



Recommendations and Guidance for Application of the Adverse Health Event Definitions

September 2013

The MHA Patient Safety Registry Advisory Council 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	Definitional Issue	Reference (CTRL-click on link)
General		
Definition of "Serious Disability"		– Recommendation 1
Definition of "Significant Injury"		– Recommendation 16
Categories with term "associated with"		– Recommendation 4
Events occurring in an outpatient setting	– When are events that occur in an outpatient setting reportable?	– Recommendation 26
Definition of a patient	<ul style="list-style-type: none"> – When does someone become a patient? – When is a patient no longer considered a patient? 	– Recommendation 27
Surgical		

Event Category	Definitional Issue	Reference (CTRL-click on link)
General Surgical	<ul style="list-style-type: none"> – Definition of surgery – Informed consent based on erroneous information 	<ul style="list-style-type: none"> – Recommendation 15 – Recommendation 20
Surgery performed on a wrong body part	<ul style="list-style-type: none"> – Right body part/wrong side component – Wrong level spine surgery – When does a surgery/ procedure begin? 	<ul style="list-style-type: none"> – Recommendation 8 – Recommendation 9 – Recommendation 10
Surgery performed on wrong patient		
Wrong surgical procedure performed	<ul style="list-style-type: none"> – Procedure inconsistent with correctly documented informed consent. 	<ul style="list-style-type: none"> – Recommendation 7
Foreign object retention	<ul style="list-style-type: none"> – Excluded foreign objects – At what point is object considered retained? – Includes retained foreign objects in vaginal deliveries as reportable events. 	<ul style="list-style-type: none"> – Recommendation 2 – Recommendation 11 – Recommendation 21
Death of normal, healthy surgical patient	<ul style="list-style-type: none"> – Definition of “immediately post-operative” – Definition of “normal, healthy” 	<ul style="list-style-type: none"> – Recommendation 22 – Recommendation 24
Product or Device Events		
Contaminated drugs, device, or biologics		
Use/function of device other than intended	<ul style="list-style-type: none"> – Additional clarification of terminology “is used or functions other than as intended” 	<ul style="list-style-type: none"> – Recommendation 18
Intravascular air embolism		
Patient Protection Events		
Patient who does not have decision-making capacity discharge to wrong person.		
Patient elopement	<ul style="list-style-type: none"> – Reporting obligation following elopement 	<ul style="list-style-type: none"> – Recommendation 23
Suicide/attempted suicide/self harm		
Care Management Events		
Medication error		
Unsafe administration of blood products		

Event Category	Definitional Issue	Reference (CTRL-click on link)
Maternal death in low-risk pregnancy	– Reporting obligation following patient discharge	– Recommendation 5
Neonate death or serious injury	–What is intended to be captured? –Definition of neonate –Definition of low-risk pregnancy	– Recommendation 31 – Recommendation 32 – Recommendation 33
Stage III, IV or Unstageable pressure ulcer	–Reportable pressure ulcers	– Recommendation 12
Falls	–Definition of a fall –Unanticipated physiological falls –Patient/family chooses comfort measures vs. treatment for fall related injuries	– Recommendation 25 – Recommendation 29 – Recommendation 30
Irretrievable loss of an irreplaceable biological specimen	–Definition of irretrievable –Definition of irreplaceable –Definition of biological specimen –Independent labs	– Recommendation 34 – Recommendation 35 – Recommendation 36 – Recommendation 37
Failure to follow up or communicate test results	–Types of test results included –What are considered radiology test results? –Determining if outcome is “resulting from” an event –Definition of “follow up or communicate” –Obligation for follow-up or communication –Examples of serious injury	– Recommendation 38 – Recommendation 39 – Recommendation 40 – Recommendation 41 – Recommendation 42 – Recommendation 43
Environmental Events		
Electric shock		
Wrong or contaminated gas		
Burns		
Restraints	– Determining whether an event is associated with the “lack of” restraints	– Recommendation 13

Event Category	Definitional Issue	Reference <i>(CTRL-click on link)</i>
Potential Criminal Events	– Relationship of reportable events to criminal charges.	– Recommendation 17
Impersonation of health care provider		
Patient abduction		
Sexual assault	– Sexual assault definition	– Recommendation 6
Physical assault	– Physical assault definition	– Recommendation 28
Radiologic Events		
MRI	– What is intended to be captured? – Mobile MRI units	– Recommendation 44 – Recommendation 45

References

Recommendation 1:

Question/Issue Addressed:

The use of the term “serious disability” is vague and needs to be more specific. Use of term “substantially limits” and “major life activities” is unclear.

*Supporting Information/
Documentation:*

Sec. 2 Subd. 4: Law Definition: Disability means (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 Disability,” the organization’s clinical team of experts needs to evaluate the outcome against each of the three elements and the Inclusion/Exclusion list. [See list directly below, or [click here for DOC](#)].

If the organization’s clinical team answers “Yes” to any of the three questions *OR* the outcome fits under the “Inclusion” list, the outcome would be considered a “Serious Disability.”

Definition of Serious Disability

In considering whether or not an event outcome meets the definition of a “serious disability,” the organization’s clinical team of experts needs to evaluate the outcome against each of the three elements and the Inclusions/Exclusions list below. If the organization’s clinical team answers “Yes” to any of the three questions *OR* the outcome fits under the “Inclusions” list, the outcome would be considered a “serious disability.”

- 1) Was there a physical or mental impairment that substantially limited one or more major life activities for the individual that lasted more than seven days or was still present at the time of discharge?
- 2) Was there a loss of bodily function that lasted more than seven days or was still present at the time of discharge?
- 3) Was there a loss of body part?

Inclusions	Exclusions
1. Bone fractures except as listed in exclusions.	1. 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).
2. Injuries requiring major intervention, e.g.: <ul style="list-style-type: none">- Surgical intervention in the OR- 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.	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).
3. Loss of body part	3. Additional monitoring without meeting criteria for higher level of care

4. 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.	4. Minor lacerations
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- Note: Inclusion criteria trump exclusion criteria
- Yes to any of the inclusion criteria qualifies that outcome as a serious disability.

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Recommendation 2:

<i>Question/Issue Addressed:</i>	What criteria should be used to determine if retained micro-items, such as small fragments and needles, are reportable as a retained foreign object?
<i>Supporting Information/Documentation:</i>	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.
<i>Recommendation/Guidance:</i>	<p>The following criteria should be used to determine if a small item should be reportable as a retained foreign object:</p> <ol style="list-style-type: none"> 1. If the object is a microneedle: <ol style="list-style-type: none"> a. <13 mm – Not Reportable b. ≥ 13 mm – Reportable 2. For other small objects: <ol style="list-style-type: none"> a. Would the object likely have been detectable with visual inspection or radiograph? <ol style="list-style-type: none"> i. No – Not Reportable ii. Yes - Reportable

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Recommendation 3: Removed – May 2013

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Recommendation 4:

<i>Question/Issue Addressed:</i>	It is often difficult to determine conclusively that an outcome is associated with a particular event.
<i>Council Recommendation/Guidance:</i>	Patient death fitting under one of the categories using the term “associated with” 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 disability than the event in question.

Case examples of determination in consultation with the clinical team regarding the association of a patient death or serious disability 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.
 - Not reportable as a death or serious disability 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.
 - Not reportable as a death associated with a fall
 - Reportable as a serious disability (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.
 - Reportable as a death associated with a fall.

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Recommendation 5:

<i>Question/Issue Addressed:</i>	What is the facility's obligation to be made aware of events 42 or 28 days out?
<i>Council Recommendation/ Guidance:</i>	Facility's obligation consists of reporting if they are made aware of the maternal death or serious disability 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).

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Recommendation 6:

<i>Question/Issue Addressed:</i>	<ul style="list-style-type: none">- 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?
<i>Supporting Information/ Documentation:</i>	<p>Joint Commission states that 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:</p> <ul style="list-style-type: none">• 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.
<i>Council Recommendation/ Guidance:</i>	<p>Adapt the Joint Commission definition of "rape" to include the requirement of one of the three corroborating factors – staff-witnessed or witnessed by other credible source, clinical evidence or perpetrator admission.</p> <ul style="list-style-type: none">• In cases where there is an allegation of sexual assault, followed by a potentially unreliable admission of assault (e.g., a patient in a delirious or psychotic state), the facility will:<ul style="list-style-type: none">▪ assess the impact of the alleged perpetrator's illness on their admission of assault;▪ decide if the admission of assault is reliable; and▪ proceed with a Registry report if the JCAHO definition of rape is met.

- What constitutes “consent” would continue to be defined by Minnesota Statute 609.341 through 609.3451
- The event would be reportable at the point at which it is substantiated by the facility. Substantiated means that it meets the definition recommendations regardless of whether there are criminal charges filed.
- Facilities are encouraged to report events that are alleged but not substantiated to the learning section of the patient safety registry so that these types of cases can be analyzed for patterns.

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Recommendation 7:

Question/Issue Addressed:

How is “procedures inconsistent with the correctly documented informed consent” determined?

*Council Recommendation/
Guidance:*

Procedure inconsistent with correctly documented informed consent:

Inclusions	Exclusions
<ol style="list-style-type: none"> 1. Omission of a consented procedure. 2. Procedures performed that are not documented and consented to by patient or patient representative. 3. Unnecessary procedure performed when documentation is present to indicate the procedure was unnecessary, e.g. procedure to remove gallbladder when documentation exists that gallbladder had already been removed. 	<ol style="list-style-type: none"> 1. Procedures performed or omitted due to change in plan made necessary by findings following surgical or procedure start. 2. 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.

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Recommendation 8:

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?”

*Council Recommendation/
Guidance:*

Recommend reporting under “Wrong Procedure” since the correct side was operated on but the wrong equipment was used in the procedure.

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Recommendation 9:

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?

*Council Recommendation/
Guidance:*

Follow the inclusion/exclusion list below to determine reportability of spine cases.

Inclusions	Exclusions
<ol style="list-style-type: none">1. 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).2. Major localization with minor execution error; surgery includes wrong segment in final result.4. 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).	<ol style="list-style-type: none">1. Minor localization error with no execution error2. Non-pathologic anatomy may be disrupted during the procedure, e.g., removal of ligamentum flavum.3. 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.

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Recommendation 10:

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.

*Council 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.

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Recommendation 11:

Question/Issue Addressed:

At what point in the procedure does a foreign object become a reportable event?

*Council Recommendation/
Guidance:*

- 1) "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.”

- 2) 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 than retaining the object, this would not be a reportable event.
- 3) Microneedles and broken screws continue to be an exception and are not reportable retained objects if retained after surgery.

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Recommendation #12:

Question/Issue Addressed:

Which types of pressure ulcers need to be reported?

*Supporting Information/
Documentation:*

The National Pressure Ulcer Advisory Panel defines unstageable pressure ulcers as full thickness tissue loss in which the actual depth of the ulcer is completely obscured by slough and/or eschar in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either Stage III or IV.

*Council Recommendation/
Guidance:*

Reportable pressure ulcers include: Stage III, IV and Unstageable Pressure Ulcers, as defined by the [National Pressure Ulcer Advisory Panel](#), acquired after admission to a facility.

Excluded:

- 1) Progression from Stage II to Stage III if Stage II was recognized and documented upon admission.
- 2) Progression from Suspected Deep Tissue Injury to Stage III, IV or Unstageable if the Suspected Deep Tissue Injury was recognized and documented upon admission.
- 3) Suspected Deep Tissue Injuries
- 4) Mucosal Pressure Ulcers (pressure ulcers found on mucous membranes).

Included:

- 1) Progression from Stage II to Stage IV or Unstageable if Stage II was recognized and documented upon admission.

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Recommendation #13:

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.

*Council Recommendation/
Guidance:*

Events should be reported under this category in cases of patient death or serious disability 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 disability or death is associated with the ordered restraint not being used or being used improperly.

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Recommendation #15

Question/Issue Addressed:

A consistent definition for surgical procedures that are reportable under the Adverse Health Care Events Reporting Law is needed.

*Council
Recommendation/Guidance:*

Adopt the Institute for Clinical Systems Improvement (ICSI) 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.

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Recommendation #16

Question/Issue Addressed:

The terminology “significant injury” used in event “Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility” has not been defined.

*Supporting
Information/Documentation:*

Joint Commission states that “serious injury” specifically includes loss of limb or function.

*Council
Recommendation/Guidance:*

[Recommendation #1](#) which defines the term “significant disability” is consistent with the Joint Commission definition of “serious injury” and should be applied in determining “significant injury.”

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Recommendation #17

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?

*Supporting
Information/Documentation:*

*Council
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.

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Recommendation #18

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:
Council
Recommendation/Guidance:*

NQF has defined “device” in their implementation guidance.

- Events that are reportable under this event category include:
 - Death or serious disability associated with the malfunction of a device.
 - Death or serious disability associated with using a device for a purpose or in a manner for which it was not designed to be used (excludes death or serious disability 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).
- Events that are not reportable under this category but that should be reportable under the “Learning Section” of the registry include:
 - Death or serious disability associated with using a device for a purpose or in a manner for which it was intended to be used but individual practitioner technique resulted in the serious outcome to the patient.
 - 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.

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Recommendation #20

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.

Council

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.

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Recommendation #21

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?”

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

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Recommendation #22

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

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

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Recommendation #23:

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

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

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Recommendation #24:

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

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

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Recommendation #25:

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

Council 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 planned witnessed falls.

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Recommendation #26:

<i>Question/Issue Addressed:</i>	When are events that occur in an outpatient setting reportable?
<i>Council Recommendation/ Guidance:</i>	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 disability 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.

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Recommendation #27:

<i>Question/Issue Addressed:</i>	<ol style="list-style-type: none">1) When does someone become a patient?2) When is a patient no longer considered a patient?
<i>Council Recommendation/ Guidance:</i>	<ol style="list-style-type: none">1) 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.2) A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team; e.g., the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.

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Recommendation 28:

<i>Question/Issue Addressed:</i>	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?
<i>Council Recommendation/ Guidance:</i>	<p>Include as criteria for defining “physical assault” the definition of “assault” in Minnesota Statute which includes “the intentional infliction of harm upon another.”</p> <p>Questions to help determine “intentional infliction”:</p> <ol style="list-style-type: none">1) Did the person have the mental capacity to know and understand what he/she was doing? <p><i>The facility will determine mental capacity on a case-by-case basis following review of clinical and other available pertinent information.</i></p>

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

If yes,

- 2) 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,

- 3) 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.”

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Recommendation 29:

Question/Issue Addressed:

Should unanticipated physiological falls (patient falls due to an unanticipated physiological cause, such as seizures, syncopal episode, or fracture of the hips) be considered a reportable fall?

*Council 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.

*See falls reportability algorithm – [Appendix A](#)

Recommendation 30:

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 disability (e.g., hip fracture) and the patient subsequently dies, how is a determination made regarding reportability of the fall as a serious disability (e.g., hip fracture) vs. a patient death?

*Council Recommendation/
Guidance:*

The patient’s care team should use the criteria outlined in Recommendation #4 to determine whether or not the fall was associated with the patient’s death.

*See falls reportability algorithm – [Appendix A](#)

Appendix A: [Falls Reportability Algorithm](#)

Appendix B: Serious Disability Definition

Recommendation 31:

<i>Question/Issue Addressed:</i>	What is the category “death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy” intended to capture?
<i>Council Recommendation/Guidance:</i>	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 <u>associated</u> with the labor and delivery process in a low-risk pregnancy.

Recommendation 32:

<i>Question/Issue Addressed:</i>	What is the definition of a neonate?
<i>Council Recommendation/Guidance:</i>	Newborn less than or equal to 28 days of age

Recommendation 33:

<i>Question/Issue Addressed:</i>	What is the definition of a low-risk pregnancy?
<i>Council Recommendation/Guidance:</i>	<ul style="list-style-type: none">○ Woman aged 18-39○ Exclusions:<ul style="list-style-type: none">▪ Previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, gestational hypertension, premature rupture of membranes, morbid obesity, placenta implementation problems, current substance abuse issues, uncontrolled or poorly controlled diabetes or other previously documented condition that poses a high risk of poor pregnancy outcome.▪ Women that have had less than or equal to 4 prenatal visits▪ Fetus/neonate with presence of congenital anomalies that is incompatible with life (e.g., Anencephalus, Trisomy 13, 18, Tracheal or Pulmonary Atresia) <u>unless</u> the serious injury or death was associated with labor and delivery and <u>not</u> with the anomaly.▪ Fetus/neonate with the diagnosis code of osteogenesis

imperfecta.

- Non-vertex fetal presentation
- Preterm infants with a birth weight less than 2,500 grams.

Recommendation 34:

<i>Question/Issue Addressed:</i>	What is considered “irretrievable loss”?
<i>Council Recommendation/ Guidance:</i>	A biological specimen that is lost, damaged, destroyed or unable to be used for its intended purpose.

Recommendation 35:

<i>Question/Issue Addressed:</i>	What is considered “irreplaceable”?
<i>Council Recommendation/ Guidance:</i>	<p>A biological specimen for which another procedure medically cannot be done to produce the specimen (excludes patient refusal for a second procedure).</p> <p>The medical team and/or pathologist deem whether or not the specimen is irreplaceable on a case-by-case basis.</p>

Recommendation 36:

<i>Question/Issue Addressed:</i>	What is the definition of “biological specimen”?
<i>Council Recommendation/ Guidance:</i>	A discrete portion of bodily fluid or tissue that has been removed from a patient’s body.

Recommendation 37:

<i>Question/Issue Addressed:</i>	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?
<i>Council Recommendation/ Guidance:</i>	<p>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.</p> <p>Example:</p> <ul style="list-style-type: none">- 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.

Recommendation 38:

<i>Question/Issue Addressed:</i>	What type of test results does this category include?
<i>Council Recommendation/ Guidance:</i>	<ol style="list-style-type: none">1. This category includes any and all test results which require attention and follow-up action. These include:<ol style="list-style-type: none">a. Critical Value Results: Any test results, if left untreated, could be life threatening or place a patient at serious risk.b. Significant Findings: Any test results which require attention and follow-up action.2. Includes tests performed, or the results of tests that are received, while a patient is receiving care at a reporting facility.3. Only includes tests that are performed on or after 10/7/2013.

Recommendation 39:

<i>Question/Issue Addressed:</i>	What are considered radiology test results?
<i>Council Recommendation/ Guidance:</i>	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.

Recommendation 40:

<i>Question/Issue Addressed:</i>	How is it determined that an outcome is resulting from a particular event?
<i>Council Recommendation/ Guidance:</i>	<p>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 or serious injury was a result of the failure to follow up or communicate laboratory, pathology or radiology test results.</p> <p>Note: This event is <u>not</u> intended to capture misdiagnosis, lack of treatment or incorrect treatment or medical plan on behalf of the healthcare staff</p>

Recommendation 41:

<i>Question/Issue Addressed:</i>	What is the definition of “follow up or communicate”?
<i>Council Recommendation/ Guidance:</i>	<ul style="list-style-type: none"> • 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.

Recommendation 42:

<i>Question/Issue Addressed:</i>	What is the obligation for follow-up or communication in various settings (e.g., clinic, ASC, emergency room)?
<i>Council Recommendation/ Guidance:</i>	<ol style="list-style-type: none"> a. 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. b. If your facility is <u>not</u> 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.

Recommendation 43:

<i>Question/Issue Addressed:</i>	What are examples of serious injury under this category?
<i>Council Recommendation/ Guidance:</i>	<p>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 <u>not</u> caused by failure to follow-up or communicates laboratory, pathology or radiology test results is excluded.</p> <p>Case examples of serious injury for this event:</p> <ol style="list-style-type: none"> 1. 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 III breast cancer.
2. 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.
 3. 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.
 4. 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.

Recommendation 44:

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 into the MRI area?”

*Council 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:
 - a. retained foreign object
 - b. external projectiles
 - c. pacemakers
- Includes items/projectiles whether or not they were known or disclosed to facility staff.

Recommendation 45:

Question/Issue Addressed:

What is the obligation for reporting if the MRI unit is a contracted service?

*Council 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.