



PUBLIC HEALTH AGENCY *of* CANADA  
AGENCE DE SANTÉ PUBLIQUE *du* CANADA



Public Health  
Agency of Canada

Agence de santé  
publique du Canada

Canada 

# The Canadian Hemovigilance Experience

- Presented:
  - To the Advisory Committee on Blood Safety and Availability (ACBSA)
  - Wed 30 Aug 2006
  - Washington

## Presented by:

- Blood Safety Surveillance & Health Care Acquired Infections Division
- Nancy McCombie
  - Senior Program Consultant
  - Transfusion Transmitted Injuries Section
- Jun Wu
  - Acting Associate Director
  - Transfusion Transmitted Injuries & Bloodborne Pathogens Sections

# PHAC Mission and Vision

- **Mission:**  
To promote and protect the health of Canadians through leadership, partnership, innovation and action in public health
- **Vision:**  
Healthy Canadians and communities in a healthier world

**Executive Director  
Corporate Secretariat**

**Chief Public Health Officer  
(CPHO)**  
*Dr.  
David Butler-Jones*

**Chief Science Advisor\***

DEPUTY CHIEF PUBLIC  
HEALTH OFFICER  
Infectious Diseases and Emergency  
Preparedness (IDEP) Branch

Director General\* Centre  
for Infectious Disease Prevention and  
Control (CIDPC)

**Director  
Blood Safety  
Surveillance and  
Health Care  
Acquired Infections  
Division  
(BSSHCAID)**

Director  
Surveillance and Risk  
Assessment Division  
(SRAD)

Director Immunization  
and Respiratory  
Infections Division  
(IRID)

Director National  
HIV and Retrovirology  
Laboratories  
(NHRL)

Director  
Community Acquired  
Infections Division  
(CAID)

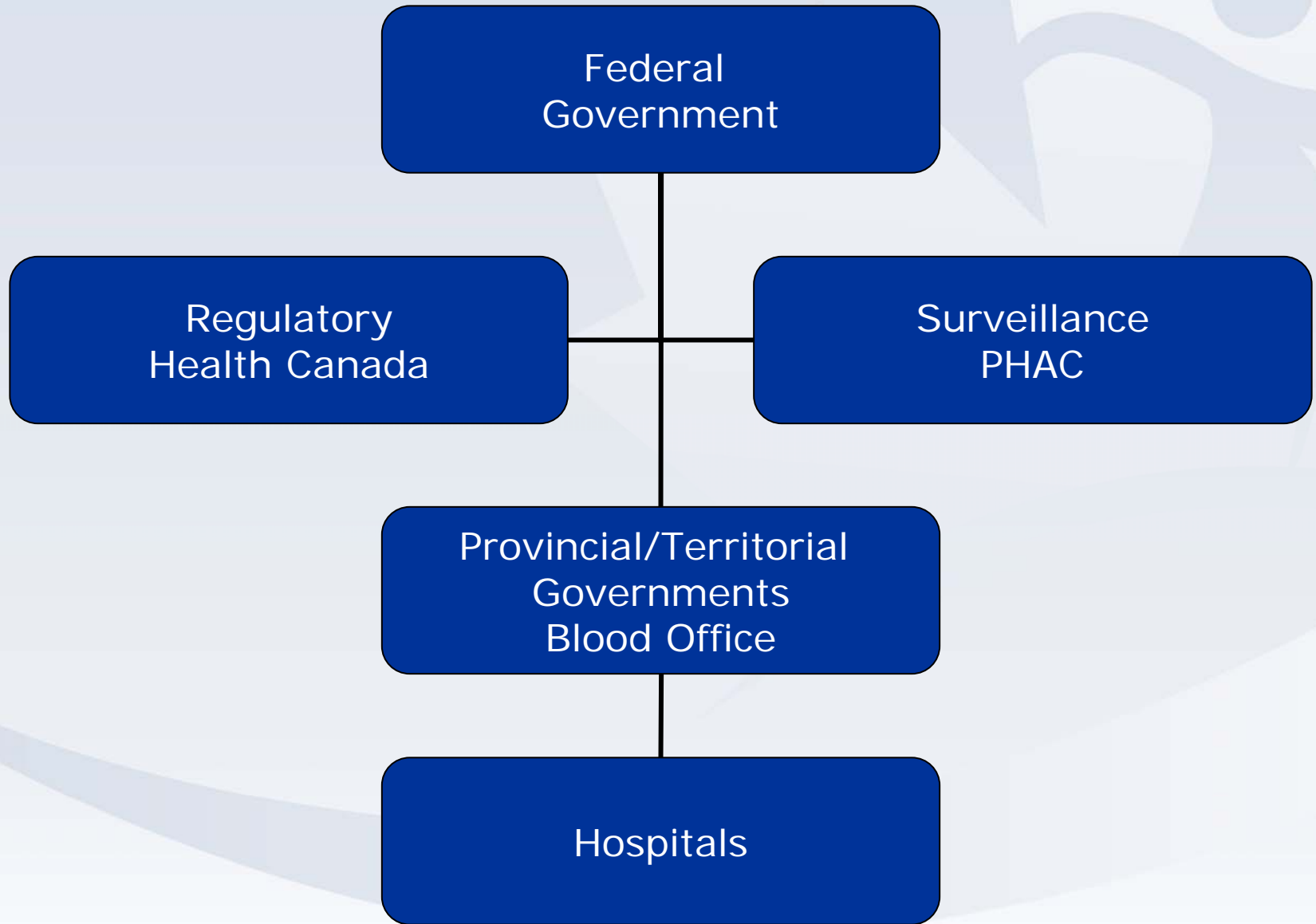
Director  
HIV/AIDS Policy,  
Coordination and  
Programs Division  
(H/APCPD)

