

# Adverse Health Events Case Studies

2010 Statewide Review

MN DEPARTMENT OF HEALTH



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# Adverse Health Events Case Studies

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## 2010 Statewide Review

This document presents the results of a statewide review of hospitals and surgical centers that assessed knowledge of Minnesota's Adverse Health Care Events reporting law through the use of case studies illustrating reportable and non-reportable events. Of the 136 registered users of the adverse health events web-based registry who received the survey, 111 (82%) completed it.

The results of this survey show that, while engagement in the reporting system remains high and facilities take their reporting responsibilities very seriously, there remain pockets of confusion related to certain types of events and their reportability. In particular, the definition of 'serious disability' for the purposes of reporting certain events was not always fully understood, and some facilities were unaware of the addition of unstageable pressure ulcers to the list of reportable events in 2007. Respondents also expressed some uncertainty related to wrong body part procedures in cases where the error was discovered during surgery, or when there was no harm to the patient. Respondents also raised several other issues that need clarification from MDH:

- How to report events that occur in outpatient areas of a hospital, or in areas that may be physically located on a hospital campus but are not covered under a hospital's license; and
- How to deal with situations where a procedure may have been discussed or raised as a possibility with a patient, but is not part of the informed consent document.

MDH and its partners will be working closely with all reporting facilities in the coming months to share these results with front line staff, patient safety leaders, and executives, as well as to develop additional resources and education to clarify problematic issues. This assessment is designed to be an educational tool for MDH as well as for reporting facilities, and will be repeated annually.

# Adverse Health Events Case Studies

## Fall with serious disability

A patient fell and sustained a laceration on her forehead, requiring 15 stitches. Patient is disoriented and is transferred to the ICU for 72 hours for observation. She is then released to home, and has no further issues related to the fall.

	Number of Responses	Percentage
Reportable	46	41.4%
Not Reportable	61	55.0%
Unknown/Need More Information	4	3.6%
<b>Total</b>	<b>111</b>	<b>100%</b>

This event would be considered reportable.

A number of respondents indicated that they did not feel this injury rose to the level of a serious disability. According to the “Definition of a Serious Disability,” attached to this document, a fall that results in a transfer to a higher level of care for more than 48 hours meets the criteria for a serious disability. Other injuries that would be considered ‘serious disabilities’ include major fractures, injuries that require surgical intervention, and injuries that lead to a loss or substantial limitation of a bodily function for seven or more days. This fall, which led to a transfer to a higher level of care for 72 hours, meets the criteria for reporting as a serious disability.

A number of respondents had additional questions about the circumstances of the fall:

- Was the patient disoriented prior to the fall, and was the disorientation the reason for the fall?
- Did the patient fall on hospital property, or on public property?

If the fall resulted in a serious disability or death, the fact that it may have been caused by disorientation (or medication interactions, or dizziness) would not change its status as a reportable event. The reason for the fall is not always irrelevant, though; if the patient suffered a fracture and then fell *as a result of the fracture* (rather than vice versa), the event would not be reportable.

The question about location of the fall is relevant; in this vignette, the assumption was that the fall occurred while the patient was in the hospital. However, if the fall had happened in, for example, the parking lot prior to admission or after discharge, the fall would not have been reportable.

# Adverse Health Events Case Studies

## Fall without serious disability

A patient was being assisted back to bed by nursing staff. During the transfer, the patient fell, sustaining a fracture to his left wrist (patient is right-handed). Patient needed a cast, but no transfer to a higher level of care.

	Number of Responses	Percentage
Reportable	35	31.5%
Not Reportable	72	64.9%
Unknown/Need More Information	4	3.6%
<b>Total</b>	<b>111</b>	<b>100%</b>

**This event would not be considered reportable.**

According to the “Definition of a Serious Disability,” attached to this document, minor fractures (including finger, thumb, wrist, toes or nose) are not considered serious disabilities unless they substantially limit a major life activity or require major intervention.

The assumption in this case is that the left wrist fracture did not substantially limit the major life activities of this right-handed patient. However, in a real situation the patient’s actual circumstances would need to be taken into consideration; if a wrist or thumb fracture led to a substantial limitation of one or more major life activities for a particular patient, that event would be reportable. Some respondents who indicated “unknown” said that they would need to determine whether the injury had an impact on any major life activities for the patient, which is correct.

# Adverse Health Events Case Studies

## Fall in non-hospital area

Patient seen for outpatient rehabilitation services. As the patient is leaving the rehabilitation area, he trips and falls and fractures his ankle. He is brought to the OR for surgical repair of the fracture. The outpatient rehabilitation area is an outpatient clinic operated by a company leasing space from the hospital.

	Number of Responses	Percentage
Reportable	27	24.5%
Not Reportable	66	60.0%
Unknown/Need More Information	17	15.5%
<b>Total</b>	<b>110</b>	<b>100%</b>

**This event would not be considered reportable.**

Some vagueness in this vignette may have made it difficult to answer, leading to a high percentage of “unknown” responses. The assumption in this case is that the patient fell within the physical space of the rehabilitation area (as opposed to in the parking lot or outside), and that the clinic in which the patient fell is not a part of the hospital or covered under its license.

The “Definition of a Serious Disability” indicates that a fall associated with an ankle fracture, requiring surgical repair in the OR, would meet the criteria for reporting (injury requiring surgical intervention). However, in this case, the fall occurred in an outpatient clinic that is not part of the hospital. While the clinic should conduct an RCA, and develop processes to prevent future falls, this fall would not be considered reportable by the hospital unless the rehabilitation area was covered under the hospital’s license.

In the near future, the reporting system will need to consider, and develop recommendations for, situations in which events occur on the physical grounds of a hospital/surgical center but within an area that is not under the control or licensure of the hospital. Conversely, responsibility for reporting in situations in which falls or other events occur in hospital-based clinics or other settings that are part of a hospital’s license but may not be physically located on a hospital campus should also be clarified.

# Adverse Health Events Case Studies

## Fall within a hospital outpatient area

Patient seen for outpatient rehabilitation services. As the patient is leaving the rehabilitation area, he trips and falls and fractures his ankle. He is brought to the OR for surgical repair of the fracture. The outpatient rehabilitation area is an outpatient clinic licensed under the hospital.

	Number of Responses	Percentage
Reportable	52	48.1%
Not Reportable	42	38.9%
Unknown/Need More Information	14	13.0%
<b>Total</b>	<b>108</b>	<b>100%</b>

### This event would be considered reportable.

The assumption in this case is that the patient fell within the physical space of the rehabilitation area (as opposed to in the parking lot or outside).

The “Definition of a Serious Disability” indicates that a fall associated with an ankle fracture requiring surgical repair would meet the reporting criteria. In this case, unlike in the previous case, the fall occurred in an outpatient area that is part of the hospital and covered under its license. This fall would be considered reportable by the hospital.

In the near future, the reporting system will need to consider, and develop recommendations for, situations in which events occur on the physical grounds of a hospital/surgical center but within an area that is not under the control or licensure of the hospital. Conversely, responsibility for reporting in situations in which falls or other events occur in hospital-based clinics or other settings that are part of a hospital’s license but may not be physically located on a hospital campus should also be clarified.

# Adverse Health Events Case Studies

## Unstageable Pressure Ulcer

A morbidly obese patient with compromised circulation and multiple co-morbidities was discovered to have an unstageable pressure ulcer on his buttocks. Patient was unable to be turned regularly. No documentation of pressure ulcers on admission.

	Number of Responses	Percentage
Reportable	81	73.0%
Not Reportable	17	15.3%
Unknown/Need More Information	13	11.7%
<b>Total</b>	<b>111</b>	<b>100%</b>

### This event would be considered reportable.

Several responders expressed some confusion related to reporting of unstageable pressure ulcers:

- “Since not stageable and only stage 3 and 4 ulcers are reportable, if not present on admission, this one doesn't seem to meet criteria for reporting.”
- “Not reportable unless debrided prior to discharge and found to be a 3 or 4”
- “There is nothing in the guidance about reporting of an unstageable pressure ulcer if the admission status (POA) is not documented.”
- “Not reportable, but National Pressure Ulcer Advisory Panel is recommending a change. If this change is approved, this would be reportable.”

*Starting with events discovered on or after October 7<sup>th</sup>, 2007, unstageable pressure ulcers have been a reportable event.* Reporting for unstageable pressure ulcers follows the same standards as for Stage 3 or 4 ulcers. These events are reportable if they were acquired after admission to a facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized and documented on admission, or progression from Suspected Deep Tissue Injury to Stage 3 or 4 if the DTI was documented on admission. In this case, there was no documentation of any pressure ulcers on admission, which means that a Stage 3, 4, or unstageable pressure ulcer would be considered reportable.

Stage 3, 4, or unstageable pressure ulcers are considered reportable even if the patient has multiple comorbidities that may have made the ulcer unpreventable. In this case, the patient was morbidly obese, had compromised circulation, and could not be turned. While preventing a pressure ulcer in this situation presents a number of challenges, the development of the unstageable ulcer still needs to be reported.

# Adverse Health Events Case Studies

## Stage 3 Pressure Ulcer

A frail elderly patient with compromised circulation and multiple co-morbidities was discovered to have a Stage 2 sacral pressure ulcer upon admission. The patient was unable to be turned regularly. The pressure ulcer evolved to Stage 3 ten days after admission.

	Number of Responses	Percentage
Reportable	38	34.5%
Not Reportable	67	60.9%
Unknown/Need More Information	5	4.5%
<b>Total</b>	<b>110</b>	<b>100%</b>

**This event would not be considered reportable.**

Pressure ulcers are reportable if they were acquired after admission to a facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized and documented on admission, or progression from Suspected Deep Tissue Injury to Stage 3 or 4 if the DTI was documented on admission. In this case, a Stage 2 pressure ulcer was discovered on admission. Assuming that the Stage 2 ulcer was documented at that time, the progression of this ulcer to a Stage 3 ulcer would not be considered reportable.

# Adverse Health Events Case Studies

## Retained Foreign Object

During a vaginal hysterectomy on a Wednesday morning, a 4 \* 4 sponge was packed into the vaginal vault. The sponge was scheduled to be removed four hours later; on Thursday afternoon patient passed the 4x4 sponge from her vagina while voiding. The patient suffered no ill effects.

	Number of Responses	Percentage
Reportable	64	57.7%
Not Reportable	41	36.9%
Unknown/Need More Information	6	5.4%
<b>Total</b>	<b>111</b>	<b>100%</b>

**This event would be considered reportable.**

The question of when an object is considered retained is a common one. An object is considered 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.

In this case, the object was not intended to remain beyond four hours, but was left in for over 24. The fact that the patient suffered no ill effects does not impact reportability; unintentionally retained objects are reportable even in the absence of harm.

Several people questioned why the sponge was not removed after four hours as intended. The assumption in this case is that there was not clear accountability for its removal - the sponge was essentially forgotten, rather than there being a clinical reason to retain it. Again, since the goal of the reporting system is to capture cases in which the object was unintentionally retained, a clinical decision to retain the sponge beyond the initial 4-hour period would render this a 'nonreportable' case.

# Adverse Health Events Case Studies

## Retained Foreign Object

During a complicated cardiac procedure, a small fragment of a surgical instrument breaks off. The surgeon discovers the breakage prior to closure, and the team explores the wound cavity for the instrument tip. They are unable to find it, and determine that the patient's condition is too precarious to continue the search. They close the patient and schedule an MRI for the next day, when the patient's condition will hopefully have stabilized. The MRI identifies the object, which is removed during a subsequent procedure.

	Number of Responses	Percentage
Reportable	55	50.0%
Not Reportable	49	44.5%
Unknown/Need More Information	6	5.5%
<b>Total</b>	<b>110</b>	<b>100%</b>

### This event would not be considered reportable.

The question of when a surgery or invasive procedure ends, for the purposes of determining reportability of retained foreign objects, has been discussed several times in recent years. The official recommendation in this area recently changed to read:

- 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.

In this case, the potentially retained object was identified prior to closure, but a clinical decision was made at that time not to continue searching for it. The object was intentionally retained until an MRI could be done and the item definitively identified. Because the process successfully identified the potentially retained object prior to closure, even though it could not be removed at that time due to the patient's condition, this is not considered a reportable event.

# Adverse Health Events Case Studies

## Wrong Body Part Surgery/ Invasive Procedure

Two biopsies from one patient were sent for pathology analysis at an outside pathology lab. One of the biopsies had an area of concern on the pathology report. The pathology report sent to radiology, and the surgeon, stated the incorrect biopsy site. This erroneous information was transcribed to the informed consent document which was reviewed and discussed with the patient prior to the procedure. The patient had a wire placed by the radiologist to localize the lesion for excision, and the lesion identified by wire localization was removed. Subsequently the surgeon identified that the incorrect lesion had been removed.

	Number of Responses	Percentage
Reportable	98	88.3%
Not Reportable	6	5.4%
Unknown/Need More Information	7	6.3%
<b>Total</b>	111	100%

**This event would be considered reportable.**

In this situation, the incorrect lesion was removed due to erroneous information on the informed consent document; the procedure was consistent with the informed consent, but the informed consent was incorrect. Surgeries or invasive procedures on the wrong patient or body part, as well as wrong surgeries/invasive procedures, are reportable events if they are consistent with the documented informed consent for that patient **but** the informed consent is based on erroneous information.

In this case, the corrective action(s) would likely focus on the processes that led to the incorrect information being transmitted to or from the pathology lab, as well as on the process of referring back to source documents when completing the informed consent.

# Adverse Health Events Case Studies

## Wrong Body Part Surgery/Invasive Procedure

Index finger, right hand marked at the patient bedside prior to transfer to the OR. Time out completed in the OR immediately prior to the start of the surgery. The right middle finger was anesthetized with a digital block performed on each side of the finger. An incision was then made in the middle finger. Surgeon identified that he had incised the middle finger, right hand. He then stopped the procedure, completed a simple closure with running sutures, and then began the surgical procedure on the index finger, right hand. Patient did not require an additional procedure.

	Number of Responses	Percentage
Reportable	100	90.9%
Not Reportable	9	8.2%
Unknown/Need More Information	1	0.9%
<b>Total</b>	<b>110</b>	<b>100%</b>

**This event would be considered reportable.**

The question of when a surgery or invasive procedure begins or ends has been covered in several recommendations over the years. A surgery performed on a wrong body part becomes 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.

In this case, a block was administered to the wrong finger, and an incision was made in the wrong finger. Although the error was discovered and corrected quickly, while the patient was still in surgery, the event became reportable when the block was administered to the wrong body part.

The level of harm to the patient, and the need for a second procedure, are not a factor in considering whether or not this event is reportable. Wrong procedure events are reportable regardless of the outcome to the patient.

# Adverse Health Events Case Studies

## Wrong Body Part Surgery/Invasive Procedure

Patient experienced pain in Post-Anesthesia Care Unit and requested a regional pain block due to right shoulder pain. Physician prepped left side and performed the left side block procedure. Approximately 15 minutes after the block the Same Day Surgery RN identified that the wrong side had been injected. Patient was asked if she wanted to have a second block on the correct side; she indicated that the pain was much better, and that she did not need a second block.

	Number of Responses	Percentage
Reportable	89	80.9%
Not Reportable	20	18.2%
Unknown/Need More Information	1	0.9%
<b>Total</b>	<b>110</b>	<b>100%</b>

**This event would be considered reportable.**

A surgery performed on a wrong body part becomes 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.

In this case, a block was administered to the wrong shoulder. Although the patient indicated that her pain had been relieved and that a second block was not needed, the event became reportable when the block was administered to the wrong body part.

The level of harm to the patient, and the need for a second procedure, are not factors in considering whether or not this event is reportable. Wrong procedure events are reportable regardless of the outcome to the patient. In this case, the fact that the patient's pain was alleviated does not negate the need to report.

# Adverse Health Events Case Studies

## Wrong Procedure

During a hip resurfacing procedure, mismatched components were used. Error was discovered via a post-op xray two hours later. Patient was re-opened and the correct components were implanted.

	Number of Responses	Percentage
Reportable	86	77.5%
Not Reportable	20	18.0%
Unknown/Need More Information	5	4.5%
<b>Total</b>	111	100%

**This event would be considered reportable.**

The pre-surgical verification process for this procedure should have included verification of the components used; size, type, material, etc. The procedure that should have happened here is a hip resurfacing using components A and B. The actual procedure included implanting components A and C. Implanting the wrong components, whether in an orthopedic procedure such as this one or in an eye procedure where the wrong power lens is implanted, is considered to be a wrong procedure event and is reportable.

This event would have been considered reportable even if a second corrective procedure had not been required. In the case of wrong-procedure events, it is not the level of harm or the need for a second procedure that leads to reporting, but rather the occurrence of the event itself.

# Adverse Health Events Case Studies

## Wrong Procedure

Physician ordered placement of double lumen Hickman catheter. Single lumen Hickman catheter was placed.

	Number of Responses	Percentage
Reportable	34	30.9%
Not Reportable	45	40.9%
Unknown/Need More Information	31	28.2%
<b>Total</b>	<b>110</b>	<b>100%</b>

**This event would be considered reportable.**

This is another case where some vagueness in the event description may have made it difficult to answer. As a result, respondents may have been relying on different sets of assumptions in their response, and many indicated a need for more information.

The assumption in this case was that the patient had consented to placement of a double lumen catheter, and that a single lumen catheter was placed not because of a change in the patient's condition or the physician's order and accompanying consent, but because of misinterpretation of the order, miscommunication between the ordering physician and interventional radiologist, or some other reason unrelated to the clinical needs of the patient. As the procedure resulted in the placement of a device other than the device that was intended and consented to, this event would be considered a wrong surgical/invasive procedure.

Several respondents asked whether the patient was harmed, and whether a subsequent procedure was necessary to place the double lumen catheter. While this information would be important for the facility to have as they conduct an RCA and develop an action plan, the level of harm to the patient and/or the need for a corrective procedure are not factors in determining reportability of a wrong-procedure event. These events, along with wrong body part and retained foreign object events, among others, are reportable even in the absence of harm to the patient.

# Adverse Health Events Case Studies

## Wrong Procedure

Patient came in for adenoidectomy, tonsillectomy, and bilateral ear evaluation. The physician had discussed the possibility of bilateral ear tube placement with patient's parents in clinic, but the consent form did not include this procedure. The patient was brought into the operating room. Both ears had been marked by the physician. The room was set up with the usual trays for tonsillectomy, adenoidectomy, and bilateral ear tube placement. Staff did not question this, as most ear evaluations lead to the placement of tubes. Following the tonsillectomy and adenoidectomy, the bilateral ear evaluation was completed and bilateral tubes placed.

	Number of Responses	Percentage
Reportable	52	48.1%
Not Reportable	42	38.9%
Unknown/Need More Information	14	13.0%
<b>Total</b>	<b>108</b>	<b>100%</b>

**This event would be considered reportable.**

With the exception of emergent cases where obtaining informed consent may not be possible, a physician does not have the authority to conduct a procedure if the patient has not given him/her authority to do so through informed consent. A procedure that is performed but that was not included in the consent form would be considered reportable unless it is part of a standing order, or unless the emergent nature of the situation precluded obtaining informed consent.

# Adverse Health Events Case Studies

## Post-Surgical Death

A 62-year old patient with moderate congestive heart failure and diabetes underwent valve replacement surgery on a Tuesday morning. There were no apparent complications during the surgery, and the patient was transferred to the ICU around noon on Tuesday. The patient suffered respiratory arrest and died on Wednesday evening.

	Number of Responses	Percentage
Reportable	19	17.6%
Not Reportable	67	62.0%
Unknown/Need More Information	22	20.4%
<b>Total</b>	<b>108</b>	<b>100%</b>

**This event would not be considered reportable (as a post-surgical death).**

As described in statute, the post-surgical death category includes “death during or immediately after surgery 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.” Several recommendations have been released to further define this event:

- ‘Immediately after surgery’ is defined to mean within 24 hours after induction of anesthesia (if surgery was not completed), surgery, or other invasive procedure was completed.
- The definition of “normal, healthy patient” includes patients classified as an ASA Class I.

In this case, a patient with moderate congestive heart failure and diabetes would likely be considered an ASA Class 2 or 3 patient, and the death occurred more than 24 hours after surgery ended. While all unexpected post-operative deaths should be investigated, this event does not meet the reporting criteria for an adverse health event in that category.

Several respondents commented that they would need to know more about the circumstances of the death in order to determine whether or not it was reportable:

- “Not sure why (the patient) had the arrest, possible that it was due to something that is reportable so need further info.”
- “What was the cause of the respiratory arrest? Was it related to the other conditions?”
- “I think we would need an autopsy to determine cause of death before we could determine if this is reportable, but my guess is that it is reportable.”
- “Need to know the etiology of the respiratory arrest and patient history.”
- “I would need to know more about the cause of the respiratory arrest and death, e.g. was it associated with a medication error, associated with a device malfunction or misuse, etc?”

If this death had been of an ASA Class 1 patient and within the 24-hour window, it would have been considered reportable as a post-surgical death even if the death was determined to be unrelated to the surgery. However, as some of these respondents noted, an investigation of the death could reveal that it was due to a medication error, device malfunction, or other reportable event. In that case, the reporting facility would need to determine which category is most appropriate based on the results of their investigation into the death.



June 17, 2009

### 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 determine the answer to each of the elements outlined in the law:

- 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?

If the organization’s clinical team answers “Yes” to any of these three questions, the outcome would be considered a “serious disability.”

Additional Guidance Inclusions	Exclusions
1. Bone fractures except as listed in exclusions.	1. Minor fractures, e.g., finger, thumb, toes, nose, ribs, wrist, hairline 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"> <li>- Surgical intervention in the OR</li> <li>- Burns needing debridement/skin grafts</li> <li>- Higher level of care, for care related to the event, for more than 48 hours, e.g. transfer to critical care unit.</li> </ul>	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

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