Ontario Guide for Reporting Transfusion Reactions

The "*Canadian Transfusion Adverse Event Reporting Form*" **(CTAERF)** can be used for reporting to the Ontario Transfusion Transmitted Injuries Surveillance System (TTISS-ON), Canadian Blood Services (CBS), Canada Vigilance Program (Health Canada) and Manufacturers of Plasma Derivatives. To download the CTAERF go to: http://www.transfusionmedicine.ca/sites/transfusionmedicine/files/ctaer_form-eng.pdf
Note: *Remove patient name and OHIP number before faxing or emailing the CTAERF.*

1. Reporting to Ontario Transfusion Transmitted Injuries Surveillance System (TTISS-ON)

All reactions (excluding minor allergic, febrile non-hemolytic and delayed serological) are reportable to TTISS-ON, including those that are not required to be reported to the Canada Vigilance Program, CBS or the Manufacturer of Plasma Derivative (e.g. Acute Hemolytic reaction due to a mislabelled specimen). TTISS-ON reports aggregate de-identified data to the Public Health Agency of Canada as part of the National TTISS program.

- **Enter information** collected using the **CTAERF** into the REDCap TTISS-ON database at https://ttiss.mcmaster.ca or **FAX** the **CTAERF** to 905-524-2983 (Attention: TTISS)

- To obtain a password to enter information in the TTISS-ON database, fill out the contact information form by clicking the link: https://ttiss.mcmaster.ca/surveys/?s=R7EEM83X7A

- For more information about TTISS-ON contact:
  Joanne Duncan, TTISS Ontario Coordinator, McMaster University, Hamilton
  Tel: 905-525-9140 ext. 22934 Email: duncanj@mcmaster.ca

2. Reporting to the Canada Vigilance Program (as per Health Canada Blood Regulations)

FAX or **Mail** the **CTAERF** to:

Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau (HPSEB)
Marketed Health Products Directorate/Health Products and Food Branch
Tunney's Pasture
Address Locator: 1908C
Ottawa, Ontario, K1A 0K9
Fax: 613-957-0335 & Telephone: (613) 957-0337
E-mail: hc.canada.vigilance.blood-sang.sc@canada.ca (**Do not send reports via email, for inquiries only)**

For reporting to Health Canada under the Medical Device Regulations:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/frm-0317-faq-eng.php

3. Reporting to Canadian Blood Services (CBS)

Refer to Page 2 and **FAX or mail** the **CTAERF** to:

Your local Canadian Blood Services Distribution Department

Note that if patient blood samples are being sent to CBS for testing, the patient's name is required

4. Reporting to Manufacturer of Plasma Derivative

Refer to Page 3 and **FAX** or **Email** the **CTAERF** to the appropriate Manufacturer of the implicated derivative. For contact information go to: https://www.blood.ca/en/hospitals/plasma-products and download the Manufacturer Contact List.

Reporting Transfusion Reactions to **BLOOD COMPONENTS*** for Hospital Transfusion Medicine Laboratories (TMLs)

**Red Blood Cells, Platelets, Frozen Plasma, Cryosupernatant Plasma, Cryoprecipitate*

Investigate and identify type of transfusion reaction**

***Referred to in this document as Adverse Transfusion Event (ATE) and in the Blood Regulations as Adverse Recipient Reaction (ARR)*

Is the ATE (ARR) one of the following?

- Minor Allergic
- Febrile Non-Hemolytic
- Delayed Serological

YES → No Further Reporting Required

NO

COMPLETE the Canadian Transfusion Adverse Event Reporting Form (CTAERF) *excluding patient name and OHIP No.*

Is the ATE the result of transfusion practice or due to an error at the bedside?

Examples: Transfusion associated circulatory overload (TACO); Incompatible transfusion due to mislabeled sample; Transfusing the wrong patient

Note: ATEs resulting from device malfunction (e.g. blood warmer, infusion pump) are also reportable to Health Canada - Medical Devices Regulations

YES

NO

Is the ATE (ARR) attributable to an activity at the hospital that affected the safety/efficacy of the component?

Examples:

- ATEs (ARRs) due to mislabeling of the component by the TML (e.g. unirradiated blood labelled as irradiated)

- Bacterial contamination due to pooling of component at the hospital or storing of blood in a malfunctioning fridge

-REPORT TO BOTH the Canadian Blood Services and the Canada Vigilance Program if it is not clear whether an ATE (ARR) is due to a hospital activity that affected the component or the component itself (e.g. contamination)

YES

Report ATE (ARR) to **Canada Vigilance Program and do required actions Section 110 of Blood Regulations** (Health Canada Blood Regulations)

FAX or mail CTAERF within 24 hours of a fatality, otherwise within 15 days *(see Instructions p.1)*

Final report is required once investigation is complete

NO

Is the ATE (ARR) one of the following?

