


Name of Policy: <u>Transplant Adverse Events</u> Policy Number: 3364-140-45 Department: Transplant Administration Approving Officer: Chief Nursing Officer Director, Renal Transplant Director, Pancreas Transplant Responsible Agent: Transplant Team Scope: The University of Toledo Medical Center	 Effective Date: July 1, 2024 Initial Effective Date: May 26, 2016				
<table> <tr> <td><input type="checkbox"/> New policy proposal</td> <td><input checked="" type="checkbox"/> Minor/technical revision of existing policy</td> </tr> <tr> <td><input type="checkbox"/> Major revision of existing policy</td> <td><input type="checkbox"/> Reaffirmation of existing policy</td> </tr> </table>		<input type="checkbox"/> New policy proposal	<input checked="" type="checkbox"/> Minor/technical revision of existing policy	<input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Reaffirmation of existing policy
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(A) Policy Statement

This policy provides a standardized process for the reporting, management, analysis, disclosure, and prevention of adverse events, which result from an organ donation by living donor or organ transplantation. Our desire is to promote patient wellness and optimize safety.

This policy does not supersede any University of Toledo Medical Center (UTMC) patient safety policies. It works in tandem with UTMC policy by providing supplemental processes necessary for compliance with transplant specific federal standards and regulations. These federal requirements are described in the Centers for Medicare & Medicaid Services (CMS) Title 42: Public Health, Part 482 – Conditions of Participation for Hospitals, Subpart E – Requirements for Specialty Hospitals §482.96 Condition of participation: Quality assessment and performance improvement (QAPI), (b) Adverse events, and elements of the Organ Procurement and Transplantation Network (OPTN) Policy 15: Identification of Transmissible Disease and 18: Data Submission Requirements.

(B) Purpose of Policy

Provide a standardized process for the reporting, management, analysis, disclosure and prevention of adverse events resulting from organ donation by living donor and organ transplantation.

(C) Definitions

Adverse event is defined at §482.70 as “An untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.” Examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.” Additional examples include, but are not limited to, medication error contributing to graft loss or delayed function; surgical site infection or other hospital acquired infection; and unplanned return to the operating room for surgical complications. The phrase ‘or the risk thereof’ contained in the definition indicates that an adverse event does not require harm, death or serious injury to have occurred; but carries the risk of serious harm or death if the event occurs. Some examples of adverse events with the risk for serious harm or death include, but are not limited to: falls; medication errors; miss-labeled laboratory results/specimens; blood transfusion errors; allergic reactions; un-timely reporting of critical lab values; discharge planning that fails to address key medication and appointment instructions; or lack of proper ABO and other vital data verification. All adverse events should be entered into the Patient Safety Net in accordance with the Patient Safety Net Reporting Policy, 3364-100-50-39.

Incident: Any event which is not consistent with the desired, normal or usual operation of the hospital, department, or medical center. An injury does not have to occur for a report to be filed. All incidents should be entered into the Patient Safety Net in accordance with the Patient Safety Net reporting Policy, 3364-100-50-39.

Organ: A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine or any portion of the gastrointestinal tract), or vascular composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.” (*Reference OPTN Policy 1.2: Definitions*)

