteria

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 for, but that occurs because of an error or other system failure.

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

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

Usually preventable recognizes that some of these events are not always avoidable, given the complexity of healthcare; therefore, the presence of an event on the list is not an a priori judgment either of a systems failure or of a lack of due care.

Rather, 27 of the items on this list are events that, since they were endorsed as voluntary consensus standards in 2002 by NQF, have continued to meet the criteria by which they were selected and have been accepted by organizations and states as appropriate for reporting, and yet have continued to occur.

List of Serious Reportable Events

Table 1 presents 28 serious reportable events that should be reported and investigated by all healthcare facilities as they occur. Each individual incident should be reported, not frequencies of events. The events are organized into six categories—five that relate to the provision of care (surgical, product or device, patient protection, care management, and environmental) and one that includes four criminal events. The criminal events involve illegal acts, or acts of misconduct, and are included because they could indicate the presence of an environment that is unsafe for patients. Although a healthcare facility cannot eliminate all risk of these types of events, it can take preventive measures to reduce that risk.

The 2006 list offers additional information to assist those who might include the list of events in implementing a patient safety event reporting system. By intent, the specifications expand and offer clarification of the events in order to support reporting efforts, while the implementation guidance (which is separate from the events and specifications) was developed from the input that was provided by implementers in order to provide context and otherwise facilitate understanding or implementation of the events.

As with the 2002 list of NQF-endorsed serious reportable events, to facilitate understanding and wide utilization, the current list is short and includes only clearly defined events. The standardized terminology used in the 2002 report remains relevant, and a number of key terms from the 2002 report glossary are included in box b, on the following page.

Box B – Definitions of Key Terms

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. (This report acknowledges that states and other entities may use alternate definitions for the term *disability*. The definition used by NQF was derived from the Americans with Disabilities Act: 5 U.S.C. 301; 28 U.S.C. 509, 510; 42 U.S.C. 12186(b). Source: Order No. 1513-91, 56 FR 35592, July 26, 1991.)

Healthcare 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. Healthcare 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.

Table 1 – List of Serious Reportable Events

1. SURGICAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE[i]**
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient.[ii] Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ■ Surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), level (spine). ■ Wrong site surgery, even if corrected intraoperatively, as long as the surgery had begun, based on the definition below. This event is not intended to capture: ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins,* regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit). Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at the time a surgical mark is made on the patient. Placing a mark on the wrong body part does not in itself constitute wrong site surgery. *(more)*

[i] Implementation guidance amplifies statements in the event and additional specifications based on the experience of those organizations/entities that have implemented the reporting of the events and the recommendations of NQF Members and the public. As such, the guidance does not purport to be—nor is it required to be— either comprehensive or uniform across the events.

[ii] Except in the case of an emergency, a physician must obtain a patient's agreement (informed consent) to any course of treatment. Physicians are required to tell the patient anything that would substantially affect his or her decision. Such information typically includes the nature and purpose of the treatment, including its risks and benefits, and alternative courses of treatment, including risks and benefits. The American Medical Association definition of informed consent is "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention" (see www.ama-assn.org/ama/pub/category/4608.html).

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.	This event is intended to capture: ■ Surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient. *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins,* regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed., regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
C. Wrong surgical procedure performed on a patient	Defined as any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ■ Insertion of the wrong medical implant into the correct surgical site. This event is not intended to capture: ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins,* regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
D. Unintended retention of a foreign object in a patient after surgery or other procedure	Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).	This event is intended to capture: ■ Occurrences of unintended retention of objects at any point after the surgery ends, regardless of setting or of whether the object is removed. *Surgery* is defined a*s* an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins,* regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
E. Intraoperative or immediately postoperative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations in which anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately postoperative means within 24 hours after surgery or other invasive procedure was completed, or after administration of anesthesia (if surgery was not completed).	This event is intended to capture: ■ ASA Class I patient death associated with the administration of anesthesia, whether or not the planned surgical procedure was carried out. *Surgery* is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. *Surgeries* include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used. *Surgery begins,* regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. *Surgery ends* after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).

(more)

Table 1 – List of Serious Reportable Events (continued)

2. PRODUCT OR DEVICE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.	The term *detectable* is intended to capture contaminations that can be seen with the naked eye or with the use of detection mechanisms that are in general use; these contaminations are to be reported when they become known to the provider or healthcare facility. Detection mechanisms may include cultures and tests that signal changes in pH or glucose levels.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.	This event is intended to capture occurrences whether or not the use is intended or described by the device manufacturers' literature. The Food and Drug Administration defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: ■ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, ■ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or ■ intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	High-risk procedures, other than neurosurgical procedures, that include a small but known risk of air embolism are reportable under this event, including, but not limited to, those involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.

(more)

Table 1 – List of Serious Reportable Events (continued)

3. PATIENT PROTECTION EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Infant discharged to the wrong person		Stedman's Online Medical Dictionary defines an infant as a child under the age of one year.
B. Patient death or serious disability associated with patient elopement (disappearance)	Excludes events involving competent adults.	This event is not intended to capture death or serious disability that occurs due to circumstances unrelated to the elopement (after the patient is located). The term *competent adult* should be interpreted in accordance with prevailing legal standards.
C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare facility" (defined in box B, previously).
4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
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 involving drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.	This event is intended to capture: ■ The most serious medication errors, including occurrences in which a patient known to have serious allergies to specific medications/agents receives those medications/agents, resulting in serious harm or death. These events may occur as a result of failure to collect allergy information; failure to review available allergy information; failure to assure the availability of allergy information and prominently display it; or through other system failures that are determined by investigation to be the cause of the adverse event. ■ Occurrences in which a patient dies or suffers serious disability as a result of failure to administer a prescribed medication. ■ Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique. This event is not intended to capture: ■ Patient death or serious disability associated with allergies that could not reasonably have been known or discerned in advance of the event. ■ *All* situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability—only those that result in death or serious disability.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products		This event is not intended to capture: ■ Patient death or disability associated with organ rejection, other than those attributable to a hyperacute hemolytic reaction. ■ Patient death or disability when the cause is not detectable by ABO/HLA matching.

(more)

Table 1 – List of Serious Reportable Events (continued)

4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.	This event is not intended to create a new obligation; the organization's obligation is to report the event when it is made aware of the maternal death or serious disability either by re-admittance or by the patient's family. A low-risk pregnancy is defined as a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.[iii]
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		Hypoglycemia is defined as blood glucose levels <60mgdL (ICD-9, 251.0).
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	*Hyperbilirubinemia* is defined as bilirubin levels >30 mg/dl. *Neonate* refers to the first 28 days of life.	The organization's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare 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		Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.[iv]
H. Artificial insemination with the wrong donor sperm or wrong egg		The organization's obligation is to report the event when it is made aware of the occurrence.

