

Saskatchewan Critical Incident Reporting Guideline, 2004

By “**critical incident**” we mean a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or health care organization (HCO).

(Additional definitions of terms can be found in Section VII of the Guideline.)

The following is a list of events that must be reported to Saskatchewan Health. The final item in each category allows for the possibility of adverse health events that fit the description given above, but were not anticipated when the list was created. Such events are also reportable.

I SURGICAL EVENTS (Surgery includes endoscopies and other invasive procedures)

- a) Surgery performed on a wrong body part
(Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.)
- b) Surgery performed on the wrong patient
(Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.)
- c) The wrong surgical procedure performed on a patient
(Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.)
- d) Retention of a foreign object in a patient after surgery or other procedure
(Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.)
- e) Death during or immediately after surgery of an ASA classification I-II¹ patient
(Includes procedures where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately after surgery means within 24 hours of surgery or other invasive procedure, or, if surgery was not completed, within 24 hours of induction of anesthesia.)
- f) Unintentional awareness during surgery with recall by the patient
- g) An adverse health event leading to death or serious disability associated with any other surgical event while a patient is receiving a health care service provided by an RHA or HCO

II PRODUCT OR DEVICE EVENTS

- a) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by an RHA or HCO
(Includes generally detectable contaminants such as infectious matter or foreign substances in drugs, devices, or biologics regardless of the source of contamination and/or product.)
- b) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
(Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and mechanical devices used to lift, bathe, or shower patients.)

¹ ASA Classification I - Normal healthy patient, II - A patient with mild systemic disease. Canadian Anesthesiologists' Society. *Appendix II: American Society of Anesthesiologists' Classification of Physical Status*. Retrieved May 2004 from website www.cas.ca.

- c) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by an RHA or HCO
(Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.)
- d) An adverse health event leading to death or serious disability associated with any other product or device while a patient is receiving a health care service provided by an RHA or HCO

III PATIENT PROTECTION EVENTS

- a) An infant discharged to the wrong person
- b) Patient death or serious disability associated with patient disappearance
(Excludes events involving competent adults.)
- c) Patient suicide or attempted suicide resulting in serious disability while being cared for by an RHA or HCO
(Defined as events that result from patient actions after admission to a facility or program of the RHA or HCO. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital.)
- d) An adverse health event leading to death or serious disability associated with any other patient protection event while a patient is receiving a health care service provided by an RHA or HCO

IV CARE MANAGEMENT EVENTS

- a) Patient death or serious disability associated with a medication or fluid error including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration
(Excludes reasonable differences in clinical judgment on drug selection and dose.)
- b) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- c) Maternal death or serious disability while being cared for by an RHA
(Includes events that occur within 42 days post-delivery.)
- d) Full-term fetal or neo-natal death or serious disability associated with labour or delivery while being cared for by an RHA
(Full-term fetus is >37 completed weeks gestation. Neonate refers to the first 28 days of life. Includes failure to screen for and prevent neonatal post-discharge dehydration or illness related to phenylketonuria.)
- e) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for by an RHA or HCO
- f) Neonatal death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia
(Hyperbilirubinemia is defined as bilirubin levels >500 µmol/L. Neonate refers to the first 28 days of life.)
- g) Stage 3 or 4 pressure ulcers acquired after admission to a facility of an RHA or HCO
(Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.)
- h) Patient death or serious disability associated with a delay or failure to transfer a patient in keeping with the Saskatchewan Health Critical Care Patient Management and Transfer Process Policy
- i) Error in diagnosis, where the treatment provided or not provided leads to patient death or serious disability

- j) An adverse health event leading to death or serious disability associated with any other care management event while a patient is receiving a health care service provided by an RHA or HCO

V ENVIRONMENTAL EVENTS

- a) Patient death or serious disability associated with electric shock while being cared for by an RHA or HCO
(Excludes events involving planned treatments such as electric countershock.)
- b) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- c) Patient death or serious disability associated with a burn incurred from any source while being cared for by an RHA or HCO
- d) Patient death associated with a fall while being cared for by an RHA or HCO
- e) Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility
- f) Patient death or serious disability associated with the failure or de-activation of exit alarms or environmental monitoring devices
- g) Patient death or serious disability incurred as a result of transport arranged or provided by an RHA or HCO
(Includes loss of control of a vehicle or aircraft, as well as actual or potential single vehicle accidents or multi-vehicle collisions, for example, transportation in a ground ambulance, air ambulance, medical taxi or chartered aircraft.)
- h) Patient death or serious disability associated with a delay or failure to reach a patient for emergent or scheduled services provided by an RHA or HCO
(Includes delay due to extreme weather conditions, poor roads, communication breakdown. Includes, but is not limited to, EMS and homecare services.)
- i) An adverse health event leading to death or serious disability associated with any other environmental event while a patient is receiving a health care service provided by an RHA or HCO

VI CRIMINAL EVENTS

- a) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
- b) Abduction of a patient of any age
- c) Sexual assault of a patient that occurs on grounds owned or controlled by an RHA or HCO
- d) Patient death or serious disability from a physical assault that occurs on grounds owned or controlled by an RHA or HCO
- e) Any sexual or physical assault of a patient perpetrated by an employee, member of the medical staff, or an individual under contract with an RHA or HCO
(Includes, but is not limited to, assaults perpetrated at a patient's home while receiving home care or mental health services.)
- f) An adverse health event leading to death or serious disability associated with any other criminal event while a patient is receiving a health care service provided by an RHA or HCO

VII DEFINITIONS

“Adverse health event”

means an unintended injury or complication that is caused by health care management rather than by the patient’s underlying disease process. Health care management includes the actions of individual staff members as well as broader systems and care processes. Health care management includes acts of omission (e.g. failure to diagnose, failure to treat) as well as acts of commission (e.g. incorrect diagnosis, incorrect treatment, poor performance).²

“Associated with”

means that it is reasonable to initially assume that the critical incident 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, but should not delay notification to Saskatchewan Health.

“Biologics”

means a drug that is prepared using a biological source material (derived from a microorganism, virus, animal, human, or plant) and using, for example, either conventional manufacturing methods, recombinant DNA technology, and/or other novel approaches. Some examples of biologics include vaccines, blood and its derivatives, certain hormones and enzymes, recombinant DNA products, gene therapies, and transgenics.³

“Disability”

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

“Patient”

means a client, resident, or patient.

“Regional Health Authority” or “Health Care Organization”

includes any services or programs offered by the entities as defined in *The Regional Health Services Act*.

VIII REFERENCES

The *Saskatchewan Health Critical Incident Reporting Guideline, 2004* is adapted from:
The National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. National Forum for Health Care Quality Measurement and Reporting, 2002.⁴

² Definition adapted from Baker, G.R., Norton, P.G., et al. *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*. CMAJ 2004; 170:1678-1686.

³ Definition adapted from Health Canada, Health Products and Food Branch, Therapeutic Products Directorate (www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html).

⁴ The National Quality Forum is a private, nonprofit, open membership organization created to develop and implement a U.S. strategy for healthcare quality measurement, and reporting.