NATIONAL QUALITY FORUM

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT

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NATIONAL QUALITY FORUM

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SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT

EXECUTIVE SUMMARY

The National Quality Forum (NQF)-endorsed® Serious Reportable Events in Healthcare were released initially in 2002. The purpose of the serious reportable events (SREs) is to facilitate uniform and comparable public reporting to enable systematic learning across healthcare organizations and systems and to drive systematic national improvements in patient safety based on what is learned both about the events and about how to prevent their recurrence. Originally envisioned as a set of events that might form the basis for a national state-based reporting system, the SREs continue to fill that purpose as organizations, independent of NQF, have put them into practice. Additionally, they have been used or adapted by national entities with the goal of illuminating such events in order to facilitate learning and improvement.

The purpose of the 2011 update is to 1) ensure the continued currency and appropriateness of each event in the list; 2) ensure that the events remain appropriate for public accountability in light of their standing as voluntary consensus standards; and 3) provide guidance gained by implementers to those just beginning the reporting of these events, across hospitals and for three newly specified settings of care—office-based practices, ambulatory surgery centers, and skilled nursing facilities.

This second update of NQF's serious reportable events presents the results of evaluation of the 28 NQF-endorsed SREs, with recommended modifications, and 12 new events considered under NQF's Consensus Development Process (CDP). After evaluation against the threshold criteria of unambiguous, largely, if not entirely, preventable, and serious, 29 events are recommended for endorsement as voluntary consensus standards suitable for public reporting.

Serious Reportable Events in Healthcare—2011 Update

1. SURGICAL OR INVASIVE PROCEDURE EVENTS
   A. Surgery or other invasive procedure performed on the wrong site
   B. Surgery or other invasive procedure performed on the wrong patient
   C. Wrong surgical ~~procedure~~ or other invasive procedure performed on a patient

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D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

2. PRODUCT OR DEVICE EVENTS
   A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
   B. Patient death or serious injury 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 injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting
3. PATIENT PROTECTION EVENTS
   A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
   B. Patient death or serious injury associated with patient elopement (disappearance)
   C. Patient suicide, ~~or~~ attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting
4. CARE MANAGEMENT EVENTS
   A. Patient death or serious injury 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 injury associated with unsafe administration of blood products
   C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
   D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy ~~while being cared for in a healthcare setting~~
   E. Patient death or serious injury associated with a fall ~~during or after~~while being cared for ~~and prior to leaving the grounds of~~in a healthcare setting
   F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
   G. Artificial insemination with the wrong donor sperm or wrong egg
   H. Patient ~~D~~death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
   I. Patient ~~D~~death or serious injury resulting from failure to follow up or communicate ~~clinical information~~laboratory, pathology, or radiology test results
5. ENVIRONMENTAL EVENTS
   A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
   B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
   C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
   D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting
6. RADIOLOGIC EVENTS
   A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

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7. POTENTIAL 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/resident of any age
   C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
   D. Death or ~~significant~~ serious 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 setting

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BACKGROUND

The NQF-endorsed® Serious Reportable Events in Healthcare were released initially in 2002, one of the first products of the ongoing effort to enable healthcare quality and safety improvement through introduction of tools for assessing, measuring, and reporting organizational performance. Those efforts were aimed, as they are now, at facilitating learning within the healthcare industry that would lead to delivery of high-quality and safer healthcare. Then, as now, the focus is on what can be done on the part of all members of the healthcare enterprise to ensure that those who seek care are protected from injury while receiving "world class" healthcare. This can only occur when all parts of the healthcare industry work together to find and correct unsafe conditions in the spirit of providing an environment that is safe for patients and for those involved in the delivery of care. Each individual event (rather than frequencies of events) should be reported and investigated by healthcare institutions as they occur.

The purpose of the NQF-endorsed list of Serious Reportable Events in Healthcare is to facilitate uniform and comparable public reporting to enable systematic learning across healthcare organizations and systems and to drive systematic national improvements in patient safety based on what is learned - both about the events and about how to prevent their recurrence. The serious reportable events (SREs) were originally envisioned as a set of events that might form the basis for a national state-based reporting system, and they continue to serve that purpose. Additionally, they have been used or adapted by national entities with the goal of illuminating such events in order to facilitate learning and improvement.

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 1) diligent effort to discover vulnerabilities that could lead to adverse events; 2) focused review and analysis of events that do occur to determine causal or contributing factors; 3) applying what is learned to continuously improve quality; and 4) public reporting to enable other organizations to apply lessons learned and take actions to prevent recurrence. All who report such events or sponsor reports should recognize and respect the fact that using reports to fix blame is counter-productive in the patient safety improvement effort. Additionally, as part of the effort to understand and reduce events it is important that

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healthcare providers and professionals communicate when events occur that cross organizational boundaries. For example, the admission of a patient into a hospital after experiencing an event in an outpatient surgicenter should result in communication between the two institutions to allow understanding and learning on the part of both organizations.

Further guidance related to publicly reporting patient safety events is available in *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report*.[1]

In keeping with the expectations set in the initial report, *Serious Reportable Events in Healthcare—2011 Update* has undergone significant changes. The purpose of the update is to 1) ensure the continued currency and appropriateness of each event in the list; 2) ensure that the events remain appropriate for public accountability in light of their standing as voluntary consensus standards; and 3) provide guidance gained by implementers to those just beginning the reporting of these events across hospitals. Additionally, effort has been made to clarify what events should be reported for three other settings of care—office-based practices, ambulatory surgery centers, and skilled nursing facilities. In large part the differences across the four settings are nuances that find their way into the implementation guidance rather than necessitate significantly different specifications. It should be noted that a focus on these four settings of care does not preclude use of the events in other settings of care.

In all events where "serious disability" was part of the event description, the term has been replaced by "serious injury" to broaden application of the event. In some events this has been further broadened to capture change in patient risk status when the risk change requires long-term care or monitoring.