(more)

[iii] NQF, *Serious Reportable Events in Healthcare: A Consensus Report,* NQF: Washington, DC; 2002.

[iv] NQF, *Serious Reportable Events in Healthcare: A Consensus Report,* NQF: Washington, DC; 2002.

Table 1 – List of Serious Reportable Events (continued)

5. ENVIRONMENTAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock/elective cardioversion.	This event is intended to capture: ■ Patient death or disability associated with unintended electric shock during the course of care or treatment. This event is not intended to capture: ■ Patient death or disability associated with emergency defibrillation during ventricular fibrillation or electroconvulsive therapies.
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 healthcare facility		
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		The event is intended to capture instances in which restraints are implicated in the death; for example, the use led to strangulation/entrapment. Death/disability resulting from falls caused by lack of restraints would be captured under falls. Restraint is currently defined by the Joint Commission, by the Centers for Medicare and Medicaid Services, and by some states. If none of those definitions apply to an institution, the following definition, which is intended to comprise definitions from the named organizations, is offered: Restraint is defined as any method of restricting a patient's freedom of movement that: is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; that is not indicated to treat the patient's medical condition or symptoms; or that does not promote the patient's independent functioning.[v] *(more)*

[v] Adapted from the Joint Commission, Comprehensive Accreditation Manual *Refreshed Core;* 2006.

Table 1 – List of Serious Reportable Events (continued)

6. CRIMINAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		
B. Abduction of a patient of any age		
C. Sexual assault on a patient within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that may use the terms *sexual assault* or *simple assault* or *criminal sexual conduct*); however, the principle and intent remain regardless of the language required based on jurisdiction.
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 a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms *first degree assault* or *second degree assault* or *battery*).

Use of Reports Based on the List

The NQF-endorsed list of *Serious Reportable Events in Healthcare* is intended to be used for public reporting that enables systematic learning across healthcare organizations and systems and drives systematic national improvements in patient safety, based on what is learned both about the events and how to prevent their recurrence. Every healthcare organization is, and should want to be, accountable for the quality of care it delivers and the safety of all it serves—staff, visitors, families, and most particularly, patients.

Accountability in this context encompasses diligent efforts to discover vulnerabilities that could lead to adverse events; focused review and analysis of events to determine causal or contributing factors; and public reporting of events to enable other organizations to apply lessons learned and prevent recurrence. It should be noted that in the patient safety improvement effort, using reports to affix blame is counterproductive.

The implementation of the Patient Safety and Quality Improvement Act of 2005 brought tremendous potential for leaping forward in preventing the 28 serious adverse events on the list. As the network of patient safety databases contemplated by the act evolves, this list offers events already tested and in use in a number of states that will be a valuable resource for patient safety organizations.

Research Recommendations

Although the list of serious reportable events has been in use to varying degrees across states and healthcare organizations, there remains a dearth of information regarding the research recommendations identified in the 2002 report; five are repeated here—one with changes. Specifically, the following research issues should be addressed:

- exploring effective mechanisms to collect data and communicate serious reportable events to the public;
- examining how data derived from using the NQF list can be disclosed in a way that meets the needs of the public and that also is balanced with the need for providers to learn from mistakes;

- testing the operational value and utility of the events on the list, including research on the need to support such a list and the public's perceptions of its impact;
- identifying ICD, CPT, or other codes that correlate with each serious reportable event on the list; and
- defining comparable risk adjustment measures when individuals' risk compared to overall experience with the event is dissimilar.

Additional areas in which research is needed have become clear as experience with the list has been gained and include the following:

- identifying effective mechanisms, including standardization of reporting systems, to permit an institution to report an event only when it occurs within its organization and only once to a single entity (from which needed information can be extracted), thus avoiding double reporting when a patient receives care in more than one healthcare organization;
- testing the ability and adequacy of the NQF-endorsed Patient Safety Event Taxonomy in capturing all the events in ways that enable analysis and systematic patient safety improvement;
- evaluating the comparability of data reported across healthcare systems to determine the degree to which comparability exists and defining next steps toward improving comparability;
- evaluating the outcomes of public reporting in terms of both the reduction in occurrences of these events and the identification and use of practices to prevent such occurrences; and
- evaluating differences based on population or geography in the rates of occurrence of these events in order to determine reporting and/or occurrence variations and to design appropriate population-specific interventions.

Acknowledgments

NQF greatly appreciates the efforts of the Serious Reportable Events Consensus Standards Maintenance Committee and those of the state representatives whose implementation experience contributed to this update.

Appendix A

State, Federal, and International Implementation

A number of governmental agencies are using *Serious Reportable Events in Healthcare* as the basis for, as a part of, or verbatim in their reporting systems. Their recommendations for improvements to the events and to the implementation guidance has enriched this report.

This appendix lists states, federal, and international governmental entities that have implemented reporting of the events, along with information about the vehicles and methods used for implementation, the facilities from which reporting is required, and the extent to which the events are used.

Appendix A – State, Federal, and International Implementation*

Implementing Enitity	Name of Program/Legislation and Date Implemented	Method of Implementation	Reporting Facilities	Use of the NQF Serious Reportable Events	Details
California	An act to amend Sections 1279.1, 1279.2, and 1279.3 and 1280.4 to the Health and Safety Code, relating to health facilities. Chaptered by Secretary of State. Chapter 647, Statutes of 2006	Legislative change to Health and Safety Code	General acute care hospitals, acute psychiatric hospitals, and special hospitals	◆	*Adverse event* is defined as an unusual occurrence, such as an epidemic outbreak, poisoning, fire, major accident, disaster, or other catastrophe, medical error, or any other unusual occurrence that threatens the welfare, safety, or health of patients, personnel, or visitors
Connecticut	Quality of Care Program, 2002	New general statute within the Department of Public Health	Hospitals and outpatient surgery centers	✚	Adds six additional events, including nosocomial infection
Illinois	Illinois Adverse Health Care Events Reporting Law of 2005	Incorporated into the Hospital Assessment Act; new legislation	Hospitals and outpatient surgery centers	▼	Excludes Care Management Events 4.E, 4.F, and 4.G. (see table 1 in the body of the report)
Indiana	Medical Errors Reporting System, 2006	Adopted in response to governor's executive order to create medical error reporting system	Hospitals, outpatient surgery centers, abortion clinics, and birthing centers	◆✚	Expands and modifies existing definitions and adds new ones for items that were not in the NQF report
Minnesota	Adverse Health Events Reporting Law, 2003-2004	Stand-alone, new legislation	Hospitals, outpatient surgery centers, and regional treatment facilities	●	First state to implement the NQF list
New Jersey	Patient Safety Act, 2004 (implemented reporting system in 2005)	Stand-alone, new legislation	All licensed healthcare facilities	✖◆	Modifies several definitions, adds an "other" event to each category, and excludes all criminal events

(more)

KEY

◆ = uses the NQF events with modifications/definition changes
● = uses the NQF events unaltered
▼ = uses the NQF events with exclusions
✚ = uses the NQF events with additions
✖ = uses the NQF events with both additions and exclusions

* Total population covered by existing programs, including California and Saskatchewan, is 82.9 million. Excluding California, 47 million are covered. State data based on 2004 U.S. Census Bureau estimates at quickfacts.census.gov/qfd/states/06000.html. Saskatchewan data obtained from Canada Bureau of Statistics at www.stats.gov.sk.ca. This table presents preliminary information for TRICARE and California.

