The Ottawa Hospital | L'Hôpital d'Ottawa

NEPHROLOGY PROGRAM
DEPARTMENT POLICIES AND PROCEDURES

Renal Transplant - Section 05 - Quality Management - RTP 5-11
Living Kidney Donation Error/Accident Reporting Procedure
No.: 01513 (TOH Standardized Policy Number)

ISSUED BY:
Living Donor Working Group /
Renal Transplant Steering Committee

DATE OF APPROVAL:
2011/08

APPROVED BY:
Program Clinical Director / Program Division Head &Transplant Medical Director

Dr. G. Knoll Signature: _____ 09/2019

LAST REVIEW/REVISION DATE:
2018/08

CATEGORY:
Quality Management

IMPLEMENTATION DATE:
2011/08

POLICY STATEMENT:

- The Ottawa Hospital (TOH) Renal Transplant Program (RTP) as a source establishment for living kidney donation is responsible for determining the safety of living kidney donor organs for transplantation in keeping with Health Canada Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues & Organs for Transplantation (2009)

DEFINITION(S):

- "Error" means a deviation from the standard operating procedure (SOP) or applicable laws that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of cells, tissues or organs. (Example – TOH forgets to perform a required screening test)

- "Accident" means an unexpected event that is not attributable to a deviation from the SOP or applicable laws and that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of cells, tissues or organs. (Example – TOH performs a screening test that shows a negative result and another establishment performs the same test, which turns out to be positive therefore, TOH performs a confirmatory test)

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ALERTS:

- The Cells, Tissues and Organs (CTO) Regulations require that suspected errors or accidents (E/A) identified after distribution of CTO and that could lead to a serious adverse reaction involving the transmission of an infectious disease or disease agent, must be reported to Health Canada within 24 hours after the start of the investigation. When TOH RTP retrieves locally or accepts a living kidney donor at TOH from an Ontario or out of province hospital, TOH is considered "**the source establishment**". In the event that TOH RTP has reasonable grounds to believe that, the safety of a living donor kidney that is or was in its possession has been compromised by the occurrence of an error or accident during processing, the following steps must take place immediately

PROCEDURE:

1. Quarantine any implicated organs in its possession

2. Send a notice to all of the following establishments:

- Any source establishment from which it received the donor referral, if applicable,
- Any source establishment to which it made a donor referral, if applicable, and
- Any establishment to which it distributed implicated organs.

3. The notice must include all of the following information:

- The reasons for the establishment's belief that the safety of the donor kidney has been compromised;
- An explanation of how the safety of the implicated donor kidney may have been compromised, if known;
- The donor identification codes of the implicated donor kidney; and
- The name of any suspected transmissible disease or disease agent, if known.

4. Initiate an investigation into the suspected error or accident

5. Enter suspected error or accident into TOH Patient Safety Learning System (PSLS)

6. If, on receipt of a notice from an establishment that is not a source establishment, TOH RTP does not have reasonable grounds to believe that an investigation is necessary; TOH RTP must notify the establishment to that effect in writing and provide its reasons for the decision not to conduct an investigation

7. If TOH RTP receives a notice from a source establishment or a copy of such notice must immediately take both the following actions:

- Quarantine all implicated organs in its possession; and
- Forward a copy of the notice to every establishment to which it distributed implicated organs.

8. Notify the following establishments:

- The relevant source establishment, and
- If the kidney was imported, the establishment that imported them.

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Initial Error/Accident Reporting

9. When TOH becomes aware of or is advised of an error/accident after organ distribution, the Living Donor Coordinator (LDC)/Manager or designate performs the following tasks:

- Notifies the Medical director and Manager of the Renal Transplant program, who will then notify the Clinical Director of the TOH nephrology programs
- Obtains the TGLN/MRN identification number of the donor. Reviews the corresponding donor chart to determine the accepting program and recipient identification number, if available
- Immediately telephones all accepting transplant programs, and notifies all pertinent establishments that an error/accident has been detected in the donor processing. The LDC provides an explanation of how the kidney may have been compromised, if known. The LDC documents these conversations in the donor chart
- Documents the *Suspected Errors/Accidents* on the error/accident form FRM-0172: Human Cells, Tissues and Organs for Transplantation - Error or Accident Investigation Preliminary Report. Faxes the report to the relevant organ establishments
- The Medical Director, Manager and Clinical director are also provided with a copy of the report

Error/Accident Preliminary Investigation Reporting

During business hours, the LDC/Manager or designate, completes FRM-0172: Human Cells, Tissues and Organs for Transplantation - Error or Accident Investigation Preliminary Report. The LDC/Manager or designate faxes the report to Health Canada within 24 hours of notification of the error/accident

10. The Medical Director or designate notifies the VP, Clinical Services of the error/accident

Error/Accident Follow-up

11. The LDC/Manager or designate is responsible for initiating an investigation into the error/accident. If it is determined that this investigation is not warranted, the reason for not further investigating will be documented in the file

12. The LDC/Manager or designate provides an update on the error/accident investigation to Health Canada after 15 days, and every 15 days thereafter until completion of the investigation

13. The LDC/Manager or designate submits a final report upon case closure, to Health Canada, including the results, root cause if known, final disposition of organ(s) and any corrective actions taken. The final report is provided to all establishments that were notified of the error/accident

14. The LDC/Manager or designate files all reports submitted to Health Canada and other establishments in the donor and recipient chart as required

Record Name	Record Holder	Record Location	Record Retention Time
1. Human Cells, Tissues and Organs for Transplantation – Error or Accident Preliminary Investigation – HC FRM 0172 (Oct 2012).	TOH RTP	TOH RTP SOP Folder: Nephrology VDrive	25 years

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RELATED POLICIES / LEGISLATION: N/A

REFERENCES:

1. Health Canada, Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues and Organs for Transplantation. current. http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/cell/cto_gd_ld-eng.php
2. Health Canada Guidance Document for Source Establishments – Reporting Adverse Reactions to Human Cells, Tissues and Organs. Health Canada, current.
3. Safety of Human Cells, Tissues and Organs for Transplantation Regulations. SOR/2007-118, current. Published by the Minister of Justice at: http://laws-lois.justice.gc.ca.
4. FRM-0172: Human Cells, Tissues and Organs for Transplantation - Error or Accident Investigation Preliminary Report http://www.hc-sc.gc.ca/dhp-mps/alt_formats/doc/compli-conform/info-prod/cell/frm-0172_doc-eng.doc

COMMENTS / SIGNIFICANT REVISIONS: N/A

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