Name of Policy: Patient Safety Event including Sentinel Events Policy **Policy Number**: 3364-100-50-38 **Approving Officer**: Chief Medical Officer, Chief Executive Officer, Chief of Staff **Responsible Agent**: Chief Medical Officer **Scope**: University of Toledo Medical Center	UTOLEDO HEALTH **Effective date:** **Original effective date**: 10/15/1998
Key words: Patient Safety Events, Sentinel Events, Evaluation, Quality and Safety	

☐	New policy proposal	☒	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) Policy Statement

The University of Toledo Medical Center (UTMC) strives to enhance quality and patient safety through the evaluation of safety events and to take appropriate steps to continuously improve quality and safety.

(B) Purpose of Policy

The purpose of this policy is to guide the identification and assessment of safety events in order to improve quality and reduce the probability of recurrent events in the keeping with Just Culture (3364-100-50-48).

(C) Definitions

1. **Adverse Event** is a serious, undesirable, and usually unanticipated patient safety event that resulted in harm to the patient but does not rise to the level of being sentinel.

2. **No-Harm** event is a patient safety event that reaches the patient but does not cause harm.

3. **Close-Call or Near-Miss** is a patient safety event that had no impact on a patient but could have had an impact if it was not aborted, discovered or if intervention occurred prior to it reaching the patient.

4. **Hazardous or Unsafe Condition** is a circumstance (other than the patient's own disease process, or condition) that increases the probability of an Adverse or Sentinel Event.

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9. **Hazardous or Unsafe Condition** is a circumstance (other than the patient's own disease process, or condition) that increases the probability of an Adverse or Sentinel Event.

~~10.~~ **Sentinel Event** ~~is 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 death, permanent harm, or severe temporary harm. Permanent harm is defined as an event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health. Severe temporary harm is 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, procedure, or treatment to resolve the condition.~~

~~**Sentinel events are a subcategory of adverse events. A sentinel event is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).**~~

~~**Sentinel events are not only events that occur during the care and treatment of individuals. Physical and verbal violence, abductions, and power failures are all potential sentinel events that can affect the health care organization and its patients. The Joint Commission considers the following list of events, though not comprehensive, to be sentinel events if they occur under any Joint Commission–accredited health care organization, although some of these events are unlikely to occur in certain health care settings:***~~

10. Sentinel Event is 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 outcomes:

- **Death**
- **Permanent harm (defined as harm that permanently alters a patient's baseline physical or mental functioning), or**
- **Severe temporary harm (defined as critical harm that requires transfer to a higher level of care, emergency life-sustaining intervention, or major treatment to resolve).**

An event is also considered sentinel if it is one of the following:

A. Death caused by self-inflicted injurious behavior if any of the following apply:
   i. While in a health care setting
   ii. Within 7 days of discharge from inpatient services
   iii. Within 7 days of discharge from emergency department (ED)
   iv. While receiving or within 7 days of discharge from the following behavioral health care services: Day Treatment/Partial Hospitalization Program (PHP)/Intensive Outpatient Program (IOP), Residential, Group Home, and Transitional Supportive Living

B. Unanticipated death of a full-term infant.

C. Homicide of any patient receiving care, treatment, and services while on site at the hospital or while under the care or supervision of the hospital.

D. Homicide of a staff member, visitor, or vendor while on site at the hospital or while providing care or supervision to patients.

E. Any intrapartum maternal death.

F. Severe maternal morbidity (leading to permanent or severe harm).

G. ***Sexual abuse/assault*** of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization

H. Sexual abuse/assault of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients (See addendum)

I. Physical assault (leading to death, permanent harm, or severe harm) of any patient receiving care, treatment, and services while on site at the hospital or wile under the care or supervision of the hospital.

J. Physical assault (leading to death, permanent harm, or severe harm) of a staff member, visitor, or vendor on the hospital site or while providing care or supervision to patients.

K. Surgery or other invasive procedure performed on the wrong patient, at the wrong site or wrong (unintended) procedure for that patient.

L. Discharge of an infant to the wrong family.

M. Abduction of any individual receiving care, treatment, or services.

N. Any elopement (that is, unauthorized departure) of a patient from a staffed around the clock care setting (including the Emergency Department), leading to death, permanent harm, or severe temporary harm to the patient.

O. Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in server temporary harm, permanent harm, or death.

P. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.

Q. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).

R. Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed.

S. Any delivery of radiotherapy to the wrong body region, or >25% above the planned radiotherapy dose.

T. Fire, flame, or unanticipated smoke, heat, or flashes Occurring during direct patient care caused by equipment operated and used by the hospital. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.

U. Fall resulting in any of the following: fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury; or a

patient with coagulopathy who receives blood products as a result of the fall; death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

Addendum for Sexual Abuse cases: Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact, including oral, vaginal, or anal penetration or fondling of the individual's sex organ(s) by another individual. Sexual abuse includes, but is not limited to, the following: Unwanted intimate touching of any kind, especially of the breasts, buttocks, or perineal area. All types of sexual assault or battery, such as rape, sodomy, and coerced nudity(partial or complete). Forced observation of masturbation and/or sexually explicit images, including pornography, texts, or social media. Taking sexually explicit photographs and/or audio/video recordings of an individual and maintaining and/or distributing them (for example, posting on social media);this would include, but is not limited to, nudity, fondling, and/or intercourse involving an individual.

Generally, sexual contact is nonconsensual in the following situations: When the individual lacks the cognitive or legal ability to consent even though appearing to want the contact to occur. When the individual does not want the contact to occur. Other examples of nonconsensual sexual contact may include but are not limited to situations where an individual is sedated, is temporarily unconscious, or is in a coma. An individual's apparent consent to engage in sexual activity is not valid if it is obtained from the individual lacking the capacity to consent, or consent is obtained through intimidation, coercion, or fear, whether it is expressed by the individual or suspected by staff. Any forced, coerced, or extorted sexual activity with an individual, regardless of the existence of a preexisting or current sexual relationship, is considered to be sexual abuse.

One or more of the following must be present to determine that it is a sentinel event:

A. Any staff-witnessed sexual contact as described above.
B. Admission by the perpetrator that sexual contact, as described above, occurred on the premises.
C. Sufficient clinical evidence obtained by the health care organization to support allegations of unconsented sexual contact.

~~12.~~11. **Never Event** is Agency for Healthcare Research and Quality (AHRQ) term referring to adverse events that are unambiguous serious (clearly identifiable and measurable resulting in death or significant disability, and largely preventable).

The National Quality Forum lists Never Events:

A. Surgical and procedural events
    1. Surgery or other invasive procedure performed on the wrong body part
    2. Surgery or other invasive procedure performed on the wrong patient
    3. Wrong surgical or other invasive procedure performed on a patient
    4. Unintended retention of a foreign object in a patient after surgery or other procedure
    5. Intraoperative or immediately postoperative/post procedure death in an American Society of Anesthesiologist Class I patient

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

C. Patient protection events

1. Discharge or release of a patient /resident of any age, who is unable to make decisions, to other than an authorized person
2. Patient death or serious disability associated with patient elopement (disappearance)
3. Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility

D. Care management events
1. Patient death or serious injury associate with a medication error
2. Patient death or serious injury associated with unsafe administration of blood products
3. Maternal death or serious injury associate with labor or deliver in a low-risk pregnancy while being care for in a health care setting
4. Death or serious injury of a neonate associate with labor or deliver in a low-risk pregnancy
5. Artificial insemination with the wrong donor sperm or wrong egg
6. Patient death or serious injury associated with a fall while being cared for in a health care setting
7. Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility
8. Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
9. Patient death or serious injury resulting from failure to follow or communicate laboratory, pathology, or radiology test results

E. Environmental events
1. Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a healthcare setting
2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
3. 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 health care setting
4. Patient death or serious injury associated with use of restraints or bedrails while being cared for in a health care setting

F. Radiological events
1. Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area

G. Criminal events
1. Any instance of care order by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
2. Abduction of a patient/resident of any age
3. Sexual abuse/assault on a patient within or on the grounds of a health care setting
4. Death or significant injury of a patient or staff member resulting from physical assault that occurs within or on the grounds of a health care setting.

(D) Safety Event Procedures

1. Immediate Response

A. Ensure patient safety- staff should ensure the safety of the patient and notify Attending Physician.

B. Secure equipment or evidence- if any device or equipment was involved in the event, remove it from service, clearly identify it, and secure it.

C. Safety event reporting- Any employee, resident, student, or physician who is aware of a safety event is responsible for immediately reporting the event to the manager or immediate supervisor. This person or his/her manager or immediate supervisor will enter the safety event in the incident reporting system (Patient Safety Net) within 24 hours of the event or knowledge of the event. Failure to report a safety event in this manner may result in disciplinary action. Under no circumstances will reporting a safety event serve as a basis for retaliatory actions to be taken against any patient, staff, or other persons making the report.

i. Manager/Director/Supervisor- upon receiving a report regarding a patient safety event, he/she immediately determines whether the event is a potential Sentinel Event or Never Event and if so, immediately notifies the House Supervisor.
ii. House Supervisor- will immediately compare the events reported against the Sentinel and Never Event criteria. If the incident has the potential to be a Sentinel Event or Never Event, then he/she notifies the Administrator On-Call. The Administrator On-Call will immediately determine whether the event is a Sentinel or Never Event and contact the CMO (or CMO designee).
iii. Upon discovery and determination of a Sentinel Event or Never event, the CMO (or CMO designee) will convene an Event Support Team (EST) within 48 hours of notification . The EST may include the CMO, Chief Executive Officer, Director of Quality Improvement and Patient Safety, Chief of Staff, Chief Nursing Officer, Chief Operating Officer, Director of Surgical Services, Legal Counsel, Risk Management, Service Chief, Pastoral Care, and any other personnel deemed necessary.
iv. All Incident Reports are protected from discoverability by ORC 2305.25 and ORC 2305.253. Therefore, they must be handled confidentially and not distributed to outside parties without the consent of the Office of Legal Affairs. The Incident Report submission contains a statement with regard to profession/peer review and quality assessment confidentiality.

2. Communicating Sentinel or Never Events to the Patient and/or Family

A. The physician or clinical practitioner will ensure Patient/Family has an initial response to the Sentinel or Never Event with a statement of "I'm Sorry," along with the statement that UTMC is investigating the incident.

B. The CMO (or CMO designee) determines whether the "I'm Sorry Procedure" should be initiated.

C. At least three members of the EST must be notified and participate in the "I'm Sorry Procedure" discussion, in addition to Legal Affairs and Risk Management.

D. The CMO or members of the EST will meet with the physician or clinical practitioner and others involved to discuss the plan of action for proper communication with the patient/family to determine:

i. Primary communicator with the Patient/Family
ii. Facts that will be communicated based on available information
iii. Determine location and team to communicate face-to-face (telephone communication may be acceptable when determined by the team)

E. Communication

i. Tell the Patient/Family the facts of what happened
ii. Apologize to the Patient/Family using the words, "I'm sorry"
iii. Assure Patient/Family of ongoing care and plan to remedy matter
iv. Commit to continued communication and support with a clearly identified point-of-contact for the Patient/Family
v. Any request by a patient or personal representative to bring an attorney must be honored
vi. Any information based on peer review for the purpose of monitoring, assessing, or documenting the quality of the diagnostic or treatment of services is confidential medical quality assurance information and may not be discussed with patients or documented in the medical record.
vii. The communication of full disclosure of the Sentinel or Never Event may be deferred to a more appropriate time but should be completed no later than the time of discharge or completion of care at UTMC.
viii. Entry of the discussion will be made into the patient's medical record by the Attending Physician or other provider who was part of the discussion.

F. Risk Management will proceed with notification of potential claims to insurers.

G. Administration will work with finance to determine appropriate waiving of cost on a case-by-case basis.

H. The Incident Report is not to be documented or placed in the patient's medical records or employee's personnel file.

3. Investigation and Reporting

A. All safety events will be reviewed, evaluated, and classified. Aggregate data regarding safety events will be presented annually to the Quality and Patient Safety Council.

B. Sentinel Events and Never Events

i. Quality Improvement and Patient Safety will begin the investigation immediately.
ii. Quality Improvement and Patient Safety will assemble a team (RCA Team) to conduct a comprehensive systematic analysis in the form of a Root Cause Analysis (RCA) within 72 hours of the reporting of the event or as soon as the initial investigation is completed.
iii. Within 45 business days of the event or of becoming aware of the event, the team will develop an action plan.
iv. Findings and recommendations will be presented to the Quality and Patient Safety Council (QPSC). The QPSC will either accept or decline the findings and action plan.
i. If accepted, it must be implemented and the QPSC will assist with action plan compliance.

ii. If declined, the RCA Team will reconvene and gather more information or modify the action plan as requested by the QPSC.
iii. Matters involving physician activity may be referred to the Peer Review as appropriate.
iv. The QPSC will be periodically updated and will help facilitate compliance with action plans.
v. The CMO (or designee) will report Never Event and Sentinel Event analysis and action plans to the UToledo Health Board.
vi. UTMC will report all Never and Sentinel Events through the process of their Patient Safety Organization (PSO). In addition, appropriate Events will be reported by UTMC administration to external agencies to the extent required in accordance with applicable laws, regulations, and the rules of accrediting agencies.
vii. All documents generated as a result of a Sentinel Event, Never Event, an Adverse Event or a Near Miss, including but not limited to the initial report, the findings and the Root Cause Analysis forms will be maintained in a strictly confidential manner by all parties who receive the documentation. These documents are considered to be confidential reports and are part of the peer review and quality assessment process of the Hospital. They are protected from disclosure pursuant to the provisions of ORC 2305.25 and ORC 2305.25.3. Unauthorized disclosure or duplication is absolutely prohibited.

E. References:

1. Revision to Sentinel Event Policy definition of Suicide Joint Commission Online - December 2023
2. Revision to Sentinel Event Policy definition of sexual abuse/assault Joint Commission Online - Oct. 19, 2022
3. The Joint Commission CAMH Update: July 2023: Sentinel Events
4. National Quality Forum: Serious Reportable Events in Healthcare-2011 Update
5. Agency for Healthcare Research and Quality: U.S. Department of Health and Human Services: Patient Safety Primer September 2019: Never Events accessed 6/30/2020 https://psnet.ahrq.gov/primer/never-events
6. Revised Sexual Abuse definition incorporates content from US Centers for Medicare & Medicaid Services State Operations Manual Appendix https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

Approved by: _____ Daniel Barbee Chief Executive Officer _____ Date _____ Michael Ellis, MD Chief Medical Officer _____ Date _____ Puneet Sindhwani, MD Chief of Staff _____ Date *Review/Revision Completed by:* *HAS, Quality Management, Chief of Staff, Office of Legal Affairs - HSC*	**Policies Superseded by This Policy:** • *7-50-38 Sentinel Events/Adverse Events* Initial effective date: 10/15/1998 Review/Revision Date: 10/15/98 03/01/99 03/02/01 11/01/03 03/10/05 06/30/05 7/13/05 3/8/06 2/27/08 2/23/2011 8/27/13 1/2/2014 7/1/2015 11/1/2016 10/23/2019 8/1/2020 1/1/2021 04/2023 Next review date: