Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

REPORTING ADVERSE TRANSFUSION EVENTS	NLBCP-037

Office of Administrative Responsibility Medical Advisor to the Provincial Blood Coordinating Program Manager, Provincial Blood Coordinating Program	**Issuing Authority** Dr. Lucinda Whitman Daphne Osborne
Author	Gail Bartlett
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Overview

Adverse transfusion events include adverse transfusion reactions and/or errors/accidents. Reporting of adverse transfusion events by the Regional Health Authorities (RHAs) is very important as it:

- may result in product recall,
- may result in donor notification and/or investigation and/or deferral,
- may result in recipient notification and investigation,
- is useful for purposes of tracking and trending (for example, a new complication or an unexpected change in frequency of a previously recognized complication), and
- contributes to safer transfusion medicine practice.

Policy

1. The RHAs 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. Nursing and transfusion service policy manuals shall include a list of common signs and symptoms of serious adverse transfusion reactions.
   1.2. All verbal communication shall be documented, and written notices shall be sent as soon as possible.
2. All RHAs shall have policies and procedures in place for documentation, reporting, investigation, evaluation, and follow-up of all incidents, errors and accidents.
3. Notification shall be provided as applicable to:
   3.1 Blood Supplier,
   3.2 Manufacturer,
   3.3 Provincial Authorities,
   3.4 Health Canada, and
   3.5 Minister of Health, Government of Canada.
4. All adverse transfusion events shall be immediately reported to the Transfusion Medicine Laboratory (TML). Once the TML is notified, investigations, including laboratory testing, shall be initiated to determine the probable cause.
   4.1. Adverse transfusion events attributable to the transfusion of **blood components** shall be reported to:
      4.1.1. Canadian Blood Services (CBS), as applicable. Report immediately to CBS any **serious** adverse event which is due to the quality and/or safety of the blood component. If a fatality occurs which upon initial investigation is believed to be attributable to the safety, quality, or efficacy of the blood component, the transfusion service shall report this to CBS within 24 hours.

4.1.2. Health Canada within 15 days of learning of a serious and/or unexpected adverse reaction, which is attributable to the quality and/or safety of the blood component and related to a Health Canada regulated activity carried out by the TML.

4.1.3. The Public Health Agency of Canada (Transfusion Transmitted Injury Surveillance System-TTISS).

4.2. Notification of adverse transfusion events attributable to the administration of **plasma protein products** shall be reported to:

4.2.1. The manufacturer as soon as possible, if the reaction is serious or unexpected.

4.2.2. Health Canada, MedEffect - Canada Vigilance Program, if the reaction is serious or unexpected.

4.2.3. The Public Health Agency of Canada (TTISS).

5. If an adverse transfusion event is attributable to an error or accident that occurred during transformation or storage activities carried out by the TML, all affected establishments shall be informed of the error or accident.

Guidelines

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

- immediate hemolytic reactions,
- delayed hemolysis,
- transfusion-related acute lung injury,
- systemic allergic reactions including anaphylactic shock,
- bacterial sepsis,
- other transfusion-transmissible infections,
- transfusion-associated graft versus host disease,
- post-transfusion purpura,
- other serious reactions, and
- death.

Procedure

Procedure – Nursing

1. **All** adverse transfusion reactions, mild to death, shall be immediately reported to the TML and the attending health care provider and/or designate.
2. **All** transfusion-related errors, accidents or incidents shall be reported to the TML and the attending health care provider and/or designate.

3. Collect and send samples as per RHA guidelines for investigation of adverse transfusion reactions. Depending on the signs and symptoms reported, serological testing, urinalysis, microbiological testing, and/or radiological examinations (chest x-ray) may be required. See Identification and Management of Adverse Transfusion Reactions and Investigation of Adverse Transfusion Reactions policy for guidance on how to respond to specific signs and symptoms.
4. Documentation of adverse transfusion reactions as per RHA guidelines including written documentation to the TML. Errors and/or accidents shall be entered into the Clinical Safety Reporting System (CSRS) as per RHA policy.
5. If an adverse transfusion **reaction** occurs as the result of an error and/or accident, the information must be reported to the TML and entered into TTISS and CSRS.

Procedure – Transfusion Safety Officer or Medical Laboratory Technologist

1. Adverse transfusion event (adverse transfusion reaction 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.
   1.1. Adverse transfusion **reactions** shall be reported to the Newfoundland and Labrador Provincial Blood Coordinating Program (NLPBCP). Adverse transfusion reactions are entered into the TTISS. All **serious** adverse transfusion reactions are to be reported to the NLPBCP as soon as possible.
   1.2. Adverse reactions related to blood products shall be reported to the MedEffect - Canada Vigilance Program.
   1.3. Errors and/or accidents that occur during transformation or storage activities carried out by the TML shall be reported to all affected establishments. If the error and/or accident is identified after the blood component is distributed or transfused and there is a reasonable probability that this could lead to a serious adverse reaction it must be reported to Health Canada within 24 hours.
   1.4. Errors and/or accidents shall be entered into the CSRS as per RHA policy.
   1.5. If an adverse transfusion **reaction** occurs as the result of an error and/or accident, the information must be reported to the TML and entered into TTISS and CSRS.
2. All *serious or unexpected* adverse transfusion events (See Guidelines) attributable to the quality of the blood component transfused shall be reported:
   2.1. Immediately to CBS. If a fatality occurs which upon initial investigation is believed to be attributable to the safety, quality, or efficacy of the blood component, the transfusion service shall report this to CBS within 24 hours.
   2.2. The Minister of Health, Government of Canada within 15 days. If it is deemed it is attributable to the **quality** of the blood component it is the responsibility of CBS to report to Health Canada within the 15 days timeframe.

