Clinical Process Instruction Manual

Tissue Error/Accident or Adverse Outcome Process Instruction

Policy:

As a referral and recovery agency for deceased tissue donors, Trillium Gift of Life Network (TGLN) is responsible for providing information to the Tissue Banks to determine safety and quality of tissues for transplantation. TGLN ensures that the requirements of the *American Association of Tissue Banks (AATB) - Standards for Tissue Banking* that it is responsible for are met. If a transplant program, tissue bank or another organ procurement organization (OPO) notifies TGLN that they have reasonable grounds to believe that the safety of tissue, organ or composite tissue has been compromised by an error or accident (E/A) or Adverse Outcome (AO), TGLN will assist the reporting organization with their investigation. As defined by the *AATB – Standards for Tissue Banking*, an:

"Error" *means a deviation from the Clinical Process Instruction (CPI), Standards, applicable laws, or regulations during donor screening or testing, or tissue recovery, collection or acquisition, processing, quarantining, labelling, storage, distribution, or dispensing that may affect the performance, biocompatibility, or freedom from transmissible pathogens of the tissue or the ability to trace tissue to the donor. (Example – TGLN forgets to perform a blood draw for serology.)*

"Accident" *means any occurrence, not associated with a deviation from a CPI, standards, or applicable laws and regulations, during donor screening or testing, or tissue recovery, collection or acquisition, processing, quarantining, labelling, storage, distribution, or dispensing that may affect the performance, biocompatibility, or freedom from transmissible pathogens of the tissue or the ability to trace tissue to the donor. (Example – TGLN performs a screening test which shows a negative result and another establishment performs the same test which turns out to be positive. Therefore, a confirmatory test needs to be done.)*

"Adverse Outcome" *means an undesirable effect or untoward complication in a recipient consequent to or reasonably related to tissue transplantation.*

"Deviation" *means an event that is a departure from a CPI or normal practice.*

Upon notification of an incident, which is typically after organ or tissue distribution, TGLN will determine whether the error, accident or adverse outcome affects organs for which TGLN is the source establishment. For errors, accidents and adverse outcomes that affect organ recipients, TGLN processes them in accordance with *Error/Accident Process Instruction, CPI-9-804* and *Unexpected Serious Adverse Reaction Process* Instruction, CPI-9-805.

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Incidents that involve only tissues where recipient safety is a concern, TGLN will provide requested information and cooperate with the Tissue Banks' investigation. Incidents that only involve quality of tissue recovered from a donor shall be processed in accordance with *Corrective and Preventative Action, QSP-14-1*.

Process:

Initial intake of Error/Accident or Adverse Outcome Incidents

1. When TGLN is advised of an error/accident or adverse outcome after tissue recovery, the Tissue Coordinator (TC) or designate performs the following tasks:

    1.1 Obtains the TGLN identification number of the donor.

    1.2 Determines if organs were recovered from the donor. If so, the TC or designate reports the error, accident or adverse outcome to the Clinical Services Coordinator (CSC) for reporting. If no organs are recovered, the TC or designate determines if the incident could affect recipient safety.

    1.3 If the incident could affect or affects recipient safety, the TC or designate informs the Tissue Bank that they will need to carry out their Error/Accident or Adverse Outcomes process. The TC or designate will provide the Tissue Bank with the contact information for other tissue banks that received tissues, if requested.

    1.4 Ensures that any implicated tissue(s) in TGLN's possession are quarantined in the designated surgical recovery storage room.

    1.5 Contacts the Director Quality or designate verbally and/or via email, after hours and on weekends.

    1.6 The TC or designate charts all information related to the Error/Accident or adverse outcome in the clinical notes.

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Error/Accident or Adverse Outcome Investigation where Patient Safety is of a concern

2. Director Quality or designate is responsible for aiding the Tissue Bank's investigation of the incident.

3. Director Quality involves the Medical Director – Tissue or designate to assist in the investigation.

4. Director Quality or designate obtains the final report from the reporting tissue bank for TGLN's records.

Error/Accident where Tissue Quality is of a concern

5. Incidents that do not affect patient safety do not require notification of tissue banks. The Director Quality or designate is responsible for raising a corrective action in accordance with *Corrective and Preventative Action, QSP-14-1*

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Tissue Bank Final Report	--	Quality Assurance Department	Quality Assurance Department	16 years

References:

- *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. A2.000, K4.000.