State, legal, or other jurisdictional boundaries that take precedence in the way the events are interpreted should be respected in reporting the events. The Steering Committee (Committee) was mindful of the jurisdictional boundaries as well as the importance of comparability within settings of care over time. For these reasons, changes to existing events were made only to the extent warranted by experience gained in their use and current evidence.

Criteria for Inclusion of Events on the List

To qualify for the list of SREs, an event must be unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting's safety systems, or important

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for public credibility or public accountability. Some SREs are universally preventable and should never occur. Others are largely preventable and may be reduced to zero as knowledge and improved prevention strategies evolve. SREs that are entirely preventable and those that are largely preventable should be publicly reported. The criteria for inclusion (see Box A) and the definitions of terms (see Appendix B, Glossary) were closely reviewed, debated, revised, and subjected to public comment prior to being finalized for use in this update. The events described in this report meet those criteria; however, they do not represent all adverse events that might be useful to report or from which the healthcare industry can learn and make improvements. Further, presence of an event on the list is not an a priori judgment either of a systems failure or a lack of due care.

The majority of events on the list are events that, over the years since they were endorsed as voluntary consensus standards, have continued to meet the criteria by which they were selected and have been accepted by organizations and states as appropriate for reporting, but yet have continued to occur.

Box A—Criteria for Inclusion

To qualify for the list of *Serious Reportable Events in Healthcare— 2011 Update* an event must be unambiguous, largely, if not entirely, preventable, serious, and any of the following:

- adverse
- indicative of a problem in a healthcare setting's safety systems
- important for public credibility or public accountability

Additionally, items included on the list 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.

STRATEGIC DIRECTIONS FOR NQF

NQF's mission includes three parts: 1) setting national priorities and goals for performance improvement; 2) endorsing national consensus standards for measuring and publicly reporting on performance; and 3) promoting the attainment of national goals through education and outreach programs. As greater numbers of quality [including safety] measures are developed and brought to NQF for consideration of endorsement, it is incumbent on NQF to assist stakeholders to

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"measure what makes a difference" and address what is important to achieve the best outcomes for patients and populations.

Several strategic issues have been identified to guide consideration of candidate consensus standards:

- **Drive toward high performance.** Over time, the bar of performance expectations should be raised to encourage achievement of higher levels of system performance.
- **Emphasize composites.** Composite measures provide much-needed summary information pertaining to multiple dimensions of performance and are more comprehensible to patients and consumers.
- **Move toward outcome measurement.** Outcome measures provide information of keen interest to consumers and purchasers, and when coupled with healthcare process measures, they provide useful and actionable information to providers. Outcome measures also focus attention on much-needed system-level improvements, since achieving the best patient outcomes often requires carefully designed care processes, teamwork and coordinated action on the part of many providers.
- **Consider disparities in all that we do.** Some of the greatest performance gaps relate to care of minority populations. Particular attention should be focused on identifying disparities-sensitive performance measures and on identifying the most relevant race/ethnicity/language strata for reporting purposes.

These strategic directions were considered as the 2011 list of serious reportable events was under development. NQF has focused on driving toward high performance through improving safety across the healthcare enterprise since its inception. *Serious Reportable Events in Healthcare,* published in 2002, was one of the first NQF publications. It was updated in 2006, and now has been further updated and refined to attend to specific issues in four designated healthcare settings. In doing so, special needs of the very young, the elderly, and those with compromised decision-making capacity have been considered.

NATIONAL PRIORITIES PARTNERSHIP

NQF seeks to endorse measures that address the National Priorities and Goals of the NQF-convened National Priorities Partnership (Partnership).[2] The Partnership represents those who

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receive, pay for, provide, and evaluate healthcare. The National Priorities and Goals focus on these areas:

- patient and family engagement,
- population health,
- safety,
- care coordination,
- palliative and end-of-life care,
- overuse,
- equitable access, and
- infrastructure supports.

NQF'S CONSENSUS DEVELOPMENT PROCESS

NQF's National Voluntary Consensus Standards for Serious Reportable Events in Healthcare—2011 Update project[3] seeks to endorse 29 serious adverse events for use by healthcare institutions, states, and other entities for public reporting.

Evaluating Potential Consensus Standards

This report presents the evaluation of an initial group of 28 endorsed and 12 proposed new serious reportable events. Candidate consensus standards and modifications to NQF-endorsed SREs were solicited through a Call for Serious Reportable Events on May 18, 2010.

The events were evaluated using NQF's standard evaluation criteria for serious reportable events, which were refined during this project (see Box A). Three Technical Advisory Panels (TAPs) (see Appendix C) evaluated the endorsed SREs and the proposed modifications thereto as well as the proposed new SREs to identify the strengths, weaknesses, and applicability to their respective settings of care to assist the Committee in making recommendations. The 20 member, multi-stakeholder Committee provided final evaluations of the events in terms of the three main criteria: unambiguous, largely preventable and serious as well as the recommendation for endorsement.

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RELATIONSHIP TO OTHER NQF-ENDORSED CONSENSUS STANDARDS

If endorsed, the 29 recommended SREs in this report will become part of a group of NQF-endorsed consensus standards that specifically address healthcare safety and therefore address the National Priorities Partnership focus on safety. Together with the consensus standards in *Safe Practices for Better Healthcare—2010 Update*,[4] *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information*,[5] and the rising number of measures related to patient safety that have been endorsed by NQF, the SREs comprise a group of consensus standards aimed at improving patient safety. This group of safety standards provides a strong array of nationally accepted tools for measuring, improving, and reporting safety-related healthcare events that enable and facilitate improvements in healthcare safety.

Although the SREs have been evaluated and defined in the context of four specific healthcare settings, they can be applied across multiple settings, professional disciplines, and healthcare conditions.

RECOMMENDATIONS FOR ENDORSEMENT

This report presents the results of the evaluation of 28 endorsed and 12 proposed new serious reportable events considered under NQF's CDP. (For more detailed specifications and implementation guidance, see Appendix A.) Twenty-nine SREs are recommended for endorsement as voluntary consensus standards suitable for public reporting.

The events are organized in seven categories—six that relate to the provision of care (surgical or invasive procedure, product or device, patient protection, care management, environmental, and radiologic) and one that includes four potential criminal events. These latter events include both illegal acts and acts of unintentional misconduct, and they are included because they could be indicative of an environment that is unsafe for patients. Although a healthcare institution cannot eliminate all risk of these types of events, it can take preventive measures to reduce that risk.

The specifications expand and offer clarification of the event to support reporting efforts, while the implementation guidance provides context and otherwise facilitates understanding of the events.

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Consistent with the 2002 and 2006 lists of NQF-endorsed serious reportable events, this 2011 list is a relatively small and carefully constructed list of events defined to facilitate understanding and wide utilization. To facilitate clear understanding, a number of terms used in this report have been defined for its use (See Appendix B).

It is particularly important to note that many of the changes and additions to the SREs, including definitions, have the potential to result in an increased number of reports. Public reports of events, individually or in aggregate, that are based on event reporting generated using these updated SREs should acknowledge this potential both on behalf of the institutions and for the benefit of consumers who are using the information to inform their decision-making.

Updated and New Candidate Consensus Standards Recommended for Endorsement

Each of these events is intended to be used for public reporting by healthcare institutions, states, and other entities as part of healthcare enterprise-wide efforts to identify, learn from, and form solutions to such events. All are largely, if not entirely, preventable, and yet all continue to occur. All are potentially indicative of a problem in the healthcare institutions' safety systems and are of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare organization. They are of concern to the public and healthcare professionals and providers, and they are important for public credibility and public accountability. When used as a set for reporting, the events provide a multidimensional view of the safety of a healthcare organization that cannot be achieved with single event-type reporting. These characteristics make each event important for public reporting.

Of the 29 events proposed for endorsement, 25 are endorsed events that have been updated. Based on the changes to these events, including the specified care settings, all are being subjected to the CDP. The four new events are identified.

Surgical or Invasive Procedure Events

Each of the surgical or invasive procedure events was originally specified as a surgery event and each was endorsed as part of the initial set of SREs in 2002. During the past eight years, these events have continued to occur without appreciable improvement. The occurrence of the first four events requires additional, otherwise unnecessary, intervention and has the potential to

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cause long-term adverse consequences for the patient. The Committee agreed that the first four events should be expanded to include a broader universe of invasive procedures, many of which occur outside the traditional operating room. Inclusion of invasive procedures in these four events makes the determination of when surgery or a procedure ends challenging, thus the definition has been updated. There was some concern that including invasive procedures with surgery in these events could reduce setting-specific learning unless settings are identified in reports. With respect to the first three events, it was agreed that, although the traditional "consent form" might not be used for procedures outside an operating suite, documentation of informed consent is essential. The definition of informed consent and a caveat in the implementation guidance of each of the three clarifies the intent.

A. Surgery or other invasive procedure performed on the wrong site. To be more inclusive of the range of occurrences that this event should capture, "body part" was changed to "site.."
B. Surgery or other invasive procedure performed on the wrong patient. Because patients undergoing procedures in outpatient settings typically will not be identified using wristbands, the implementation guidance for this event includes a caveat about identification procedures.
C. Wrong surgical ~~procedure~~ or other invasive procedure performed on a patient.
D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure. The definition of "end of surgery" has been modified to ensure that it does not create a circumstance in which carrying out standard procedures for discovery of a foreign object would create a reporting requirement.
E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient. The Committee discussed the possibility of broadening this event or creating a new event to capture any death during or within some specified period after a procedure. The decision was made to be explicit about the settings to which the event as specified applies and to reconsider modifying the event specifications at a future update.

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Product or Device Events

A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting. Initially endorsed in 2002, this event has been modified to clarify the issue of detectability. Often contaminants are not visible to the naked eye but can be detected through monitoring. There has been a dramatic increase in the spread of pathogens such as hepatitis and HIV due to the reuse or improper repurposing of medical equipment (e.g., endoscopy tubes, syringes) as well as misuse of medication vials, injection devices, and containers (e.g., single-use vials used for more than one patient, inappropriate access of multi-dose vials, and pooling of medications). When such uses become known, it is essential that organizations investigate and that appropriate patient monitoring, which follows national guidelines or standards for care, occur. The serious injury that occurs in such cases could be development of disease or the threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event.

B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended. As in the previous event, failure to properly clean and maintain a device or misuse of a device that exposes a patient to disease or injury imposes a "serious injury" when it changes his or her risk status for life, requiring previously unneeded monitoring or treatment.

C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting. Discussion of this endorsed event centered on concern that the exclusions allow the occurrence of neurosurgical procedures identified only as presenting a high risk of intravascular air embolism to remain unreported. The American Academy of Neurologic Surgeons provided information that in those cases where surgery is performed in a position that puts the head above the heart to reduce venous pressure, development of air embolism is a known risk that is not entirely preventable. Pediatric experts, while agreeing that air embolism is not entirely preventable in some neurosurgical procedures, expressed differing points of view about reporting. To be consistent, the exclusion is retained for both adults and children at this time.

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Patient Protection Events

A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person. This event had been limited to infants. The Committee determined that it should be expanded to apply to any individual of any age who lacks decision-making capacity. The two areas of concern discussed by the Committee related to the challenges associated with applying the event in an outpatient setting and the meaning of the term "authorized." The former has been addressed through the implementation guidance and the latter through definition and explanatory language in the implementation guidance. Additionally, a definition of decision-making capacity has been added to the glossary.

B. Patient death or serious injury associated with patient elopement (disappearance). Although the issue of accepting an individual into care who subsequently goes missing is important, the struggle with this event focused on what elopement or disappearance means. The determination was made that the term "elopement" as defined in the glossary and the exclusion of competent (with decision-making capacity) adults who leave against medical advice or voluntarily leave without being seen addresses the concern. It was also noted that some states and other jurisdictions have defined elopement and, where applicable, those definitions are to be respected.

C. Patient suicide, ~~or~~ attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting. The determination was made that this remains an important event to be reported. While the threshold of serious injury associated with a suicide attempt ~~should be~~was initially deleted, concerns about creating a reporting requirement for specious events lead to its reinsertion. The ~~rationale for this decision was that~~responsibility for ensuring safety once an individual is accepted into care~~a responsibility for ensuring his or her safety exists~~ remains in any case. The struggle lies in the determination of when the individual has been accepted into care because it is not reasonable to impose a duty on an institution for an individual who is on the premises of the institution but has not yet presented him- or herself for care (e.g., attempts suicide in a restroom prior to checking in for care). This was addressed through modification of the additional specifications.

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Care Management Events

A. Patient death or serious injury 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 high rate of medication errors resulting in injury and death makes this event important to endorse again. With this update, two significant additions to the additional specifications have been made. One is the administration of a medication for which there is serious contraindication. The other relates to failure to observe safe injection practices (i.e., the improper use of single dose/single use and multi-dose containers leading to injury or death as a result of ~~contamination or~~ dosages). Because this update of the SREs focuses on hospitals, office-based practices, ambulatory surgery centers, and skilled nursing facilities, a significant number of serious and fatal events resulting from community pharmacy dispensing errors are not captured. When such events occur during dispensing of medications ordered from the identified sites of care, they should be included in analyses of causes, as appropriate.

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B. Patient death or serious injury associated with unsafe administration of blood products. The Committee was of the opinion that this event should be entirely preventable in any setting. Changes made to this event included broadening the event beyond hemolytic reaction and changing "serious disability" to "serious injury." There was concern about operationalizing "unsafe". Implementation guidance has been added to address this concern.

C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting. The single change to this event was the change from "serious disability" to "serious injury" made to all other events with this language. Although there was discussion of removing the exclusions, this is not recommended at this time. It will be revisited when the list is next reviewed.

D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy ~~while being cared for in a healthcare setting~~. (NEW) This new event is a companion to, and equally important as, death or serious injury of the mother in similar circumstances. To capture the more full range of potential birthing locations, the home setting has been included in the additional specifications.

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E. Patient death or serious injury associated with a fall ~~during or after~~ while being cared for ~~and prior to leaving the grounds of~~ ~~the~~ in a healthcare setting. This event was endorsed in 2002. ~~It has been refined to improve clarity related~~Initial changes sought ~~-~~to include ~~the boundaries within which reporting is to occur, both in terms of the~~ physical ~~boundary~~ boundaries where institution staff ~~and the~~have a continuing relationship with the patient. These changes were seen as especially significant in identifying the current gaps that offer opportunity for improvement, such as in the case of a post-operative patient who may have remaining influence of medications who is moving from the interior of a healthcare setting to a vehicle. At the same time, it was important that there be no responsibility for an individual prior to acceptance as a patient. With additional input and discussion, the 2006 language was retained. The Committee decided to move this event from the Environmental Events group to the Care Management Events group at this time. The question of moves of other events as well as the typology used for grouping events will be further considered in future updates to the SREs.

F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ presentation to a healthcare setting. Updates to this event include the addition of "unstageable" based on harmonization with the National Pressure Ulcer Advisory Panel's (NPUAP) position and definitions. Although possible inclusion of deep tissue injury was discussed, determination was made that this would amount to reporting an unconfirmed suspicion. Also, there was discussion of preventability and, while acknowledging that some pressure ulcers cannot be prevented, determination was made that pressure ulcers as defined by this event and the NPUAP should be reported.

G. Artificial insemination with the wrong donor sperm or wrong egg. This event, first endorsed in 2006, is continued unchanged other than to specify three settings of care to which it applies.

H. Patient ~~D~~death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen. (NEW) The Committee readily agreed on the importance of this newly submitted event. Discussion of this event centered on the meaning of "irretrievable," which was addressed both in the specifications and implementation guidance. As with the event related to use of contaminated drugs, etc., serious injury could be the progress of an undiagnosed disease or it could be the threat of disease that

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changes the patient's risk status for life, requiring monitoring not needed before the event.

I. Patient ~~D~~death or serious injury resulting from failure to follow up or communicate ~~clinical information~~laboratory, pathology, or radiology test results. (NEW) The Committee agreed on the importance of this newly submitted event and acknowledged that the issue of failure to follow up or communicate imposes significant increased risk of death or serious injury (e.g., change in stage of cancer). With continued discussion, the event was modified to limit its scope to those areas from which critical information in the form of test results most often come with an expectation that it could be expanded in future updates.

Environmental Events

A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting. This event, which was endorsed in 2002, has been expanded to include staff death or serious injury. Explanation of the intent of the addition has been added to the implementation guidance.

B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or is contaminated by toxic substances. This event, which was endorsed in 2002, has been refined to ensure that events involving both remote and bedside systems are included and that cases in which gas is not delivered when it has been prescribed are captured.

C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting. This event was endorsed in 2002. It has been expanded to include staff death or serious injury. Implementation guidance has been added to provide examples of the array of burns that are possible.

D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting. The single change to this event, initially endorsed in 2002, was the addition of "physical." The Committee acknowledged concern about the issue of chemical restraints but determined that difficulty in defining such events makes their inclusion infeasible at present.

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Radiologic Events

A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area. (NEW) This event is an adaptation of a newly proposed event. The occurrence of such events continues to be recognized, suggesting that there is an opportunity for discovery and learning to reduce the occurrence. After discussion and consultation with experts in MRI processes and environments, the event was clarified and expanded to include death or serious injury of staff as well as patients. Because radiologic events of various types are occurring with increasing frequency, this event is included in a new category, "Radiologic Events," in anticipation that additional events will be added to this category in future SRE updates.

Potential Criminal Events

The category title has been changed by the addition of "potential," recognizing that at the time of occurrence, there may be no determination of intent. In fact, the occurrence may be determined to be unintentional very early on (e.g., the patient with dementia who harms another). Although the latter event results in unintentional harm, it can indicate a problem with the safety systems in the healthcare setting. The overarching discussion about this group of events was related to redundant reporting and the potential for compromising the event-related information. Committee members experienced in medical event-related judicial proceedings noted that the legal pathway has no interest in learning, improvement, or prevention; thus the events are appropriately included in the SREs for those reasons. Further, these events are rare, and although there is a certain amount of redundancy in data collection or reporting, the burden should be relatively light. Of note, use of the term "patient" in these events is intended to convey that the individual has presented for care, is under care, or has received care and has not yet left the healthcare setting grounds.

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider. No changes were made to the specifications of this event, which was initially endorsed in 2002. Implementation guidance was added to provide some clarification regarding what it is intended to capture.

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B. Abduction of a patient/resident of any age. This event, endorsed in 2002, was changed to include "resident" in keeping with the nomenclature used in long-term care settings. Implementation guidance was added to clarify what it is intended to be captured.

C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting. This event, endorsed in 2002, was changed to add staff to the reporting requirement.

D. Death or ~~significant~~ serious 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 setting. The change made to this event, endorsed in 2002, is limited to changing "significant" to "serious" and "facility" to "setting", for consistency across the events.

Consensus Standards Recommended for Retirement

Three Care Management events are recommended for retirement. The Committee recommends that when an event represents an example of a type of event, it be reported under the rubric of the event type or category rather than creating a proliferation of single events representative of the type or category. Two events recommended for retirement are examples.

Formerly **Care Management Event 4.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**

Onset of hypoglycemia in a healthcare setting is an example of a medication management event, and as such, the Committee recommends that events related to insulin dosing be included as an explicit example of occurrences to be reported under the Care Management event related to death or serious injury associated with a medication error (4.A.). Further, the "Additional Specifications" of that event have been changed to include over- or under-dosing.

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

Development of kernicterus is an example of failure to follow up or communicate clinical information, a new care management event proposed for this 2011 update. The committee, therefore, recommends that the event be retired and that its intent be added to the "Additional

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Specifications" of the new event. This recognizes the importance of continued diligence in the effort to detect signs of hyperbilirubinemia and the potential for kernicterus, while providing a category for capturing a wider range of events related to failure to follow up on important clinical information.

Formerly **Care Management Event 4.G. Patient death or serious disability due to spinal manipulative therapy**

The Committee identified this event as one that targets a specific group of healthcare providers. Further, the event is related to individual provider behavior rather than facility safety systems. Based on these facts, it is recommended that this event be retired.

Candidate Consensus Standards Not Recommended for Endorsement

Of the eight proposed new SREs that are not recommended for endorsement, elements of three have been incorporated into the implementation guidance of other SREs for which endorsement is recommended. Additionally, some of the eight events not recommended in this update can be expected to be included in future updates as experience and the evidence evolves.

Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or 25 percent above or below the planned radiotherapy dose

The complexity of this proposed event coupled with the input from experts in fluoroscopy and radiotherapy resulted in the Committee recommending against advancing this event at this time. At present, fluoroscopy equipment does not provide dose maps after a procedure, and the measurement systems used for dosages are changing. Further, dosages differ based on a number of factors including body location. These factors would require extensive, detailed specifications that would depend on the ability to clearly articulate a number of variables, some of which are transitioning to new methods. The Committee recommends this event be held for consideration at the next update of SREs.

Patient death or serious injury related to a central line associated blood stream infection (CLABSI)

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The development of blood stream infections associated with clinical care is an important occurrence that can be related to failure of organizational policy and procedures or the enforcement and surveillance of these policies and procedures. The Committee opined that development of such an infection (versus death or serious injury) should be reported; however, the event is not recommended for endorsement at this time because of issues related to attributing causality as well as relative lack of measurement experience and reporting. The event will be revisited in the next SRE update cycle.

Death among surgical patients with serious treatable complications (failure to rescue)

In the context of a SRE, ascertainment would be difficult due to the potential breadth of complications to be defined and linked to failure to rescue. At this juncture, the event can best be captured, albeit in the aggregate, using a performance measure. NQF has endorsed three such measures, and although similar each measure applies to different populations. At some future date, the feasibility of linking the SREs with performance measures should be explored; however, the complexity of individual event reporting that would result requires careful consideration.

Arterial misplacement and use of a central venous catheter

Diagnostic testing error resulting in unnecessary invasive procedure, serious disability or death

Incorrect placement of a feeding (gastrointestinal) or ventilation tube, which results in patient harm

A guiding principle applied by the Committee in its deliberations of the three foregoing proposed events was that individual examples of event types should, where possible, be captured within SREs that capture the broader type rather than as individual events. The three events above are examples of broader categories of events in the proposed list and have been included as such in the relevant event implementation guidance.

Death or serious injury resulting from care provided by an impaired healthcare worker

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Death or significant injury of a patient as a consequence of staff impaired by recreational drugs or alcohol use

The Committee acknowledged that the issue at the center of these two foregoing proposed events is important. However, the issue is complex given the range of substances that could be involved, including at least one that may be legalized in some states; the types of impairments that could be involved; the ability to determine or verify the impairment objectively; and the point at which impairment could be declared and reported. Due to these challenges, these events are not recommended at this time.

ADDITIONAL RECOMMENDATIONS

Although the list of serious reportable events has been in use to varying degrees across states and healthcare organizations, significant opportunity for improving the list through research remains. The NQF report, *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information*,[6] outlined a number of recommendations, of which four are repeated here either verbatim or modified to be specific to SREs.

- Research and evaluation should be conducted to determine which events convey a valid, reliable perspective of healthcare organization safety.
- Research should be conducted to evaluate the impact of public reporting of patient safety information on patients, consumers, and healthcare institutions.
- Organizations that collect patient safety reports from healthcare providers, those that design collection systems for such reports, those that design classification systems for event reporting, and other stakeholders should come together and begin to harmonize standardized systems for defining, measuring, reporting, analyzing, and classifying patient safety information in a way that produces greater data integrity, completeness, and reliability and, therefore, greater understanding of events, and reduces opportunity costs associated with these activities.
- Health information technology systems and any funds that become available to improve them should include provision for facilitating patient-safety related data capture in ways that can be used for public reporting.

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Additionally, *Serious Reportable Events in Healthcare*, 2002 and the 2006 Update included recommendations that remain relevant and should be addressed. These include:

- 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 public's needs, yet 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 necessity to support such a list and the public's perceptions of the impact of the list;
- identifying ICD, CPT, or other codes that correlate with each serious reportable event on the list; and
- identifying effective mechanisms, including standardization of reporting systems, to permit institutions to report an event that occurs in their organization only once to a single entity from which needed information can be extracted and to avoid double reporting when a patient receives care in more than one healthcare organization;
- evaluating comparability of data reported across healthcare systems to determine the degree to which comparability exists and to define next steps toward improving comparability;
- evaluating outcomes of public reporting in terms of both reduction in occurrences of these events and identification and use of practices to prevent such occurrences; and
- evaluating population- or geographic-based differences in rates of occurrence of these events for purposes of determining reporting and/or occurrence variations and designing appropriate population-specific interventions.

NOTES

1 National Quality Forum (NQF), *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report*, NQF: Washington, DC; publication pending.
2 NQF, *National Priorities Partnership*, Washington, DC: NQF. Available at www.nationalprioritiespartnership.org. Last accessed October 1, 2010.
3 Available at http://qualityforum.org/projects/hacs_and_sres.aspx . Last accessed October 1, 2010.
4 NQF. *Safe Practices for Better Healthcare—2010 Update: A Consensus Report*, NQF: Washington, DC; 2010.

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5 NQF. *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report*, NQF: Washington, DC; publication pending.
6 Ibid.

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APPENDIX A
EVENT SPECIFICATIONS AND IMPLEMENTATION GUIDANCE

The following table presents the specifications for the proposed consensus standards. The information presented represents an update of the 2006 report with revision and additions made by the Serious Reportable Events Steering Committee utilizing NQF Member and public submissions and consultation with experts in the various fields. These proposed voluntary consensus standards are the intellectual property of the National Quality Forum and as such they are open source, fully accessible, and disclosed.

Definitions of key terms are included in the Glossary (Appendix B) and, where the terms are used in the event description or additional specifications, are considered part of the specifications of the events.

Implementation Guidance is not proposed for endorsement. It amplifies statements in the Event and Additional Specifications, which are proposed for endorsement, with examples and explanations based on experience of those organizations/entities that have implemented event reporting as well as recommendations of the NQF Serious Reportable Events Steering Committee. It does not purport to be either comprehensive or even across the events and is *not* a requirement of either.

1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Surgery or other invasive procedure performed on the wrong site Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Office-based Practices • Long-term Care/Skilled Nursing Facilities	Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints. Excludes emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.	It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record. Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at time the surgical mark is made on the patient. Placing a mark on the wrong body part or site does not in itself constitute wrong site surgery. Wrong site surgery or invasive procedure, corrected during

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
		the procedure, is still a wrong site procedure if the surgery/ procedure had begun, based on the definition in glossary. This event is intended to capture instances of: • surgery or other invasive procedure on the right body part but on the wrong location/site on the body; e.g. left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull; • delivery of fluoroscopy or radiotherapy to the wrong region of the body; • use of incorrectly placed vascular catheters; • use of incorrectly placed tubes (for example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus). This event is not intended to capture: • changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).
B. Surgery or other invasive procedure performed on the wrong patient Applicable settings: • Hospitals	Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens	It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record. This event is intended to capture:

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
• Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	implants, lesion removal, injection into joints.	• surgical procedures (whether or not completed) initiated on one patient intended for a different patient. Use of accepted patient identification procedures is key to avoiding such events.
C. Wrong surgical or other invasive procedure performed on a patient Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Defined as any surgical or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints. Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent.	It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record. 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 entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/ procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place. Excludes a) objects present prior to surgery or other invasive procedure that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery/procedure 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/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery; • unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings.
E. Intraoperative or immediately postoperative/ postprocedure death in an ASA Class I patient Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure 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.

2. PRODUCT OR DEVICE EVENTS

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EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product. Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event	This event is intended to capture: • contaminations that can be seen with the naked eye or with use of detection mechanisms in general use. ~~*Often, contaminants, including such things as hepatitis and HIV, are not visible to the naked eye.*~~ *These contaminations are to be reported at such time as they become known to the provider or healthcare organization. Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye (e.g., hepatitis and HIV) or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). Contamination that is inferred and changes risk status for life (e.g., consider a syringe or needle contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set).* ~~*(Detection mechanisms may include such things as cultures and tests, including sterilization monitoring devices that signal changes in pH or glucose levels.)*~~ This event is intended to capture: • administration of contaminated vaccine or medication (e.g., intramuscular antibiotic); • serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel); • occurrences related to use of improperly cleaned or maintained device.~~.~~

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2. PRODUCT OR DEVICE EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.	This event is intended to capture: • occurrences whether or not the use is intended or described by the device manufacturers' literature; • ~~occurrences related to improper cleaning or maintenance of the device.~~ •
C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers, • Long-term Care/Skilled Nursing Facilities	Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	This event is intended to capture: • high-risk procedures, other than neurosurgical procedures, that include, but are not limited to, procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures and liver transplantation; • low-risk procedures including those related to lines placed for infusion of fluids in vascular space.

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3. PATIENT PROTECTION EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person. Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		The terms "authorized" and "decision-making capacity" are defined in the glossary ~~as used here includes the definition in the glossary~~. Release to "other than an authorized person" includes removing the patient/resident without specific notification and approval by staff even when the person is otherwise authorized. Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's. Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision-making capacity.
B. Patient death or serious injury associated with patient elopement (disappearance). Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes events that occur after the individual presents him/herself for care in a healthcare setting. Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.	The term "elopement" and "competent" adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions. *Of note, an assessment that identifies patients at 'risk' of elopement or a chief complaint and findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.* This is not intended to capture: • death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.

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3. PATIENT PROTECTION EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
C. Patient suicide, ~~or~~ attempted suicide, or self–harm that results in serious injury, while being cared for in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes events that result from patient actions after they present themselves for care in a healthcare setting. Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation 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 setting "as defined in the glossary.

4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**

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4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Patient death or serious injury 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) Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Excludes reasonable differences in clinical judgment on drug selection and dose. Includes, but is not limited to, death or serious injury associated with a) over- or under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindication, c) drug-drug interactions for which there is known potential for death or serious injury, d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of ~~contamination or~~ dose adjustment problems.	This event is intended to capture: • the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication or a patient, known to have serious allergies to specific medications/ agents, receives those medications/ agents, resulting in serious injury or death. *These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organization to assure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event.* • occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication; • occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices "High Alert Medication List"; • occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique. This event is not intended to capture: • patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.

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4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
B. Patient death or serious injury associated with unsafe administration of blood products Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facility		Unsafe administration includes, but is not limited to, hemolytic reactions and administering a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled. This event is not intended to capture : • patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction • patient death or injury when cause is not detectable by ABO/HLA matching.
C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers	Includes events that occur within 42 days post-delivery. 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 made aware of the maternal death or serious injury either by readmittance or by the patient's family.
D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy ~~while being cared for in a healthcare setting~~	Includes, for the office-based surgery, ~~or~~ birthing center or "home" setting, unplanned admission to an inpatient setting within 24 hours of delivery	Unplanned admission to other than the birth setting should be verified with the identified birth setting.

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4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers		
E. Patient death or serious injury associated with a fall ~~during or after~~ while being cared for ~~and prior to leaving the grounds of a~~ in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage	*Of note, an assessment that identifies patients at 'risk' of fall, findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.*
F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ presentation to a healthcare setting Applicable settings:	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation.	Although this event could occur in the ambulatory surgery environment based on patient condition and surgery time, it will be difficult to discern. Pre- and post- skin assessment will be key.

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4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
• Hospitals • Outpatient/Office-based Surgery Centers • Long-term Care/ Skilled Nursing Facilities		
G. Artificial insemination with the wrong donor sperm or wrong egg Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices		The organization's obligation is to report the event when made aware of the occurrence.
H. Patient ~~D~~death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen. Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen Includes progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event	This event is not intended to capture: • procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic. Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ removal.

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4. CARE MANAGEMENT EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
I. Patient ~~D~~death or serious injury resulting from failure to follow up or communicate ~~clinical information~~ laboratory, pathology, or radiology test results. Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities	Includes events where failure to report increased neonatal bilirubin levels result in kernicterus.	Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer). Failure to follow up or communicate can be limited to healthcare staff or can involve communication to the patient. ~~Examples of clinical information for which failure to follow up could occur include imaging or laboratory reports, biopsy results, or other test results~~.

5. ENVIRONMENTAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers	Excludes events involving patients during planned treatments such as electric countershock /elective cardioversion.	This event is intended to capture: • patient death or injury associated with unintended electric shock during the course of care or treatment; • staff death or injury associated with unintended electric shock while carrying out duties directly associated with a patient care process, including preparing for care delivery. This event is not intended to capture:

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5. ENVIRONMENTAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
• Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		• patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies; • injury to staff who are not involved in patient care.
B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		This event is intended to capture: • events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines.
C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based		This event is intended to capture burns that result from: • operating room flash fires, including second degree burn in these cases; • hot water; • sunburn in the patient with decreased ability to sense pain; • smoking in the patient care environment.

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5. ENVIRONMENTAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		
D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		The event is intended to capture: • instances where physical restraints are implicated in the death; e.g., lead to strangulation/entrapment, etc. ~~Death/injury resulting from falls caused by lack of restraints would be captured under "falls."~~

6. RADIOLOGIC EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**

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A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices	Includes events related to material inside the patient's body or projectiles outside the patient's body.	This event is intended to capture injury or death as a result of projectiles including: • retained foreign object • external projectiles • pacemakers

7. POTENTIAL 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 Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		This event is intended to capture: • those without licensure to provide the care given; • those with licensure who represent themselves and act beyond the scope of their licensure. It is not intended to capture individuals who are practicing within the scope of their license whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider.

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7. POTENTIAL CRIMINAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
B. Abduction of a patient/resident of any age Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		This event is intended to capture: • removal of a patient/resident, who does not have decisionmaking capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting. Examples of individuals who do not have decisionmaking capacity include: newborns, minors, adults with Alzheimer's.
C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.

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7. POTENTIAL CRIMINAL EVENTS		
EVENT	**ADDITIONAL SPECIFICATIONS**	**IMPLEMENTATION GUIDANCE**
D. Death or ~~significant~~ serious 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 setting. Applicable settings: • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities		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").

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APPENDIX B
GLOSSARY

The following terms are defined as they apply to the NQF list of serious reportable events. To the extent practicable, they have been harmonized with definitions used in other NQF safety-related products, the Agency for Healthcare Research and Quality's Common Formats, and the World Health Organization's evolving International Classification for Patient Safety. The Common Formats are a product of the requirements of the Patient Safety and Quality Improvement Act of 2005 that provides a structure for reporting adverse events, while the latter provides structure for classifying such events.

