Section 9 Clinical Policies Subject 9.13 General Procedures **Policy 9.13.16 Sentinel Events**	07/26/99 -Originated 08/01/13 -Reviewed w/ changes -Reviewed w/o changes 09/05/13 - Effective Quality Management -Author

Sentinel Events

Definitions

Sentinel Event: an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

***Adverse Event*:** serious incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided. Adverse events may result from acts of commission or omission (e.g. administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). Some examples of adverse events include: patient falls, medication errors, procedural errors/complications, completed suicides, para-suicidal behaviors (attempts/gestures/threats), and missing patient events. An adverse event can also be categorized as either a sentinel event or near miss.

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 determinate 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 timeframes without delay for additional information such as autopsy results.

***Near Miss*:** *(also called a close call)* is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. An example of a near miss would be: surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance. Near misses are opportunities for learning and afford the chance to develop preventive strategies and actions. Near misses will receive the same level of scrutiny as adverse events that result in actual injury.

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Definitions, continued

***Root Cause Analysis (RCA*):** a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or near misses. RCA will be the form of focused review that is used for all adverse events or near misses requiring analysis since it further refines the implementation and increases the quality and consistency of our focused reviews.

***Major permanent loss of function*:** sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment for 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.

***Rape*:** as a reviewable sentinel event, is defined as un-consented 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 un-consented sexual contact
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises.

Policy

UTMB is committed to patient safety. Any employee who has knowledge of a sentinel event, an adverse event, or a potential adverse event or a near miss that could lead to a sentinel event or adverse event, involving a UTMB patient must notify his/her supervisor or nurse administrator. The supervisor or the administrator must notify Quality Management or Risk Management immediately. **All unusual events should be reported by using the Patient Safety Net (UHC Safety Intelligence).**

In addition, for patients who are also subjects in a research protocol other

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reporting may be required per Institutional Review Board (IRB) policy.

A formal RCA will be conducted under the auspices of the UTMB Safety Event Action Team (SEAT) for events that meet the definition of sentinel event, adverse event, or near miss as stated above, including:

A. Events that 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
B. The following events (even if the outcome was not death or major permanent loss of function):
    1. Suicide of any individual receiving care, treatment, or services in a staffed around- the-clock care setting or within 72 hours of discharge
    2. Unanticipated death of a full-term infant
    3. Abduction of any patient receiving care, treatment, or services.
    4. Discharge of an infant to the wrong family
    5. Rape, assault (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment or services
    6. Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site
    7. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
    8. Surgery or other invasive procedure on the wrong individual or wrong body part
    9. Unintended retention of a foreign object in an individual after surgery or other invasive procedure
    10. Severe neonatal hyperbilirubinemia (bilirubin more than 30 milligrams/deciliter)
    11. Prolonged fluoroscopy with cumulative dose more than 1500 rads to a single field or any delivery of radiotherapy to the wrong body region or more than 25 percent above the planned radiotherapy dose.

Procedure

Risk Management will initiate investigation of a reported sentinel event/near miss immediately after notification and will work with Health

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Procedure, continued

System leadership to determine if a RCA should be conducted. An RCA may be conducted for occurrences that do not meet the criteria for a sentinel event if the SEAT determines that it is appropriate.

All RCA's will involve UTMB staff whose departments are associated with the event. Risk Management and/or the Quality & Healthcare Safety department will work with the applicable departments to determine participants in the RCA meeting. When appropriate, staff directly involved in the actual event will participate.

Risk Management will develop a flow of events based on interviews with staff directly involved in the event, which will be presented to the RCA team. The RCA team will review, correct, and discuss the flow to determine the root cause(s). The team will then develop an action plan to address the root cause(s) identified and describe the organization's risk reduction strategies and measures for evaluating their effectiveness. The action plan will include who will be responsible for implementation of action items and a timeline of when the items will be complete. This RCA and action plan will be completed within 45 calendar days of the event or of becoming aware of the event or of UTMB becoming aware of the event. Quality & Healthcare Safety will be responsible for monitoring the action plans for completion of action items and will report this information through the Performance Improvement, Risk Management, and Safety (PIRMS) Committee.

References

45-CFR-46.103

21 CFR 312.32), 21CFR312.62 , 21 CFR 50.27 (a)Expedited Safety Reporting Requirements for Human Drug and Biological Products – Final Rule (21 CFR Parts 20, 310, 312, 314, and 600) [Docket No. 93N-0181] Vol. 62, No. 194, pg. 52237 - 52253

Policy 6.1.4 Significant Event Reporting

Policy 9.13.13 Unusual Event Reporting

Policy 9.13.14 Adverse Drug Events

Policy 9.13.18 Disclosure of Unanticipated Outcomes