The Ottawa Hospital | L'Hôpital d'Ottawa

NEPHROLOGY PROGRAM
DEPARTMENT POLICIES AND PROCEDURES

Renal Transplant Program - Section 05 - Quality Management - RTP 5-12
Living Kidney Donation Unexpected Serious Adverse Reaction
No.: 01514 (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 and / Transplant Medical Director

Dr. G. Knoll Signature: _____08/2018

LAST REVIEW/REVISION DATE:
2018/08

CATEGORY:
Quality Management

IMPLEMENTATION DATE:
2011/08

POLICY STATEMENT:

- As source establishment for living kidney donation and transplantation, The Ottawa Hospital (TOH) Renal Transplant Program (RTP) is responsible for determining the safety of living kidney organs for transplantation. TOH RTP ensures that the requirements of the *Safety of Human Cells, Tissues & Organs for Transplantation Regulations* are met. If a transplant program or another organ procurement organization to which an organ was supplied, notifies TOH RTP of an adverse reaction, TOH RTP will fully investigate the case and ensure the appropriate establishments are notified of the adverse reaction. TOH RTP will determine if the adverse reaction is serious and/or unexpected

- A Serious Adverse Reaction is defined as: "*An undesirable response in a tissue or organ recipient, including transmission of disease or disease agent".* It can result in any of the following consequences to the recipient of an organ or tissue transplant:

  a. in-patient hospitalization or its prolongation;
  b. persistent or significant disability or incapacity (including transmission of a disease or failure of the transplant's function or integrity);
  c. medical, dental or surgical intervention to preclude a persistent or significant disability or incapacity;
  d. a life-threatening condition; and
  e. death

- Only unexpected serious adverse reactions require Health Canada notification. As such, in cases of known risk (i.e. exceptional distribution), a serious adverse reaction does not need to be reported to Health Canada
- If the reaction is both serious and unexpected, TOH RTP will ensure it is appropriately reported to Health Canada (Canada Vigilance) and relevant establishments (transplant programs, organ procurement organizations)
- TOH RTP retains all documentation related to adverse reaction reporting and investigation in the TOH donor and recipient charts for a minimum of ten (10) years

DEFINITION(S): N/A

ALERTS: N/A

PROCEDURE:

TOH RTP as Source Establishment

1. When TOH retrieves locally or accepts a living kidney organ from an Ontario or out of province hospital, TOH is considered to be "the source establishment"

Initial Unexpected Serious Adverse Reaction Reporting

2. When TOH RTP becomes aware or is advised of an unexpected serious adverse reaction, the Living donor coordinator (LDC) 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 recipient and donor. Reviews the corresponding donor and recipient charts.
- Immediately telephones all accepting transplant programs, and notifies all pertinent establishments that an unexpected serious adverse reaction has been detected in the a recipient of the donor. The LDC or designate provides an explanation of how the kidney may have been compromised, if known. The LDC or designate charts these conversations in the donor chart
- Documents the *Serious Adverse Reaction Report* with the Canada vigilance report appendix I (see page 4). Faxes the report to the relevant organ establishments, such as:
  - Establishment which was distributed implicated organ
  - The Medical Director, Manager and Clinical director are also provided with a copy of the report

Canada Vigilance Reporting

3. During business hours, the LDC or designate, in collaboration with the Medical Director/Manager, completes the *Canada Vigilance Report*. See Appendix I for instructions on completing the *Canada Vigilance Report*. The LDC or designate faxes the report to Canada Vigilance within 24 hours of notification of the adverse reaction

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

Unexpected Serious Adverse Reaction Follow-up

5. The LDC or designate is responsible for initiating an investigation into the adverse reaction situation. If it is determined that this investigation is not warranted, the reason for not further investigating will be documented in the file
6. The LDC or designate provides an update on the adverse reaction investigation to Health Canada after 15 days, and every 15 days thereafter until completion of the investigation
7. The LDC or designate submits a final report to Health Canada upon case closure, 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 unexpected serious adverse reaction
8. TOH RTP files all reports submitted to Health Canada and other establishments in the TOH donor chart

DOCUMENTATION:

Record Name	Record Holder	Record Location	Record Retention Time
Canada Vigilance Report Adverse Reaction Reporting Form HC Pub 100251 (Jan 2011)	TOH RTP	TOH RTP SOP Procedures Folder: Nephrology VDrive	25 years

