Section 1 Introduction

Critical incident means a serious adverse health event that:

a) occurred while receiving a health service provided by, or a program operated by, the Saskatchewan Health Authority (SHA), a health services provider or the Saskatchewan Cancer Agency (SCA), hereinafter collectively referred to as "health services entity", and
b) was not expected or intended to occur, and
c) is serious and undesired, such as
    i. death, disability, injury or harm, or
    ii. unplanned admission to a health facility or an unusual extension of a stay in a health facility, or
    iii. a significant risk of substantial or serious harm to the safety, well-being or health of the patient, and
d) does not result primarily from the individual's underlying health condition or from a known risk inherent in providing the health services.

For clarity, given the definition of a critical incident as provided above, it is intended that all events are to be read and understood as including both actual (i and ii) and potential (iii) harm, and are to include incidents occurring through the provision of health services by a health services entity, unless otherwise specified in the individual category. The definition of critical incident is meant to provide overall guidance for determining what is reportable when considering incidents that result in actual or potential harm (psychological, emotional, spiritual, and physical) or death to a patient. The following specific events are not intended to be an exhaustive list of reportable events, but rather to provide a list of readily identifiable events that must be reported to the Ministry of Health.

The **Pan-Canadian Never Events (PCNE)** are patient safety incidents that result in serious patient harm or death, and that *can be prevented* by using organization checks and balances. The Ministry of Health has adapted the PCNE into its critical incident reporting system, some of which were incorporated into the previous version of the Critical Incident Reporting Guidelines (2004). The Ministry has created some additional categories based on regularly reported events.

This Guidance Document contains the current list of critical incidents and incorporates events currently determined by designated external regulators, as being subject to mandatory event occurrence reporting. Critical incident categories have been adapted from:

- National Quality Forum (2011). *Serious Reportable Events in Healthcare-2011 Update*.[1] https://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx
- Canadian Patient Safety Institute. (2015). *Never Events for Hospital Care in Canada*.[2] https://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf

[1] 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.
[2] The Canadian Patient Safety Institute (CPSI) was established in 2003 by Health Canada, as a not-for-profit organization to raise awareness and facilitate implementation of ideas and best practices to achieve transformation in patient safety. CPSI and the Canadian Foundation for Healthcare Improvement amalgamated in 2021 as a new organization, Healthcare Excellence Canada.

Section 2 Critical Incident Categories Summary List

1	**SURGICAL AND INVASIVE PROCEDURE EVENTS**
NE1.	Surgery performed on the wrong body part or the wrong patient, or conducting the wrong procedure. Surgery includes endoscopies and other invasive procedures
NE3.	Unintended foreign object left in a patient following a procedure
1A.	Death during or immediately after surgery of an ASA classification I-II[3] patient
1B.	Unintentional awareness during surgery with recall by the patient
1C.	A critical incident associated with any other surgical event
2	**PRODUCT OR DEVICE EVENTS**
NE2.	Wrong tissue, biological implant or blood product given to a patient
NE4.	Patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by a health services entity
2A.	A critical incident associated with the use or function of a device in patient care in which the device is used as intended
2B.	A critical incident associated with off-label use of medical devices
2C.	A critical incident associated with intravascular air embolism
2D.	A critical incident associated with a failure of Information Technology equipment, including hardware or software
3	**PATIENT PROTECTION EVENTS**
3A.	Wrongful discharge of a patient of any age, who does not have decision-making capacity
NE12.	Patient under the highest level of observation leaves a secured facility without the knowledge of staff
NE13.	Patient suicide, or attempted suicide that resulted in serious harm, in instances where suicide-prevention protocols were to be applied to patients under the highest level of observation
3B.	Patient suicide, attempted suicide or self-harm
3C.	A critical incident associated with any other patient protection event
4	**CARE MANAGEMENT EVENTS**
4A.	A critical incident associated with a medication or fluid error
4B.	A critical incident associated with off-label use of medication
NE5.	Patient death or serious harm due to a failure to inquire whether a patient has a known allergy to medication, or due to administration of a medication where a patient's allergy had been identified
NE7.	Patient death or serious harm as a result of one of five pharmaceutical events. The following five pharmaceutical events represent errors that can result in serious consequences for patients: • Wrong-route administration of chemotherapy agents, such as vincristine administered intrathecally (injected into the spinal canal). • Intravenous administration of a concentrated potassium solution. • Inadvertent injection of epinephrine intended for topical use. • Overdose of hydromorphone by administration of a higher-concentration solution than intended (e.g., 10 times the dosage by drawing from a 10 mg/mL solution instead of a 1 mg/mL solution, or not accounting for needed dilution/ dosage adjustment). • Neuromuscular blockade without sedation, airway control and ventilation capability.
4C.	A critical incident associated with the delay or improper administration of blood or blood products

[3] 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.

4D.	A critical incident related to a mother, associated with either the birthing process (labour, birth, or postpartum) or an intrauterine procedure up to 42 days postpartum
4E.	A critical incident related to a full-term fetus or neonate, associated with labour or delivery
NE8.	Patient death or serious harm as a result of failure to identify and treat metabolic disturbances
NE9.	Stage 3, stage 4 or unstageable pressure ulcers acquired after admission to a health services entity facility
4F.	A critical incident associated with a delay in patient transfer to a facility for appropriate level of care
4G.	A critical incident associated with an error in diagnosis or treatment
4H.	A critical incident associated with a delay in diagnosis or treatment
4I.	The loss or physical compromise of a biological specimen or patient information related to the specimen
4J.	A critical incident as a result of deviation from generally accepted performance standards
4K.	Death associated with a healthcare-associated infection
4L.	Failure to follow or implement a health care directive that results in an undesired outcome for the patient
4M.	A critical incident associated with any other care management event
5	**ENVIRONMENTAL EVENTS**
NE6.	Patient death or serious harm due to the administration of the wrong inhalation or insufflation gas
NE10.	Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area
NE11.	Patient death or serious harm due to an accidental burn
NE15.	Patient death or serious harm as a result of transport of a frail patient, or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment
5A.	A critical incident associated with electric shock
5B.	Patient death associated, and occurring within 14 days of, a fall
5C.	A critical incident resulting from or associated with the use or lack of restrictive interventions such as physical, mechanical, manual or environmental restraint
5D.	A critical incident as a result of transport arranged or provided by a health services entity
5E.	A critical incident associated with a delay or failure to reach a patient for emergent or scheduled services
5F.	A critical incident associated with any other environmental event
6	**CRIMINAL EVENTS**
6A.	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other health care provider
NE14.	Infant abducted, or discharged to the wrong person
6B.	Abduction of a patient of any age
6C.	Criminal act towards a patient that occurs on grounds owned or controlled by a health services entity
6D.	A critical incident associated with any other criminal event

Section 3 Critical Incidents Implementation Guidance

1 SURGICAL AND INVASIVE PROCEDURE EVENTS

	Category	Additional Specification/Guidance
NE1.	Surgery performed on the wrong body part or the wrong patient, or conducting the wrong procedure. Surgery includes endoscopies and other invasive procedures	Surgery is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Surgery on the wrong body part is intended to capture: • Surgery on the right body part, but on the wrong location in the body; for example, left versus right (appendages and/or organs) or level (spine), • Wrong site surgery, even if corrected intra-operatively, as long as the surgery had begun, based on the definition below. Surgery on the wrong body part is ***not*** intended to capture: Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk or burden of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g. adhesions, spine level/extra vertebrae). Surgery on the wrong patient is intended to capture surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient.
NE3.	Unintended foreign object left in a patient following a procedure	This event is intended to capture occurrences of unintended retention of objects such as swabs, needles or instruments other than micro-needles at any point after the procedure ends, regardless of setting or whether the object is removed. Includes retention of objects beyond the planned therapeutic time frame. Excludes: • Objects present prior to the procedure that are intentionally left in place,

	Category	Additional Specification/Guidance
		• Objects intentionally implanted as part of a planned intervention, • Objects not present prior to the procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as micro-needles, broken screws).
1A.	Death during or immediately after surgery of an ASA classification I-II[4] patient	Includes all ASA Class I and II patient deaths in situations in which anaesthesia was administered; the planned surgery or intervention procedure may or may not have been carried out. This event is intended to capture ASA Class I and II patient death associated with the administration of anaesthesia. An interventional procedure is defined as any procedure used for diagnosis or treatment that involves incision; puncture; entry into a body cavity; or the use of ionising, electromagnetic or acoustic energy. Immediately after surgery means within 24 hours after surgery or other interventional procedure was completed or after administration of anaesthesia (if surgery was not completed).
1B.	Unintentional awareness during surgery with recall by the patient	Awareness is the postoperative recall of sensory perception during general anaesthesia.
1C.	A critical incident associated with any other surgical event	Includes all other surgical and invasive procedure events that do not fall under the previous categories.

2 PRODUCT OR DEVICE EVENTS

	Category	Additional Specification/Guidance
NE2.	Wrong tissue, biological implant or blood product given to a patient	This event refers to any incorrect tissue or device introduced into a patient's body. This can include: • Blood products and organs that are incompatible with a patient's blood type, • A wrong product, • The wrong donor egg or sperm. Excludes events where: • A provider exercises clinical judgment to deviate from a surgical plan (i.e. intentionally opting for a different implant), • The correct implant proves to be suboptimal following surgery.
NE4.	Patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by a health services entity	Includes instances where: • A sterile instrument becomes contaminated prior to use (e.g., a patient receives an injection from a contaminated vial), • Equipment (e.g., a scope) is improperly cleaned. Excludes manufacturer contamination, as this is an industrial safety concern, not an error at the point of care.
2A.	A critical incident associated with the use or function of a device in	Includes, but is not limited to: • Failure of the device,

[4] 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.

	Category	Additional Specification/Guidance
	patient care in which the device is used as intended	• Deterioration in the effectiveness of the device, • Any inadequacy in its labelling or in its directions for use. Medical device covers a wide range of medical instruments used to treat, reduce, diagnose or prevent a disease or abnormal physical condition. It may refer to any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and /or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: • Diagnosis, prevention, monitoring, treatment alleviation of or compensation for an injury or handicap, • Investigation, replacement or modification of the anatomy or of a physiological process, Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Note that hospitals are also required to report these medical device incidents (MDI) to Health Canada under the federal Medical Device Regulations (also known as Vanessa's law).
2B.	A critical incident associated with off-label use of medical devices	Includes, but is not limited to: • Use for a different indication, • Use in different environments, • Use under different conditions, • Duration of use, • Use with different devices, • Use by a different patient group than what is indicated in the licensing conditions.
2C.	A critical incident associated with intravascular air embolism	All high-risk procedures are reportable under this event. Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism, and Left Ventricular Assist Device insertions that have a small but known risk of air embolism.
2D.	A critical incident associated with a failure of Information Technology equipment, including hardware or software	Includes all other product or device events that do not fall under the previous categories.

3 PATIENT PROTECTION EVENTS

	Category	Additional Specification/Guidance
3A.	Wrongful discharge of a patient of any age, who does not have decision-making capacity	Includes discharge to the wrong person or a discharge without a confirmed, safe plan. 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). Note that infants discharged to the wrong person should be reported under the Criminal Events category of NE14 (Infant abducted, discharged to the wrong person).
NE12.	Patient under the highest level of observation leaves a secured facility without the knowledge of staff	This event pertains only to patients whose condition (e.g., dementia, psychosis, at risk of suicide) requires them to be cared for in a secure facility or unit. It can involve a patient deliberately leaving the ward or facility, or accidentally wandering away.
NE13.	Patient suicide, or attempted suicide that resulted in serious harm, in instances where suicide-prevention protocols were to be applied to patients under the highest level of observation	It is recognized that suicide is not always preventable. Health facilities are not designed or resourced to continuously monitor a patient. However, in cases where a patient has been identified as being at high risk of suicide, monitoring and safe-environment protocols should be set and followed.
3B.	Patient suicide, attempted suicide or self-harm	These are events that occur: a) after admission to any type of facility or program, or b) in the community while receiving mental health and addictions services, or c) in the community while waiting to receive community based mental health and addictions services, or d) within seven (7) days after patient presented with mental health and addiction concerns including suicidal ideation or self-harm, and attended the emergency room, urgent care centre, SHA intake services, or crisis and community management services Excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital unless the patient was receiving services from a health services entity prior to that admission.
3C.	A critical incident associated with any other patient protection event	Includes all other patient protection events that do not fall under the previous categories.

4 CARE MANAGEMENT EVENTS

	Category	Additional Specification/Guidance
4A.	A critical incident associated with a medication or fluid error	Includes, but is not limited to, errors involving the wrong: • Drug, • Dose, • Patient, • Time, • Rate, • Preparation, • Route of administration.

	Category	Additional Specification/Guidance
		Also includes errors of omission. Excludes reasonable differences in clinical judgment on drug selection and dose.
4B.	A critical incident associated with off-label use of medication	Includes, but is not limited to, use: • for a different indication, • of a different dosage, • of dosing frequency or duration of use, • of a different method of administration, • by a different patient group than what is indicated in the product monograph.
NE5.	Patient death or serious harm due to a failure to inquire whether a patient has a known allergy to medication, or due to administration of a medication where a patient's allergy had been identified	This event involves a situation where a patient is aware of a medication allergy but is given the medication anyway either because the hospital failed to ask about allergies or because they knew about the allergy but failed to avoid administering that medication. Excludes events where the allergy was unknown to the patient, or instances where a medication had to be administered in an emergency (e.g., contrast agents for imaging), or to an unconscious patient. However, it is important to acknowledge that harm from these emergency events can still be minimized by effective monitoring and response.
NE7.	Patient death or serious harm as a result of one of five pharmaceutical events. The following five pharmaceutical events represent errors that can result in serious consequences for patients: • Wrong-route administration of chemotherapy agents, such as vincristine administered intrathecally (injected into the spinal canal). • Intravenous administration of a concentrated potassium solution. • Inadvertent injection of epinephrine intended for topical use. • Overdose of hydromorphone by administration of a higher-concentration solution than intended (e.g., 10 times the dosage by drawing from a 10 mg/mL solution instead of a 1 mg/mL solution, or not accounting for needed dilution/ dosage adjustment). • Neuromuscular blockade without sedation, airway control and ventilation capability.	

	Category	Additional Specification/Guidance
4C.	A critical incident associated with the delay or improper administration of blood or blood products	Note that wrong blood product actually given or potentially given to a patient should be reported under the Product or Device Events category of NE2.
4D.	A critical incident related to a mother, associated with either the birthing process (labour, birth, or postpartum) or an intrauterine procedure up to 42 days postpartum	
4E.	A critical incident related to a full-term fetus or neonate, associated with labour or delivery	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, • Illness related to phenylketonuria, • Known sexually transmitted infections.
NE8.	Patient death or serious harm as a result of failure to identify and treat metabolic disturbances	This event will focus only on hypoglycaemia in an admitted patient and hyperbilirubinemia in neonates.
NE9.	Stage 3, stage 4 or unstageable pressure ulcers acquired after admission to a health services entity facility	Pressure ulcers are also known as bed sores and they are categorized in four stages: • Stage I — The skin is a slightly different colour, but there are no open wounds, • Stage II — The skin breaks open and an ulcer forms, • Stage III — The sore becomes worse and creates a crater in the tissue, • Stage IV — The sore is very deep causing extensive damage; these sores can harm muscle, bone and tendons. Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission. Includes, but is not limited to, events where: • The pressure ulcer was reasonably believed to be preventable considering the patient's underlying condition(s), the care plan, circumstances and context, and clinical judgment, • There was equipment malfunction, breakdown, misuse or a failure to provide necessary equipment that could have contributed to the development or progression of the pressure ulcer, • The use or misuse of restraints was a contributing factor in the development or progression of the pressure ulcer, • There was a breach of policy that could have contributed to the development or progression of the pressure ulcer, • There were modifiable environmental factors involved that contributed to the development or progression of the pressure ulcer.
4F.	A critical incident associated with a delay in patient transfer to a facility for appropriate level of care	Includes events where the transfer is delayed on the receiving end/and or sending end of the transfer.

	Category	Additional Specification/Guidance
4G.	A critical incident associated with an error in diagnosis or treatment	Error in diagnosis is the failure to make a correct explanation of a patient's health problem, regardless of whether or not there is harm. Refer to Appendix B: Modified Diagnosis Error Evaluation and Research (DEER) Taxonomy for more information. Error in treatment means a patient received a treatment that is inappropriate for the diagnosis.
4H.	A critical incident associated with a delay in diagnosis or treatment	Delay in diagnosis is the failure to provide a timely explanation of a patient's health problem, regardless of whether or not there is harm. Refer to Appendix B: Modified Diagnosis Error Evaluation and Research (DEER) Taxonomy for more information. Delay in treatment means a patient did not receive the treatment that was ordered in the timeframe intended to be delivered.
4I.	The loss or physical compromise of a biological specimen or patient information related to the specimen	Biological specimen includes both replaceable and irreplaceable specimen. Excludes events where the specimen was properly handled, but the specimen proved to be non-diagnostic.
4J.	A critical incident as a result of deviation from generally accepted performance standards	Performance standards should include external as well as internal sources of information such as established policies, procedures, and protocols; nationally recognized best practices and standards of care; industry imposed practice mandates and requirements; implied professional standards. Reporting of this event is intended to identify potential improvements to system performance, rather than individual performance issues.
4K.	Death associated with a healthcare-associated infection	A healthcare associated infection (HAI) is an infection that a patient contracts (or acquires) in a setting where healthcare is delivered (e.g. a hospital) or in an institution (e.g. a long-term care facility) or in a home care arrangement. The infection was neither present nor developing at the time the individual was admitted (or started treatment). It includes, but is not limited to, surgical site infections, catheter associated urinary tract infections, ventilator-acquired pneumonia, central venous catheter-associated bloodstream infections, Methicillin-resistant Staphylococcus aureus infection (MRSA), Vancomycin-resistant enterococci (VRE) infections, and Clostridium difficile (C. difficile).
4L.	Failure to follow or implement a health care directive that results in an undesired outcome for the patient	In Saskatchewan, a health care directive is legal and protected under the Health Care Directives and Substitute Health Care Decision Makers Act, 2015.
4M.	A critical incident associated with any other care management event	Includes all other care management events that do not fall under the previous categories.

5 ENVIRONMENTAL EVENTS

	Category	Additional Specification/Guidance
NE6.	Patient death or serious harm due to the administration of the wrong inhalation or insufflation gas	Includes the administration of the wrong gas due to any cause, such as provider error, a labelling error or the incorrect use of gas- specific connectors. These gases may be inhaled or blown into a body cavity, such as to sinuses or the abdomen.
NE10.	Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area	Magnetic resonance imaging (MRI) equipment creates very powerful magnetic fields. When metallic and magnetic objects, such as metal in clothing, an implanted device, a pair of scissors, or even a hospital wheelchair are in the same area as an MRI machine they can become dangerous, rapidly moving projectiles that can injure or even kill patients.
NE11.	Patient death or serious harm due to an accidental burn	Includes burns that occur during the care process, such as those due to oxygen fires, unintended burns occurring during surgery, and heat or cold burns from assisted bathing, the use of hot or cold packs and wound care. Excludes burns due to other environmental risks, such as patient use of kitchen equipment.
NE15.	Patient death or serious harm as a result of transport of a frail patient, or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment	When frail patients or those with dementia are transported home or to another facility or ward, they must be left with appropriate support. It is crucial that those providing transport ensure the patient is left in a safe environment and with proper notification given to caregivers.
5A.	A critical incident associated with electric shock	Excludes events involving planned treatments such as electric counter shock.
5B.	Patient death associated with, and occurring within 14 days of, a fall	Includes, but is not limited to, fractures, head injuries, and intracranial hemorrhage. Includes, but is not limited to, events where: • The fall was reasonably believed to be preventable considering the patient's underlying condition(s), the care plan, circumstances and context, and clinical judgment, • There was equipment malfunction/failure, breakdown, misuse or a failure to provide necessary equipment that could have contributed to the fall, • The use or misuse of restraints was a contributing factor in the fall, • There was a breach of policy that could have contributed to the fall, • There was modifiable environmental factors involved that contributed to the fall.
5C.	A critical incident resulting from or associated with the use or lack of restrictive interventions such as physical, mechanical, manual or environmental restraint	Physical restraint can be defined as "any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that the individual cannot easily remove that restricts freedom of movement or normal access to one's body".
5D.	A critical incident as a result of transport arranged or provided by a health services entity	Includes loss of control of a vehicle or aircraft, as well as actual or potential single vehicle accidents or multi-vehicle collisions,

	Category	Additional Specification/Guidance
		for example, transportation in a ground ambulance, air ambulance, medical taxi or chartered aircraft.
5E.	A critical incident associated with a delay or failure to reach a patient for emergent or scheduled services	Includes delay due to extreme weather conditions, poor roads, communication breakdown and ambulance availability. Includes, but is not limited to, ground and air EMS and homecare services.
5F.	A critical incident associated with any other environmental event	Includes all other environmental events that do not fall under the previous categories.

6 CRIMINAL EVENTS

	Category	Additional Specification/Guidance
6A.	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other health care provider	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.
NE14.	Infant abducted, or discharged to the wrong person	Includes all instances where an infant is abducted or discharged to someone who is not the parent or legal guardian, or to a biological parent who does not have legal custody. In the latter case, the failure point would be not establishing legal status with the legal parent, or failing to check a documented status at discharge.
6B.	Abduction of a patient of any age	Includes children with an order of apprehension who are taken by a family member.
6C.	Criminal act towards a patient that occurs on grounds owned or controlled by a health services entity	Includes, but is not limited to: • Sexual assault or non-consensual sexual acts, • Physical assault, • Assaults perpetrated at a patient's home while receiving home care or mental health services. Includes events perpetrated by other patients, an employee, member of the medical staff or an individual under contract with the health services entity, a member of the public and children under the age of 12 who cannot be considered to have committed a criminal act.
6D.	A critical incident associated with any other criminal event	Includes all other criminal events that do not fall under the previous categories.

APPENDIX A: DEFINITIONS

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 the Saskatchewan Ministry of 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.[5]

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

Health services entity
means (a) the Saskatchewan Health Authority (SHA); (b) a health services provider; or (c) the Saskatchewan Cancer Agency;

Health care management
includes the actions of individual staff members as well as broader systems and care processes. It 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).

Patient
means a client, resident, or patient.

[5] 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).

APPENDIX B: MODIFIED DIAGNOSIS ERROR EVALUATION AND RESEARCH (DEER) TAXONOMY

The Diagnosis Error Evaluation and Research (DEER) taxonomy[6] is used by the Pennsylvania Patient Safety Authority to identify wherein the diagnostic process an error may have occurred. The following table lists the taxonomy's diagnostic process step and failure point.

Diagnostic Process Step	Failure Point
1. Access/ Presentation	A. Failure or delay in patient seeking care
	B. Failure or denial of access to care
2. History	A. Failure or delay in providing or eliciting a piece of history data
	B. Inaccurate or misinterpreted piece of history data
	C. Suboptimal weighing of a piece of history data
	D. Failure or delay in acting on or following-up on a piece of history data
3. Physical Examination/ Assessment	A. Failure to perform a physical examination or assessment
	B. Inaccurate or missed physical examination or assessment finding
	C. Suboptimal weighing of a physical examination or assessment finding
	D. Failure or delay in acting on of following-up on a physical examination or assessment finding
4. Testing (Laboratory/ Radiology/ Other)	A. Failure or delay in ordering needed test(s)
	B. Failure or delay in performing needed test(s)
	C. Suboptimal test sequencing
	D. Wrong test(s) ordered
	E. Test(s) ordered the wrong way
	F. Identification failure (e.g., sample mix-up, mislabeled specimen, or test performed on the wrong patient)
	G. Technical or processing error (equipment problem, poor processing of specimen/text, or skill issue)
	H. Specimen delivery problem (e.g., specimen never sent, delayed delivery, or lost specimen)
	I. Misread or misinterpreted test(s)
	J. Failure or delay in transmitting or communicating test result to healthcare provider
	K. Failure or delay in acting on or following-up on test result (including results not communicated to the patient)
5. Hypothesis Generation	A. Failure or delay in considering correct diagnosis
	B. Suboptimal weighing or prioritizing
	C. Too much weight given to lower probability or priority diagnosis
6. Referral/ Consultation	A. Failure or delay in ordering a referral or consult
	B. Failure or delay in obtaining or scheduling an ordered referral or consult
	C. Failure or delay in communicating consultation findings
7. Monitoring/ Follow-Up	A. Failure or delay in monitoring (e.g., failure to routinely check vital signs, failure to apply monitor, technical issue)
	B. Inaccurate or missed physiologic monitoring finding (e.g., misinterpreted fetal monitor strip)
	C. Failure or delay in recognizing urgency of condition or complication
	D. Failure or delay in communicating findings among healthcare team members
	E. Failure to refer the patient to appropriate setting or for appropriate monitoring
	F. Failure or delay in timely following-up with or rechecking the patient

[6] http://patientsafety.pa.gov/pst/Documents/Diagnostic%20Error/audit.pdf

Appendix C: CRITICAL INCIDENT NOTIFICATION

GENERAL INFORMATION

Ministry of Health (MoH) Reference Number:		**CI 2324-**			
SHA / SCA Patient Safety Contact:					
Date of Event:		**Date Patient Safety Notified:**		**Date MoH Notified:**	

EVENT LOCATION

SHA Network/SCA:		**Location Category:**	
Facility/Ambulance Service:			

EVENT TYPE

Service Line/Clinical Area:	
Event Category:	

PATIENT SUMMARY

Age:		**Sex:**	☐ Male ☐ Female ☐ X

PATIENT OUTCOME

Level of Patient Harm:	
Physical and Psychological Harm /Impact of Event on Patient (1-3 sentences)**:**	

If Patient Outcome was Death

Cause of Death:	
Coroner Notified:	☐ Yes ☐ No

SUMMARY OF CI (3-5 sentences, enter below)

Appendix D: CRITICAL INCIDENT REPORT

PATIENT SUMMARY

Weight (kg):	
Medications (if applicable to critical incident)**:**	

TEAM REVIEW & REPORT DATES

Date of Team Review:		**Date Report Due:**	
Date Report Submitted:		**Date 1st Extension Requested:**	
		Date 2nd Extension Requested:	
Review Participants:	☐ RN ☐ RPN ☐ Nursing Unit Manager ☐ CCA/SCA ☐ Physician ☐ Pharmacy Manager ☐ LPN ☐ Student ☐ Others (role): _____		

SEQUENCE OF RELEVANT EVENTS

Date/Time	Source of Information	Description of Event

SEQUENCE OF RELEVANT EVENTS

Date/Time	Source of Information	Description of Event

DISCLOSURE TO PATIENT AND / OR SUBSTITUTE HEALTHCARE DECISION MAKER

Disclosure:	☐ Yes ☐ No
If no, explain rationale:	

If Disclosure Occurred

Disclosed By:		**Disclosure Date:**	
Patient/Substitute Healthcare Decision Maker Perspective:			

CONTRIBUTING FACTORS

Description	Category

RECOMMENDED ACTIONS

Each contributing factor should have a recommended action. One contributing factor may have multiple recommended actions. The table below must be completed for each recommended action.

Contributing Factor (copy and paste from previous section)**:**			
Recommended Action:			
Position of Individual Responsible:		**Priority:**	
System Level Response:		**Hierarchy of Effectiveness:**	
Implementation Status:		**Implementation Deadline:**	
Data Indicator(s) for Measuring Effectiveness after Implementation:		**Monitoring Period:**	
		Reporting Frequency:	
Data Indicator(s) for Measuring Sustainment after Implementation:		**Monitoring Period:**	
		Reporting Frequency:	
Applicable to other areas not included in implementation?	☐ No ☐ Yes (list areas): _____		
If yes, is implementation in those areas being considered?	☐ Yes ☐ No		
Please elaborate:			

Additional Relevant Comments (enter below)

REPORTING TO EXTERNAL GOVERNING BODIES

Was this CI referred to another committee/professional organization?	☐ Yes ☐ No
If yes, which one(s)?	

Critical Incident Notification: Documentation Guidelines

Form Field	Entry Type	Additional Guidance
Ministry of Health (MoH) Reference Number	Free Text	Reference number provided by the MoH.
SHA/SCA Patient Safety Contact	Free Text	Name of the Patient Safety Specialist assigned to the investigation.
Date of Event	Date (dd/mm/yy)	Date the event occurred, or the date when the reporting organization became aware of the event.
Date Patient Safety Notified	Date (dd/mm/yy)	Date the event was reported to Patient Safety. This will be considered as the date the provincial health authority became aware of the event.
Date MoH Notified	Date (dd/mm/yy)	Date the MoH received the completed Critical Incident Notification template.
SHA Network/SCA	Drop-down	SHA network where the event occurred, if being reported by the SHA.
Location Category	Drop-down	Type of location where the event occurred.
Facility/Ambulance Service	Free Text	Name of facility where the event occurred, or name of ambulance service if the event occurred while in transit.
Service Line/Clinical Area	Drop-down/ Free Text	Service line/clinical area where the event occurred.
Event Category	Drop-down	Type of event as per the *Saskatchewan Critical Incident Reporting Guideline, 2023*.
Age	Free Text	Age of the patient impacted by the event. If age is not provided in years, please specify the unit of time (e.g. days, weeks, months, etc.).
Sex	• Male • Female • X	Sex of the patient associated with the Health Services Number information
Level of Patient Harm	Drop-down	Level of physical or psychological patient harm as a result of the event. • **Death** – unexpected death not related to the natural or expected course of the patient's illness or underlying condition. • **Severe Harm** – Patient outcome is symptomatic, requiring life-saving intervention or medical – surgical intervention, shortening life expectancy or causing major, permanent or temporary harm or loss of function. Can include severe psychological injury. • **Moderate Harm** – Patient outcome is symptomatic requiring intervention (e.g. additional operative procedure, additional therapeutic treatment), an increased length of stay, or causing permanent or temporary harm, or loss of function. Can include psychological injury.

Form Field	Entry Type	Additional Guidance
		• **Mild Harm** – Patient outcome is symptomatic, symptoms are mild or loss of function or harm is minimal or intermediate, but short-term, and minimal or no intervention (e.g. extra observation, intervention, review, or minor treatment), is required. Can include emotional distress or anxiety. • **No Detectable Harm / No Harm** – Patient is asymptomatic. No symptoms are detected and no treatment is required. Not able to discover or ascertain the existence, presence, or fact of harm, but harm may exist. Insufficient information is available, or unable to determine any harm. Harm may appear later. • **Near Miss** – event occurred but did not reach the patient • **Close Call** – event did not occur and so could not reach the patient • **Unknown** – level of harm is unknown at the time of reporting For the purposes of initial notification to the Ministry, this field is completed based on what is known at the time. However, this field, along with "Physical and Psychological Harm/ Impact of Event on Patient", should be updated as appropriate in the CI report that is submitted to the Ministry.
Physical and Psychological Harm/ Impact of Event on Patient	Free Text	1-3 sentences on the physical and psychological harm/impact on the patient which is wholly or partially attributable to an event. If applicable, include whether or not an Advanced Care Directive (ACD) was in place and if yes, specify whether the actions taken were consistent with the ACD. For the purposes of initial notification to the Ministry, this field is completed based on what is known at the time. However, this field, along with "Level of Patient Harm", should be updated as appropriate in the CI report that is submitted to the Ministry.
Cause of Death	Free Text	Cause of death if known (e.g. preferably as documented on the discharge summary in patient's chart), which may or may not be attributed to the event. Must be completed if the outcome was death.
Coroner Notified	• Yes • No	Must be completed if the outcome was death.
Summary of CI	Free Text	Succinct summary (2-5 sentences) of the event, including patient health status before the event, pertinent facts that

Form Field	Entry Type	Additional Guidance
		led to the event including relevant history, and any actions that have already been taken. Abbreviations and acronyms should be expanded in brackets for clarity. There are several disciplines represented at the CI Review table and abbreviation/acronyms may have different meanings unique to each discipline.

Note: If an event no longer meets the definition of a critical incident (CI) upon further examination by the reporting organization, then a request to retract the CI, including the rationale, may be emailed to the Provincial Quality of Care Coordinators (PQCCs). A response from a PQCC will be received typically within 1-2 weeks on whether the request is approved or denied.

Critical Incident Report: Documentation Guidelines

Form Field	Entry Type	Additional Guidance/Evaluation Criteria
Weight	Free Text	Weight in kilograms of the patient impacted by the event.
Medications (if applicable)	Free Text	Patient medications that were relevant to the event. This is mandatory for events in categories 4A, 4B, NE5, and NE7 of the *Saskatchewan Critical Incident Reporting Guideline, 2023*.
Date of Team Review	Date (dd/mm/yy)	Date the reporting organization's investigation team met to review the CI.
Date Report Due	Date (dd/mm/yy)	Date the written report is due, calculated as 60 days from when the reporting organization became aware of the event.
Date Report Submitted	Date (dd/mm/yy)	Date the MoH received the written report by email.
Date of 1st Extension	Date (dd/mm/yy)	Date the request to extend the written report deadline was submitted to the MoH by email.
Date of 2nd Extension	Date (dd/mm/yy)	Date the request to extend the written report deadline was submitted to the MoH by email.
Review Participants	Checkboxes	Roles of the participants on the reporting organization's investigation team that met to review the CI.
Sequence of Relevant Events	Free Text	Provide a chronological account of the CI, broken down by date/time, source of information (e.g. patient chart, lab results, etc.), and description of events. Include only chronology relevant to incident and factual information only, including the patient health status before the event, facts that led to the event including relevant history, and any actions that have already been taken. The Saskatchewan Cancer Agency may attach their completed timeline template in lieu of entering information into the table.
Disclosure to Patient and/or Substitute Healthcare Decision Maker	• Yes • No	Must indicate whether the event/harm was disclosed to the patient and/or family.
If no, explain rationale	Free Text	Rationale for why the reporting organization did not disclose the event/harm to the patient and/or family. All CIs should be disclosed to the patient and/or family.
Disclosed By	Free Text	Person from the reporting organization that disclosed the event/harm to the patient and/or family.

Form Field	Entry Type	Additional Guidance/Evaluation Criteria
Disclosure Date	Date (dd/mm/yy)	Date the event/harm was disclosed to the patient and/or family.
Patient / Substitute Health Care Decision Maker Perspective	Free Text	A description of the feedback from the patient and/or family about the event/harm after disclosure. This may include their perspective on the facts of the event (which sometimes differs from the reporting organization's understanding of the events) and any impact statement that describes the physical and emotional harm/loss that the patient and/or family has suffered. The impact statement gives patients and families a voice in the health care system. It allows them to explain to the reporting organization, in their own words, how the event has affected them.
Contributing Factor Description	Free Text	A statement identifying any current practice, procedure or factor involved in the provision of the health service or the operation of the program that: a) contributed to the occurrence of the critical incident; and b) if corrected or modified, may prevent the occurrence of a similar critical incident in the future; This will be the basis for developing recommended actions.
Contributing Factor Category	Drop-down • Care Team - Direct • Care Team - Supporting • Communication • Equipment • Patient Characteristics • Organization - Capacity • Organization - Culture • Organization - Policies & Priorities • Task (care/work process) • Work Environment • Other	Most applicable category that the identified Contributing Factor falls under. Refer to pages 89-91 of the Canadian Incident Analysis Framework for more information. Note that the categories of "Communication" and "Language and/or Cultural Barriers" were created by the Ministry.
Recommended Action	Free Text	Recommended action that the reporting organization will implement to address the

Form Field	Entry Type	Additional Guidance/Evaluation Criteria
		identified Root Cause. Implementation of the action should be likely to prevent the incident or mitigate the harm. Consideration should be given to the Hierarchy of Effectiveness and System Level Response (see next 2 form fields below). Actions should be written using the "SMART" format: • Specific – tackle a clearly defined issue and have a clear scope; • Measurable – can demonstrate impact on process and outcomes; • Attainable – can be achieved with available resources; • Realistic – do a reality check to predict if it will be accepted, implemented; and • Timely – have a timeframe for implementation.
Position of Individual Responsible	Free Text	Title, service line, and area (if applicable) of the individual responsible for implementing the recommended action (e.g. Director, Patient Safety, Regina). Assign responsibility at the appropriate level in the organization.
Priority	• High • Medium • Low	Priority of the recommended action. This should be based on the level of harm and likelihood of event recurrence if the recommended action is not implemented.
System Level Response	Drop-down • Micro (Unit/ Department) • Meso (Service Line/ Program/Site) • Macro (Network/ Region/Site) • Mega (Provincial)	System level category that implementation of the identified recommended action falls under. Reporting organizations should target the actions at the right level of the system and ensure the action is appropriate for that level.

Hierarchy of Effectiveness	Drop-down
	• High Leverage
	• Medium Leverage
	• Low Leverage
		Hierarchy of effectiveness category that the identified recommended action falls under.
		• High Leverage examples:
		  ○ Forcing Functions and Constraints
		  ○ Automation
		• Medium Leverage examples:
		  ○ Simplification / Standardization

Form Field	Entry Type	Additional Guidance/Evaluation Criteria
		○ Reminders / Checklists / Double Checks • Low Leverage examples: ○ Rules and Policies ○ Education and Information Reporting organizations should utilize the most effective solution that is reasonable or possible given the circumstances. Note that items such as training and policy development are necessary components, but when used alone, do not change the underlying conditions that led to the incident. From a human factors standpoint, the strongest interventions are "physical rather than procedural, and permanent rather than temporary." Refer to pages 57-58 of the Canadian Incident Analysis Framework for more information.
Implementation Status	Drop-down • Planning Phase • Partially Implemented • Fully Implemented	Implementation status of the recommended action at time of report submission.
Implementation Deadline	Date (dd/mm/yy)	Target deadline for implementation of recommended action. This should be appropriate based on the recommended action's priority. If the recommended action has already been completed, enter the actual implementation date.
Data Indicator(s) for Measuring Sustainment	Free Text	Indicator(s) that will be used to measure and monitor whether implementation of the recommended action is having the desired outcome.
Data Indicator(s) for Measuring Sustainment	Free Text	Indicator(s) that will be used to measure and monitor whether implementation of the recommended action is sustained.
Monitoring Period	Free text	Period in which the indicator(s) will be measured and monitored after the recommended action is implemented (e.g. number of months, quarters, years, etc.), in order to have reasonable confirmation that implementation is having the desired outcome (for measuring effectiveness) and sustained (for measuring sustainment).

Form Field	Entry Type	Additional Guidance/Evaluation Criteria
Reporting Frequency	Free text	Reporting frequency (e.g. weekly, monthly, etc.) of the indicator(s) that is regular enough to identify whether potential barriers/challenges are occurring so that timely corrective actions can be taken. This should also align with the priority of the recommended action (e.g. high priority actions should be monitored more frequently).
Applicable to other areas not included in implementation?	• No • Yes	Indicate whether the recommended action is applicable to other areas (e.g. units, programs, facilities, networks, areas) in the reporting organization, and if yes, list what those areas are. Consider areas that function similarly to where the recommended action is being implemented.
If yes, is implementation in other areas being considered?	• Yes • No	Indicate whether there are current or future plans to evaluate if the recommended action should be implemented in other applicable areas.
Please elaborate	Free Text	If yes to question above, please provide a short, high-level description on who is responsible and how that follow-up will occur (e.g. Patient Safety Executive Director is meeting with Acute Care Executive Directors to decide if/how to implement in all intensive care units). If no to question above, please provide a short explanation of the rationale.
Was this CI referred to another committee/ professional organization? **If yes, which one(s)?**	• Yes • No	If yes, list the committee (e.g. morbidity and mortality review rounds), organization (e.g. College of Physicians and Surgeons; other licensing body), and/or agency (e.g. Public Health Agency of Canada). Note that hospitals are also required to report certain medical device incidents (MDI) to Health Canada under the federal Medical Device Regulations (also known as Vanessa's law).

Note: CI written reports submitted by reporting organizations must have all applicable fields completed. Furthermore, according to regulations, reporting organizations must make changes to a report if requested, to bring the report into compliance with the regulations and guideline. At this point, the CI written report is considered "Closed" and it moves to the "Implementation & Monitoring" phase. The reporting organization must then provide regular status updates on the implementation status of recommended actions (until implementation is complete), and the effectiveness of each recommended action after implementation (in accordance with the duration and frequency of data collection specified in the written report).