- Transfusion-Related Acute Lung Injury (TRALI or Possible TRALI)
- Severe allergic reaction/anaphylaxis
- Bacterial contamination
- Post transfusion infection (e.g. HIV, Hepatitis, Chagas, Malaria, West Nile)
- Adverse events due to suspected CBS mislabelling
- Unexplained new acute severe neutropenia or thrombocytopenia (transfusion-related alloimmune neutropenia or thrombocytopenia)
- Other unusual reaction where the hospital is concerned the blood

YES

Report ATE (ARR) to **Canadian Blood Services (CBS)**

FAX the CTAERF to local Medical Office *(see Instructions p.1)* Report the ATE(ARR) immediately if fatality or if suspected to be attributable to quality of component (e.g. bacterial or viral contamination). Other reactions are to be reported as promptly/immediately as possible

Note: *CBS reports as required to the Canada Vigilance Program*

NO

Report ATE (ARR) to Ontario **Transfusion Transmitted Injuries Surveillance System (TTISS-ON)**

Enter data directly into the TTISS-ON web database or send CTAERF by **FAX** within 3 months *(see Instructions p.1)*

Reporting Transfusion Reactions to **PLASMA DERIVATIVES*** for Hospital Transfusion Medicine Laboratories

- *Referred to as Plasma Protein Products (PPPs) by Canadian Blood Services and Blood Products by Health Canada. These include IVIg, Prothrombin Complex Concentrate, RhIg, Albumin, S/D Plasma, Coagulation Factor Concentrates, etc.*

Investigate and identify type of transfusion reaction**

***Referred to in this document as Adverse Transfusion Event (ATE)*

Is the ATE (ARR) a minor reaction common to the plasma derivative (blood product)?
(ie. FNHTR or minor allergic)

NO → **YES**

Did the minor ATE (ARR) appear in "clusters"
(ie clusters of FNHTRs, or minor allergic reactions)

NO → No Further Reporting Required See ⌘

YES

YES

COMPLETE the Canadian Transfusion Adverse Event Reporting Form (CTAERF) *excluding patient name and OHIP No.*

Is the ATE (ARR) **serious** or acute as defined by the Food and Drug Regulations?
That resulted in:

a. Death
b. Life-threatening
c. Caused disability
d. Admitted to hospital
e. Lengthened hospital stay
f. Congenital malformation
g. Required medical intervention to avoid any of (a) to (f)

Examples:

- Serious acute/delayed hemolytic reactions
- Serious TACO/TAD/hypotensive reactions
- Aseptic meningitis
- Transfusion-Related Acute Lung Injury (TRALI or Possible TRALI)
- Severe allergic reaction/anaphylaxis
- Bacterial contamination
- Post transfusion infection (e.g. Hepatitis)
- Unexplained new acute severe neutropenia or thrombocytopenia (transfusion-related alloimmune neutropenia or thrombocytopenia)
- Other unusual reaction where the hospital is concerned the plasma derivative is the cause like acute kidney injury, thromboembolic event

OR

Is the ATE (ARR) CLUSTER of minor allergic or FNHTRs?

YES →

Report ATE (ARR) to **Canada Vigilance Program as per *Vanessa's Law* and the *Food and Drug Regulations*** **(Appendix 1)**
(Food and Drug Act)

FAX or mail CTAERF within 24 hours of a fatality, otherwise within 15 days
(see Instructions p.1)

Final report is required once investigation is complete

NO →

Report ATE (ARR) to **Manufacturer of Plasma Derivative (Blood Product)**

FAX or email the CTAERF to the appropriate manufacturer
(see Instructions p.1)

Report the ATE immediately if fatality or if suspected to be attributable to product quality (e.g. bacterial or viral contamination). Otherwise as soon as possible.
⌘ *Manufacturers do not discourage any reactions from being reported*

Report ATE to Ontario **Transfusion Transmitted Injuries Surveillance System (TTISS-ON)**
Enter data directly into the TTISS-ON web database to Ontario TTISS each month *(see Instructions p.1)* ⌘ *TTIIS encourages all reactions to be reported*

Appendix 1: Impact of Vanessa's Law (The Protecting Canadians from Unsafe Drugs Act)

Vanessa's Law will not impact the regulatory requirements with respect to investigation and reporting of adverse recipient transfusion reactions as per the *Blood Regulations (*sections 110- 116). What is meant by that is that transfusion ARs occurring with blood and blood components (labile blood products NOT further manufactured into plasma protein products [PPP] or fractionated plasma products or other manufactured plasma products with a DIN number) are to be reported as they are now. Vanessa's Law will not impact those.

Unlike blood components (labile blood products), plasma protein products (such as albumin, immune globulins, plasma-derived blood clotting factors like factor VIII, etc), are manufactured stable blood products that are regulated by Health Canada as drugs (under the *Food and Drug Regulations*). As such, plasma protein products (PPP) are subject to the new hospital mandatory reporting to Health Canada (Vanessa's Law).

What type of information about serious adverse drug reactions (ADRs) needs to be reported to Health Canada under Vanessa's Law?

Based on the proposed regulations, hospitals are required to report certain information about serious ADRs if the information is in the control of the hospital.

For serious ADRs (in this case involving PPP), the following information is required:

(a) the name of the hospital and the contact information of a representative of that hospital;
(b) the drug's brand name, proper name or common name;
(c) in the case of a drug imported under Part C, Division 10 of the Food and Drug Regulations (subsection C.10.001(2)), the identifying number or code of the drug;
(d) the drug identification number (DIN) assigned for the drug, if applicable;
(e) the patient's age and sex;
(f) a description of the serious adverse drug reaction;
(g) the date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug;
(h) the date on which the serious adverse drug reaction first occurred and, if applicable, the date on which the patient's health was restored to its state prior to the adverse drug reaction;
(i) any medical condition of the patient that directly relates to the serious adverse drug reaction;
(j) any concomitant therapeutic products used by the patient; and
(k) the result of the serious adverse drug reaction on the patient's health.

However, Health Canada are open to considering some flexibility in the form in which we are willing to accept reports of serious adverse drug reactions for different product lines. In order to reduce some of the administrative burden associated with having to complete two different forms to report a serious ADR related to a PPP (i.e. reporting to TTISS and hospital mandatory reporting to Health Canada), we may be able to consider accepting a completed TTISS form for a serious adverse reaction related to a PPP. As long as the regulatory requirements for hospital mandatory reporting (noted above) are met within the TTISS form this would be acceptable.