

Washington State Hospital Association
Patient Safety



**Serious Reportable
Events with Definitions**

National Quality Forum (NQF)

Table 1 – List of Serious Reportable Events

1. SURGICAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE ⁱ
A. Surgery performed on the wrong body part	<p>Defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient.ⁱⁱ</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), level (spine). ■ Wrong site surgery, even if corrected intraoperatively, as long as the surgery had begun, based on the definition below. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). <p><i>Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</i></p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</i></p> <p><i>Surgery ends after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</i></p> <p>Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at the time a surgical mark is made on the patient. Placing a mark on the wrong body part does not in itself constitute wrong site surgery.</p> <p style="text-align: right;"><i>(more)</i></p>

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

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

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
B. Surgery performed on the wrong patient	<p>Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient. <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>C. Wrong surgical procedure performed on a patient</p>	<p>Defined as any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Insertion of the wrong medical implant into the correct surgical site. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS (continued)		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
D. Unintended retention of a foreign object in a patient after surgery or other procedure	Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Occurrences of unintended retention of objects at any point after the surgery ends, regardless of setting or of whether the object is removed. <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

(more)

Table 1 – List of Serious Reportable Events (continued)

1. SURGICAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>E. Intraoperative or immediately postoperative death in an ASA Class I patient</p>	<p>Includes all ASA Class I patient deaths in situations in which anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>Immediately postoperative means within 24 hours after surgery or other invasive procedure was completed, or after administration of anesthesia (if surgery was not completed).</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ ASA Class I patient death associated with the administration of anesthesia, whether or not the planned surgical procedure was carried out. <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

(more)

Table 1 – List of Serious Reportable Events (continued)

2. PRODUCT OR DEVICE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.	The term <i>detectable</i> is intended to capture contaminations that can be seen with the naked eye or with the use of detection mechanisms that are in general use; these contaminations are to be reported when they become known to the provider or healthcare facility. Detection mechanisms may include cultures and tests that signal changes in pH or glucose levels.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.	This event is intended to capture occurrences whether or not the use is intended or described by the device manufacturers' literature. The Food and Drug Administration defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: <ul style="list-style-type: none"> ■ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, ■ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or ■ intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	High-risk procedures, other than neurosurgical procedures, that include a small but known risk of air embolism are reportable under this event, including, but not limited to, those involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.

(more)

Table 1 – List of Serious Reportable Events (continued)

3. PATIENT PROTECTION EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Infant discharged to the wrong person		Stedman’s Online Medical Dictionary defines an infant as a child under the age of one year.
B. Patient death or serious disability associated with patient elopement (disappearance)	Excludes events involving competent adults.	This event is not intended to capture death or serious disability that occurs due to circumstances unrelated to the elopement (after the patient is located). The term <i>competent adult</i> should be interpreted in accordance with prevailing legal standards.
C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the “healthcare facility” (defined in box B, previously).
4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment involving drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.	This event is intended to capture: <ul style="list-style-type: none"> ■ The most serious medication errors, including occurrences in which a patient known to have serious allergies to specific medications/agents receives those medications/agents, resulting in serious harm or death. These events may occur as a result of failure to collect allergy information; failure to review available allergy information; failure to assure the availability of allergy information and prominently display it; or through other system failures that are determined by investigation to be the cause of the adverse event. ■ Occurrences in which a patient dies or suffers serious disability as a result of failure to administer a prescribed medication. ■ Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique. This event is not intended to capture: <ul style="list-style-type: none"> ■ Patient death or serious disability associated with allergies that could not reasonably have been known or discerned in advance of the event. ■ All situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability—only those that result in death or serious disability.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products		This event is not intended to capture: <ul style="list-style-type: none"> ■ Patient death or disability associated with organ rejection, other than those attributable to a hyperacute hemolytic reaction. ■ Patient death or disability when the cause is not detectable by ABO/HLA matching.

(more)

Table 1 – List of Serious Reportable Events (continued)

4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.	This event is not intended to create a new obligation; the organization's obligation is to report the event when it is made aware of the maternal death or serious disability either by re-admittance or by the patient's family. A low-risk pregnancy is defined as a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome. ⁱⁱⁱ
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		Hypoglycemia is defined as blood glucose levels <60mg/dL (ICD-9, 251.0).
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	<i>Hyperbilirubinemia</i> is defined as bilirubin levels >30 mg/dl. <i>Neonate</i> refers to the first 28 days of life.	The organization's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3, if Stage 2 was recognized upon admission.	
G. Patient death or serious disability due to spinal manipulative therapy		Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin. ^{iv}
H. Artificial insemination with the wrong donor sperm or wrong egg		The organization's obligation is to report the event when it is made aware of the occurrence.

*(more)*ⁱⁱⁱ NQF, *Serious Reportable Events in Healthcare: A Consensus Report*, NQF: Washington, DC; 2002.^{iv} NQF, *Serious Reportable Events in Healthcare: A Consensus Report*, NQF: Washington, DC; 2002.

Table 1 – List of Serious Reportable Events (continued)

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

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

Table 1 – List of Serious Reportable Events (continued)

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