Name of Policy: Communication of Sentinel or Never Events ("I'm Sorry Protocol") **Policy Number**: 3364-100-60-10 **Approving Officer**: Chief Executive Officer – UTMC Chief of Staff **Responsible Agent**: Chief Medical Officer Special Assistant to VP & General Counsel **Scope**: UTMC and UT Clinical Enterprises	THE UNIVERSITY OF TOLEDO MEDICAL CENTER **Effective Date:** 09/28/2020 **Original effective date**: December 12, 2001
Key words:	

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

(A) Policy statement

It is The University of Toledo Medical Center's (UTMC) policy to treat patients with respect, openness, honesty and empathy and to notify patients of unanticipated outcomes as a result of a Sentinel or Never Event (defined below).

(B) Purpose of policy

The purpose of this policy is to establish guidelines for providing patients, their families, and appropriate hospital personnel with information with regard to results that differ significantly from what was anticipated. Communication about certain aspects of a patient's care and treatment that includes Sentinel Events enables patients to make informed decisions regarding future medical care. The communication of Sentinel Events demonstrates respect for the patient, professionalism, accountability, and a commitment to improving care.

(C) Scope

UTMC and its ambulatory clinics.

(D) Definitions

Never Event – is an AHRQ and Leapfrog term referring to adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and largely preventable. Below is the current National Quality Forum list of Never Events:

- **Surgical and procedural events**
    - Surgery or other invasive procedure performed on the wrong body part
    - Surgery or other invasive procedure performed on the wrong patient
    - Wrong surgical or other invasive procedure performed on a patient

  - Unintended retention of a foreign object in a patient after surgery or other procedure
  - Intraoperative or immediately postoperative/post procedure death in an American Society of Anesthesiologist Class I patient

- **Product or device events**
  - Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
  - 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
  - Patient death or serious injury associated with intravascular air embolism that occurs while being care for in a healthcare setting.

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

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

- **Environmental events**
  - Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a healthcare setting

  - 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
  - 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
  - Patient death or serious injury associated with use of restraints or bedrails while being cared for in a health care setting

- **Radiologic events**
  - Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area

- **Criminal events**
  - Any instance of care order by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
  - Abduction of a patient/resident of any age
  - Sexual abuse/assault on a patient within or on the grounds of a health care setting
  - 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

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 (1) death, (2) permanent harm, or (3) severe temporary harm. An event is also considered sentinel if it is one of the following:

- Suicide of any patient receiving care, treatment, or services in a staffed around-the clock care setting or within 72 hours of discharge, including from the organization's emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, or services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED) leading to the death, permanent harm, or severe temporary harm of the patient
- 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 severe temporary harm, permanent harm, or death
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, or services while on site at the organization
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization
- Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient

- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- 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.
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm
- Transplant Adverse Events, as defined in the Transplant Adverse Events Policy #3364-140-45, are also included in the definition of Sentinel Event and are reported and investigated as defined in this policy.

(E) Procedure

(1) Protocol for Communicating Sentinel or Never Events to the Patient and/or Family:

(a) The physician involved in the Sentinel or Never Event and support staff must first ensure the patient is safe and that a treatment plan is in place for the patient.

(b) Any health care provider, including but not limited to, a physician, advanced practice provider, nurse, medical assistant, surgical technician, medical student, resident, or UTMC employee, who is aware of the Sentinel or Never Event must notify his/her unit manager, the House Supervisor and enter an Incident Report into Patient Safety Net.

(c) The House Supervisor will notify the Administrator-On-Call and the Chief Medical Officer (CMO), or a designee of the CMO if the CMO is not available, as per the Communication Flow Chart, which is attached for reference, of the Sentinel Events/Never Events/Adverse Events policy # 3364-100-50-38.

(d) The CMO (or the CMO's designee) follows through with notifying individuals of the Sentinel or Never Event as per the Communication Flow Chart.

(e) The CMO (or the CMO's designee) will determine if this policy (the "I'm Sorry Protocol") should be initiated and make the preliminary decision as to the appropriate composition of the Event Support Team (EST). The CMO (or the CMO's designee) will notify Legal Affairs and Risk Management to initiate this I'm Sorry Protocol along with the preliminary composition of the EST.

(f) Once this I'm Sorry Protocol is initiated, Legal Affairs and Risk Management will notify the EST as soon as possible. At least three members of the EST must be notified and participate in the I'm Sorry discussion. Members of the EST include:

(i) CMO;

(ii) Chief Nursing Officer;

(iii) Administrator for Surgical Services (when involving surgical procedure);

(iv) Chief Executive Officer, UTMC;

(v) Risk Manager;

(vi) Chief Operating Officer;

(vii) Hospital Quality Administrator;

(viii) Legal Counsel; and

(ix) Patient & Family Support & Pastoral Care.

