Name of Policy: Communication of Serious Adverse 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 **Effective Date**: July 1, 2017 **Initial Effective Date**: December 12, 2001

_____	New policy proposal	X	Minor/technical revision of existing policy
_____	Major revision of existing policy	_____	Reaffirmation of existing policy

(A) Policy Statement

It is the policy of The University of Toledo that patients are treated with openness, honesty and empathy and that a patient's right to know their medical status is respected.

(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 Serious Adverse Events enables patients to make informed decisions regarding future medical care. The communication of Serious Adverse Events demonstrates respect for the patient, professionalism, accountability, and a commitment to improving care.

(C) Serious Adverse Events

A Serious Adverse Event is an event with an unanticipated outcome resulting in death, or severe or permanent harm.
A Sentinel Event is a Serious Adverse Event that involves an unexpected event resulting in death, serious physical harm, psychological injury, or the risk thereof that involves any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Sentinel Events include any events that meet the following criteria:

- 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, including but not limited to:
  - Unanticipated neurological, sensory or systemic deficits, including brain damage, spinal cord injury, paralysis or nerve injury, organ failure or sepsis.

- Severe burns, including thermal, chemical, radiological or electrical, resulting in extensive hospitalization and/or skin grafting.
- Severe internal injuries, lacerations, infectious processes, or sensory or reproductive organ injuries.
- Substantial disabilities, including fractures, amputations or disfigurements.

- 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.
  - Birth related injury, including maternal or fetal death.
  - Discharge of an infant to the wrong family.
  - Abduction of any individual receiving care, treatment or services.
  - Sexual abuse/assault (including rape) of any patient/individual receiving care, treatment or services.
  - 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 at UTMC.
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities. (i.e. ABO, Rh, other blood groups)
  - Surgery and non-surgical invasive procedure on the wrong patient, wrong site or wrong procedure.
  - Unintended retention of a foreign object in a patient after surgery or other invasive procedures.
  - 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.

Kidney transplant safety events are defined in Adverse Event Policy #3364-140-45 and will be reported and investigated as defined in this policy.

(D) Protocol for Communicating Serious Adverse Events or Sentinel Events to the Patient/Family:

1. The physician and support staff must first ensure the patient is safe and ensure that a treatment plan is in place for the patient.

2. Any nurse, physician, medical student, resident, or UTMC employee who is aware of the Serious Adverse Event must notify his/her unit manager, the House Supervisor and enter an Incident Report into Patient Safety Net.

3. The House Supervisor will notify the Administrator-On-Call and the Vice President of Medical Affairs (VPMA), or a designee of the VPMA if the VPMA is not available, as per the Communication Flow Chart, which is attached for reference, of the Sentinel Events/Adverse Events policy # 3364-100-50-38.

4. The VPMA follows through with notifying individuals of the Serious Adverse Event as per the Communication Flow Chart.

5. The VPMA (or the VPMA's designee) will determine if the I'm Sorry Protocol should be initiated and make the preliminary decision as to the appropriate make- up of the Event Support Team (EST). The VPMA (or the VPMA's designee) will notify Legal Affairs/Risk Management Department to initiate the I'm Sorry Protocol.

6. If the I'm Sorry Protocol is to be initiated, Legal Affairs/Risk Management Department will notify the EST. At least three members of the EST must be notified and participate in the I'm Sorry discussion. Members of the EST include:

    a. Vice President of Medical Affairs;
    b. Chief Nursing Officer;
    c. Administrator for Surgical Services (when involving surgical procedure);
    d. Chief Executive Officer, UTMC;
    e. Risk Manager;
    f. Chief Administrative Officer, Quality and Patient Safety;
    g. Service Excellence Officer;
    h. Legal Counsel; and
    i. Patient & Family Support & Pastoral Care.

7. 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.

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

9. 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.

10. Communication held with the Patient/Family

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

    b. 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.

    c. 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.

    d. 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.

    e. The timing of the discussion regarding a Serious Adverse 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.*

f. 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.

g. At a minimum, the patient will be informed about:

   i. The factual information of the outcome that occurred.
   ii. Any known repercussions that the outcome may have on the patient's care and on short-and-long-term health.
   iii. The proposed plan to respond to these repercussions and ways that are being implemented to fix the problem(s).
   iv. Point of contact for further questions or follow-up.
   v. In the event of a preventable Serious Adverse Event, an apology is very important to the discussion and promotes humility and empathy. When discussing a preventable Serious Adverse 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."

h. How to communicate necessary information with the patient:

   i. Delivery of the Serious Adverse Event discussion will be with empathy and compassion, communicating and detailing all known and relevant facts.

   ii. The discussion regarding a Serious Adverse 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.

   iii. 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.

   iv. Patients should be given time and opportunity to ask questions.

i. 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.

j. The communication of full disclosure of the Serious Adverse 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.

k. In cases involving the death of a patient:

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

11. 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 Serious Adverse Event.

12. 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 Serious Adverse 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."

13. 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.

14. 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.*

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

Approved by:	**Review/Revision Date:**
21 Aug 2017 Daniel Barbee, RN, BSN, MBA Chief Executive Officer - UTMC — Date	12/12/2001 5/1/2008 8/27/2013 1/2/2014 7/1/2017
2-22-17 Samer Khouri, M.D. Chief of Staff — Date	**Next Review Date:** 7/1/2020
Policies Superseded by This Policy: *3364-100-60-10 Disclosure of Unanticipated Outcomes*	

Communication Flow Chart