Recommendations and Guidance for Application of the Adverse Health Event Definitions

May 2024

The MHA Patient Safety Registry Advisory Committee has been working on recommendations for definitional questions that have arisen related to the adverse health event reporting law. In order to create more accurate and consistent reporting across facilities, MHA is making these recommendations available to facilities required to report adverse health events to provide guidance as they review potential reportable events.

The Minnesota Department of Health (MDH) supports thorough and consistent reporting of adverse events in Minnesota's hospitals and surgical centers as defined in law. To that end, MDH appreciates and supports the work that MHA and other local experts and organizations have done to provide clarification when questions arise about whether to report an event or how best to categorize an event. MDH will participate in discussions with MHA and other experts as requested.

It is ultimately the decision of the reporting facility whether to report an event and how to best categorize the event given the requirements of the law. MDH hopes that the deliberations of MHA and other qualified experts can inform this decision. MDH will continue to address questions as they arise on a case-by-case basis.

Event Category	Question/Issue Addressed	Recommendation/Guidance
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Maternal death in low-risk pregnancy	• Definition of low risk pregnancy • Maternal hemorrhage • Reporting obligation following patient discharge	CMR 17 p. 26-27 CMR 18 p. 27 CMR 19 p. 27
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General Recommendations

General Recommendation 1:

Question/Issue Addressed:

The use of the term "serious injury" is vague and needs to be more specific as it applies to **patients.** Use of term "substantially limits" and "major life activities" is unclear.

Supporting Information/ Documentation:

144.7063 Subd. 4: Law Definition: Serious Injury (1) a physical or mental impairment that substantially limits one or more major life activities of an individual. (2) A loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility or, (3) loss of a body part.

Recommendation/Guidance:

In considering whether or not an event outcome meets the definition of a "Serious Injury," the organization's clinical team needs to evaluate the outcome against each of the three elements of serious injury as defined by the AHE law 144.7063 Subd. 4. If an event meets any of these three elements and there continue to be additional questions please see Inclusion/Exclusion list.
If the organization's clinical team answers "Yes" *OR* the outcome fits under the "Inclusion" list, the outcome would be considered a "Serious Injury."

Inclusions:

- Bone fractures (e.g., hip, pelvic, newborn and adult skull) except as listed in exclusions.
- Injuries requiring major intervention, e.g.:
    - Surgical or procedural intervention
    - Burns needing debridement/skin grafts
- Higher level of care, for care related to the event, for more than 48 hours, e.g., transfer to critical care unit, transfer to inpatient setting from outpatient setting.
- Loss, or substantial limitation of, bodily function lasting greater than 7 days, e.g.,
    - Bodily functions related to: breathing; dressing/undressing; drinking; eating; eliminating waste products; getting into or out of bed, chair, etc; hearing; seeing; sitting; sleeping; or walking.
- Loss of body part

Exclusions:

- Minor fractures, e.g., finger, thumb, toes, nose, ribs, wrist, non-displaced or minimally-displaced fractures (unless these fractures substantially limit one or more major life activities

such as those listed in Inclusion #4 or require major intervention such as listed in Inclusion #2).

- Head injuries with intracranial bleeding that do not require major intervention (Inclusion Criteria #2) or do not substantially limit one or more major life activities (Inclusion Criteria #4).
- Additional monitoring without meeting criteria for higher level of care
- Minor lacerations – e.g. lacerations that are able to be closed with sutures rather than needing surgical intervention, and immobilization of area is not required after being repaired, function of the area is not affected
    - This would include self-harm but NOT suicide attempt

*Note: Inclusion criteria trump exclusion criteria

- Yes, to any of the inclusion criteria qualifies that outcome as a serious injury.

General Recommendation 2:

Question/Issue Addressed: The use of the term "serious injury" is vague and needs to be more specific as it applies to **employees.** Use of term "substantially limits" and "major life activities" is unclear.

Supporting Information/ Documentation: 144.7063 Subd. 4: Law Definition: Serious Injury (1) a physical or mental impairment that substantially limits one or more major life activities of an individual. (2) A loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility or, (3) loss of a body part.

Recommendation/Guidance: Consideration for serious injury to staff is only applicable to physical assault events. In considering whether or not an event outcome meets the definition of a "Serious Injury," the organization's clinical team and employee health need to evaluate the outcome against each of the three elements of serious injury as defined by the AHE law 144.7063 Subd. 4. If an event meets any of these three elements and there continue to be additional questions please see Inclusion/Exclusion list. If the organization's clinical team answers "Yes" *OR* the outcome fits under the "Inclusion" list, the outcome would be considered a "Serious Injury."

Inclusions:

Type of Injury	**Severity**
Any work-related injury that results in loss of consciousness	Serious Injury

Any work-related injury requiring medical treatment beyond OSHA's First Aid List (see list below)*	Serious Injury
Any work-related fractured or cracked bones or teeth and punctured eardrums	Serious Injury
Psychological counseling by a physician or licensed health care professional to treat a diagnosis**	Serious Injury
Results in an inpatient hospitalization (any length of time)	Serious Injury

*****This does include the use of physical therapy or chiropractic care
******This does not include self-referral or non-prescriber referral to support programs like Employee Assistance Programs or utilization of other support persons or material.

Exclusions:
OSHA's First Aid List (This is a complete list of all treatments considered first aid)

a) Using a nonprescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes);
b) Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment);
c) Cleaning, flushing or soaking wounds on the surface of the skin;
d) Using wound coverings such as bandages, Band-Aids™, gauze pads, etc.; or using butterfly bandages or Steri-Strips™ (other wound closing devices such as sutures, staples, etc. are considered medical treatment);
e) Using hot or cold therapy;
f) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);
g) Using temporary immobilization devices while transporting an accident victim (e.g., splints, slings, neck collars, back boards, etc.).
h) Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;
i) Using eye patches;
j) Removing foreign bodies from the eye using only irrigation or a cotton swab;

k) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means;
l) Using finger guards;
m) Using massages (physical therapy or chiropractic treatment are considered medical treatment); or
n) Drinking fluids for relief of heat stress.

General Recommendation 3:

Question/Issue Addressed: It is often difficult to determine conclusively that an outcome is 'Associated with' a particular event.

Recommendation/Guidance: "Associated with" can be further defined as the event having a high clinical likelihood of contributing to or causing serious injury or death. This should be reported unless there is evidence, e.g. autopsy findings, or in the absence of evidence, a determination in consultation with the clinical team caring for the patient based on review of clinical information, that there was a different cause for the death or serious injury than the event in question.

Case examples of determination in consultation with the clinical team regarding the association of a patient death or serious injury with an adverse event.

1. Patient fall with nasal fracture which did not need surgical repair. Patient deteriorated and died one week later. Autopsy not performed. The clinical team caring for the patient reviewed all records and determined that the final diagnosis was cardiopulmonary arrest secondary to adenocarcinoma. Secondary diagnosis included fall secondary to syncopal episode. A clinical decision was made that the adenocarcinoma/cardiopulmonary arrest was the cause of death rather than the fall.
    a. Not reportable as a death or serious injury *associated with* a fall.
2. Patient with end-stage kidney disease and dementia was hospitalized after a fall at a skilled nursing facility. While in the hospital, patient experienced another fall, which led to a hip fracture. The family opted against a surgical intervention, given the patient's terminal status. After a two-day stay in the hospital, the patient was transferred back to the nursing facility and died a week later. The hospital clinical team that cared for the patient reviewed all records and determined that the outcome of the fall was the hip fracture which would have been repairable with surgery, however, the death was associated with the end-stage kidney disease rather than the fall.
    b. Not reportable as a death *associated with* a fall

c. Reportable as a serious injury (hip fracture) *associated with* a fall.

3. Patient was admitted to the Emergency Department with complaints of weakness. Tests were completed and patient ready to be discharged. Patient observed ambulating without incident but fell after returning to bedside. Patient suffered a blow to the head, was dazed but no loss of consciousness. Initially was reported to do well with regard to head injury, but patient experienced a myocardial infarction and expired 2 days after fall. An autopsy was not performed. The clinical team caring for the patient did not feel that there was enough clinical evidence to rule out that the fall contributed to the death of this patient.
    a. Reportable as a death *associated with* a fall.

General Recommendation 4:

Question/Issue Addressed:	When are events that occur in an outpatient setting reportable?
Supporting Information/ Documentation:	Minnesota statute 144.7063, Subd. 3 Facility. "Facility" means a hospital or outpatient surgical center licensed under sections 144.50 to 144.58.
Recommendation/Guidance:	If the setting in which the event occurs is licensed under the reporting facility it is reportable; if the setting is not licensed under the reporting facility it is not reportable; e.g., a fall with serious injury occurring in an ambulatory clinic not physically located within the hospital but licensed under the hospital would be reportable; a fall in an outpatient clinic physically located within the hospital but not licensed under the hospital would not be reportable.

General Recommendation 5:

Question/Issue Addressed:	When does someone become a patient?
Recommendation/Guidance:	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.

General Recommendation 6:

Question/Issue Addressed:	When is a patient no longer considered a patient?
Recommendation/Guidance:	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 patient has signed or been given discharge paperwork, or the patient has signed or been given AMA papers and is refusing care; or the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.

General Recommendation 7:

Question/Issue Addressed: If multiple events happen during a patients' hospital stay, how many reports are required?

Recommendation/Guidance:

- When more than one event happens during a hospital stay, e.g. falls, this would require separate reports even if it is the same event type. The exception would-be pressure injuries.
    - If a patient has more than 1 pressure injury, in the same location only 1 report is required with the multiple pressure injuries identified within the report. However, if the patient has pressure injuries in different locations it would be requires separate reports.

Surgical/Invasive Procedure Events

Minnesota Surgical Event Statute 144.7065, Subd. 2:

Events reportable under this subdivision are:

1) Surgery or other invasive procedure performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent
2) Surgery or other invasive procedure performed on the wrong patient
3) The wrong surgical or other invasive procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent
4) Retention of a foreign object in a patient after surgery or other invasive procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained
5) Death during or immediately after surgery or other invasive procedure of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance

Surgical/Invasive Procedure Recommendation 1:

Question/Issue Addressed:	A consistent definition for surgical procedures that are reportable under the Adverse Health Care Events Reporting Law is needed.
Recommendation/Guidance:	Adopt the MHA definition of Surgical, High-risk, or Other Invasive Procedures, which is based on the definition of the Department of Veterans Affairs, as a guide for facilities to determine whether or not an event related to a procedure is reportable under the Adverse Health Care Events surgical categories. See Appendix A for a complete list of invasive, high risk or surgical procedures

Surgical/Invasive Procedure Recommendation 2:

Question/Issue Addressed:	How is “procedures inconsistent with the correctly documented informed consent” determined?
Recommendation/Guidance:	An event is considered reportable if one of the following occurs:

- Procedure not consistent with correctly documented informed consent
- Correct procedure performed with incorrect documented consent

Inclusions:

- Omission of a consented procedure.
- Procedures performed that are not documented and consented to by patient or patient representative.
- Unnecessary or incorrect procedure performed or procedure performed on incorrect side/site when documentation is available to any team member (including surgeon/proceduralist performing the procedure) indicating the procedure was unnecessary (e.g., procedure to remove gallbladder when documentation exists that gallbladder had already been removed) or a different procedure should have been performed or performed on a different side/site (e.g., incorrect cataract lens placed, procedure in multi-procedure surgery omitted).

Exclusions:

- Procedures performed or omitted due to change in plan made necessary by findings following surgical or procedure start.
- Unnecessary procedure due to diagnostic error when documentation does not exist that procedure is unnecessary, e.g., procedure to remove gallbladder when studies suggest that the procedure is necessary and there is no documentation that gallbladder had been previously removed.
- Incorrect procedure performed, or procedure performed on incorrect side/site, when documentation is not available to any team member (including surgeon/proceduralist performing the procedure) to indicate a different procedure should have been performed or performed on a different side/site.

Surgical/Invasive Procedure Recommendation 3:

Question/Issue Addressed: There are questions on the reportability of “wrong body part,” “wrong procedure,” “wrong patient” events when the procedure performed is consistent with the documented informed consent but the document informed consent is incorrect. For example, the procedure was completed on the wrong patient due to a lab mix-up — the procedure is consistent with the informed consent document but the document informed consent is incorrect.

Recommendation/Guidance: Surgeries (and other invasive procedures) that are performed on a wrong body part or wrong surgical procedures (or other invasive procedures) that are performed are reportable events if they are consistent with the documented informed consent for that patient **but** the informed consent is based on erroneous information. Examples: A pathology mix-up results in a biopsy for a patient that did not need the biopsy — the procedure is consistent with the informed consent, however, the informed consent is based on erroneous information; an X ray is flipped over and misread resulting in an informed consent that reads "left side." The left side procedure is completed consistent with the informed consent, however, the informed consent is based on erroneous information.

Surgical/Invasive Procedure Recommendation 4:

Question/Issue Addressed: It is not clear when a wrong surgical procedure becomes a reportable event if the error is caught prior to or during the surgery.

Recommendation/Guidance: A surgery performed on a wrong body part would become reportable at the point of surgical entry, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. This excludes venipuncture, intravenous therapy, NG insertion, and Foley catheters. A regional block anesthetic administered in the wrong body part would be a reportable event because the regional block itself would be considered an invasive procedure.

Surgical/Invasive Procedure Recommendation 5:

Question/Issue Addressed: If a procedure is performed on the correct side/site but a wrong-sided component is placed, i.e., left knee component placed in the right knee, should the event be reported under the category of "Wrong Body Part" or "Wrong Procedure?"

Recommendation/Guidance: Recommend reporting under "Wrong Procedure" since the correct side was operated on but the wrong equipment was used in the procedure.

Surgical/Invasive Procedure Recommendation 6:

Question/Issue Addressed: Should spine level procedures be considered wrong site/procedure events when the incision and work completed to expose the spine is not conducted at the correct level but the verification completed prior to performing the procedure identifies the correct level and the procedure is executed at the correct level?

Recommendation/Guidance: Follow the inclusion/exclusion list below to determine reportability of spine cases:

Inclusions:

- Major localization and execution error (complete procedure done at the wrong segment of the spine), e.g. fusing the spine at the incorrect level, discectomy).
- Major localization with minor execution error; surgery includes wrong segment in final result.
- Laminotomy, or similar procedure, is the intended procedure and is executed at the incorrect level (the laminotomy is not performed only to localize the correct level for a procedure beneath this structure).

Exclusions:

- Minor localization error with no execution error
- Non-pathologic anatomy may be disrupted during the procedure, e.g., removal of ligamentum flavum.
- Non-de-stabilizing bone work may occur, e.g. laminotomy to localize the correct level beneath this structure with correction prior to execution of final procedure.

Surgical/Invasive Procedure Recommendation 7:

Question/Issue Addressed: Is the implanting of an unintended implant (i.e., wrong power lens) or device (i.e. pacemaker) reportable?

Recommendation/Guidance: Yes, the implanting of an unintended implant or device is reportable.

Surgical/Invasive Procedure Recommendation 8:

Question/Issue Addressed: At what point in the procedure does a foreign object become a reportable event?

Recommendation/Guidance:

- "An item is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient's body after the patient has been taken from the operating or procedure room. For bedside procedures, an item is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient's body after the procedure is complete."
- If a retained object is discovered prior to wound closure and a clinical decision is made to retain the object because removing it would do more harm to the patient then retaining the object, this would not be a reportable event.
- Microneedles and broken screws continue to be an exception and are not reportable retained objects if retained after surgery.
- For procedures that involve packing; packed items would be considered reportable if packing is intended to remain after the patient leaves the OR but was not removed at the prescribed time.
- Items are considered reportable if an item is intentionally retained and intended to be removed after the patient leaves the

procedural area, but a portion or all of the item was not removed as intended or in the timeframe originally intended.

Exception:

- A conscious decision was made to change the original plan for removal.
- The item retained was not placed by the organization removing the item.

Surgical/Invasive Procedure Recommendation 9:

Question/Issue Addressed: What criteria should be used to determine if retained micro-items, such as small fragments and needles, are reportable as a retained foreign object?

Supporting Information/ Documentation: Research has shown that needles smaller than 13 mm cannot be consistently visualized on X ray and have not been shown to cause harm to the patient if retained.

Recommendation/Guidance: The following criteria should be used to determine if a small item should be reportable as a retained foreign object:

- If the object is a microneedle:
  - <13 mm – Not Reportable
  - ≥ 13 mm – Reportable
- For other small objects:
  - Would the object likely have been detectable with visual inspection or radiograph?
    - Yes – Reportable
    - No – Not Reportable

Surgical/Invasive Procedure Recommendation 10:

Question/Issue Addressed: Is a foreign object that is retained following a vaginal delivery considered a "retention of a foreign object in a patient after surgery or other procedure?"

Recommendation/Guidance: A foreign object (e.g., a sponge or sharp) unintentionally retained following a vaginal delivery would be considered a reportable retained object.

Surgical/Invasive Procedure Recommendation 11:

Question/Issue Addressed: What is the definition of "normal, healthy" patient?

Recommendation/Guidance: Includes patients classified as an ASA Class I.

Surgical/Invasive Procedure Recommendation 12:

Question/Issue Addressed: What is the definition of "immediately post-operative"?

Recommendation/Guidance: Within 24 hours after induction of anesthesia (if surgery was not completed), surgery, or other invasive procedure was completed.

Product/Device Event Recommendations

Minnesota Product/Device Event Statue 144.7065, Subd. 3:

Events reportable under this subdivision are:

1) Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product
2) Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended. "Device" includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.
3) Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism

Product/Device Event Recommendation 1:

Question/Issue Addressed:	Additional clarity is needed for the terminology “use or function of a device in patient care in which the device is used or functions other than as intended.”
Supporting Information/ Documentation:	NQF has defined “device” in their implementation guidance.
Recommendation/Guidance:	Events that are reportable under this event category include: • Death or serious injury associated with the malfunction of a device. • Death or serious injury associated with using a device for a purpose or in a manner for which it was not designed to be used • Death or serious injury associated with using a device for a purpose or in a manner in which it was intended to be used but individual practitioner technique resulted in the serious outcome to the patient. • Death or serious injury associated with using a device for a purpose or in a manner for which it was intended to be used but unintentional error (user or human error) resulted in the serious outcome to the patient.

Events that are not reportable under this category but that should be reportable under the “Learning Section” of the registry include:

- Complications that could reasonably be expected related to appropriate usage of the device resulted in the serious outcome to the patient.

Refer to the U.S. Food and Drug Administration (FDA) definition of a medical device — “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.

Patient Protection Events

Minnesota Patient Protection Event Statute 144.7065, Subd. 4:

Events reportable under this subdivision are:

1) A patient of any age, who does not have decision-making capacity, discharged to the wrong person
2) Patient death or serious injury associated with patient disappearance, excluding events involving adults who have decision-making capacity
3) Patient suicide, attempted suicide resulting in serious injury, or self-harm resulting in serious injury or death while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility

Patient Protection Event Recommendation 1:

Question/Issue Addressed: What is "patient of any age, who does not have decision-making capacity, discharge to the wrong person" intended to capture?

Recommendation/Guidance: Release to "wrong person" includes removing the patient from the facility without specific notification and approval by staff, even when the person is otherwise authorized. Examples of individuals who do not have decision-making capacity include but are not limited to: newborns, minors, individuals with cognitive impairment. 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.

Patient Protection Event Recommendation 2:

Question/Issue Addressed: What is the facility's obligation to be made aware of and report a serious injury or death outcome to a patient following long-term elopement?

Recommendation/Guidance: Facility's obligation consists of reporting if they are made aware of the serious injury or death of an eloped patient within a timeframe that could reasonably be attributed to the elopement.

Example:

Patient arrived in emergency room for seizures and intoxication, patient admitted to med/surg. Physician initiated 72 hour hold paperwork and civil commitment process. Patient was seen walking in the hallway and ran when nurses approached him. Nurses

immediately searched for patient and contacted the police department. County Search & Rescue and Police searched for patient for two weeks. Patient was found deceased two weeks later in a drainage ditch.

Care Management Events

Minnesota Care Management Event Statute 144.7065, Subd. 5

Events reportable under this subdivision are:

1) Patient death or serious injury associated with a medication 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, excluding reasonable differences in clinical judgment on drug selection and dose
2) Patient death or serious injury associated with unsafe administration of blood or blood products
3) Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy
4) Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
5) Stage 3 or 4 or unstageable ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission
6) Artificial insemination with the wrong donor sperm or wrong egg
7) Patient death or serious injury associated with a fall while being cared for in a facility
8) The irretrievable loss of an irreplaceable biological specimen
9) Patient death or serious injury resulting from the failure to follow up or communicate laboratory, pathology, or radiology test results

Care Management Event Recommendation 1:

Question/Issue Addressed:	What is the event “medication error” intended to capture?
Supporting Information/ Documentation:	Includes, but is not limited to, death or serious injury associated with: a) over- or under-dosing; b) administration of a medication to

which a patient has a known allergy or serious contraindication, c) drug-drug interactions for which there is known potential for death or serious injury, and d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems.

Recommendation/Guidance: This event is intended to capture:

- Occurrences in which a patient receives a medication for which there is a contraindication, or a patient known to have serious allergies to specific medications/agents, receives those medications/ agents, resulting in serious injury or death.
- Occurrences in which a patient dies or suffers serious injury as a result of failure during medication reconciliation or failure to administer an ordered medication (e.g. inappropriate discontinuation of anticoagulant after hemorrhage);
- Occurrences in which a patient is administered a medication other than intended (errors in prescribing, dispensing and/or administration) and results in serious injury or death.
- Occurrences in which a patient is administered an over- or under-dose that results in a serious injury or death.
- Occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique.
- Occurrences of errors in medication reconciliation that affect transitions of care and result in serious injury or death.

This event is not intended to capture:

- Patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.
- Patient death or serious injury associated with a reaction a prescribed drug that could not have been reasonably known or anticipated.
- Reasonable differences in clinical judgment on drug selection and dose.
- Errors of omission due to diagnostic delays or failures (e.g.- failure to order antibiotics per sepsis protocol.)

Care Management Event Recommendation 2:

Question/Issue Addressed: Which types of pressure injuries need to be reported?

Recommendation/Guidance: Reportable pressure ulcers, hereafter referred to as pressure injuries, include: Stage 3, 4 and Unstageable Pressure Injuries, as defined by the National Pressure Injury Advisory Panel and the European Pressure Ulcer/Injury Advisory Panel, acquired after

admission to a facility. If a patient has more than 1 pressure injury, in the same location only 1 report is required with the multiple pressure injuries identified within the report. However, if the patient has pressure injuries in different locations it would be require separate reports. This does include pressure injuries that are stage 1 and progress to a stage 3, 4, or Unstageable.
See Appendix B for the pressure injury reportability algorithm

Inclusion:

- Pressure injuries that are Stage 1 and progress to stage 3, 4 or Unstageable
- Suspected Deep Tissue Pressure Injury that develops during hospital stay and evolves to reveal a stage 3, 4 or unstageable pressure injury during the hospital stay
- Pressure injuries that "heal" prior to discharge
- Pressure injuries that developed and patient passes away during hospital stay
- Despite definitions published by various organizations, there are no universally accepted criteria for determining whether a pressure injury was avoidable or unavoidable in acute care hospitals. Current Minnesota law does not exclude unavoidable pressure injuries.
- Development of pressure injury over site with previous partial thickness injury that does not originate from pressure (e.g. including, but not limited to, Medical Adhesive Related Skin Injury (MARSI), Moisture Associated Skin Damage (MASD) and Incontinence Associated Dermatitis (IAD).

Exclusion:

- Pressure Injuries that are present on admission (documented as Stage 2, 3, 4, or Unstageable on admission)
    a. Joint Commission states, "a nursing assessment is to be performed within 24 hours of admission". Pressure injuries present during this assessment should be considered present on admission.
- Suspected Deep Tissue Injuries present on admission
- Pressure Injury that form over scar tissue (areas with previous full thickness loss)
- Mucosal Pressure Injuries (pressure injuries found on mucous membranes).

Care Management Event Recommendation 3:

Question/Issue Addressed: What is the definition of a fall?

Recommendation/Guidance: An unplanned descent to the floor (or extension of the floor, e.g. bed, chair or other equipment) with or without injury to the patient. All types of falls are to be included whether they result from physiological reasons (fainting) or environment reasons (slippery floor). Include assisted and controlled falls (when a staff member

attempts to minimize the impact of the fall). Excludes intentional witnessed falls.
See Appendix C for falls reportability algorithm

Care Management Event Recommendation 4:

Question/Issue Addressed: Should unanticipated physiological falls (patient falls due to an unanticipated physiological cause, such as seizures, syncopal episode, or facture of the hips) be considered a reportable fall?

Recommendation/Guidance: If the patient's care team determines that the patient fall was due to an acute unanticipated physiological event (patient had no previous history or symptoms) which caused them to collapse, this would not be a reportable fall event.

Care Management Event Recommendation 5:

Question/Issue Addressed: If a patient and/or patient's family opt for comfort measures vs. treatment for a fall that initially resulted in a serious injury (e.g., hip fracture) and the patient subsequently dies, how is a determination made regarding reportability of the fall as a serious injury (e.g., hip fracture) vs. a patient death?

Recommendation/Guidance: The patient's care team should use the criteria outlined in General Recommendation #2 to determine whether or not the fall was associated with the patient's death.

Care Management Event Recommendation 6:

Question/Issue Addressed: What is the definition of "biological specimen"?

Recommendation/Guidance: A discrete portion of bodily fluid or tissue that has been removed from a patient's body with the intention of transporting it to the lab for the purpose of clinical testing. Gross examination would be considered clinical testing.
See Appendix D for exempt pathology list
See Appendix E for gross pathology list

Care Management Event Recommendation 7:

Question/Issue Addressed: What is considered "irretrievable loss"?

Recommendation/Guidance: A biological specimen that is lost, damaged, destroyed or unable to be used for its intended purpose.

Care Management Event Recommendation 8:

Question/Issue Addressed: What is considered "irreplaceable?

Recommendation/Guidance: A biological specimen for which another procedure medically cannot be done to produce the specimen (excludes patient refusal for a second procedure).
The medical team and/or pathologist deem whether or not the specimen, including blood specimens, is irreplaceable on a case-by-case basis.

Care Management Event Recommendation 9:

Question/Issue Addressed: What is the event "biological specimen" intended to capture?

Recommendation/Guidance: This event is intended to capture:

- Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen

This event is not intended to capture:

- Procedures where the specimen was not removed or collected (e.g. colonic polyp lost in the body during retrieval).
- Procedures where the specimen was properly handled, but the specimen proved to be non-diagnostic.

Care Management Event Recommendation 10:

Question/Issue Addressed: What if a reporting facility sends a biological specimen for testing at an independent lab and the independent lab loses or destroys the sample prior to testing?

Recommendation/Guidance: For the initial roll out of this event, only cases where the biological specimen originates from and is tested at a
reporting facility will be reportable.
Example:

- A patient has breast tissue removed during a surgical procedure at a Minnesota hospital. The breast tissue is then sent to another Minnesota hospital for testing
- A patient has blood work drawn at a licensed ambulatory surgical center in Minnesota and that blood work is sent to a Minnesota hospital lab for testing.

Care Management Event Recommendation 11:

Question/Issue Addressed: Who is responsible to report the event should the biological specimen be lost during transportation?

Recommendation/Guidance: If there is documentation that a specimen was signed out of the originating facility by a courier, and no documentation of that specimen being received by the receiving facility, then the courier would be responsible. If the courier is contracted by a hospital or

ambulatory surgical center (ASC), the hospital or ASC would be subject to reporting under their license

Care Management Event Recommendation 12:

Question/Issue Addressed: What is the definition of "follow up or communicate"?

Recommendation/Guidance:

- Follow-up is defined as "documented action in response to a test result, even if the decision is that no further follow-up is required."
- Communicate is defined as "documented communication or documented "good faith" attempt at communication to the appropriate provider/person, which may be the patient." This excludes cases in which there is documented communication or documented attempted communication with the patient, but the patient does not follow-up with the appropriate provider.

Care Management Event Recommendation 13:

Question/Issue Addressed: What type of test results does this category include?

Recommendation/Guidance: This category includes any and all test results which require attention and follow-up action. These include:

- Critical Value Results: Any test results, if left untreated, could be life threatening or place a patient at serious risk.
- Significant Findings: Any test results which require attention and follow-up action.

Includes tests performed, or the results of tests that are received, while a patient is receiving care at a reporting facility.

- Only includes tests that are performed on or after 10/7/2013.

Care Management Event Recommendation 14:

Question/Issue Addressed: How is it determined that an outcome is resulting from a particular event?

Recommendation/Guidance: Patient death or serious injury fitting under the category using the term "resulting from" should be reported if it has been determined by the clinical team that the death, serious injury. In this event type, the definition of serious injury includes addition of a new diagnosis, or an advancing state of an existing condition/disease state was a result of the failure to follow up or communicate laboratory, pathology or radiology test results.
Note: This event is not intended to capture misdiagnosis or incorrect treatment or medical plan on behalf of the healthcare staff.

Care Management Event Recommendation 15:

Question/Issue Addressed: What is the obligation for follow-up or communication in various settings (e.g., clinic, ASC, emergency room)?

Recommendation/Guidance:

- If your facility is responsible for follow-up and/or treatment of the patient in your setting, the obligation of the facility is to follow-up with the appropriate provider/person, which may be the patient, while the patient is still in your facility.
- If your facility is not responsible for follow-up or treatment of the patient in your setting, the obligation of the facility is to communicate the test results, or make a documented "good faith" attempt to communicate, to the appropriate provider/person, which may be the patient.

Care Management Event Recommendation 16:

Question/Issue Addressed: What are examples of serious injury under this category?

Recommendation/Guidance: Serious injury includes the definitions already established for adverse health events with the addition of a new diagnosis, or an advancing state of an existing diagnosis. An advancing stage of a disease that is not caused by failure to follow-up or communicates laboratory, pathology or radiology test results is excluded.

Case examples of serious injury for this event:

- Patient was seen on 10/10/2013 and a small 2cm nodule was noted on mammogram of left breast. This was not followed-up on or communicated to the patient or her provider. At patient's next mammogram on 10/20/2015, a large 18cm mass was noted on left breast and patient was subsequently diagnosed with stage 3 breast cancer.
- Patient seen in emergency department and routine blood work sent to laboratory. Critically low platelet value was noted on labs, however, laboratory technician did not notify provider. Two hours later the patient suffered a large hemorrhagic stroke.
- Patient had daily labs drawn while in medical/surgical ICU. K+ level of 2.1 was noted on lab results, however, there was no follow-up with immediate treatment and patient suffered a myocardial infarction.
- Newborn patient had neonatal bilirubin level drawn routinely on day two of life. There was a failure to report an increased value in that laboratory result and the patient later developed and was diagnosed with kernicterus.

Care Management Event Recommendation 17:

Question/Issue Addressed: What is the definition of a low-risk pregnancy?

Recommendation/Guidance: Woman aged 18-39

Exclusions:

- Diagnosis of:
  - Antepartum:
    - Essential Hypertension
    - Renal Disease
    - Collagen-Vascular Disease
    - Liver Disease
    - Cardiovascular Disease
    - Placenta Previa
    - Vasa Previa
    - Multiple Gestation
    - Intrauterine Growth Restriction
    - Gestational Hypertension
    - Preeclampsia
    - HELLP (hemolysis, elevated liver enzymes, low platelet count) Syndrome
    - Premature Rupture of Membranes (< 37weeks)
    - Morbid Obesity (BMI > 40 pre-pregnancy)
    - Placenta Implantation Problems
    - Current Substance Abuse Issues
    - Uncontrolled or poorly controlled diabetes
    - Other or previously documented conditions that pose a high risk of poor pregnancy outcomes
    - Women who have had less than or equal to 4 prenatal visits
    - Pulmonary or amniotic fluid embolism
    - Acute fatty liver of pregnancy
    - Cardiomyopathy
  - Intrapartum:
    - Non-vertex fetal presentation (e.g. face, brow, breech, transverse, compound)

Care Management Event Recommendation 18:

Question/Issue Addressed: When is a postpartum hemorrhage reportable as a serious injury?

Recommendation/Guidance: Serious injury from postpartum hemorrhage can be defined as receiving 4 or more units of blood products and a transfer to a higher level of care for greater than 48 hours. if unrelated to a primary diagnosis of placenta previa, vasa previa, and/or problems with placental implantation.

Case example:

- A G1P0 woman was admitted for a medically indicated induction of labor. Her cervix was long and closed, a long induction ensued. After a lengthy labor and pushing she had a vaginal birth. After spontaneous delivery of an intact placenta, she hemorrhaged profusely. She required 6 units of packed red blood cells and was transferred to the ICU for 52 hours.

Care Management Event Recommendation 19:

Question/Issue Addressed: What is the facility's obligation to be made aware of events 42 or 28 days out?

Recommendation/Guidance: Facility's obligation consists of reporting if they are made aware of the maternal death or serious injury either by re-admit or by patient/family contact. This law does not intend to change the standard of practice (i.e., if a facility does not normally check up on the patient for the 42 days they are not expected to under this new law; however, they would be required to report if they were made aware of an event).

Care Management Event Recommendation 20:

Question/Issue Addressed: What is the definition of a neonate?

Recommendation/Guidance: Newborn less than or equal to 28 days of age

Care Management Event Recommendation 21:

Question/Issue Addressed: How do you determine whether or not an event is "associated with labor and delivery?"

Recommendation/Guidance: **Inclusions:** *(Events under these categories must meet the criteria of low-risk pregnancy and results in neonatal death or serious injury)*

- **Note:** Events may include elements of multiple contributing factors involving these categories which in combination resulted in a neonatal death or serious injury

Tachystole - lack of recognition, not responding, or delayed response

Abnormal maternal vital signs and disease - lack of monitoring, not responding, or delayed response

- *Examples – including, but not limited to:*
  - Lack of recognition, not responding, or delayed response, to:
    - signs and symptoms of preeclampsia/eclampsia
    - bleeding indicating abruption/accreta/placenta previa
    - signs of infection

        - increased temperature, laboratory results, vital signs
        - uterine hypertonus
        - cord prolapse
        - other related monitoring, response issues

Abnormal fetal heart tones - lack of recognition, not responding, or delayed response

- *Examples – including, but not limited to:*
    - Misinterpretation or misidentification of category 2/3 tracings
    - Delayed response to category 2/3 fetal heart rate
    - Lack of response to maternal complaints of no fetal movement

Instrument injuries

- *Examples – including, but not limited to:*
    - Forceps or vacuum injury

Newborn resuscitation - Inadequate or delayed

Cesarean Section - Inability to perform or delay in performing

Induction of labor when a vaginal delivery is contraindicated

Intrauterine fetal demise that occurs **after** a patient is **admitted** to the hospital

Newborn drowning

- *Examples – including, but not limited to:*
    - Water birth drowning or near-drowning

Excludes:

- Intrauterine fetal demise that occurs prior to arrival at the hospital.
- Clavicle fracture due to shoulder dystocia.
- Deliveries that are high risk upon admission, i.e., patient comes in to the hospital with an emergent issue that places the delivery at high risk.

Cases for further review:

Cases involving neonatal serious injury or death in a low-risk pregnancy that do not meet the inclusion or exclusion criteria should be submitted to the Minnesota Hospital Association (MHA).

- **Cases will be de-identified and reviewed by an expert group. Feedback on whether or not the case meets the reporting definition will be provided to the submitting**

Care Management Event Recommendation 22:

Question/Issue Addressed: What is the category “death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy” intended to capture?

Recommendation/Guidance: It is intended to capture cases in which a patient is admitted to the hospital with a viable fetus, but a neonatal death or serious injury occurs during the hospital stay that is associated with the labor and delivery process in a low-risk pregnancy. See Care Management Event Recommendation 17

Includes intrauterine fetal demise that occurs after a patient is admitted to the hospital; excludes intrauterine fetal demise that occurs prior to arrival at the hospital.

Excludes clavicle fracture due to shoulder dystocia.

Environmental Events

Minnesota Environmental Event Statute 144.7065, Subd. 6:

Events reportable under this subdivision are:

1) Patient death or serious injury associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock
2) 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
3) Patient death or serious injury associated with a burn incurred from any source while being cared for in a facility
4) Patient death or serious injury associated with the use or lack of restraints or bedrails while being cared for in a facility

Environmental Events Recommendation 1:

Question/Issue Addressed: How should the definition of "lack of restraint" under the restraint category be addressed?

Supporting Information/ Documentation:	In a JCAHO Sentinel Event Alert related to restraints issued in 1998, the cases included in this category were related specifically to the use of physical restraints rather than the lack of restraints or bedrails. A number of national groups such as CMS and the Hospital Bed Safety Workgroup have recommended the careful consideration of the use of restraints or bedrails due to the significant patient safety risk they pose to patients.
Recommendation/Guidance:	Events should be reported under this category in cases of patient death or serious injury associated with the **use of** restraints or bedrails while being cared for in a facility (e.g., patient is suffocated due to getting trapped between the bedrail and the mattress). A workable interpretation for events reportable under the **lack of** restraints or bedrails is to report under lack of use of restraints only if there is an order for a restraint and serious injury or death is associated with the ordered restraint not being used or being used improperly.

Potential Criminal Events

Minnesota Potential Criminal Event Statute 144.7065, Subd. 7:

Events reportable under this subdivision are:

1) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
2) Abduction of a patient of any age
3) Sexual assault on a patient within or on the grounds of a facility
4) Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility

Potential Criminal Event Recommendation 1:

Question/Issue Addressed:	Do events being considered for reporting under one of the criminal categories have to meet the legal definition of criminal events and/or be charged as criminal events under the legal system?

Recommendation/Guidance: Events under the criminal category would reportable at the point at which they are substantiated by the facility. Substantiated means that the event meets the definition of one of the criminal categories regardless of whether or not there are criminal charges filed.

Potential Criminal Event Recommendation 2:

Question/Issue Addressed: There have been cases that involve allegations of sexual assault but no proof that the sexual assault occurred. This makes it difficult to determine if an event occurred and to identify a root cause.

At what point does unwanted contact become sexual assault?

Recommendation/Guidance: Joint Commission states sexual abuse/assault (including rape) as a reviewable sentinel event is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the organization, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine reviewability:

- Any staff-witnessed sexual contact as described above;
- Sufficient clinical evidence obtained by the organization to support allegations of unconsented sexual contact;
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises.

Link to Minnesota Statue 609.3451, Criminal Sexual Conduct in the Fifth Degree

Potential Criminal Event Recommendation 3:

Question/Issue Addressed: How is physical assault under the category "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" defined?

Recommendation/Guidance: Include as criteria for defining "physical assault" the definition of "assault" in Minnesota Statute which includes "the intentional infliction of harm upon another."

Questions to help determine "intentional infliction":

- Did the person have the mental capacity to know and understand what he/she was doing? (*The facility will determine mental capacity on a case-by-case basis following review of clinical and other available pertinent information.)*

If not, this would not meet the definition of "assault."

If yes,

- Did the person engage in the act with the intention to cause immediate bodily harm?

If yes, this would meet the definition of “assault.”

Or,

- Did the person engage in the act under circumstances that show there was no intention to cause bodily harm or that it was done by accident?

If yes, this would not meet the definition of “assault.”

Radiologic Events

Minnesota Radiologic Event Statue 144.7065, Subd. 7a:

Events reportable under this subdivision are:

1) Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area are reportable events under this subdivision

Radiologic Event Recommendation 1:

Question/Issue Addressed:	What are considered radiology test results?
Recommendation/Guidance:	Radiology test results include any imaging results. This includes, but is not limited to: X-Ray, CT, MRI, IR, Ultrasound, PET, Mammography, Echocardiography and Fluoroscopy. This category does not include EKG, EEG or MEG.

Radiologic Event Recommendation 2:

Question/Issue Addressed: What is intended to be captured by the event-"death or serious injury of a patient associated with the introduction of a metallic object in the MRI area?"

Recommendation/Guidance:

- Includes events related to material inside the patient's body or projectiles outside the patient's body.
- This event is intended to capture injury or death as a result of projectiles including:
  - Retained foreign objects
  - External projectiles
  - Pacemakers
- Includes items/projectiles whether or not they were known or disclosed to facility staff

Radiologic Event Recommendation 3:

Question/Issue Addressed: What is the obligation for reporting if the MRI unit is a contracted service?

Recommendation/Guidance: If the MRI unit was a contracted service by a hospital or ambulatory surgical center (ASC), the hospital or ASC would be subject to reporting under their license.

Minnesota Root Cause Analysis; Corrective Action Plan
Statute 144.7065, Subd. 8

Following the occurrence of an adverse health care event, the facility must conduct a root cause analysis of the event. In conducting the root cause analysis, the facility must consider as one of the factors staffing levels and the impact of staffing levels on the event. Following the analysis, the facility must:

1. Implement a corrective action plan to implement the findings of the analysis
2. Report to the commissioner any reasons for not taking corrective action

If the root cause analysis and the implementation of a corrective action plan are complete at the time an event must be reported, the findings of the analysis and the corrective action plan must be included in the report of the event. The findings of the root cause analysis and a copy of the corrective action plan must otherwise be filed with the commissioner within 60 days of the event.

RCA and CAP Recommendation 1:

Question/Issue Addressed:	What is the intent of the due date for the RCA and CAP, is it 60 days from when the event occurred, or 60 days from when an event is discovered?
Recommendation/Guidance:	Because it is possible for events to be discovered greater than 60 days from when the event occurred (as is possible in the case of a retained foreign object), the due date for the RCA and CAP to be entered in the patient safety registry should be interpreted to mean within 60 days from date of discovery.

Appendix A: List of Invasive, High Risk or Surgical Procedures

- Any procedures involving skin incision
- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation
- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of body fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube)
- Biopsy (e.g., bone marrow, breast, liver, muscle, kidney, genitourinary, prostate, bladder, vulva, skin)
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion, elective cardioversion)

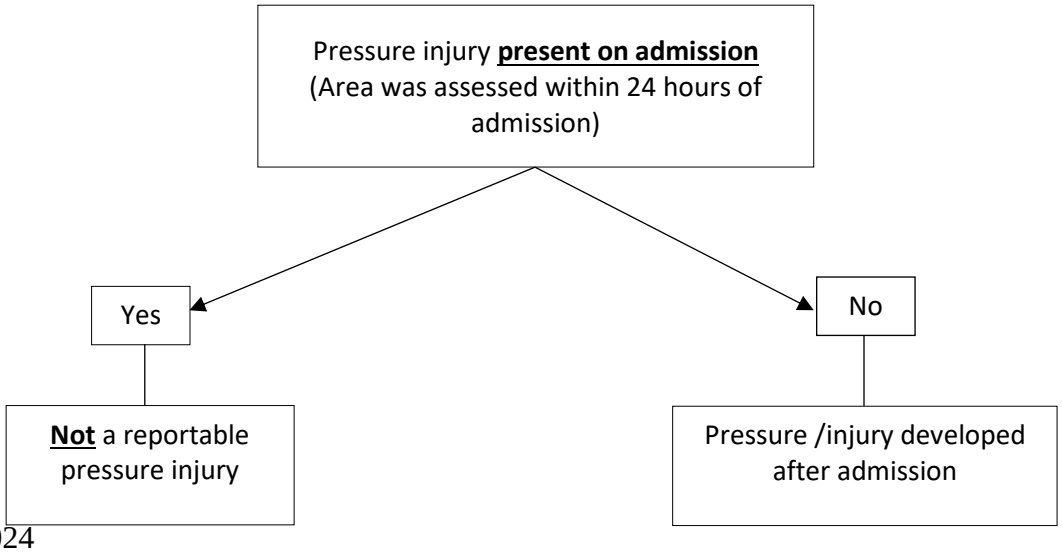
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastrostomy, J-tube placements, nephrostomy tube placements)
- Laparoscopic procedures (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy, laparoscopic oophorectomy)
- Invasive radiological procedures (e.g., angiography, angioplasty, percutaneous biopsy)
- Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions – excluding cryotherapy for benign lesions)
- Invasive ophthalmic procedures, including miscellaneous procedures involving implants
- Oral procedures including tooth extraction and gingival biopsy
- Podiatric invasive procedures (removal of ingrown toenail, etc.)
- Skin or wound debridement performed in an operating room
- Electroconvulsive treatment
- Radiation oncology procedures
- Central vascular access device insertion (e.g. Swan-Ganz catheter, percutaneous intravascular catheter line, Hickman catheter)
- Gynecology procedures (e.g. colposcopy with biopsy, cervical cone biopsy, cervical cryoblation, endometrial biopsy, hysteroscopy diagnostic or operative, dilatation and curettage, hysterosalpingogram)

Procedures NOT considered surgical, high-risk or invasive include the following:

- Electrocautery of lesion
- Venipuncture
- Manipulation and reductions
- Chemotherapy/oncology procedure
- Intravenous therapy
- Nasogastric tube insertion
- Foley catheter insertion
- Flexible sigmoidoscopy
- Vaginal exams (Pap smear

References:
VA National Center for Patient Safety (2015, June 3). Ensuring Correct Surgery. Retrieved from:
https://www.va.gov/vhapublications/ViewPublication.asp?

Appendix B: Pressure Injury Reportability Algorithm



****Exception****

If **admitted with a Stage I (1) & developed** into a Stage 3, Stage 4 or Unstageable

Then it **is a reportable pressure injury** event

Yes

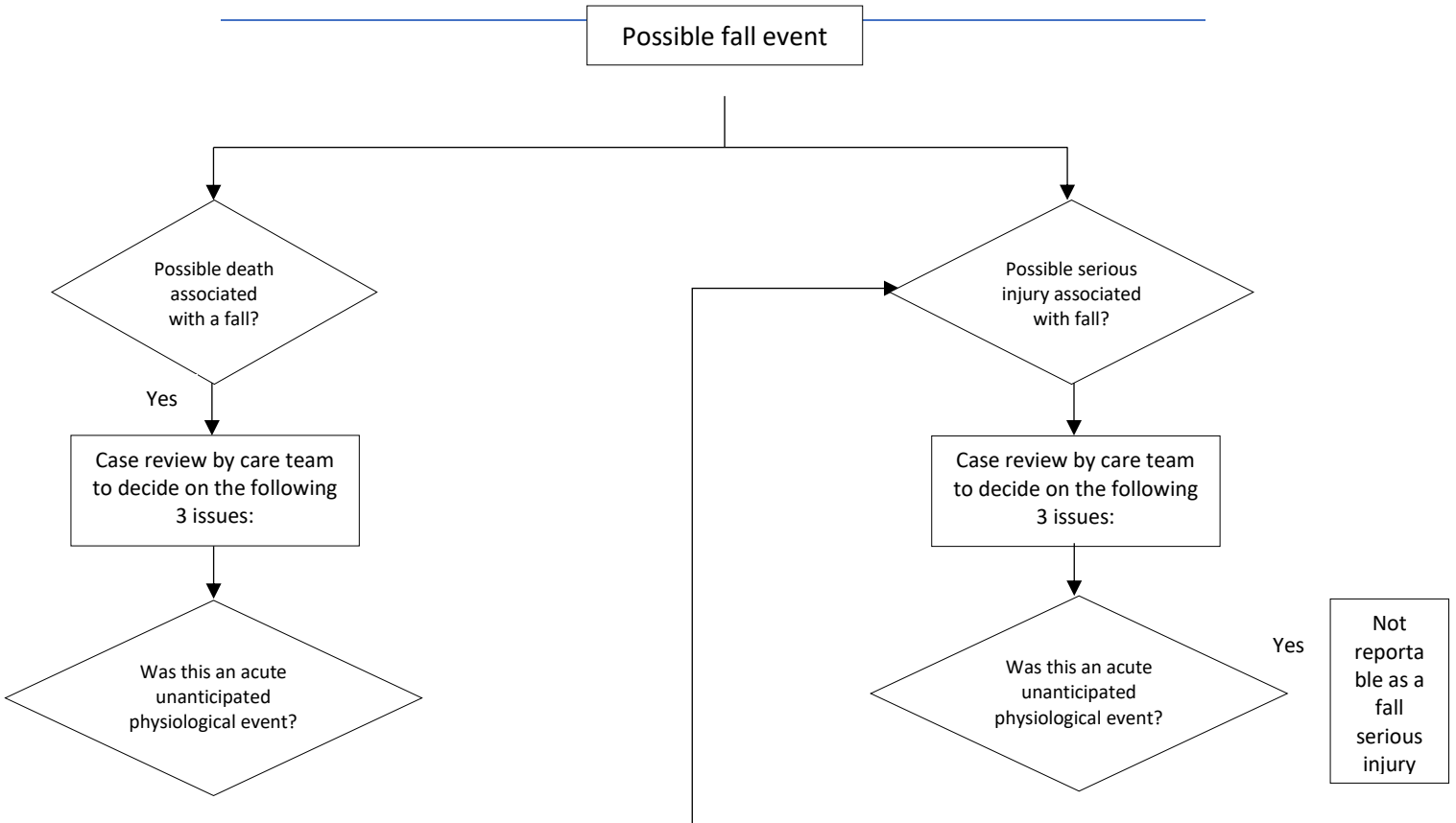
Pressure injury is noted as:
- Over scar formation
- Stage 1
- Stage 2
- Deep Tissue Injury
- Mucosal

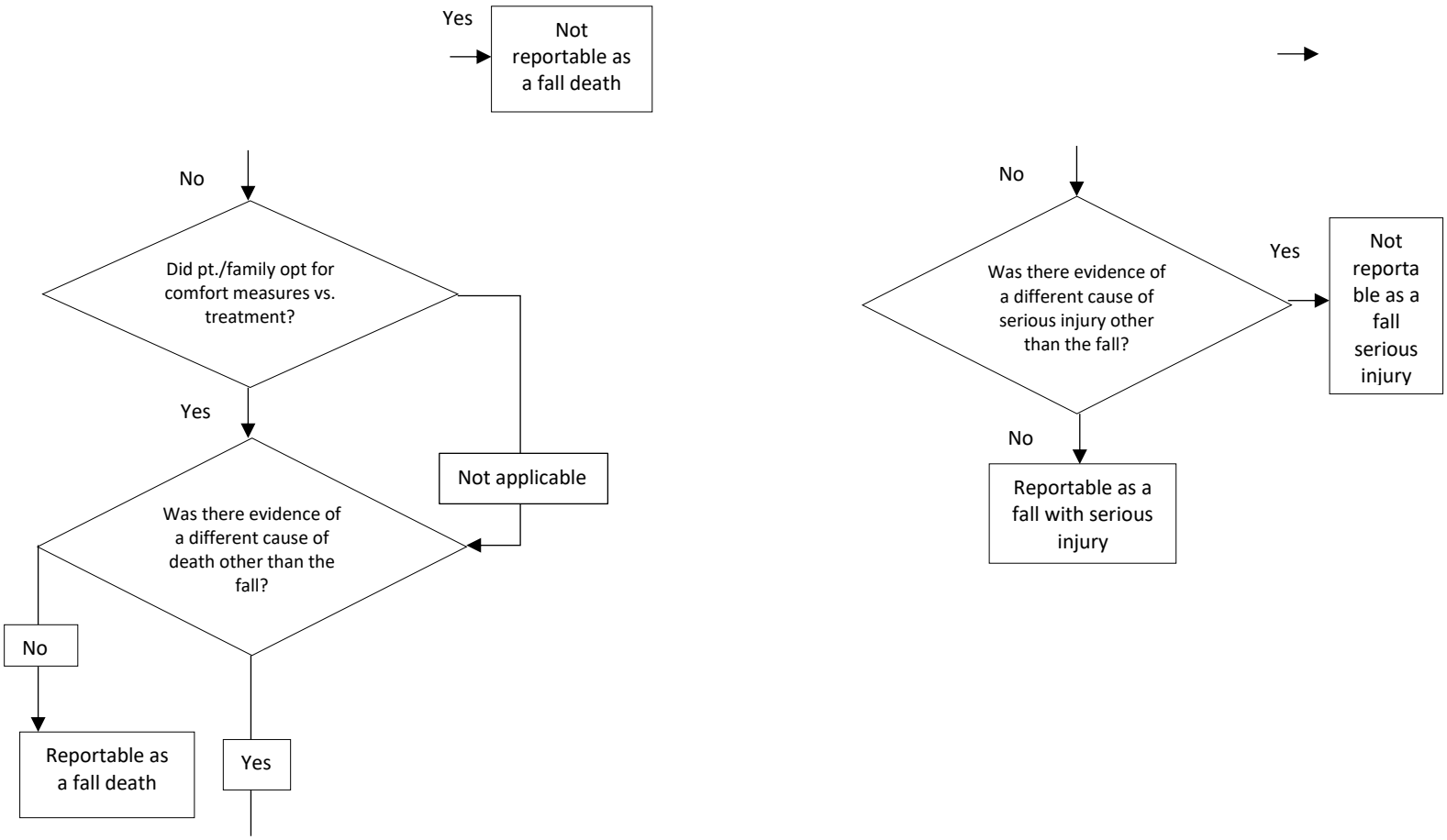
Not a reportable pressure injury event

Pressure injury is noted as:
- Stage 3
- Stage 4
- Unstageable
- Deep Tissue Injury that progresses to stage 3 or 4

Reportable pressure injury event

Appendix C: Fall reportability algorithm





Appendix D: Exempt from Pathology

Specimens in this category do not need to be sent for any pathology examination unless the specimen is contiguous with a pathologic or suspected lesion or if there is a request from the ordering provider.
Specimen types:

- Autotransplantation tissue
- AV fistulas
- Bones
    - Bone bank tissue
    - Bunions/Hammertoes
    - Femoral Heads (*except for pathological fracture*)
    - Fragments
    - Ribs
- Calculi (*stones*)
- Cartilage
- Cataracts
- Colostomy

- Corneas
- Cosmetic surgery tissue (*except for mammoplasty tissue*). Examples include:
    - Eyelids
    - Skin
    - Fat
    - Pannus
    - Scars
- Digits
- Donor organs
- Excess normal tissue
- Explants (*except for explants associated with litigation, recall or failure*)
    - Dental appliances
    - Intrauterine devices
    - Medical devices
    - Orthopedic hardware
    - Therapeutic hardware
    - Therapeutic radioactive sources
- Fingernails and toenails
- Foreign bodies (*except if examination needed for forensic purposes*)
- Foreskin (*newborn age <28 days*)
- Hemorrhoids
- Hernia sacs
- Intraocular lens
- Intravertebral discs
- Ligaments
- Meniscus shavings
- Nasal tissue shavings
- Placenta (*normal*)
- Plaque
- Rotator cuff
- Tendons
- Tonsils/adenoids (*up to age 16*)
- Teeth
- Trabeculectomy specimens
- Urinary calculi (*may request stone analysis*)
- Vaginal repair tissue
- Varicoceles
- Varicose veins
- Wound tissue

Appendix E: Gross Examination Only List

Specimens in this category need to be sent to the laboratory for a gross only pathology examination unless the specimen is contiguous with a pathologic or suspected lesion or if there is a request from the ordering provider. There may be additional testing needed following gross review.

Specimen types:

- Amputations (*due to trauma or if gangrenous*)
- Breast implants
- Bursa
- Eyes
- Foreskin (*if patient age >28 days*)
- Hidradenitis
- Hydrocele/spermatocele
- Meninges/meningocele
- Vaginal mucosa associated with prolapse

Resources

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National Pressure Injury Advisory Panel

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