   Note: Any event suspected to be related to bacterial contamination of a component or product shall be reported to CBS immediately (within 24 hours).

3. Serious or unexpected adverse reactions directly attributable to an error or accident during transformation or storage activities carried out by the TML shall be reported to the Biologics and Genetic Therapies Directorate (BGTD).

   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.

4. The original report of a serious adverse transfusion event shall become part of the recipient's medical record and a copy is to be kept on file at the TML with recommendations for future transfusions included. A system shall be in place for checking this information in the event that the recipient requires further transfusions.

Procedure – Provincial Blood Coordinating Program

Non-nominal data shall be reported by the Transfusion Safety Officers (TSOs) to the Public Health Agency of Canada, Surveillance – Blood Safety, TTISS. The NLPBCP shall review the cases in TTISS to ensure that all required information is included and complete. The NLPBCP compiles an annual report on adverse transfusion reactions reported in NL.

Key Words

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

Supplemental Materials

Appendix A: Adverse reaction reporting table
Appendix B: Adverse reaction reporting algorithm

References

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Appendix A

Type of Adverse Transfusion Reaction	Reporting Requirements	
	Blood Components	Plasma Protein Products
FNH, minor Allergic, TACO, TAD, Hypotensive reaction, Delayed Hemolytic Reaction, IVIG Headache, Aseptic Meningitis and all other reactions not related to the quality of the component/product.	Enter into TTISS within 30 days of conclusion of investigation.	Enter into TTISS within 30 days of conclusion of investigation.
● Severe allergic/anaphylactic/anaphylactoid ● Acute hemolytic reaction ● Significant hyperkalemia ● Graft vs host disease ● Post transfusion purpura ● Post transfusion infections ● Unusual reactions e.g. red-eye syndrome ● Positive culture (bacterial contamination of sample doubtful) ● Incorrect ABO (e.g. SD Plasma)	Enter into TTISS and report to NLPBCP. Report to CBS. Report to both as soon as suspected and upon conclusion of investigation.	Enter into TTISS and report to NLPBCP. Report to manufacturer. Report to both as soon as suspected and upon conclusion of investigation.
Adverse reactions associated with the quality and/or safety of the component/product including: ● TRALI (possible TRALI) ● Suspected bacterial contamination ● Product labelling issues including incorrect ABO/D ● Product quality issues e.g. hemolysis ● Any other component/product issue that would require recall and quarantine to prevent other recipients from being exposed ● Any other serious or unexpected reaction resulting in inpatient hospitalization or prolongation, persistent or significant disability or incapacity, medical or surgical intervention to minimize disability or incapacity, or any other life threatening condition. **Death linked to transfusion**	Enter into TTISS and report to NLPBCP. Report to CBS include CBS TRALI Form for TRALI cases. Report to both as soon as suspected and upon conclusion of investigation. Report to Canada Vigilance Program (Health Canada) by the *Investigating Establishment within 15 days of being notified (24 hours if linked to death) and upon conclusion of investigation. Canada Vigilance form and Form 337	Enter into TTISS and report to NLPBCP. Report to manufacturer. Report to both as soon as suspected and upon conclusion of investigation.

*From the preliminary investigation, this is the establishment that is deemed to have carried out the activity that was the root cause of the adverse reaction.

Appendix B

Recognition of an adverse transfusion reaction or an error/accident contributing to an adverse or unexpected reaction to a blood component or plasma protein product.

Report to Transfusion Medicine Laboratory and prescriber

Adverse reaction to component

Was it serious or unexpected and/or did it occur due to:

1. Product Quality or
2. CBS activity or
3. An error or accident during the performance of a "regulated" activity at a hospital?

Yes to **All**

Immediately report to NLPBCP. Report to CBS if due to product quality or CBS activity. Enter into TTISS. Report to Health Canada (CBS to report if due to product quality or CBS activity). If deemed **serious**, report must be done within **24 hours**.

No to **Any**

Report to NLPBCP. Enter into TTISS.

Adverse reaction to plasma protein product

Was it serious?

YES

Immediately report to NLPBCP, Canada Vigilance, the manufacturer, and enter into TTISS.

NO

Report to NLPBCP via TTISS.

Error or accident

Did it:

1. Occur during a "regulated" activity?
2. Get identified after the component/product was distributed or transfused?
3. Have reasonable probability that it could lead to a serious reaction?

Yes to **All**

Immediately, call Health Canada. Report to NLPBCP and enter into CSRS.

No to **Any**

Enter into CSRS.

Definition:
"Regulated" activities include processing, transformation, labeling, storing, record keeping, importing, and distributing.

Contact information:
NLPBCP: 729-5246, 729-5250, 729-6573
CBS: Fax (709)758-5322
Health Canada: 1-866-234-2345
Side effect reporting form
Errors/Accidents Form 337