SHARE YOUR HEALTH
AND VITALITY WITH
SOMEONE IN NEED

Adverse Event Reporting to CBS

ORBCoN Spring Symposium
April 2013

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Canadian Blood Services
it's in you to give

Objectives

- Understand importance of reporting adverse events
- Understand CBS role in reporting adverse events
- Understand why the difference in reporting adverse events between fresh components and fractionation products
- Understand how players fit together

Definition CSA Z902-10

- **Definition of Adverse event** – an undesirable and unintended occurrence during or after administration of whole blood, blood components or blood products, whether or not considered to be related to the administration of the blood, blood component or blood product.

- **Definition of Serious adverse event** – an adverse event that
  - Requires in-patient hospitalization or prolongation of existing hospitalization directly attributable to the event;
  - Results in persistent or significant disability or incapacity;
  - Necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function;
  - Is life-threatening; or
  - Results in death

Definition cont.

18.2.1 includes but is not limited to;

- Immediate hemolytic reactions
- Delayed hemolytic
- TRALI
- Systemic allergic reactions, including anaphylactic shock
- Bacterial sepsis
- Other transfusion –transmissible infections
- TA-GVHD
- PTP
- Other serious reactions
- Death (clause 18.2.5 shall apply) 18.2.5 timelines for reporting death

18.2.4 –The transfusion service shall immediately report to the blood centre any serious adverse event that appears to be caused by an attribute of the whole blood or blood components

Why report

It is required by CSA standards

It is important that transfusion services report adverse transfusion events to Canadian Blood Services, and/or the Public Health Agency of Canada (PHAC) - Transfusion Transmitted Injuries Surveillance System, and/or Canada Vigilance, as appropriate. This information is important because:

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

Mission

- Canadian Blood Services operates Canada's blood supply in a manner that gains the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood, blood products and their alternatives.

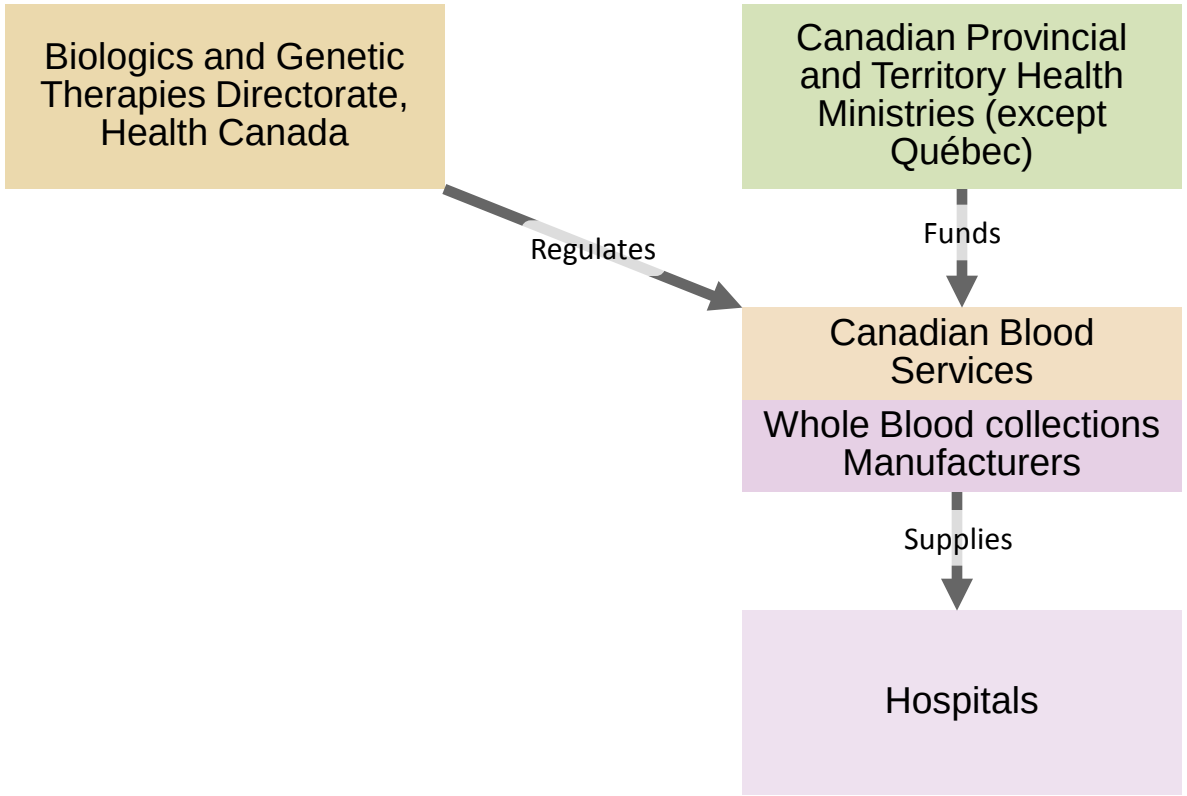
What is CBS

- CBS is a manufacturer of fresh components. eg. Red cells, FP, Cryo etc.
- CBS sends and buys plasma for custom fractionation (but is NOT a manufacturer)

BUT

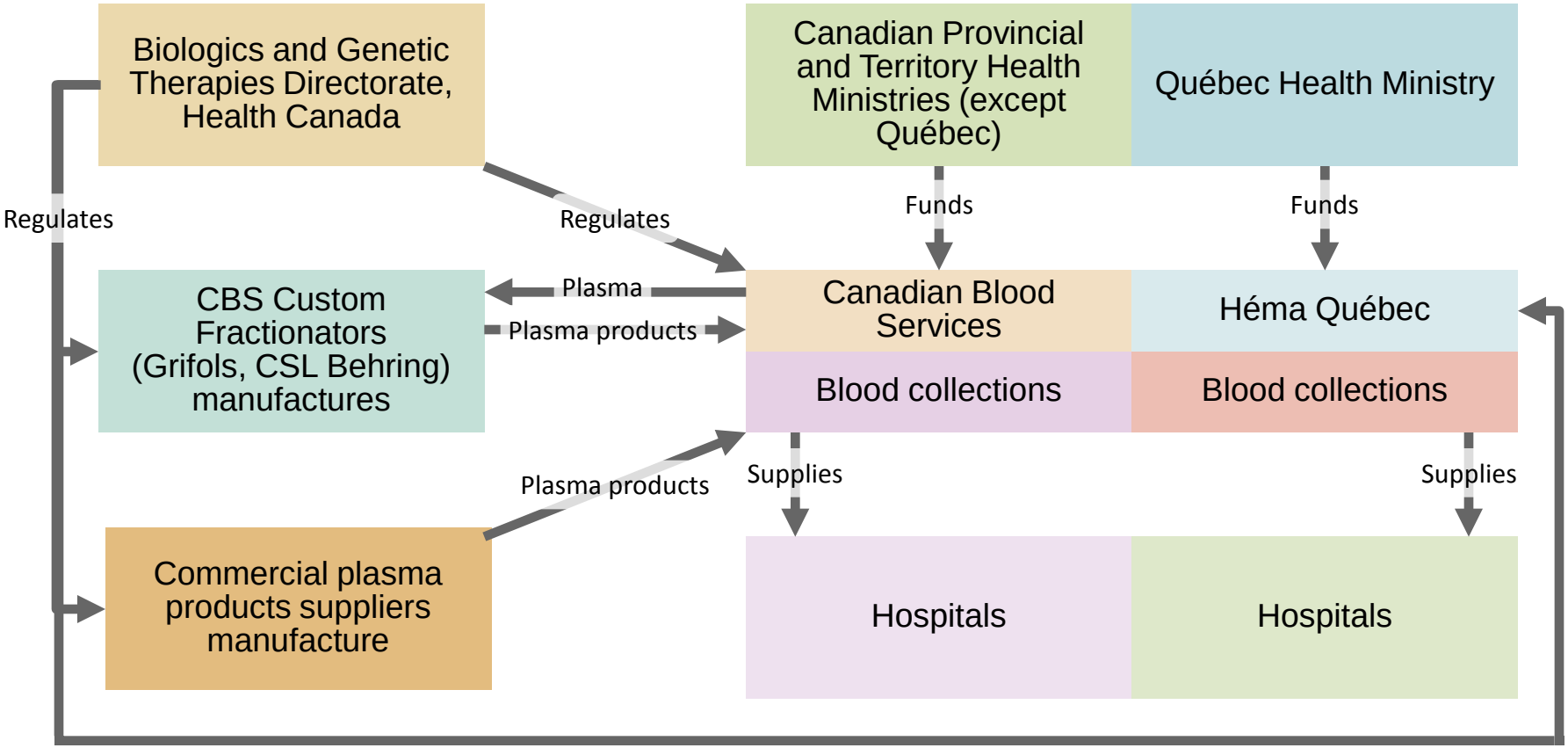
- CBS is the wholesaler for plasma products. eg. albumin, IVIG, FVIII etc.

Whole Blood Supply System in Canada



Adapted from Review of Australia's Plasma Fractionation Arrangements: Chapter 4: How other countries meet their needs

Plasma Supply System in Canada



Canadian Blood Services
it's in you to give

Adapted from Review of Australia's Plasma Fractionation Arrangements: Chapter 4: How other countries meet their needs

Who is interested in adverse events

- Health Canada
  - Biologics and Genetic Therapies Directorate
  - Public Health Agency of Canada - TTISS
  - Canada Vigilance
- CBS – manufacturer of components
- Drug companies – for plasma derived and recombinant products

Reporting to Health Canada

- Fresh components and fractions are both drugs
- Hospitals must report adverse events related to both to manufacturer – therefore:
- Fresh components

Fresh components	Fractions
Manufact. =CBS	Manufact.=company
Supplier =CBS	Supplier = CBS

All reports go to Health Canada eventually

Health Canada

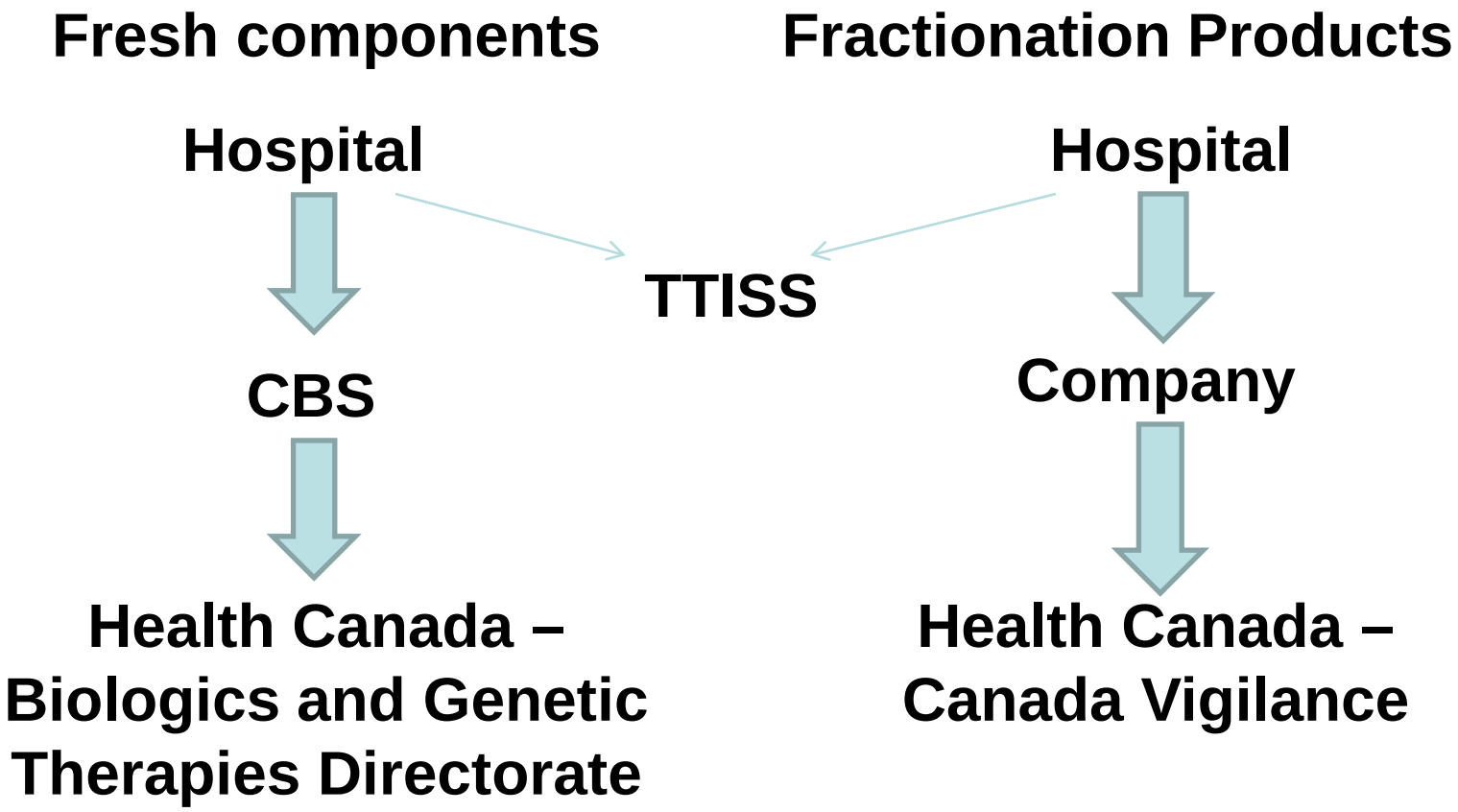
- Biologics and genetic therapies directorate
  - Adverse events from CBS regarding components
- TTISS
  - Voluntary hemovigillance arm - all adverse event with components even minor (and fractionation products)
- Canada Vigilance
  - Fractionated/recombinant products (and medications) from drug company