Appendix A – State, Federal, and International Implementation* (continued)

Implementing Enitity	Name of Program/Legislation and Date Implemented	Method of Implementation	Reporting Facilities	Use of the NQF Serious Reportable Events	Details
Oregon	Oregon Patient Safety Reporting Program for Hospitals, 2006/Oregon Patient Safety Commission, 2003	Patient Safety Commission adopted as new set of administrative rules; program is voluntary and confidential	Open to hospitals, nursing homes, retail pharmacies, ambulatory surgery centers, out-patient renal dialysis facilities, and freestand-ing birthing centers	◆✖▼	Eliminates criminal events and modifies some definitions. Adds "any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams." Healthcare facilities other than hospitals may report adverse events with a variation of the original list
Washington	Second Substitute House Bill 2292, 2006	New legislation currently being worked into hospital licensing regulations	Hospitals, childbirth centers, psychiatric hospitals, correctional medical facilities, and outpatient surgery centers	●	The NQF list is used verbatim in the legislation and directly mandates updating/changing the list only as it is modified by NQF
Wyoming	House Bill No. HB1001 (2004) W.S. 35-2-901 through 35-2-912	Passed into law by statute, the list is included in the rules and regulations for healthcare facility safety event reporting by the Wyoming Department of Health	Healthcare facilities and hospitals where the sick or injured are given medical or surgical care	◆	Expands on and modifies existing definitions and adds new ones for items not in the NQF report
TRICARE	Clinical Quality Management Program, 2002	Component of the TRICARE Operations Manual	All contractors who supply medical services to TRICARE beneficiaries	●	The program requires additional reporting requirements regarding the severity level of each event reported
Saskatchewan Province, Canada	Saskatchewan Critical Incident Reporting Guideline, 2004	Statute incorporated into the Regional Health Services Act	Events occurring during the administration of services or programs offered by any regional health authority or healthcare organization	✖	Addition of several new events, including an "other" event to each category, and exclusion of death or disability from spinal manipulative therapy

KEY

◆ = uses the NQF events with modifications/definition changes
● = uses the NQF events unaltered
▼ = uses the NQF events with exclusions
✚ = uses the NQF events with additions
✖ = uses the NQF events with both additions and exclusions

* Total population covered by existing programs, including California and Saskatchewan, is 82.9 million. Excluding California, 47 million are covered. State data based on 2004 U.S. Census Bureau estimates at quickfacts.census.gov/qfd/states/06000.html. Saskatchewan data obtained from Canada Bureau of Statistics at www.stats.gov.sk.ca. This table presents preliminary information for TRICARE and California.

Appendix B
Members and Board of Directors

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AFT Healthcare
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Consumers Advancing Patient Safety
Consumers' Checkbook
Consumer Coalition for Quality Health Care
Coordinating Center
International Association of Machinists
March of Dimes
National Breast Cancer Coalition
National Citizens' Coalition for Nursing Home Reform
National Coalition for Cancer Survivorship
National Consumers League
National Family Caregivers Association
National Partnership for Women and Families
Service Employees International Union
State of California - Office of the Patient Advocate

HEALTH PROFESSIONAL, PROVIDER, AND HEALTH PLAN COUNCIL

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Adventist HealthCare
Advocate Health Partners
Aetna
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American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Pediatrics
American Association of Nurse Anesthetists
American Clinical Laboratory Association
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American College of Chest Physicians
American College of Emergency Physicians
American College of Gastroenterology
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Geriatrics Society
American Heart Association
American Hospital Association
American Managed Behavioral Healthcare Association
American Medical Association
American Medical Group Association
American Nurses Association
American Optometric Association
American Osteopathic Association
American Society for Gastrointestinal Endoscopy

*When voting under the NQF Consensus Development Process occurred for this report.

American Society for Therapeutic Radiology and Oncology
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Health-System Pharmacists
American Society of Interventional Pain Physicians
American Society of Plastic Surgeons
Ascension Health
Association of Professors of Medicine
Atlantic Health System
Aurora Health Care
Baptist Memorial Health Care
Bayhealth Medical Center
Baylor Health Care System
Beverly Enterprises
BJC HealthCare
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Bon Secours Health System
Bronson Healthcare Group
Bronx Lebanon Hospital Center
Calgary Health Region - Quality Improvement and Health Information
Carolinas Medical Center
Catholic Health Association of the United States
Catholic Health Initiatives
Catholic Healthcare Partners
Cedars-Sinai Medical Center
Centura Health
Chesapeake Bay ENT
Child Health Corporation of America
Children's Hospitals and Clinics of Minnesota
CHRISTUS Health
CIGNA Healthcare
Clark Consulting
College of American Pathologists
Condell Health Network
Connecticut Hospital Association
Council of Medical Specialty Societies
Detroit Medical Center
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The Heart Center of Indiana
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MedStar Health
Memorial Health University Medical Center
Memorial Hermann Healthcare System
Memorial Sloan-Kettering Cancer Center
Mercy Medical Center
Meridian Health System
The Methodist Hospital
Milliman Care Guidelines
Munson Medical Center
National Association for Home Care & Hospice
National Association of Chain Drug Stores
National Association of Children's Hospitals and Related Institutions
National Association of Public Hospitals and Health Systems
National Consensus Project on Quality Palliative Care
National Consortium of Breast Centers
National Hospice and Palliative Care Organization
National Rural Health Association
Nebraska Heart Hospitals
Nemours Foundation
New York Presbyterian Hospital and Health System
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North Carolina Baptist Hospital
North Mississippi Medical Center
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Norton Healthcare
Novant Health
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PacifiCare
PacifiCare Behavioral Health
Palmetto Health Alliance
Park Nicollet Health Services
Pharmacy Quality Alliance

Partners HealthCare
Premier
Presbyterian Healthcare Services
Providence Health System
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Robert Wood Johnson University Hospital-Hamilton
Robert Wood Johnson University Hospital–New Brunswick
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Sodexho Healthcare Services
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[1] Chair through December 2005; Chair Emeritus since January 2006
[2] Appointed to the Board of Directors and named Chair-Elect in May 2005; became Chair in January 2006
[3] Through September 2005
[4] Since March 2006
[5] Through December 2005
[6] February 2005 through August 2005
[7] NQF President and CEO since February 2006; also was Liaison Member representing the Institute of Medicine through May 2005
[8] Since March 2006
[9] Through December 2004
[10] Through February 2005
[11] Through January 2005
[12] Since February 2006
[13] NQF President and CEO through November 2005
[14] Since August 2006
[15] Since February 2006
[16] Through October 2006
[17] Since March 2006
[18] Through October 2006
[19] Since January 2005
[20] October 2005 to August 2006
[21] Through October 2005
[22] Since January 2005
[23] Since October 2005
[24] Through December 2005
[25] Since August 2005
[26] October 2005 to June 2006
[27] Since April 2006

Appendix C
Maintenance Committee and Project Staff

Maintenance Committee

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[2] Through November 2005
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Appendix D
Commentary

Introduction

In August 2005, the National Quality Forum (NQF) convened a Consensus Standards Maintenance Committee (CSMC) to update its list of serious reportable events in healthcare. This list of serious, largely preventable adverse events that are of concern to both the public and healthcare providers was endorsed by NQF in 2002 and published with the support of a number of organizations whose unflagging support of improvement in the quality and safety of healthcare continues.[1]

The CSMC included consumers, providers, purchasers, and research and quality improvement organizations. Many of these key stakeholders were involved with the initial project. NQF's early work in developing the list of adverse events was undertaken at the behest of the federal government and was to be used as part of a national, state-based healthcare error reporting system. Although this vision was not realized, the list has been used by a number of states, as well as by the Department of Defense in its TRICARE program. The experiences of states such as Connecticut, Illinois, Minnesota, and New Jersey have helped to indicate where more precision in the list is needed. States also have generously contributed to implementation guidance, which can assist new users in reporting. (Appendix A presents a description of state, federal, and international implementation activities.)

[1] National Quality Forum (NQF), *Serious Reportable Events in Healthcare: A Consensus Report,* Washington, DC: NQF; 2002. Support for the 2002 report was provided by the Milbank Memorial Fund, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Robert Wood Johnson Foundation, the California HealthCare Foundation, the Horace W. Goldsmith Foundation, the Department of Veterans Affairs, and the United Hospital Fund of New York.

After careful deliberation, the CSMC recommended that the list continue to be used as a means of institutional accountability. It also recommended, more fundamentally, that the list be used as a tool for systematic learning and improvement and therefore developed an updated list of 28 serious reportable events. For this update, in addition to the original list of 27 events, 1 event was added, and 3 of the original 27 events were materially changed, as were the specifications for 4 of the events.

The list of serious reportable events was updated in order to ensure that it remained current and consistent with the best medical and scientific evidence.[2] This commentary summarizes the discussions of the CMSC and the rationale supporting its recommendations for updating the list. NQF's Consensus Development Process (CDP) and the NQF document *The Purpose, Structure, and Function of Consensus Standards Maintenance Committees* were used to identify material changes in the list.[3]

Approach

The CSMC began by revisiting the original purpose of the list. The Committee agreed that the criteria for inclusion that were used in 2002 remained relevant and appropriate and should continue unchanged. Accordingly, to qualify for the list in 2006, an event must be 1) unambiguous; 2) usually preventable; 3) serious; and 4) any of the following:

- adverse; and/or
- indicative of a problem in a healthcare facility's safety systems; and/or
- important for public credibility or public accountability.

The CSMC then considered, in turn, the following:

- the existing list of events;
- implementation and reporting issues;
- the proposed modification of existing events; and
- new candidate events.

The CSMC agreed that the recommended changes to the list should include only those changes required to bring the list up to date with current knowledge. It also determined that the changes should include compelling new events, new definitions, additional specifications, and a new element—implementation guidance. In its efforts, the CSMC considered the following:

- revised specifications and definitions to facilitate consistent collection and reporting on serious reportable events by health professionals, providers, and policymakers;
- criteria for the removal of events from the list of serious reportable events;

[2]NQF keeps endorsed consensus standards current through its Consensus Standards Maintenance Committees (CSMCs), whose purpose is to continuously review assigned sets of consensus standards for currency and appropriateness. CSMCs were approved by the NQF membership and board in September 2003, when approving version 1.6 of the Consensus Development Process (although at that time these entities were called "working groups"). The board approved a plan in 2004 detailing how these committees would function. Nominations for the CSMC on *Serious Reportable Events* were sought from NQF Members in early 2005, and the group was convened in the summer of 2005.

[3]NQF, *The Purpose, Structure, and Function of Consensus Standards Maintenance Committees*; September 1, 2005. Available at www.qualityforum.org.

- combining or re-ordering events to facilitate consistent reporting;
- the addition of events based on the emergence of adverse events that were not previously reported or that were occurring with increased frequency; and
- implementation guidance to facilitate consistency in reporting. (Although it was outside the scope of this update to include detailed perspectives on the vast reporting experience obtained using the list, the list was augmented to include selected implementation guidance.)[4]

Overall, the CSMC's discussions included many of the same issues that had been raised during the deliberations leading to the development of the 2002 list. As noted in the following sections, the Committee did not a priori dismiss potential revisions to the core framework and definitions to be used for identifying events. Rather, it thoughtfully and carefully reconsidered these issues in the context of the current environment.

The CSMC agreed that the seriousness of an event, particularly the level of harm resulting to the patient, should be considered of primary importance. Therefore, the Committee spent considerable time reflecting on the term *serious* and continued to apply that criterion in such a way that events involving patient death or disability received the greatest attention. In its deliberations (after receiving reviewer comments), the CSMC again discussed the definition of *serious* (see box A in the report) in the context of the language "…lasting more than seven days or still present at the time of discharge…." The Committee noted that some organizations have established mechanisms for postdischarge follow-up that would permit them to ascertain whether serious sequelae had resolved within the specified period, even after discharge. The Committee agreed that the intent of the language is to ensure standardized reporting and that if a patient is discharged before the eighth day in a facility and an organization is not able to determine that the serious disability has resolved before the eighth day, the event should be reported.

The Committee also felt that some events so strongly indicate a high risk of potential harm that they should be reported, even if the actual harm to a particular patient is not serious. Surgery performed on the wrong patient, for example, was deemed to meet this criterion, even if the surgery does not result in the death or disability of the patient.

The abilities to clearly define, quantify, and audit events were considered as separate issues. The Committee agreed that these concepts should be captured by the term *unambiguous*. Implementation guidance in the 2006 update seeks to provide additional direction and examples about what should be reported, and, conversely, what is not to be reported for respective events.

During the Committee's review, *unintended* was considered as an alternative to *preventable* as a criterion for events

[4]The CSMC recommended that NQF convene patient safety experts, policymakers, researchers, providers, consumers, and purchasers to identify effective tools for event reporting, data collection, and analysis.

(as it had been during the deliberations for the 2002 list). The CSMC agreed that *preventable* was a more relevant criterion for a list used for public accountability. Because only a small number of events are always preventable, the CSMC reaffirmed the original criterion that an event be *usually preventable* to qualify for the list. Committee members agreed that additional contextual information would be useful in future report iterations.

The Committee agreed that the term *associated with* should be further clarified and that when used it should indicate that it would be reasonable to assume that the adverse outcome to the patient was related to the action or reaction described by the event, at least initially. However, the CSMC also noted that the event might be subject to further investigation and/or root cause analysis in order to confirm or refute the presumed relationship. The Committee decided that if, following such investigation or analysis, the patient death or serious disability is determined to be unrelated to the event, any reports that were made should be modified to minimize misidentification.

Finally, the CSMC contemplated several issues related to reporting and how they should or could be addressed, including the following:

- the desirability of definitional clarification when definitions are fixed and/or determined by statute, regulation, or practice. One example was the definition of *disability*. The CSMC observed that federal law does not define serious disability per se and determined that the definition should be included and expanded;
- avoiding a focus on blame in reports based on the list;
- the importance of including appropriate confidentiality and legal protections in reporting systems to encourage reporting;
- data validity challenges associated with the collection of information about serious reportable events once a patient has left a healthcare facility, including the extent to which individual patients comply with aftercare recommendations and/or attend follow-up appointments that could contribute to the event;
- the importance of feedback to individual providers, event reporters, and patients about findings of root cause analyses and other quality improvement activities in order to enhance patient safety;
- technical assistance for implementing the list, acknowledging that until a standardized reporting framework is in place, the burden will continue to be placed on providers and healthcare facilities to meet the requirements of reporting systems; and
- the rarity of occurrences of the events, because some believe that rare events should not be used for comparison or for making judgments about an institution's quality.

Purpose of the List

The NQF serious reportable events were developed to help identify failures in the healthcare system whether or not they can be attributed to the entity reporting the event. The reporting provider may be involved with a patient and become aware of an event that was not under the control of the reporting provider but that reflects a

serious breakdown in another part of the healthcare system. The Committee agreed that, until mechanisms exist to enable reporting only by the organization where they occurred, events should be reported whether they are the result of a failure in the reporting provider's processes or a failure in another part of the healthcare system. It also was noted that although the events are almost always preventable, in certain circumstances (such as pressure ulcers in the moribund patient or falls) they may develop despite taking every reasonable precaution; therefore, a few of the reported events may not have been preventable. Nonetheless, the CSMC believed that such events should be reported.

A diverse array of healthcare stakeholders on the Committee achieved consensus that the occurrence of the 28 events on the list is almost always under the control of healthcare facilities and that they should not occur—and that when they do, they should be publicly reported.

The updated list of events, for which the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility, constitutes a short list of the most serious adverse events that may indicate serious organizational safety system lapses. The CSMC re-emphasized that the events on this list are clearly identifiable and measurable and that therefore it would be feasible to expect reporting compliance within a public reporting system.

Purpose of the Update

NQF updated the list and added implementation guidance so that it continues to reflect the adverse events that meet the accepted criteria and remains current with the state of medical and scientific knowledge. Because the list is used for public accountability, in order to maintain its validity and usefulness, periodic monitoring and updating are particularly important.

NQF's update considered the fact that the list is intended to complement private and public sector national reporting activities—such as the Joint Commission's Sentinel Event Reporting System and the Food and Drug Administration's (FDA's) MedWatch system—and that the events on the list feed into databases that capture a larger universe of less serious healthcare errors and near misses.

The update also was to ensure that there would be a relevant and appropriate list for defining requirements for patient safety databases to be established under the Patient Safety and Quality Improvement Act of 2005 and to serve as a resource for patient safety organizations that will be established under the act.

Criteria for Selection, Modification, or Withdrawal of Serious Reportable Events

In August 2005, NQF issued a Call for candidate new serious reportable events and for updates to the current NQF-endorsed™ list. The Call was sent to the more-than 260 NQF member organizations

and to more than 1,300 individuals and non-member organizations. It specified that the criteria for considering a new event would be the same as those used to identify the events on the 2002 list. It also specified that a recommended modification should be accompanied by the specific rationale for the proposed change; that to remain endorsed any change must not be material; and that any recommendations involving material change would be subject to voting pursuant to the NQF CDP.

In response to the Call, NQF received recommendations for the addition of 22 new events; 1 recommendation to withdraw endorsement of 1 event (4G), and 44 comments recommending modifications to 18 of the endorsed events (1A, 1B, 1C, 1D, 1E, 2A, 2B, 2C, 3B, 4A, 4B, 4C, 4E, 4F, 5A, 6A, 6C, and 6D). (See table 1 in the report.) All of the recommendations were considered by the CSMC in its deliberations and are reflected in the events, specifications, implementation guidance, and/or this commentary.

Of the 22 candidate events, the Committee recommended that 2 be incorporated into 1 new event (artificial insemination with the wrong donor sperm or wrong egg). In addition, the Committee believed that 6 candidate events were captured by existing events and that 12 events, while important, either did not meet one or more of the criteria or were definitionally ambiguous. Notably, three proposed new events concerned occurrences involving organ transplantation and did not meet one or more of the criteria. Two of the proposed new events related to physical plant safety rather than patient safety per se. The Committee chose to retain the patient focus of the events in the belief that plant safety should be and is addressed under the reporting requirements of the Occupational Safety and Health Administration. The CSMC recommended that the list of serious reportable events and the plant safety events should be monitored by healthcare organizations' safety oversight body(ies), where coordinated mitigation strategies can be designed.

The NQF-Endorsed Consensus Standards

The CSMC recommended that 21 of the currently endorsed events should continue without change; that material modifications should be made to 3 events and the specifications of 4 events (1 of which also has changes to the event language); and that 1 new event should be added to the list, bringing the total serious reportable events in the NQF-endorsed list to 28.

Events with Material Change

1. SURGICAL EVENTS

1D. Unintended retention of a foreign object in a patient after surgery or other procedure

CSMC members commented generally on the value of collecting quality-related information on surgical materials retained in a patient following surgery and the need for providers and healthcare facilities to share important information about defects and other surgical material malfunctions. In 2002, the only objects excluded from the event were those present prior to surgery that a provider had made a decision to leave in (e.g., bullets, shrapnel).

The Committee considered specific requests to exclude the retention of items such as broken microneedles and surgical screws. The rationale for exclusion in these specific instances was that the retention of these items is generally not expected to cause significant harm if left in a patient, and/or the removal could cause more damage. The Committee discussed these exclusions and agreed that the retention of broken microneedles would be of sufficiently low risk that they could be excluded. However, the CSMC decided that the retention of broken screws, although a seemingly minor problem, can confound the treatment of fractures and may necessitate further reconstructive surgery and that therefore, the retention of broken screws should be included in the event. The latter discussion was revisited after NQF Member and public review and additional research, and the specification was modified. At the same time, a non-material change was made to the event with the addition of the word *unintended*.

Finally, the Committee discussed the point at which a foreign object is determined to be "retained." Two suggestions were made. The first suggestion was that a determination should be based on the location where the retained object was discovered (e.g., postanesthesia recovery room versus surgical suite) and the course of intervention that was decided. The second suggestion was that a determination should be based on whether additional surgery would be required to remove the foreign object. Because the second suggestion helped clarify the issue, it became the preferred context for consideration, and the CSMC recommended that instead of modifying the event, the implementation guidance should be clarified. It also recommended that if the occurrence is discovered after surgery ends, as defined in the implementation guidance, an object should be considered "retained" whether or not the patient returns to the operating room for new surgery to remove it.

3. PATIENT PROTECTION EVENTS

3B. Patient death or serious disability associated with patient elopement (disappearance)

The CSMC affirmed the seriousness of this event and public interest in reporting elopement, especially the elopement of patients who are not competent, regardless of how long they have been missing. Therefore, the CSMC recommended the deletion of the phrase *for more than four hours*. In response to comments, the implementation guidance was modified to state that death or serious disability occurring after a patient is located that is unrelated to the elopement is not reportable.

4. CARE MANAGEMENT EVENTS

4A. 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)

The Committee considered the issues related to reporting, including the fact that many of these occurrences may become known only as the result of a root cause analysis. Committee members agreed that *wrong drug* includes 1) a medication to which a patient has a known allergy and 2) a medication that is known to cause serious drug-drug interactions.

Upon further deliberation, the CSMC expanded the second specification for clarity. This represented an addition to the specifications that met the criteria for inclusion and that emphasized that the failure to screen for allergies and known drug interactions is a serious flaw in a healthcare organization's safety systems.

4B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products

Based on CSMC recommendations, this event was expanded to include instances in which human leukocyte antigen (HLA) incompatibility leads to patient death or disability. The Committee noted that these occurrences might be prevented by ensuring that the donor and the recipient have the same or very similar HLA types and by using immunosuppressant drugs if there is an HLA incompatibility between donor and recipient.

5. ENVIRONMENTAL EVENTS

5A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility

The CSMC recommended that elective cardioversion be added to the exclusion already specified for this event because it may not be possible to determine conclusively whether a death is associated with the use of a planned treatment or from other causes.

5D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility

The CSMC recommended that the event and specifications be modified to include instances of serious disability (because of examples that implementers identified). The CSMC acknowledged that certain patients are at greater risk for harm, but nonetheless, it determined that because falls that result in serious disability are usually preventable, any such occurrence should be reported.

New Event

4. CARE MANAGEMENT EVENTS

4H. Artificial insemination with the wrong donor sperm or wrong egg

Although the CSMC recognized that instances in which the wrong sperm or egg is used may not be readily known to the institution, provider, or recipients, it determined that such occurrences 1) indicate system failures, and/or flawed organization policies and procedures and 2) meet the criteria for inclusion. Accordingly, the CSMC recommended adding the event to the list and noted that when such events become known, they should be reported.

Events Without Material Change

Although the Committee ultimately recommended against making any material changes to the events described in this section, it did provide implementation guidance for most of them that is based on the experiences and suggestions of organizations that have reported the events. The CSMC noted that although the list and implementation guidance will evolve, the guidance is neither all-inclusive nor equally developed across the events. The guidance was changed based on comments received during the review phase of the CDP.

This section summarizes the CSMC's views and recommendations associated with these events.

1. SURGICAL EVENTS

The CSMC considered the existing wrong surgical events, and because of their similarity the events were considered concurrently:

1A. Surgery performed on the wrong body part

1B. Surgery performed on the wrong patient

1C. Wrong surgical procedure performed on a patient

Any single event can be reported in multiple categories. For example, an appendectomy on the wrong patient is also surgery on the wrong body part (for that patient) and is the wrong procedure (for that patient). To eliminate duplicative reporting of the same event, the CSMC established a logical priority for reporting, based on the following matrix:

EVENT	PATIENT	BODY PART	PROCEDURE
1B	Wrong	N/A	N/A
1A	Right	Wrong*	N/A
1C	Right	Right	Wrong

*A correct procedure performed on the correct patient, but in the wrong place (e.g., left versus right confusion; wrong levels such as in spinal surgery) is to be categorized as surgery performed on the wrong body part.

An event should be reported in only one category.

The Committee defined *surgery* as including a range of procedures, which is reflected in the implementation guidance for events 1A through 1E. The Committee also noted that the event should refer to the concept of informed consent, which is reflected in a note to event 1A (see table 1).

Finally, based on comments received during the review phase of the CDP, the word *correctly* was added before *documented* in the first sentence of the additional specification for events 1A through 1C as a non-material change. In addition, the word *surgical* was added to the first sentence of the additional specifications for event 1C as a non-material change.

1E. Intraoperative or immediately postoperative death in an ASA Class I patient

The CSMC considered whether it would be of benefit to expand the event beyond ASA Class 1 to include patients classified as ASA Class 2. Following discussion, the CSMC recommended against expanding the scope of this event because patients characterized as ASA Class 2 have significant risk factors that could be expected to increase the likelihood of having an adverse event—that is, the event would not be wholly unanticipated. Based on a comment received during the review phase of the CDP, the word *induction* in the second sentence of the additional specifications was replaced with *administration* as a non-material change.

2. PRODUCT OR DEVICE EVENTS

2A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility

The Committee reaffirmed that this event recognizes failures in processes to detect and act on contamination in drugs, devices, and biologics and failures in system accountability. The Committee believed that although contamination may occur before the drug, device, or biologic enters

the healthcare facility, the harm outweighs any concern regarding the location in which the contamination originated. Therefore, while acknowledging that the root cause of contamination could take place during many points in the manufacturing chain, the Committee agreed that such contamination should be reported when death or disability results.

Committee members discussed a number of other proposed exclusions to this event and noted that it is intended to capture occurrences that are not seen with the eye and that become known only as part of a root cause analysis. The CSMC acknowledged that although liability concerns could accompany a disclosure that points to a potential manufacturing defect, a report of contamination in drugs, devices, or biologics is not an a priori judgment of liability.

Considerable discussion ensued regarding the use of the term *generally detectable*. The CSMC recognized that it is an ambiguous term and recommended removing the word *generally* from the specification. The Committee agreed that the word *detectable* refers to a contamination that can be seen with the eye, such as those that may be seen on pumps, wiring, casings, and packaging, but that reports of contamination should be made when the event becomes known as a matter of course (e.g., during testing) and/or through a root cause analysis, even when the contamination cannot be seen with the eye. CSMC members who participated in the discussions for the 2002 serious reportable events report noted that the use of the word *generally* was intended to recognize the view that some contaminations will not always be identifiable, given the complexity of medical device manufacture, pharmaceutical compounding, and viral transmission. Although it opted to recommend deleting *generally* from the specification, the Committee decided that additional clarification for *detectable* should be addressed in the implementation guidance.

The Committee considered excluding organs that are contaminated with rabies from this event, but ultimately did not make this exclusion. The rationale for the proposed exclusion was that the risk of acquiring rabies competes with the benefit of timely organ transplant. However, the Committee concluded that although rabies testing may not be part of the routine organ screening process throughout the United States, in certain areas screening should be conducted.

2B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended

The Committee briefly discussed the use of the term *associated with*. (As in the 2002 report, *associated with* refers to the assumption that the adverse event occurred because of 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.) The CSMC discussed the complexity of the concept at length and concluded that, in the absence of a suitable replacement term and definition that communicates the concept, *associated with* should be retained.

The CSMC noted that although *intended use* is based on labeling approved by FDA and/or the National Institute of Standards and Technology, off-label uses are often undertaken in the absence of formal approval. The Committee reinforced its commitment to focus on the occurrence of an adverse event rather than on its source, but it also considered the relative value of collecting information about events that occur as a result of provider-intended use versus manufacturer-intended use. The Committee noted that the occurrence of this event should not lead to a priori judgments about individual practitioner technique.

2C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

The CSMC clarified in the implementation guidance that this event should include reports of air embolisms that lead to death or disability, with the single exception noted in the event specifications—when their occurrence is regarded as a system failure. Based on comments received during the review phase of the CDP, the phrase *or serious disability* was added to the additional specifications as a non-material change.

3. PATIENT PROTECTION EVENTS

3A. Infant discharged to the wrong person

This event remained unchanged; there was no detailed discussion or dissent.

3C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

The CSMC reaffirmed that this event requires the reporting of occurrences resulting from patient actions after admission to a healthcare facility. It excludes deaths resulting from self-inflicted injuries that were the original reason for admission to the healthcare facility.

4. CARE MANAGEMENT EVENTS

4C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility

The CSMC clarified in the implementation guidance that the event is not intended to create a new obligation for an institution, but that the institution should report these occurrences if and when it has been notified that one has occurred. Despite the limitations related to the discovery of post-discharge death or disability, reports of these events are important for public accountability, and many states require this information to be captured when it becomes known. The Committee acknowledged that although institutions are not consistently aware of these events and comparisons between institutions are difficult to achieve, given their seriousness, the event should be retained.

4D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility

The Committee acknowledged that there may be opportunities for exclusions, but it noted that death and disability from hypoglycemia are so rare that exclusions are not recommended.

4E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates

CSMC discussion focused on the challenge involved in consistently reporting kernicterus or death in neonates once a patient has left a hospital. The Committee did not recommend any changes to the event, but developed implementation guidance that states that institutions should have mechanisms in place to assess patients at risk for hyperbilirubinemia; should take steps to raise awareness about the potential for kernicterus and its risk factors; and should have policies and practices in place to follow up with high-risk patients after discharge. The CSMC cited American Academy of Pediatrics guidelines that emphasize the importance of follow-up and awareness of the risk of hyperbilirubinemia and kernicterus for inclusion in implementation guidance.[5]

4F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility

This event is one of the most frequently reported, according to implementers' experience. Staging and preventing pressure ulcers is challenging because certain patients are especially vulnerable to developing them (e.g., patients with spinal cord injuries or multisystem failures). Although CSMC members recognized the challenges involved and noted that these concerns merit a statement about the difficulty of staging, they did not recommend exclusions. The CSMC did note that if future research demonstrates that certain exclusions are appropriate, they would be considered.

4G. Patient death or serious disability due to spinal manipulative therapy

The CSMC considered withdrawing endorsement of this event because of the rarity of these occurrences. The Committee also noted that these events may not always be related to an institution's safety systems, but rather often are associated with individual provider action. The CSMC ultimately decided to continue endorsement. It also recommended that patients be consistently monitored and that immediate and appropriate action be taken when this event becomes apparent.[6] Institutional policy and procedure regarding the credentialing and granting of privileges should address concerns related to individual providers.

5. ENVIRONMENTAL EVENTS

5B. 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

This event remained unchanged; there was no detailed discussion or dissent.

5C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility

This event remained unchanged; there was no detailed discussion or dissent.

[5] American Academy of Pediatrics Subcommittee on Hyperbilirubinemia, Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation, *Pediatrics*, 2004;114(1):297-316.

[6] Childs JD, Flynn TW, Fritz JM, Screening for vertebrobasilar insufficiency in patients with neck pain: manual therapy decision-making in the presence of uncertainty, *J Orthop Sports Phys Ther,* 2005;35(5):300-306.

5E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

The Committee considered expanding the event to include instances during which the lack of restraints (restraints were ordered but not in place) followed by a fall leads to death and disability, but for the purposes of consistent reporting, it recommended that these events be captured under the category of falls. The Committee also considered the inclusion of a statement that serious disability or death associated with the use of restraints with frail and infirm patients might require risk adjustment, but concluded that it was not appropriate to do so for this single event.

6. CRIMINAL EVENTS

6A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

6B. Abduction of a patient of any age

6C. Sexual assault on a patient within or on the grounds of a healthcare facility

6D. 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 a healthcare facility

The CSMC affirmed that these events are included in order to ensure a broad view of patient safety and the safety of the healthcare environment. The Committee also affirmed that the healthcare institution has a duty to patients, employees, and guests to ensure a safe environment and should have surveillance systems in place to do so.