- **Abduction** means the taking away of a person by persuasion, by fraud, or by open force or violence. It includes convincing someone, particularly a minor or a woman he/she is better off leaving with the persuader, telling the person he/she is needed, or that the mother or father wants him/her to come with the abductor.
- **Adverse** describes a consequence of care that results in an undesired outcome. It does not address preventability.
- **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.
- **Authorized** means the guardian or other individual(s) having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient.
- **Decision-making capacity** is the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).

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- **Deep tissue injury** presents as a purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.
- **Device.** See Medical Device.

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- **Elopement** refers to a situation where a patient or resident who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders/walks/runs away, escapes, or otherwise leaves a caregiving institution or setting unsupervised, unnoticed, and/or prior to their scheduled discharge.
- **Event** means a discrete, auditable, and clearly defined occurrence.
- **Healthcare setting** means any facility or office, including a discrete unit of care within such 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 settings include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers, office-based practices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, ambulatory surgical centers, and pharmacies. The boundary of a healthcare setting (the "grounds") is the physical area immediately adjacent to the setting's main buildings. It does not include nonmedical businesses such as shops and restaurants located close to the setting.
- **High alert medications** are those medications that have a high risk of causing serious injury or death to a patient if they are misused. Examples of high-alert medications include anticoagulants and IV antithrombotics, insulin, cytotoxic chemotherapy, concentrated electrolytes, IV digoxin, opiate narcotics, neuromuscular blocking agents, and adrenergic agonists. *The recommended "High Alert Medication List" is available at the Institute for Safe Medication Practices' website, http://www.ismp.org.*
- **Infant** is a child under the age of one year. (SRE 2006; Stedman's online dictionary)

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- **Informed consent** involves a process of shared decisionmaking in which discussion between a person who would receive a treatment, including surgery or invasive procedure, and the caregiver/professional person who explains the treatment, provides information about possible benefits, risks and alternatives, and answers questions that result in the person's authorization or agreement to undergo a specific medical intervention. Documentation of this discussion should result in an accurate and meaningful entry in the patient record, which could include a signed "consent form." Signing a consent form does not constitute informed consent; it provides a record of the discussion.
- **Injury,** as used in this report has a broad meaning. It includes physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event. *(Of note, states and other entities may use alternate definitions for the term "disability.")*
- **Largely preventable** recognizes that some of the events on the SRE list are not universally avoidable, given the complexity of healthcare and current knowledge.
- **Low-risk pregnancy** refers to a woman aged 18-39, with 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.
- **Medical device** is 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

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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.[i]

- **Medication error** means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.[ii]
- **Neonate** is a newborn less than 28 days of age.
- **Patient** means a person who is a recipient of healthcare. *A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.*[iii]
- **Pressure Ulcer, Stage 3** is defined as full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle is *not* exposed. Slough may be present. May include undermining and tunneling. The depth of a Stage 3 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and Stage 3 ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage 3 pressure ulcers. Bone/tendon is not visible or directly palpable.[iv]

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- **Pressure Ulcer, Stage 4** is defined as full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Stage 4 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/tendon is visible or directly palpable.[v]
- **Pressure Ulcer, Unstageable** is defined as full thickness tissue loss in which the ~~base~~ actual depth of the ulcer is completely ~~covered~~ obscured by slough and/or eschar in the wound bed. Until enough slough and/or exchar are removed to expose the base of the wound, the true depth cannot be determined; but it ~~Unstageable pressure ulcers, by definition,~~ will be either Stage 3 or Stage 4.[vi]
- **Preventable** describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.
- **Restraints** is defined by The Joint Commission, the Centers for Medicare & Medicaid Services, and by some states. The appropriate source(s) should be consulted for the definition required by the setting and/or jurisdiction in which a presumptive event occurs. In the event none of those definitions apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered: Restraints means 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; is not indicated to treat the patient's medical condition or symptoms; or does not promote the patient's independent functioning.
- **Serious** describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).

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- **Sexual abuse** is defined as the forcing of unwanted sexual activity by one person on another, as by the use of threats or coercion or sexual activity that is deemed improper or harmful, as between an adult and a minor or with a person of diminished mental capacity.
- **Surgery** is an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multiorgan transplantation. It does not include use of such things as otoscopes and drawing blood. *Organizations may choose to adopt a list of surgical procedures to supplement the definition above; one example of such a list in common use is that of the Institute of Clinical Systems Improvement.*
- **Surgery begins**, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs.
- **Surgery ends** after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room.
- **Unambiguous** refers to an event that is clearly defined and easily identified.
- **Unintended retention** of a foreign object refers to a foreign object introduced into the body during a surgical or other invasive procedure, without removal prior to the end of the surgery or procedure, which the surgeon or other practitioner did not intend to leave in the body.

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[i] Food and Drug Administration. Available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm Last accessed January 19, 2011.

[ii] National Coordinating Council for Medication Error Reporting and Prevention. Available at http://www.nccmerp.org/aboutMedErrors.html. Last accessed January 7, 2011.

[iii] Minnesota Department of Health.

[iv] National Pressure Ulcer Advisory Panel. Available at: http:www.npuap.org/Final_Quick_Treatment_for_web_2010.pdf. . Last accessed January 31, 2011.

[v] National Pressure Ulcer Advisory Panel. Available at: http:www.npuap.org/Final_Quick_Treatment_for_web_2010.pdf . Last accessed January 31, 2011.

[vi] National Pressure Ulcer Advisory Panel. Available at: http:www.npuap.org/Final_Quick_Treatment_for_web_2010.pdf . Last accessed January 31, 2011.

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APPENDIX C
STEERING COMMITTEE, TECHNICAL ADVISORY PANELS, AND NQF STAFF

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