CBS versus TTISS

- TTISS –voluntary hemovigilance and is interested in all aspects of transfusion

- CBS – manufacturer of components primarily interested in events where the component is “abnormal”. Eg. Bacterial contamination, antibodies to platelets or white cells, infectious agents, incorrect labelling etc.

Who gets report ?



FORM

Fractionation product

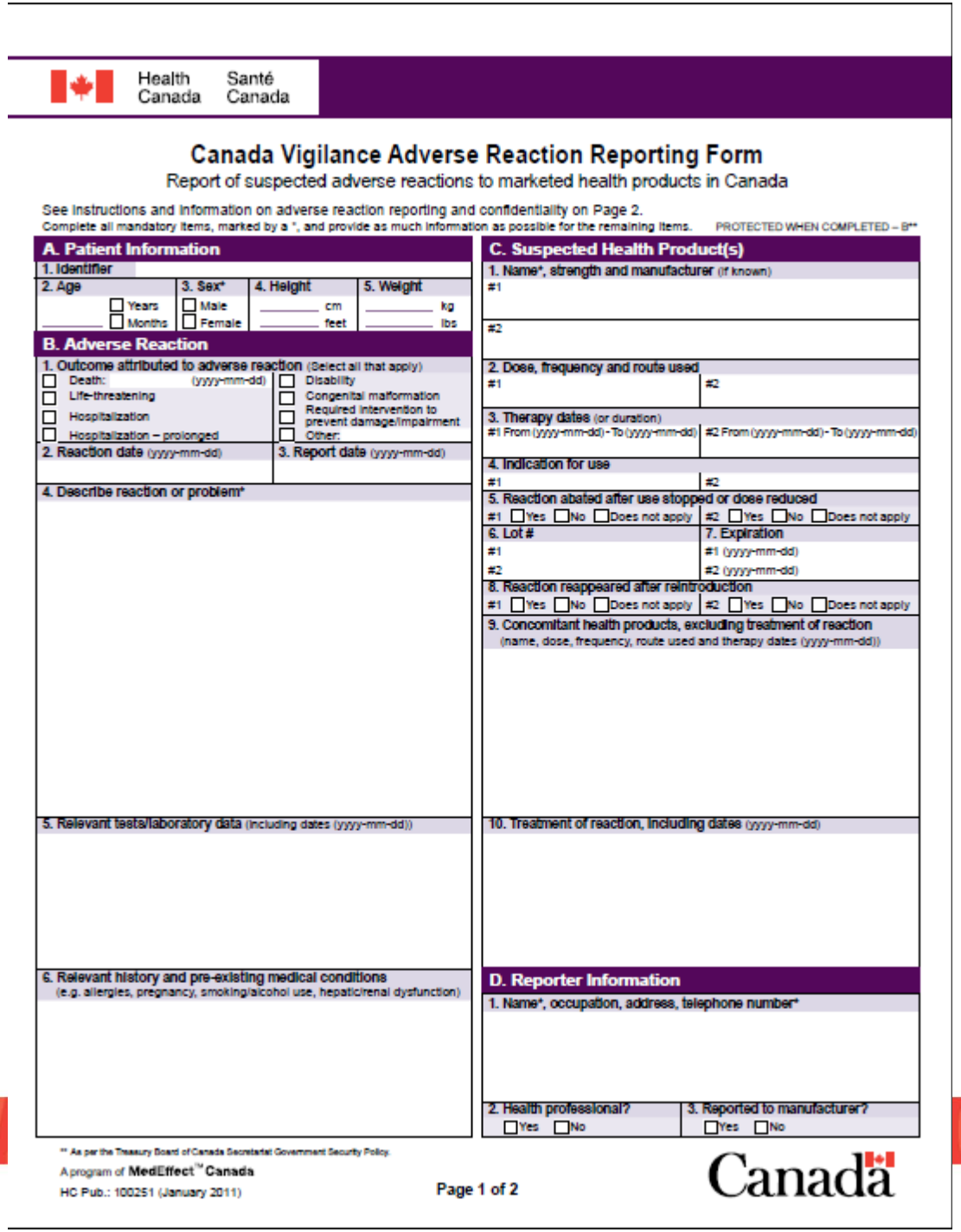
Hospital

↓

Company

↓

Health Canada



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 — ☐ Years ☐ Months
3. Sex* — ☐ Male ☐ Female
4. Height — _____ cm _____ feet
5. Weight — _____ 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.

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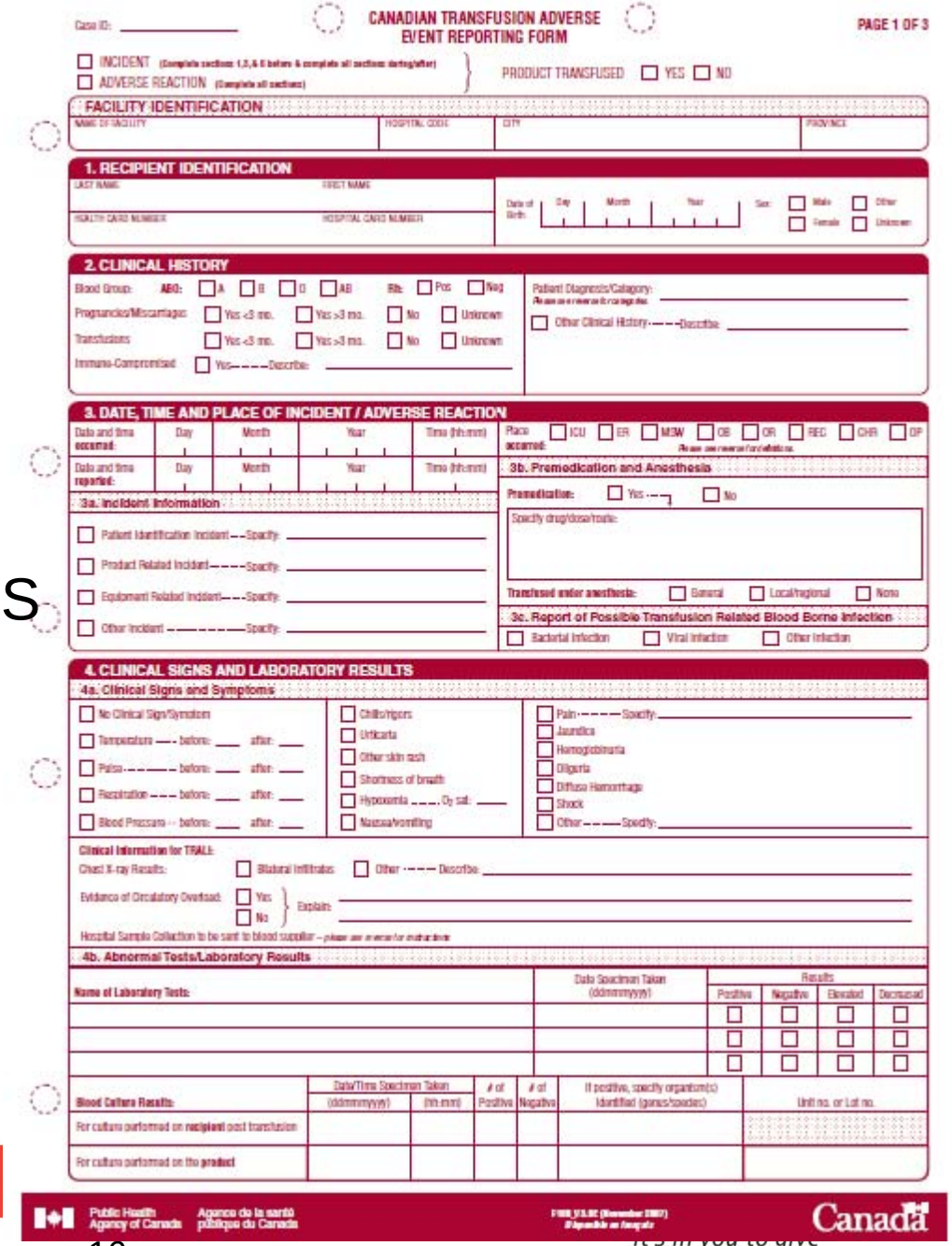
Canada

FORM

Fresh Components

Hospital → TTISS

Hospital → CBS → Health Canada



CANADIAN TRANSFUSION ADVERSE EVENT REPORTING FORM

PAGE 1 OF 3

Case ID: _____

☐ INCIDENT (Complete sections 1,2,3 & 5 before & complete all sections during/after)
☐ ADVERSE REACTION (Complete all sections)

PRODUCT TRANSFUSED ☐ YES ☐ NO

FACILITY IDENTIFICATION

NAME OF FACILITY | HOSPITAL CODE | CITY | PROVINCE

1. RECIPIENT IDENTIFICATION

LAST NAME | FIRST NAME

HEALTH CARD NUMBER | HOSPITAL CARD NUMBER

Date of Birth: Day / Month / Year | Sex: ☐ Male ☐ Female ☐ Other ☐ Unknown

2. CLINICAL HISTORY

Blood Group: ABO: ☐ A ☐ B ☐ O ☐ AB Rh: ☐ Pos ☐ Neg

Pregnancies/Miscarriages: ☐ Yes <3 mo. ☐ Yes >3 mo. ☐ No ☐ Unknown

Transfusions: ☐ Yes <3 mo. ☐ Yes >3 mo. ☐ No ☐ Unknown

Immuno-Compromised: ☐ Yes — Describe: _____

Patient Diagnosis/Category: _____

☐ Other Clinical History — Describe: _____

3. DATE, TIME AND PLACE OF INCIDENT / ADVERSE REACTION

Date and time **occurred**: Day / Month / Year / Time (hh:mm)

Date and time **reported**: Day / Month / Year / Time (hh:mm)

Place **occurred**: ☐ ICU ☐ ER ☐ MSW ☐ OB ☐ OR ☐ REC ☐ CHR ☐ OP

3a. Incident Information

☐ Patient Identification Incident — Specify: _____

☐ Product Related Incident — Specify: _____

☐ Equipment Related Incident — Specify: _____

☐ Other Incident — Specify: _____

3b. Premedication and Anesthesia

Premedication: ☐ Yes ☐ No

Specify drug/dose/route:

Transfused under anesthesia: ☐ General ☐ Local/regional ☐ None

3c. Report of Possible Transfusion Related Blood Borne Infection

☐ Bacterial Infection ☐ Viral Infection ☐ Other Infection

4. CLINICAL SIGNS AND LABORATORY RESULTS

4a. Clinical Signs and Symptoms

☐ No Clinical Sign/Symptom
☐ Temperature — before: ___ after: ___
☐ Pulse — before: ___ after: ___
☐ Respiration — before: ___ after: ___
☐ Blood Pressure — before: ___ after: ___
☐ Chills/rigors
☐ Urticaria
☐ Other skin rash
☐ Shortness of breath
☐ Hypoxemia ___ O2 sat: ___
☐ Nausea/vomiting
☐ Pain — Specify: _____
☐ Jaundice
☐ Hemoglobinuria
☐ Oliguria
☐ Diffuse Hemorrhage
☐ Shock
☐ Other — Specify: _____

Clinical Information for TRALI:

Chest X-ray Results: ☐ Bilateral Infiltrates ☐ Other — Describe: _____

Evidence of Circulatory Overload: ☐ Yes ☐ No Explain: _____

Hospital Sample Collection to be sent to blood supplier – please see reverse for instructions

4b. Abnormal Tests/Laboratory Results

Name of Laboratory Tests:	Date Specimen Taken (ddmmmyyyy)	Results: Positive	Negative	Elevated	Decreased
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐

Blood Culture Results:	Date/Time Specimen Taken (ddmmmyyyy)	(hh:mm)	# of Positive	# of Negative	If positive, specify organism(s) identified (genus/species)	Unit no. or Lot no.
For culture performed on **recipient** post transfusion						
For culture performed on the **product**						

Public Health Agency of Canada / Agence de la santé publique du Canada

Canada

Questions ?