Events or Specifications Considered But Not Included

The Committee considered a number of events and exclusions that were not included on the 2002 list. Many of these events were considered when the list was first endorsed, with exclusion resulting primarily because an event met some, but not all, of the criteria for inclusion. The events and exclusions the Committee considered were as follows:

- ***Death, disability, or material change in treatment resulting from or substantially due to the loss, misplacement, destruction of, and/or failure to communicate diagnostic test results to the patient.*** The Committee was unable to identify specifications to differentiate between serious and non-serious failures.
- ***Patient death from a healthcare-associated infection.*** The CSMC concluded that there was insufficient evidence regarding whether many of these types of infections are preventable and agreed that the issue of risk adjustment would complicate reporting of this event.
- ***Any other patient death or serious injury/illness not anticipated in the normal course of events and believed to be due to the processes of care.*** The Committee believed this category of event to be too difficult to specify and operationalize.
- ***Perforations occurring during open, laparoscopic, and/or endoscopic procedures resulting in death or serious disability.*** The CSMC did not recommend this event for inclusion because of the difficulty in identifying exclusions for high-risk procedures and the likelihood

that these occurrences are specific to surgical technique and not a hospital's safety system per se.

- ***Obstetrical events resulting in death or serious disability to the neonate.*** Occurrences of these events may not be clearly identifiable or unambiguous, because numerous variables factor into such occurrences—for example, congenital anomaly, immature cardio-respiratory systems, and prematurity.
- ***Laboratory error, laboratory epidemics, or laboratory mishaps resulting in >10 persons receiving incorrect results.*** The Committee did not add this event because it believed it would be difficult to differentiate between serious and non-serious occurrences or to prove a negative occurrence (that something did not happen).

Events Suggested for Addition But Captured by Existing Events

- ***Mistaken removal of a healthy organ.*** The CSMC agreed that this event already is included on the existing list in events 1A, 1B, or 1C: surgery performed on the wrong body part; surgery performed on the wrong patient; and wrong surgical procedure performed on a patient.
- ***Unintended amputation of a body part.*** The Committee agreed that this event already is included on the existing list in events 1A, 1B, or 1C: surgery performed on the wrong body part; surgery performed on the wrong patient; and wrong surgical procedure performed on a patient.
- ***Disinfection mishaps resulting in persons being exposed to actual or possible infection from incorrectly disinfected equipment (e.g., endoscopes); or a non-disinfectant chemical agent (e.g., hydraulic fluid).*** Committee members agreed that this event is captured in event 2A: patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.
- ***Death or serious disability caused by excessive radiation associated with radiation therapy mishaps.*** The Committee agreed that this event is similar to event 2B: patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.
- ***Infectious disease transmission from tissue transplants (skin, cartilage, bone, organs, etc.).*** The CSMC agreed that this event is included in event 2A, in cases of death and disability.
- ***Death or serious disability from a medication event involving a known drug-drug interaction, known allergy, or known condition.*** The Committee agreed that this event is encompassed by event 4A—patient death or serious disability associated with a medication error.

Research Recommendations

Throughout its work, the CSMC considered gaps in the current knowledge of patient safety and noted that a number of areas would benefit from additional research. The Committee emphasized that the research recommendations are not intended to be all-inclusive. Rather, the list of recommendations focuses on priority areas that would facilitate consistent reporting through implementation.

Additional Issues

During the May 2006 to June 2006 review period, NQF received comments on issues that were not previously discussed or discussed in detail by the CSMC. Because *Serious Reportable Events in Healthcare* will continue to undergo regular maintenance, a number of the comments were held for discussion by the CSMC during its next maintenance cycle. A few comments resulted in non-material changes to events to clarify the implicit link that has existed since 2002 between four of the events and their additional specifications. Overall, the nature, array, and volume of comments provide a rich source of data for the CSMC's future work.

In considering the comments received during the review period, the CSMC determined that the implementation guidance should be limited to that related to reporting the events; therefore, all guidance related to the prevention of the events was removed.

Additional Events Recommended During the Review Period

During the review period, four additional events were recommended for inclusion in the list and will be evaluated by the CSMC at its next maintenance cycle. The first of these has been considered previously, but will be reconsidered in light of the current NQF project related to healthcare-associated infections.

The additional events are as follows:

- nosocomial infections resulting in death or disability;
- loss of function of a device that leads to death or disability;
- any unexpected death; and
- unintended injury due to a medical device.

Additional Research Topics Recommended During Review

Comments received during the review phase of the CDP for expanding two of the research topics were incorporated into the list of research recommendations. In addition, three research items will be considered by the CSMC during its next maintenance cycle. First, a comment was made that more research is needed into barriers to standardization across states, in order to work toward greater comparability. Second, while not couched as a research topic per se, the question was raised regarding whether the list should be linked to payment policies—for example, whether underreporting of adverse events should be linked to a reduction in pay for performance. It was noted that this concern will be considered in terms of how it could or should be framed as a research topic. Finally, the CSMC added preventability of pressure ulcers as an important topic for further consideration.

Appendix E
Consensus Development Process: Summary

The National Quality Forum (NQF), a voluntary consensus standards-setting organization, brings together diverse healthcare stakeholders to endorse performance measures and other standards to improve healthcare quality. Because of its broad stakeholder representation and formal Consensus Development Process (CDP), NQF-endorsed™ products have special legal standing as voluntary consensus standards. The primary participants in the NQF CDP are NQF member organizations, which include:

- consumer and patient groups;
- healthcare purchasers;
- healthcare providers, professionals, and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement may apply to be a member of NQF. Membership information is available on the NQF web site, www.qualityforum.org.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www.qualityforum.org.

Each project NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four

critical stakeholder perspectives.* With the assistance of NQF staff and technical advisory panels and with the ongoing input of NQF Members, a Steering Committee conducts an overall assessment of the state of the field in the particular topic area and recommends a set of draft measures, indicators, or practices for review, along with the rationale for proposing them. The proposed consensus standards are distributed for review and comment by NQF Members and non-members.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous, either within or across all Member Councils, for consensus to be achieved. If a majority of Members within each Council do not vote approval, staff attempts to reconcile differences among Members to maximize agreement, and a second round of voting is conducted. Proposed consensus standards that have undergone this process and that have been approved by all four Member Councils on the first ballot or by at least two Member Councils after the second round of voting are forwarded to the Board of Directors for consideration. All products must be endorsed by a vote of the NQF Board of Directors.

Affected parties may appeal voluntary consensus standards endorsed by the NQF Board of Directors. Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF CDP, version 1.7, was in effect. The complete process can be found at www.qualityforum.org.

* For this project, a Consensus Standards Maintenance Committee (CMSC) was used. To ensure that consensus standards are kept current and consistent with the best evidence, CSMCs review and make recommendations, based on specific criteria, to continue endorsement; withdraw endorsement; "sunset" or "retire"; review to ensure consistency across settings of care, conditions, etc.; or pursue new candidate consensus standards or areas of performance measurement.

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