(D) Policy Procedure

1. It is the policy of UTMC Transplant Center to identify, report, and prevent Adverse or Sentinel events in transplant patients during any phase of transplantation, living donation, or implantation and the center abides by the hospital policy for reporting and reviewing these events.
2. Review and analysis of complications and adverse events are essential components of the transplant-specific QAPI program. These are reviewed monthly and quarterly as aggregate data to identify trends. The results are used to identify system patterns resulting in potential or actual patient harm that needs to be addressed through policy and process changes.
3. All patient safety incidents and events will be reported and managed in accordance with UTMC policies, Sentinel Events/Adverse Events Policy 3364-100-50-38 and Patient Safety Net Reporting Policy 3364-100-50-39. Adverse events in all phases of transplant recipient or LD care must be reported to the hospital per hospital policies and procedures.
4. CMS CoPs describe adverse events directly resulting from an organ donation by living donor or organ transplantation to include, but are not limited to:
 - a. Serious medical complications or death caused by living donation.
 - b. Unintentional transplantation of organs of mismatched blood types.
 - c. Transplantation of organs to unintended recipient.
 - d. Unintended transmission of infectious disease to a recipient.
5. The Organ Procurement & Transplantation Network (OPTN) requires the timely reporting of transplantation and living donor adverse events through the United Network for Organ Sharing (UNOS) Improving Patient Safety System. The UNOS Improving Patient Safety System can be accessed via the on-line portal contained on the UNet homepage. OPTN policy requires that the transplant program report all transplantation and living donor adverse events through the Improving Patient Safety System within 72 hours of becoming aware of any of the following events:
 - a. A transplant of the incorrect organ into an organ recipient occurs
 - b. A transplant of an organ in the incorrect organ recipient occurs
 - c. A donor organ is identified as incorrect during pre-transplant processes conducted according to either UNOS Policy 5.8 A: Pre-Transplant Verification Prior to Organ Receipt or Policy 5.8 B: Pre-Transplant Verification Upon Organ Receipt
 - d. The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either UNOS Policy 5.8 A: Pre-Transplant Verification Prior to Organ Receipt or Policy 5.8 B: Pre-Transplant Verification Upon Organ Receipt
 - e. An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ
 - f. The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ
 - g. An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either UNOS Policy 5.8 A: Pre-Transplant Verification Prior to Organ Receipt or Policy 5.8 B: Pre-Transplant Verification Upon Organ Receipt
 - h. A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia, a report must be submitted within 72 hours of the aborted organ recovery procedure.
 - i. A living donor dies within 2 years after the organ donation
 - j. A living kidney donor is listed on the kidney wait list within 2 years after organ donation.
 - k. A living kidney donor begins regularly administered dialysis as an ESRD patient within 2 years after organ donation
 - l. A living donor organ is recovered but not transplanted into any recipient, a report must be submitted within 72 hours of the organ recovery.

m. A living donor organ is recovered and transplanted into someone other than the intended recipient, a report must be submitted within 72 hours of the organ recovery.

6. OPTN policy requires the reporting of incidents when a recipient is “suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition, including infections and malignancies, and there is substantial concern that it could be from the transplanted organ.” the Transplant Center will notify by phone and provide documentation to, within 24 hours of learning of the event, the living donor hospital, if applicable, and the Organ Procurement Organization (OPO). The center will report the event through the OPTN Improving Patient Safety Portal as soon as possible. If the Adverse Event was related to an infectious disease present in a recovered organ from a deceased donor that could have been transmitted to other recipients who received organs from that same donor, or an otherwise compromised organ that was not detected either through the donor screening or organ transport process, it must be reported to the OPO by the Transplant Center.

7. In addition, the transplant program requires reporting of the triggers noted below to one of the following people: surgical director, medical director, a member of the QA staff or the program administrator. These will be reviewed at the program quality meetings but may not necessarily require a full RCA:

- a. Death or graft loss within the first year post-transplant
- b. All mortalities involving transplant service inpatients
- c. Primary graft non-function
- d. Unexpected return to the operating room after transplantation or living donation
- e. Other items identified in the Transplant Quality Plan
- f. Other events which are identified via the hospital’s electronic Event Reporting System (e.g. falls without injury, mislabeled specimens, and other issues which do not result in harm to the patient)

RESOURCES:

UNOS Policy 14.0 – Living Donation:

http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_14

COP Quality Assessment and Performance Improvement (X099-X104) -

<https://www.cms.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf> - CMS 482.96

UNOS Policy 15.0 – Identification of Transmission

http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_15

UNOS Policy 18.0 – Data Submission Requirements

http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf

Policies Superseded by This Policy: