



# Serious Reportable Events In Healthcare—2011 Update: A Consensus Report

## 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.

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- *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).
- *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.
- *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)
- *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

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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 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.<sup>1</sup>
- *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.<sup>2</sup>
- *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.<sup>3</sup>*

- *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.<sup>4</sup>
- *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.<sup>5</sup>
- *Pressure Ulcer, Unstageable* is defined as full thickness tissue loss in which the actual depth of the ulcer is completely obscured by slough and/or eschar in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either Stage 3 or Stage 4.<sup>6</sup>
- *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

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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).
- *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.

## NOTES

1. Food and Drug Administration. Available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm> Last accessed January 19, 2011.
2. National Coordinating Council for Medication Error Reporting and Prevention. Available at <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed January 7, 2011.
3. Minnesota Department of Health.
4. National Pressure Ulcer Advisory Panel. Available at: [http://www.npuap.org/Final\\_Quick\\_Treatment\\_for\\_web\\_2010.pdf](http://www.npuap.org/Final_Quick_Treatment_for_web_2010.pdf) . Last accessed January 31, 2011.
5. National Pressure Ulcer Advisory Panel. Available at: [http://www.npuap.org/Final\\_Quick\\_Treatment\\_for\\_web\\_2010.pdf](http://www.npuap.org/Final_Quick_Treatment_for_web_2010.pdf) . Last accessed January 31, 2011.
6. National Pressure Ulcer Advisory Panel. Available at: [http://www.npuap.org/Final\\_Quick\\_Treatment\\_for\\_web\\_2010.pdf](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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