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)
Refer to Page 2 and **FAX** or **Mail** the **CTAERF** to:

Canada Vigilance Program
Marketed Health Products and Effectiveness Information Bureau
Marketed Health Products Directorate/Health Products and Food Branch
Health Canada, Postal Locator: 0701E
Ottawa, Ontario K1A 0K9
Fax (613) 957-0335 Telephone (613) 957-0337
E-mail: CanadaVigilance@hc-sc.gc.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 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 attributable to an activity at the hospital that affected the safety/efficacy of the component?

Examples:

- ATEs 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 is due to a hospital activity that affected the component or the component itself (e.g. contamination)

YES → Report ATE to **Canada Vigilance Program** (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 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 component is the cause

YES → Report ATE to **Canadian Blood Services (CBS)**

FAX the CTAERF to local Medical Office *(see Instructions p.1)*

Report the ATE immediately if fatality or if suspected to be attributable to quality of component (e.g. bacterial or viral contamination). Otherwise as soon as possible.

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

NO

Report ATE 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

**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 a minor reaction common to the plasma derivative?
(e.g. Minor Allergic)

YES → No Further Reporting Required See ⌘

NO

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

Could the ATE have been caused by an activity at the hospital that affected the safety/efficacy of the product or is the ATE due to a complication of transfusion practice or an error?

Examples: *improper storage, contamination during pooling, Transfusion Associated Circulatory Overload (TACO)*

REPORT TO BOTH **the Manufacturer of the Plasma Derivative and TTISS-ON if it is not clear whether suspected bacterial contamination is due to an activity at the hospital**

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

NO

Is the ATE serious as defined by the Food and Drug Regulations?

Examples:

- Serious acute/delayed hemolytic 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

YES → Report ATE to **Manufacturer of Plasma Derivative**

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*

Note: *The Manufacturer is required to report to the Canada Vigilance Program*

NO → Report ATE to Ontario **Transfusion Transmitted Injuries Surveillance System (TTISS-ON)**

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

Acknowledgement

Created by the TTISS-ON Education Committee

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