



ASANTE WIDE

EFFECTIVE:	06/2006	POLICY #:	400-PI-006
PREVIOUS DATE:	02/2004 (Incident Reporting)	POLICY NAME:	Disclosure of Adverse Events
REVIEW DATE:		CATEGORY:	Performance Improvement
PREVIOUS POLICY #:	400-PI-001	JCAHO STANDARD	RI 2.90
<input checked="" type="checkbox"/> Asante Wide	<input type="checkbox"/> Hearthstone	HIPAA REGULATIONS	
<input type="checkbox"/> Asante Work Health	<input type="checkbox"/> TRCH	Key Words: Adverse Event; Incident; Harm; Disclosure, Sentinel Event	
<input type="checkbox"/> RVMC	<input type="checkbox"/> OTHER		
<input type="checkbox"/> Genesis			
<u>AUTHORIZATION:</u>			
Chief Quality Officer _____			
Date: _____			

POLICY SUMMARY:

Patients are entitled to information about the outcomes of their diagnostic tests, medical treatments and surgical intervention whether the results are expected or unanticipated, positive or negative. All outcomes are shared with patients as a part of their care and treatment through communication between the patient and their healthcare providers.

In accordance with our values of respect, honesty and service, it is Asante’s policy to disclose adverse events to patients who have been harmed in the course of their care. If the patient is deceased, incapacitated, or otherwise unable to take part in a process of adverse event disclosure, the process will include the patient’s representative and anyone who is designated by the representative.

POLICY DETAIL:

Clinicians and organizational leaders will work together to ensure that appropriate disclosure to patients or their representatives is a routine part of the response to an adverse event.

Definitions:

Adverse Event: Any unanticipated, usually preventable, consequence of patient care that results in patient death or serious physical injury. This includes all Sentinel Events as defined by JCAHO (Addendum A) and Serious Adverse Events as defined by the Oregon Patient Safety Commission (Addendum B)

Event Disclosure: Forthright and empathetic discussion of clinically significant facts between providers and patients or their representatives about the occurrence of an adverse event that resulted in patient harm.

Patient's Personal Representative: Any person who, under applicable law, has authority to act on behalf of the individual when making decisions related to healthcare, or to act on behalf of a deceased individual. The following progression of authority may be used for a patient if no individual has been appointed as a representative:

1. Spouse
2. An adult child
3. Either parent
4. An adult sibling

GUIDELINES:

1. When it has been determined that there was an adverse event, the attending physician caring for the patient is responsible to inform the patient or patient representative. Assistance is available from the Chief Quality Officer, Medical Director, Director of Patient Care Services, Supervisor or Risk Manager.
2. The use of a designee is discouraged since the silence of the patient's physician might lead someone to draw the inference that the provider did something wrong.
3. The disclosure communication should take place in private setting in consideration of the patient and/or family's comfort.
4. The factual details of the event as initially known should be communicated to the patient as promptly as possible, ideally within 24 hours of the discovery of the event, or as soon as the patient is physically and psychologically able to receive this information.
5. Use of apology during event disclosure helps to begin the healing process.
6. An apology does not constitute an admission of liability. This issue is addressed in the Oregon Revised Statutes:

Expression of regret or apology by licensee.

(1) For the purposes of any civil action against a person licensed by the Board of Medical Examiners, any expression of regret or apology made by or on behalf of the person, including an expression of regret or apology that is made in writing, orally or by conduct, does not constitute an admission of liability for any purpose.

(2) A person who is licensed by the Board of Medical Examiners, or any other person who makes an expression of regret or apology on behalf of a person who is licensed by the Board of Medical Examiners, may not be examined by deposition or otherwise in any civil or administrative proceeding, including any arbitration or mediation proceeding, with respect to an expression of regret or apology made by or on behalf of the person, including expressions of regret or apology that are made in writing, orally or by conduct. [ORS 677.082]

7. Communication needs to include that there may NOT be enough information at the time to determine exactly what happened or why.
8. Care should be given to avoid speculation, conjecture, innuendo or blame.

DISCLOSURE CONTENT:

Disclosure communication should consist of the following:

- **A clear, understandable explanation of known facts.** Describe what happened and leave details of how and why for follow-up discussions at the conclusion of event investigation.
- **A statement of apology.** Apologizing is an essential part of disclosure of an event. For example, say to the patient, *"I really regret this happened. I know it's not what either of us wanted or expected, and I'd like you to know how very sorry I am for what you're going through."*

- **A statement of the event’s effect on the patient, treatment plans and any impact on the patient’s future health status.** Tell the patient what is being done to correct the health problems they now have, how it will affect their health over the short and long term and recommended next steps.
- **Accountability statement.** Taking accountability for investigation of an adverse event is an essential step in adverse event follow-up. Disclosure should include an offer of a remedy that corrects the error and/or prevents it from recurring, such as *“We are going to find out what happened and do everything we can to see to it that is doesn’t happen again. I will let you know what we find as soon as I know.”* The statement of accountability should occur whether or not the event resulted from a specific act. The patient wants to know that someone is in charge and has control over the situation.
- **Follow-Up.** It is important to maintain open communication with a patient following disclosure. Frequently additional questions arise that need to be addressed and updated information can be provided. Follow-up conversations also provide an essential show of concern and support.

DOCUMENTATION:

The physician providing the disclosure should enter documentation of all discussions in the progress notes of the patient’s medical record. The documentation should include:

- Time, date and place of discussion
- Names of those present
- Factual information shared
- Questions that the patient/representative posed and the answers received
- Do NOT include any speculation or theorizing about what happened in the medical record (or in any communication to the patient).

NOTE: The Asante employee with the greatest knowledge of the event will complete an Incident Report with full detail as soon as possible after the incident occurs and submit to the Department Manager/Supervisor.

STAFF DISCLOSURE OF MINOR EVENTS:

Refer to policy 400-PI-001, “Incident Reporting in a Culture of Safety”, for disclosure of these events.

OREGON’S MANDATORY REPORTING OF ADVERSE EVENTS:

Because Asante Health System participates in the Oregon Patient Safety Reporting Program of Oregon’s Patient Safety Commission, we are required by OAR 325-010-0035 to report all adverse events to the Commission. Hospital participants must submit a completed Event Report to the Commission within 45 calendar days of discovery of a Reportable Serious Adverse Event.

1. Oregon’s “Event Report” form will be used in reporting all adverse events to the Commission.
2. The Risk Manager for each respective Asante County will submit the required reports.
3. As required by the Commission, Risk Management will provide a letter summarizing what the physician has disclosed to the patient or representative. This written disclosure will be reviewed by legal counsel prior to mailing and will be provided within 45 days of awareness of the adverse event.

If the hospital believes the Commission should immediately issue an alert to all Oregon hospitals based on a specific Reportable Serious Adverse Event, such as a problem with technology or equipment, the hospital will provide an initial report to the Commission within 3 business days of discovery of the event. Asante will work closely with the Commission to determine the content of the alert.

REFERENCES:

Oregon Revised Statutes

Oregon Patient Safety Commission

American Society of Healthcare Risk Management

Healing Words: The Power of Apology in Medicine. Michael S. Woods, M.D. 2004

When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. March 2006

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ADDENDUM A

JCAHO REVIEWABLE SENTINEL EVENTS

Includes any occurrence that meets any of the following criteria:

- 1) The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
- 2) The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
 - Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge
 - Unanticipated death of a full-term infant
 - Abduction of any individual receiving care, treatment or services
 - Discharge of an infant to the wrong family
 - Rape
 - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
 - Surgery on the wrong individual or wrong body part
 - Unintended retention of a foreign object in an individual after surgery or other procedure
 - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
 - Prolonged fluoroscopy with cumulative dose >1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition (not reviewed under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment (including "recognized complications") or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition (reviewable). In indeterminate cases, the event will be presumed reviewable and the organization's response will be reviewed under the Sentinel Event Policy according to the prescribed procedures and time frames without delay for additional information such as autopsy results.

"Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When major permanent loss of function cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.

For laboratories, as required by standard QC.5.280, a confirmed fatal transfusion reaction must be reported to the FDA Center for Biologics and the Joint Commission within seven days.

Rape, as a reviewable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or unknown perpetrator while being treated or on the premises of the health care 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.

All events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure.

ADDENDUM B

OREGON PATIENT SAFETY COMMISSION REPORTABLE ADVERSE EVENTS

Type of Events
1. GENERAL CATEGORY
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.
2. SURGICAL EVENTS
A. Surgery performed on the wrong body part.
B. Surgery performed on the wrong patient.
C. Wrong surgical procedure performed on a patient.
D. Retention of a foreign object in a patient after surgery or other procedure.
E. Intraoperative or immediately post-operative death in an ASA Class I patient. (ASA is the American Society of Anesthesiologists. Class I means a healthy patient, no medical problems.)
3. PRODUCT OR DEVICE EVENTS
A. Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.
B. Patient death or serious physical 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 or is difficult to use as intended.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
4. PATIENT PROTECTION EVENTS
A. Infant discharged to the wrong person
B. Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours.
C. Patient suicide, or attempted suicide resulting in serious physical injury, while being cared for in a healthcare facility.
5. CARE MANAGEMENT EVENTS
A. Patient death or serious physical injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).
B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
C. Maternal death or serious physical injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.
D. Patient death or serious physical injury associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
E. Death or serious physical injury (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
G. Patient death or serious physical injury due to spinal manipulative therapy.
H. Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.
6. ENVIRONMENTAL EVENTS
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.
D. Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility.
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.