Director  
Foodborne, Waterborne  
and Zoonotic Infections  
Division (FWZID)

**Transfusion  
Transmitted Injuries  
(TTI) Section**

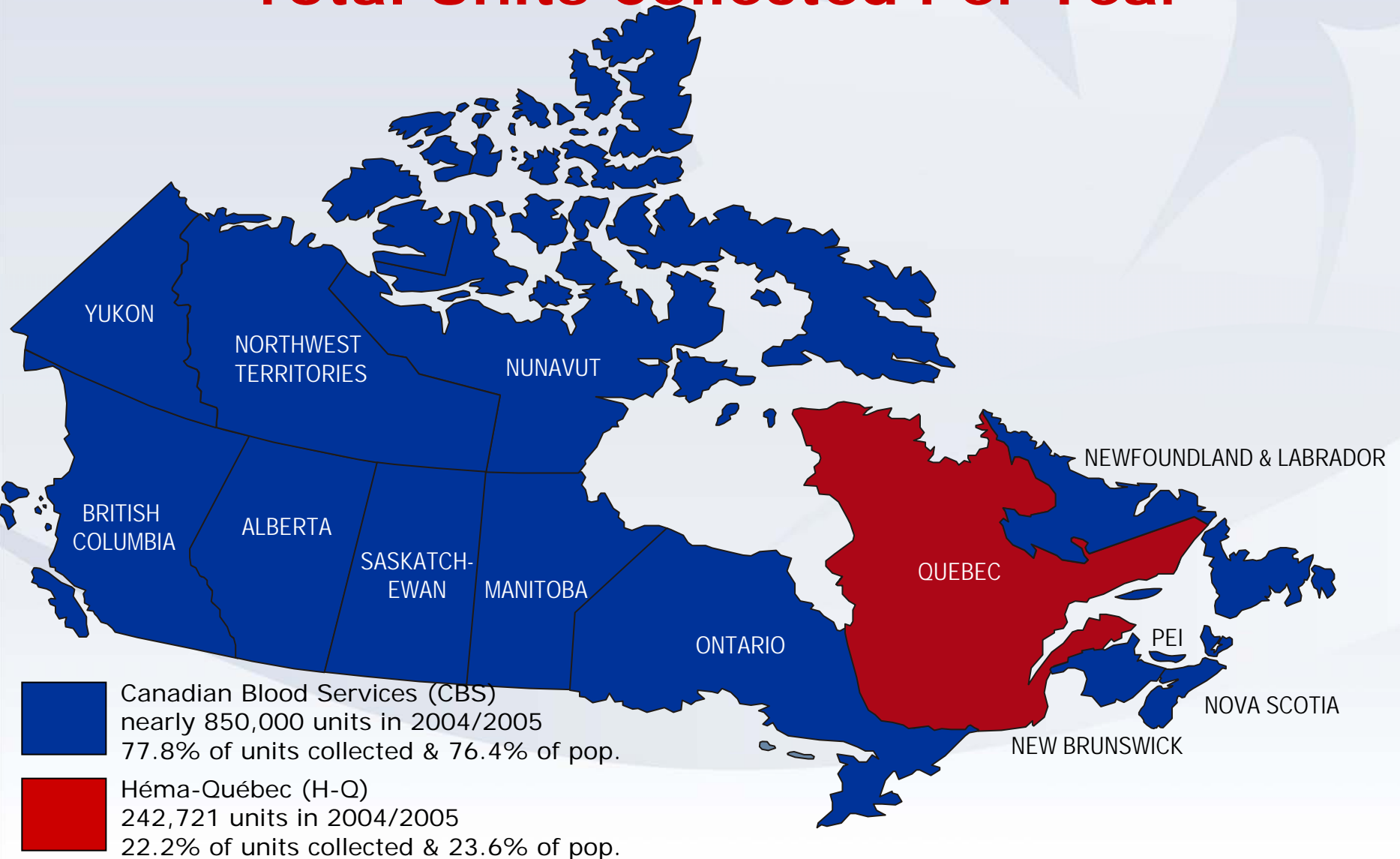
\*Notes:

1. The Scientific Director General, National Microbiology Laboratory, is also the Chief Science Advisor to the Chief Public Health Officer (CPHO)
2. (A) = Acting



# Blood Manufacturers

## Total Units Collected Per Year



## **Transfusion Transmitted Injuries Section (TTI)**

**Transfusion Transmitted Injuries Surveillance System (TTISS)**

**Transfusion Error Surveillance System (TESS)**

**Cell, Tissue, Organ & Assisted Reproduction Surveillance System (CTOAR-SS)**

- To capture data on moderate and severe adverse events, including the risk of transmission of infectious diseases, due to transfusion of blood, blood components or blood products (plasma derivatives) and transplantation of cells, tissues, organs, and assisted reproduction
- To capture data on serious errors/near misses of blood/blood component transfusion
- To perform data analysis to determine the risk of blood transfusion

# Background

- **late 1970s through to the 1980s:** transfusion-transmitted infections occurred
- **November 1997:** “Krever” Commission of Inquiry on Blood Safety, Final Report
- **March 1998:** Surveillance and Epidemiology of Transfusion (SET) working group formed
- **November 1998:** Blood Safety Surveillance and Health Care Acquired Infections Division formed to carry out surveillance aspects of blood safety programs
- **March 1999:** Federal authorities requested the ten Provinces and three Territories to submit proposals for funding



## Background (cont'd)

- **November 1999 to March 2002:** Four provinces participated in the **Pilot TTISS Project** to develop & implement transfusion adverse event reporting system in Canada.
- **April 2002 – present:** National implementation of the **Transfusion Transmitted Injuries Surveillance System (TTISS)**
- **2004 to 2005:** Four provinces began participating in the **Pilot Transfusion Errors Surveillance System (TESS) Project** to develop and implement transfusion error reporting system in Canada
- **2005:** Submission approved by Treasury Board to develop surveillance system for cells, tissues, organs and assisted reproduction

# TTISS Pilot Project Participants (Nov 1999-Mar 2002)

- Four Provinces:
  - British Columbia
  - Québec
  - Nova Scotia
  - PEI
- Health Canada Regulatory
- Blood Manufacturers

# TTISS Project Agreements

- Standardized reporting form
- Standardized definitions
- User's Manual
- Data elements exported to the Public Health Agency of Canada (non-nominal, aggregated)
- The conditions for reporting of National Data
- TTISS system to be used for reporting to Health Canada's regulatory branch & CBS
- Database developed by the Public Health Agency of Canada

# TTISS Standardized Materials

## TTISS Reporting Form

## TTISS User's Manual

## TTISS Database

**Health Canada Santé Canada** CANADIAN TRANSFUSION ADVERSE EVENT REPORTING FORM PAGE 1 OF 2

Order/ID: \_\_\_\_\_ Last modified by: \_\_\_\_\_ Reported on: \_\_\_\_\_ Date ID: \_\_\_\_\_

INCIDENT (Complete sections 1,3,4, 6 below & complete all sections as applicable)  
 ADVERSE REACTION (Complete all sections)

**1. RECIPIENT IDENTIFICATION**

LAST NAME: \_\_\_\_\_ FIRST NAME: \_\_\_\_\_  
 HEALTHCARE SETTING: \_\_\_\_\_ POSITION/CARE SETTING: \_\_\_\_\_  
 ADDRESS OF FACILITY: \_\_\_\_\_ STREET # \_\_\_\_\_ STREET NAME \_\_\_\_\_ CITY \_\_\_\_\_ PROVINCE \_\_\_\_\_ POSTAL CODE \_\_\_\_\_  
 HOME TELEPHONE: \_\_\_\_\_ OTHER TELEPHONE: \_\_\_\_\_ FAX # \_\_\_\_\_  
 Date of Birth: \_\_\_\_\_ Sex:  Male  Female  Other \_\_\_\_\_  
 Date of Onset: \_\_\_\_\_ Day \_\_\_\_\_ Month \_\_\_\_\_ Year \_\_\_\_\_  
 Sick  Well  Deceased  Other \_\_\_\_\_  
 Not Given  Unknown

**2. CLINICAL HISTORY**

Preoperative Medication:  Yes  No  Unknown  Yes  No  Unknown  
 Transfusions:  Yes  No  Unknown  Yes  No  Unknown  
 Prevalent diagnosis: \_\_\_\_\_  
 Current diagnosis: \_\_\_\_\_

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

Date/Time/Place Occurred: \_\_\_\_\_ Date/Time Reported: \_\_\_\_\_ Date/Time Received: \_\_\_\_\_  
 Patient Identification Incident  Product/Infused Incident  Other Incident  Product/Transfused Error

**3a. Incident Information**

Patient Identification Incident  Product/Infused Incident  Other Incident  Product/Transfused Error

**3b. Use of equipment and premedication**

Filter:  Used  None/Problem  Blood container  Used  None/Problem  Premedication  Yes  No  
 Presence device:  Used  None/Problem  Identification  Used  None/Problem  Specify device/brand: \_\_\_\_\_  
 Other: \_\_\_\_\_

**3c. Report of possible transfusion related life-threatening infection**

Yes  No  Suspected, specify organism/species: \_\_\_\_\_  
 Suspected, specify organism/species: \_\_\_\_\_  
 Other: \_\_\_\_\_

**4. CLINICAL SIGNS AND LABORATORY RESULTS**

Signs:  None  Hematuria  Sclerotic  Other (specify): \_\_\_\_\_  
 Fever  P. infection  P. other  Chills/rigors  Dark, specify: \_\_\_\_\_  
 Headache  T. infection  T. other  Plasma Hemorrhage  Shortness of breath  Hemoglobinuria  
 Hypotension  BP failure  BP other  Neurological/paralytic  Shock  Other, specify: \_\_\_\_\_  
 Hypertension  BP failure  BP other  Death  Death

Abnormal Laboratory Results: \_\_\_\_\_ Date specimen taken: \_\_\_\_\_ Treatment administered: \_\_\_\_\_  
 Results: \_\_\_\_\_  
 Blood Culture Recipient: Date & Time Taken: \_\_\_\_\_ # of Bags: \_\_\_\_\_ # of Pks: \_\_\_\_\_ Organism identified (specify): \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Blood Culture Provider: Date & Time Taken: \_\_\_\_\_ # of Bags: \_\_\_\_\_ # of Pks: \_\_\_\_\_ Organism identified (specify): \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Yes  No  Not in Unit # \_\_\_\_\_

**5. SUSPECT PRODUCTS**

Product/Component	Manufacturer	Lot #	Expiry Date	Batch #	Site of Origin	Specimen/Component	Volume/Amount	Transfusion Started Date/Time	Transfusion Ended Date/Time	Transfusion Related Signs/Symptoms

Comments: \_\_\_\_\_

1 800 273 8242 (toll free)

