



**Transfusion Medicine Best Practices
Policy: Reporting Adverse Transfusion Events**

1.0 Policy Statements

- 1.1 All Regional Health Authorities shall have policies and procedures in place for documentation, reporting, investigation, evaluation and follow-up of all adverse transfusion events deemed related to transfusion of blood components or administration of plasma derived blood products.
 - 1.1.1 All verbal communication shall be documented, and written notices shall be sent as soon as possible.
- 1.2 All Regional Health Authorities shall have policies and procedures in place for documentation, reporting, investigation, evaluation and follow-up of all incidents, errors and accidents.
- 1.3 Notification shall be provided as applicable to:
 - 1.3.1 Blood Supplier;
 - 1.3.2 Manufacturer;
 - 1.3.3 Provincial Authorities;
 - 1.3.4 Health Canada; and
 - 1.3.5 Minister of Health, Government of Canada.
- 1.4 All adverse transfusion events shall be immediately reported to the transfusion medicine laboratory.
 - 1.4.1 Adverse transfusion events attributable to the transfusion of blood components shall be reported to:
 - 1.4.1.1 Canadian Blood Services, as applicable.
 - 1.4.1.2 The Public Health Agency of Canada.
 - 1.4.2 Notification of adverse transfusion events attributable to the administration of plasma protein products shall be reported to:
 - 1.4.2.1 Health Canada, MedEffect - Canada Vigilance Program.
 - 1.4.2.2 The Public Health Agency of Canada (TTISS).
 - 1.4.3 Adverse transfusion events attributable to the *quality* of the blood component or blood product shall be *immediately* reported to the blood supplier or the blood product manufacturer as applicable.
- 1.5 If an adverse transfusion event is attributable to an error or accident that occurred during transformation or storage activities carried out by the transfusion medicine laboratory, all affected establishments shall be informed of the error or accident.

- 1.5.1 The Regional Manager, Inspectorate Program shall be notified of any errors and/or accidents during transformation or storage activities.
- 1.5.2 The Biologics and Genetic Therapies Directorate (BGTD) shall be notified of any adverse recipient reactions attributable to an error or accident during transformation or storage activities.

2.0 Linkages

Blood, Tissues, Organs and Xenografts Unit, Health Products and Food Branch Inspectorate. Available at:

<http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/insp-btox-stox-eng.php>

Canada Vigilance Reporting Form. Available at:

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

MedEffect Canada-Canada Vigilance Program. Available at:

<http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php>

3.0 Scope

This policy applies to:

- 3.1 All health care professionals who participate in transfusion of blood components and/or administration of plasma derived blood products.
- 3.2 All transfusion safety officers or designated laboratory technologists.
- 3.3 Provincial Blood Coordinating Program.

4.0 General Information

5.0 Process

5.1 Procedure – Nursing

- 5.1.1 **All** adverse transfusion reactions, mild to death, shall be immediately reported to the transfusion medicine laboratory.
- 5.1.2 **All** transfusion-related errors, accidents or incidents shall be reported to the transfusion medicine laboratory.
- 5.1.3 The attending health care provider shall be notified of adverse transfusion events.

5.2 Procedure – Transfusion Safety Officer or Laboratory Technologist

- 5.2.1 Adverse transfusion event and /or error/accident reports shall be submitted by the transfusion safety officer or designated laboratory technologist to appropriate authorities as required by regional, provincial/territorial, and national regulations.
- 5.2.1.1 Adverse events shall be reported to the Newfoundland and Labrador Provincial Blood Coordinating Program. The completed Canadian Transfusion Adverse Event Reporting Form shall be sent to the Program.
- 5.2.1.2 Adverse events related to blood products shall be reported to the MedEffect - Canada Vigilance Program.
- 5.2.1.3 Errors and/or accidents that occur during transformation or storage activities carried out by the transfusion medicine laboratory shall be reported to all affected establishments, and to the Biologics and Genetics Therapies Directorate (BGTD).
- 5.2.1.4 Adverse events shall be entered into the Clinical Safety Reporting System as per Regional Health Authority policy.
- 5.2.2 All *serious or unexpected* adverse transfusion events (See Guidelines) attributable to blood component transfusion shall be reported to:
- 5.2.2.1 The blood supplier within 24 hours.
- 5.2.2.2 The Minister of Health, Government of Canada within 15 days.
- Note: Any event suspected to be related to bacterial contamination of a component or product shall be reported to CBS immediately (within 24 hours).***
- 5.2.3 A death attributable to transfusion of a blood component or administration of a blood product shall be reported to the Blood Supplier, and to the Minister of Health, Government of Canada within 24 hours.
- 5.2.4 Serious or unexpected adverse reactions directly attributable to an error or accident during transformation or storage activities carried out by the transfusion medicine laboratory shall be reported to the Biologics and Genetic Therapies Directorate (BGTD).

5.2.4.1 If the root cause of the adverse reaction is attributable to an activity carried out by another establishment, notification shall be provided to:

- The establishment that collected the implicated blood;
- The establishment from which the implicated blood was received; and
- Any establishment to which the implicated blood was distributed.

5.3 Procedure – Provincial Blood Coordinating Program

5.3.1 Non-nominal data shall be reported by the (NL) Provincial Blood Coordinating Program, to the Public Health Agency of Canada, Surveillance – Blood Safety, Transfusion Transmitted Injury Surveillance System.

5.4 Guidelines

Serious adverse (transfusion) reactions include, but are not limited to:

- 5.4.1 Immediate and delayed hemolytic reactions;
- 5.4.2 Transfusion-related acute lung injury;
- 5.4.3 Significant Hyperkalemia
- 5.4.4 Systemic allergic reactions, including anaphylaxis;
- 5.4.5 Bacterial contamination;
- 5.4.6 Transfusion-transmissible infectious diseases;
- 5.4.7 Transfusion-associated graft versus host disease;
- 5.4.8 Post-transfusion purpura; and
- 5.4.9 Death.

5.5 Materials (N/A)

6.0 Acronyms

CTAER	Canadian Transfusion Adverse Event Reporting Form
PBCP	Provincial Blood Coordinating Program
TTISS	Transfusion Transmitted Injury Surveillance System

7.0 Definitions

Accident	Unexpected or unplanned event not attributable to a deviation from standard operating procedures or applicable laws or regulations, that could adversely affect the safety of the recipients, or the safety, quality or efficacy of the blood component or plasma derived blood product.
Adverse Event	An undesirable and unintended occurrence during or after the administration of blood components or plasma derived blood products whether or not considered to be related to the administration of these products. Adverse events include: incidents, accidents, errors, adverse reactions. Adverse events may also be classified as <i>serious</i> or <i>unexpected</i> .
Adverse Reaction	An undesirable and unintended recipient response that is considered to be definitely, probably or possibly related to the administration of blood components or plasma derived blood products.
Error	An unexpected, unplanned deviation from standard operating procedures or applicable laws and regulations, usually attributable to a human or system problem, that could adversely affect the safety of recipients or the safety, efficacy, or quality of the blood component or plasma derived blood product.
Incident	An accident or error that could lead to an adverse outcome affecting the safety of the recipient, or the safety, efficacy or quality of the blood component or plasma derived blood product.
Serious Adverse Event	An adverse reaction that results in in-patient hospitalization or prolongation of same; persistent or significant disability or incapacity; medical or surgical intervention; a life-threatening condition; or death.
Transfusion Medicine Laboratory	Hospital Blood Bank
Transfusionist	A health care professional who administers blood components and/or plasma derived blood products.
Unexpected Adverse Event	An adverse event that is not identified in nature, severity, frequency or outcome among the current known adverse effects associated with the administration of blood components or plasma derived protein products.



8.0 Records Management

- 8.1 The report of an adverse transfusion event shall be placed in the recipient's health record.
- 8.2 All adverse transfusion event reports shall be retained in the transfusion medicine laboratory.
- 8.3 The report of *investigation* of all **serious** adverse transfusion reactions shall be retained in the transfusion medicine laboratory indefinitely.
- 8.4 Recommendations pertaining to special blood component requirements or preparation requirements for subsequent transfusions shall be placed in the recipient's transfusion history.

9.0 Key Words

Adverse, adverse reaction, adverse event, error, incident, occurrence, reaction, reporting, transfusion

10.0 Supporting Documents

10.1 Process Flow/Algorithm N/A

10.2 Tables/Charts N/A

References

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