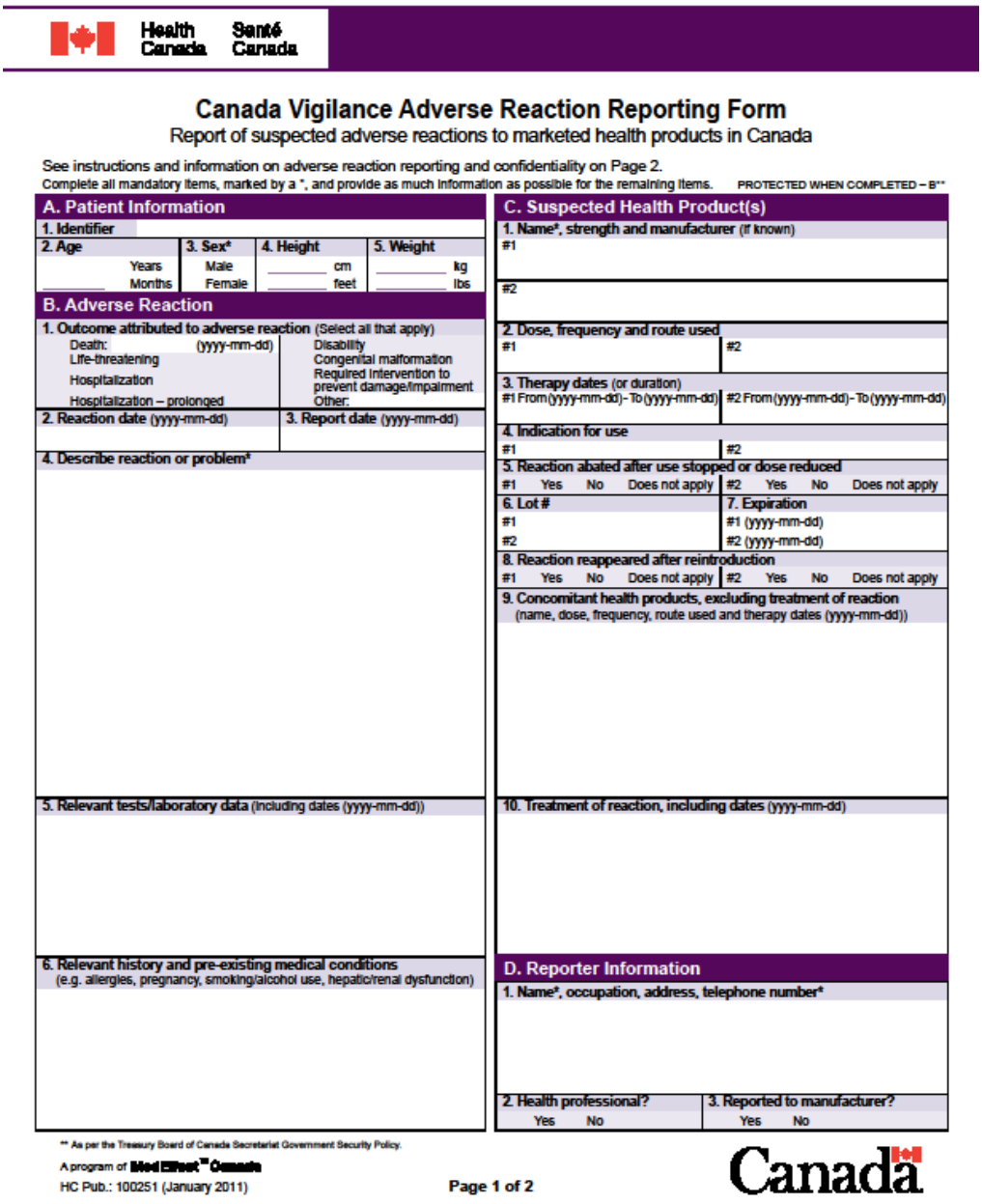
RELATED POLICIES / LEGISLATION: N/A

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. Canada Vigilance Report HC Pub 100251 (Jan 2011) Health Canada Adverse Reaction Reporting Form. www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php
5. Appendix I: Canada Vigilance Adverse Reaction Reporting Form http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/ar-ei_form-eng.pdf (page 4)
6. Appendix II: How to Fill Out the Health Canada Adverse Reaction (AR) Report (page 6)

COMMENTS / SIGNIFICANT REVISIONS: N/A

Appendix I: Canada Vigilance Adverse Reaction Reporting Form



Health Canada / Santé Canada

Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality on Page 2.

Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED – B**

A. Patient Information

1. Identifier

2. Age	3. Sex*	4. Height	5. Weight
Years / Months	Male / Female	cm / feet	kg / lbs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (Select all that apply)
Death: (yyyy-mm-dd); Life-threatening; Hospitalization; Hospitalization – prolonged; Disability; Congenital malformation; Required intervention to prevent damage/impairment; Other:

2. Reaction date (yyyy-mm-dd)

3. Report date (yyyy-mm-dd)

4. Describe reaction or problem*

5. Relevant tests/laboratory data (including dates (yyyy-mm-dd))

6. Relevant history and pre-existing medical conditions (e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

C. Suspected Health Product(s)

1. Name*, strength and manufacturer (if known)
#1
#2

2. Dose, frequency and route used
#1 #2

3. Therapy dates (or duration)
#1 From (yyyy-mm-dd) - To (yyyy-mm-dd) #2 From (yyyy-mm-dd) - To (yyyy-mm-dd)

4. Indication for use
#1 #2

5. Reaction abated after use stopped or dose reduced
#1 Yes No Does not apply #2 Yes No Does not apply

6. Lot #
#1
#2

7. Expiration
#1 (yyyy-mm-dd)
#2 (yyyy-mm-dd)

8. Reaction reappeared after reintroduction
#1 Yes No Does not apply #2 Yes No Does not apply

9. Concomitant health products, excluding treatment of reaction (name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

10. Treatment of reaction, including dates (yyyy-mm-dd)

D. Reporter Information

1. Name*, occupation, address, telephone number*

2. Health professional? Yes No

3. Reported to manufacturer? Yes No

** As per the Treasury Board of Canada Secretariat Government Security Policy.

A program of MedEffect™ Canada

HC Pub.: 100251 (January 2011)

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Canada

Instructions to Complete the Canada Vigilance Adverse Reaction Reporting Form

- Use this form only to report adverse reactions to Canadian marketed health products, including prescription and non-prescription medications; natural health products; biologically derived products such as vaccines and fractionated blood products; cells, tissues and organs; radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.
- All sections of the form should be filled in as completely as possible. Use a separate form for each patient. Up to two suspected health products for a particular adverse reaction may be reported on one form. Attach an additional form if there are more than two suspected health products for the adverse reaction being reported. Additional pages may be attached if more space is required.
- For the "Identifier" box, provide some type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information; do not use the patient's name. See the Confidentiality disclaimer at the bottom of this page.
- Any follow-up information for an adverse reaction that has already been reported can be submitted using a new form, indicating that it consists of follow-up information, including, if known, the date of the original report and the Adverse Reaction Number provided in the acknowledgement letter.
- **Reports can be faxed** to 1-866-678-6789 (toll-free) **or mailed** to: Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Postal Locator 0701E, Ottawa, Ontario K1A 0K9. Postage paid labels are available at www.health.gc.ca/medeffect or by calling 1-866-234-2345 (toll-free). Do not send reports by e-mail.

Information on Adverse Reaction Reporting

What is an adverse reaction?

An adverse reaction is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.

A serious adverse reaction is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

Which adverse reactions should be reported?

All suspected adverse reactions should be reported, especially those that are:

- *unexpected*, regardless of their severity, i.e., not consistent with product information or labelling; or
- *serious*, whether expected or not; or
- reactions to *recently marketed health products* (on the market for less than five years), regardless of their nature or severity.

Alternative ways to report

You can also report side effects to health products to the Canada Vigilance Program:

- By calling 1-866-234-2345 (toll-free)
- Online: www.health.gc.ca/medeffect

The Canada Vigilance Adverse Reaction Reporting Form is also available online at www.health.gc.ca/medeffect or at the back of the *Compendium of Pharmaceuticals and Specialties* (CPS).

Other Information

- Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.
- Adverse reaction reports are, for the most part, only suspected associations. A temporal or possible association is sufficient for a report to be made. Reporting of an adverse reaction does not imply a definitive causal link.
- Health professionals and consumers may also report adverse reactions to the market authorization holder (MAH). Indicate on your adverse reaction report sent to Health Canada if a case was also reported to the product's MAH.

For additional information, contact a Canada Vigilance Regional Office by telephone at 1-866-234-2345 (toll-free) or:

Canada Vigilance Regional Office – British Columbia and Yukon
400-4595 Canada Way, Burnaby, BC V5G 1J9
CanadaVigilance_BC@hc-sc.gc.ca

Canada Vigilance Regional Office – Alberta and Northwest Territories
Suite 730, 9700 Jasper Ave, Edmonton, AB T5J 4C3
CanadaVigilance_AB@hc-sc.gc.ca

Canada Vigilance Regional Office – Saskatchewan
101 - 22nd Street East, Saskatoon, SK S7K 0E1
CanadaVigilance_SK@hc-sc.gc.ca

Canada Vigilance Regional Office – Manitoba
510 Lagimodière Blvd, Winnipeg, MB R2J 3Y1
CanadaVigilance_MB@hc-sc.gc.ca

Canada Vigilance Regional Office – Ontario and Nunavut
2301 Midland Ave, Toronto, ON M1P 4R7
CanadaVigilance_ON@hc-sc.gc.ca

Canada Vigilance Regional Office – Québec
Suite 202-40, East Tower
200 René-Lévesque Blvd. West, Montréal, QC H2Z 1X4
CanadaVigilance_QC@hc-sc.gc.ca

For New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador:

Canada Vigilance Regional Office – Atlantic
Suite 1625, 1505 Barrington St., Halifax, NS B3J 3Y6
CanadaVigilance_ATL@hc-sc.gc.ca

Confidentiality

Personal information collected, used or disclosed under the Canada Vigilance Program is confidential and protected. For the purposes of the Canada Vigilance Program, information related to the identity of a patient and/or reporter of the adverse reaction will be protected as personal information under the Privacy Act, and under the Access to Information Act, in the case of an access to information request. Provision of the information requested on this form is voluntary. Information from adverse reaction reports is maintained in a computerized database and used for the monitoring of marketed health products, which may contribute to the detection of potential product-related safety issues, as well as to the benefit-risk assessments of these products. For details about personal information collected under this program, visit the Government of Canada web site on Institution-Specific Personal Information Banks under Health Canada, Health Products and Food Branch, Branch Incident Reporting System, PIB # ppu 088 at: http://infosource.gc.ca/inst/shc/fed07-eng.asp (Health Products and Food Branch, Branch Incident Reporting System).

Appendix II: How to Fill Out the Health Canada Adverse Reaction (AR) Report

Website:
www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php
Form:
http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/ar-ei_form-eng.pdf

Mark CTO at the top of the form

Section A: Patient Information

- In the "Identifier" box document the donor TGLN Identification number

Section B: Adverse Reaction

- In Box B1 check off all the boxes that are attributed to the Adverse Reaction
- Provide all relevant information including any information on the CTO that you are not able to provide in Section C

Section C: Suspected Product(s)

Box C1: - Provide the common name of the CTO followed by "Organ" in parenthesis [Kidney (Organ)]
- Include the TGLN donor identification number

Box C2: Not applicable
Box C3: Document date of transplant surgery
Box C4: Provide the diagnostic reason or indication for the transplantation
Box C5: Check "doesn't apply"
Box C6: Not applicable
Box C7: Not applicable
Box C8: Check "doesn't apply"
Box C9: Provide information on the drugs, biological products or devices that patient received (e.g. patient's regular medication, perfusion solution, blood transfusions, etc)

Section D: Reporter Information

- Indicate your name (the person reporting to Health Canada)
- Provide the name, mailing address, telephone, fax and email address of the "Privacy & Special Programs Officer"
- If you are a health care professional, check the appropriate box

Other Required Information

- Report Source: Indicate how TGLN became aware of the AR
- Indicate the date that TGLN was made aware/received information of the AR
- Mark "Preliminary Report"
- Include TOH's full address, telephone and CTO registration number (100043)

Fax the form to:

Canada Vigilance, MHPD, Health Canada,

Tunney's Pasture, Address Locator: 0701C, Ottawa, Ontario K1A 0K9 Fax: 613-957-0335