(g) The physician or clinical practitioner will ensure the patient has an initial response to the pending issue with a statement of "I'm Sorry," a statement of how we are in the process of investigating the incident and that we will get back with the patient or family very quickly.* EST will be available to the physician or clinical practitioner, if not in person, then by telephone, to provide assistance in information to be provided during this initial meeting with the patient/family.

(h) EST, through either Quality or Risk Management, will begin the process of examination of the issue and of gathering the pertinent information.

(i) 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.

(j) Communication held with the Patient/Family

(i) If a patient needs urgent treatment to minimize injuries resulting from the event, the discussion with the patient/family must not be delayed.

(ii) Physicians or clinical practitioners have the primary responsibility for ensuring that the patient is informed about outcomes of care/treatment. If more than one service is involved, they should collaborate in discussing outcomes of care when appropriate.

(iii) Physicians or clinical practitioners will provide timely and concise information to patients, and when appropriate and when also permitted under applicable policy and law, to families/significant others, about all aspects of a patient's medical care, including results and response to treatment.

(iv) Prior to discussion with the patient, the physician or clinical practitioner should notify and meet with at least one member of EST to create a plan and outline details of the discussion with the patient. In the case where urgent treatment or discussion is required, the physician may delay notifying a member of EST until after the initial discussion with the patient/family.

(v) The timing of the discussion regarding a Sentinel or Never Event should be as soon as possible, knowing that each case varies with the specific circumstances in that situation. Professional judgment will determine when the information will be shared.

(vi) Any request by a patient or personal representative to bring an attorney must be honored. Social workers, pastoral care, or other staff may be present to help the patient or representative cope with the news and to offer support, if needed.

(vii) At a minimum, the patient will be informed about:

(a) The factual information of the outcome that occurred.

(b) The proposed plan to respond to these repercussions and ways that are being implemented to fix the problem(s).

(c) Point of contact for further questions or follow-up.

(d) In the event of a Sentinel or Never Event, an apology is very important to the discussion and promotes humility and empathy. When discussing a Sentinel or Never Event to a patient or family member/representative, the physician or clinical practitioner must recognize the event by delivering a sincere apology that includes the word "sorry."

(viii) How to communicate necessary information with the patient:

(a) Delivery of the Sentinel or Never Event discussion will be with empathy and compassion, communicating and detailing all known and relevant facts.

(b) The discussion regarding a Sentinel or Never Event needs to occur in an appropriate setting and be done face-to-face. The location needs to be a quiet, private place and adequate time needs to be set aside, with no interruptions.

(c) Communications with a patient needs to express concern for the patient's welfare, and reassure the patient or representative that steps are being taken to gather information regarding the situation, remedy any injury, and prevent further harm.

(d) Patients should be given time and opportunity to ask questions.

(ix) 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.

(x) 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, completion of care at UTMC or immediately thereafter.

(xi) In cases involving the death of a patient:

(a) Notify the coroner's office regarding potential indication for a post mortem examination pursuant to policy #3364-100-53-17.

(b) If a post mortem examination is not ordered or required by the coroner's office, a member of EST or the attending physician should encourage such examination as part of the investigative process.

(xii) Make any other further arrangements for: a second opinion, if necessary, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the severity of the Sentinel or Never

Event.

(xiii) Entry of the discussion will be made into the patient's medical record by the attending physician or other provider that was a party to the discussion with the patient/family if the discussion did not include the attending physician.

Note: If the event, after examination, does not meet the definition of Sentinel or Never Event and is instead a known risk and complication, this outcome and the fact that the outcome was a known risk and complication should be fully documented in the medical record.

An example of the entry in the medical record would be: "Spoke with patient to describe stroke she had following catheter procedure. We discussed treatment plan and admission to rehabilitation. I also discussed fact that stroke was a potential complication that we discussed prior to the procedure. She recalled that discussion. She will be discharged to rehab and I will follow her there."

(k) If a patient or family member asks whether further information will be gathered and whether the patient or representative will be notified of the additional information, the patient or representative is to be informed that only the results may be released.

(l) Risk Management will proceed with notification of potential claims to insurers and Quality will proceed with ensuring that the events are taken through the proper channels for system improvements and data tracking.[1]

Approved by:	**Policies Superseded by This Policy: NONE**
/s/_____ Richard P. Swaine, CPA Chief Executive Officer – UTMC 09/30/2020_____ Date /s/_____ Amanda Lenhard, MD Chief of Staff 09/30/2020_____ Date *Review/Revision Completed by: Office of Legal Affairs/CEO*	Initial effective date: 12/12/2001 Review/Revision Date: 5/1/2008 8/27/2013 1/2/2014 7/1/2017 2/4/2019 9/1/2020 Next review date: 9/1/2023

[1] May be handled differently if provider is not insured by the University's captive.