



Clinical Process Instruction

Emerging Diseases, Endemics and Pandemics Process Instruction

Policy:

From time to time, emerging diseases, endemics and pandemics may occur. As such TGLN must be prepared to handle these situations as it relates to asking pertinent questions on the existing donor medical social and history questionnaire (MSHx), developing screening tools, identifying cases which have been affected by these situations and any steps required to ensure donation and transplantation is facilitated in a safe manner with compliance to Health Canada requirements.

This process instruction provides the methodology of ensuring all steps are taken by TGLN in response to an emerging disease, endemic or pandemic to ensure safe donation and transplantation.

Process:

Identification of emerging diseases, endemics and pandemics and the action plan

1. Health Canada, American Association for Tissue Banks (AATB), Eye Banks of America Association (EBAA), Tissue Banks, Transplant Programs and/or TGLN Clinical Leadership identifies an emerging disease, endemic, and/or pandemic situation and notifies the Director Quality.
2. The Director Quality will immediately call a meeting with TGLN Clinical Leadership to develop an action plan for addressing any gaps in documentation to ensure the safety and efficacy of organs and/or tissues recovered and transplanted. The action plan should also address a containment plan to use existing documentation and methods to evaluate the safety and efficacy of organs and/or tissues as a result of the emerging disease, endemic and/or pandemic.
3. The Director- PRC Organ, Director – Tissue Program, Director Hospital Programs and/or their designates should meet with Human Resources (HR) to discuss any Health and Safety issues that may affect clinical staff.
4. The Director Quality will carry out the action plan which must include items listed in the sections below at a minimum. Director Quality will track the completion of the action plan and revise the plan as necessary.
5. If items in the action plan which are deemed necessary can not be carried out in a timely manner to ensure the efficacy and safety of organs, the Director Quality will recommend all organs be offered as per *Exceptional Distribution, CPI-9-217* with the possible transmission of the emerging disease, endemic and/or pandemic being the reason for exceptional distribution.



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Donor Medical and Social History Questionnaire

6. Hospital Programs Manager(s) and Manager PRC Tissue notify staff which situation has occurred and reminds staff to ask questions regarding the disease or disease agent identified in the context of the current donor medical and social history questionnaire (Questions 33, 34 and 71). These questions relate to emerging diseases which include endemics and pandemics.
7. Director – PRC Organ, Director – Tissue Program or designate will identify any changes to the *Donor Medical and Social History Questionnaire, CSF-9-14* and the *Donor Medical and Social History Questionnaire Rationale, CSF-9-13* and submit them to the Quality Department. The Director, Quality may choose to implement a supplemental MSHx until the changes to the electronic MSHx can be implemented in iTransplant. Changes to iTransplant are done in accordance with *iTransplant Change Request Process Instruction, QPI-9-1*.
8. For tissue exclusive donors, the Director – Tissue Program or designate will identify any changes to the following documents and submit them to the Quality Department:
 - *Eye-Only Uniform Donor Risk Assessment Interview (Donor > 12 years old), CSF-9-214*
 - *Eye-Only Uniform Donor Risk Assessment Interview (Child Donor ≤ 12 years old), CSF-9-215*
 - *Eye-Only Uniform Donor Risk Assessment Interview Birth Mother, CSF-9-216*
9. If no changes are required, the Director Quality will record in the Action Plan that the MSHx Questionnaire and MSHx Questionnaire Rationale was reviewed and deemed to be acceptable.

Emerging Diseases, Endemics and Pandemics Screening Tools

10. Director – PRC Organ or designate will identify if a screening tool is required for organ donors. If so, they will develop the tool in association with any available information on the emerging disease, endemic and/or pandemic in consultation with the Transplant Support Physician – Infectious Diseases (TSP-ID).
11. Director – PRC Organ is responsible for ensuring the TSP-ID reviews the final draft of the document and approves it in a timely manner (ideally within 24 hours).
12. If the TSP-ID does not respond within 24 hours, it will be assumed the draft document has been approved by them for use.



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13. Director – Tissue Program or designate may implement a separate screening tool which may or may not be used in conjunction with the organ donor screening tool. Similar to the organ screening tool, the tissue screening tool will be sent to the Director Quality for approval prior to use.
14. Screening tools may be used in draft form as the situation develops as approved by the Director Quality. In this situation, the document receives quality review status in TGLN's Quality Management System (QMS). The document will be then sent for read and understand immediately to all clinical staff via iTransplant's log-in acknowledgement feature. More details for the use of draft documents and their approval can be found in *Document and Data Control, QSP-5-1*. The Quality Team Lead or designate is responsible for maintaining records of the Director Quality's approval and read and understand documentation.
15. Quality Team Lead publishes both drafts or final screening tools to the Online Resource Centre (ORC) in a location as determined by the Director Quality. Staff will only use the version posted to the ORC as it will be the most up-to-date approved for use copy available.
16. Once a finalized screening tool is developed, the Director – PRC Organ and/or PRC Manager – Tissue will submit the finalized form to the Quality Department to become a controlled document.

Tracking

17. For each donor that is affected by an emerging disease, endemic and/or pandemic, it shall be documented in the donor chart in a location determined by the Director – PRC Organ or designate.
18. Director Quality or designate will gather data from identified cases to determine effectiveness of operations and may present it to the VP, Clinical Transplant Systems or designate when deemed necessary.

Emerging Diseases, Endemics and/or Pandemics Action Plan Review

19. Director Quality will review the completed action plan for comprehensiveness and completeness to determine if any corrective or preventive actions are required in order to create lessons learned to provide TGLN Senior Leadership with opportunities to improve TGLN's response to future emerging diseases, endemics and/or pandemics. This will be performed at a minimum of once per situation identified.



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Records:

- No records

References:

- Document and Data Control, QSP-5-1
- iTransplant Change Request, QPI-9-1
- Donor Medical and Social History - Organ or Combined Organ & Tissue, CPI-9-207
- Exceptional Distribution, CPI-9-217
- Deceased Donor Exclusion Criteria and Suitability Screening, CPI-9-218
- Medical & Social History – Tissue, CPI-9-261