

POLICY

Title: Disclosure of Unanticipated Outcomes - "C"

Location: Centennial Hills, Desert Springs Hospital, Henderson Hospital, Spring Valley, Summerlin, Valley Hospital

Policy Number:

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Department of Document Owner: RISK MANAGEMENT

Original Effective Date: 05/01/2011

Last Review Date: 03/2018

Last Revision Date: 06/2016

Section: Leadership

I. Scope:

Hospital wide

II. Purpose:

To ensure the timely, accurate, communication of unanticipated outcomes to patients and families

III. Definitions:

- A. Disclosure: providing information to a patient and/or family about an adverse event or unanticipated outcome
- B. Adverse Event: Any event caused by medical management rather than the patient's underlying disease or condition.
- C. Sentinel Event: a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:
 - Death
 - Permanent harm
 - Severe temporary harm (defined as a critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery.)
- D. Serious Reportable Event ("Never Event") - as defined by the National Quality Forum (NQF), (the State of NV adopts the NQF reporting of the 29 NQF Serious Reportable Events) is an event that is unambiguous, largely, if not entirely, preventable, serious, and any of the following:
 - Adverse
 - Indicative of a problem in a healthcare setting's safety systems
 - Important for public credibility or public accountability
- E. Unanticipated Outcome: A result that differs significantly from what was anticipated to be the result of a treatment or procedure.
- F. Disclosure Team: Group of individuals identified by the hospital to facilitate disclosure to include but not be limited to the licensed independent practitioner (LIP), who is most closely associated with the event, Chief Executive Officer or designee, Chief Nursing officer or designee, Chief Medical Officer, Risk Manager, and Quality Manager. At a minimum this team must consist of the LIP, member of Administration, and the Risk Manager.

IV. Policy:

It is the policy of the hospital that patients, and when appropriate, their families will be notified of Adverse Events, Serious Reportable Events, Sentinel Events and Unanticipated Outcomes while in the hospital. These communications will occur in a timely, factual, and sensitive manner while respecting the patient's right to privacy.

V. Procedure:

- A. Any Adverse Events will be investigated by the facility Risk Manager with assistance from members of the healthcare team. Facts derived from the investigation are shared with the Disclosure Team in anticipation of the disclosure
- B. Although disclosure of unanticipated outcomes is the responsibility of the LIP, it should only occur after consultation with the Disclosure Team (exceptions should be made in emergent situations when disclosure is crucial for additional consent). Actual disclosure to the patient and/or family should be performed by the patient's LIP with a member of the Disclosure Team based on the facts of the event and person most suited for the disclosure. Some cases may require a single member of the team to perform the actual disclosure whereas others might require multiple members of the team. In cases where members of the disclosure team are unavailable for the actual disclosure communication, due to extenuating circumstances, a designated management level hospital employee should participate in the disclosure process with the available LIP.
- C. Disclosure should occur as close to the event's occurrence as possible after careful and deliberate consultation and collaboration amongst the Disclosure Team. A delay of the disclosure may be appropriate in the instance where the patient might suffer harm or if the disclosure could interfere with care.
- D. Disclosure will occur in a caring and compassionate manner. At a minimum:
 - The patient will be informed about the facts surrounding the Adverse Event, known or expected complications and short and long term impact on his/her care in a factual, objective manner; free of speculation or blame.
 - Outline the plan to respond to any complications.
 - An apology should be offered if warranted.
 - The disclosure should include any steps taken to remediate process failures and actions taken to prevent similar events.
 - Identify for the patient a facility contact person for future communications.
 - Charges related to the Adverse Event will be reviewed to determine if waiving is required.
 - The facts and content of the disclosure should be documented in the patient's medical record associated with the event. The patients' reaction to the disclosure and the plan for future care should be included in the documentation.
- E. In the event that members of the Disclosure Team cannot agree on key components of the disclosure, efforts should be undertaken to resolve this conflict. The team should consult with facility leadership, medical staff leadership and/or the facility ethics committee. Disclosure should not occur until conflict is resolved, but should not be unnecessarily delayed.
- F. The facts and content of the disclosure should be documented in the patient's medical record. The patient's reaction to the disclosure and the plan for future care should be included in the documentation along with any other relevant communications between the members of the disclosure team.

VI. References:

- A. American Society for Healthcare Risk Management (ASHRM): Disclosure of unanticipated events: creating an effective communication policy [monograph]. Chicago: ASHRM; 2003 Nov.
- B. ECRI: Healthcare Risk Control: Disclosure of Unanticipated Outcomes. 2008, January.
- C. *Disclosing Harmful Medical Errors to Patients*, Gallagher, Thomas H., et. al., N Engl J Med 2007; 356; 2713-9.
- D. AHRQ Error Disclosure. Accessed from: <https://psnet.ahrq.gov/primers/primer/2/error-disclosure>
- E. O'Connor et. al. Disclosure of patient safety incidents: a comprehensive review. Accessed from <http://dx.doi.org/10.1093/intqhc/mxq042371-379> First published online: 13 August 2010.
- F. State of NV Department of Health and Human Services, Division of Public and Behavioral Health: [http://dpbh.nv.gov.com/Programs/SER/dta/Forms/Sentinel_Event_Registry_\(SER\)_-_Forms/](http://dpbh.nv.gov.com/Programs/SER/dta/Forms/Sentinel_Event_Registry_(SER)_-_Forms/)

VII. Related Hospital Policies:

- A. Event Reporting
- B. Sentinel Event

VIII. Attachment:

- A. Key Points to Ensure a Successful Disclosure
- B. National Quality Forum (NQF) 29 Serious Reportable Events

Attachment A

Key Points to Ensure a Successful Disclosure

1. A brief, factual discussion of the unanticipated outcome. Acknowledge the event occurred, when and where and how it occurred if known.
2. Presentation of sincere concern, regret and empathy
3. Apologize if warranted
4. How the unanticipated outcome will affect the patient's current treatment plan
5. Address patient concerns
6. Review any steps that may have already been taken or will be taken to minimize a recurrence
7. Revise next steps, as appropriate

Attachment B

National Quality Forum (NQF) 29 Serious Reportable Events

1. SURGICAL OR INVASIVE PROCEDURE EVENTS:

- 1A. Surgery or other invasive procedure performed on the wrong site
- 1B. Surgery or other invasive procedure performed on the wrong patient
- 1C. Wrong surgical or other invasive procedure performed on a patient
- 1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- 1E. Intraoperative or immediately postoperative/post-procedure death in an ASA Class 1 patient

2. PRODUCT OR DEVICE EVENTS:

- 2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
- 2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as
- 2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

3. PATIENT PROTECTION EVENTS:

- 3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- 3B. Patient death or serious injury associated with patient elopement (disappearance)
- 3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare

4. CARE MANAGEMENT EVENTS:

- 4A. Patient death or serious 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)
- 4B. Patient death or serious injury associated with unsafe administration of blood products
- 4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
- 4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- 4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting

4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting

4G. Artificial insemination with the wrong donor sperm or wrong egg

4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen

4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5. ENVIRONMENTAL EVENTS:

5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting

5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances

5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting

5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

6. RADIOLOGIC EVENTS:

6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

7. POTENTIAL CRIMINAL EVENTS:

7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

7B. Abduction of a patient/resident of any age

7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting

7D. Death or serious 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