**Health Canada Santé Canada**

# User's Manual

**Canadian Transfusion Adverse Event Reporting Form**

**Main Switchboard**

**Health Canada Santé Canada** *Blood Safety Surveillance & Health-Care Acquired Infections Division*

**Transfusion Transmitted Injuries Surveillance System**

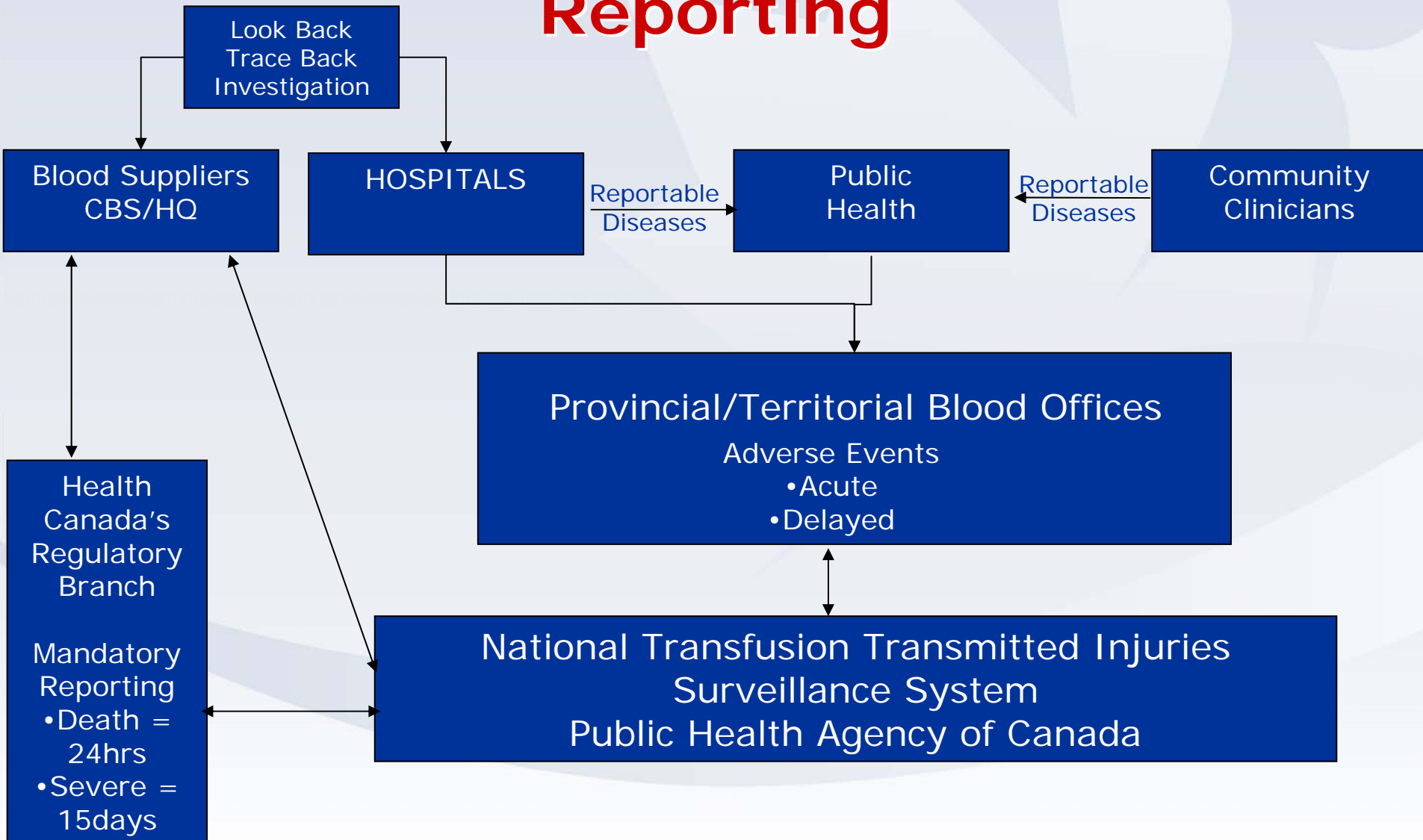
- Forms
- Reports
- Administrator Switchboard
- Help Switchboard

Logout  
 Exit This Database

## TTISS Database

- Developed & maintained by PHAC
- MS Access Database
  - web based next version
- Provincial Blood Coordinating Offices (PBCO) export encrypted non-nominal data to PHAC quarterly

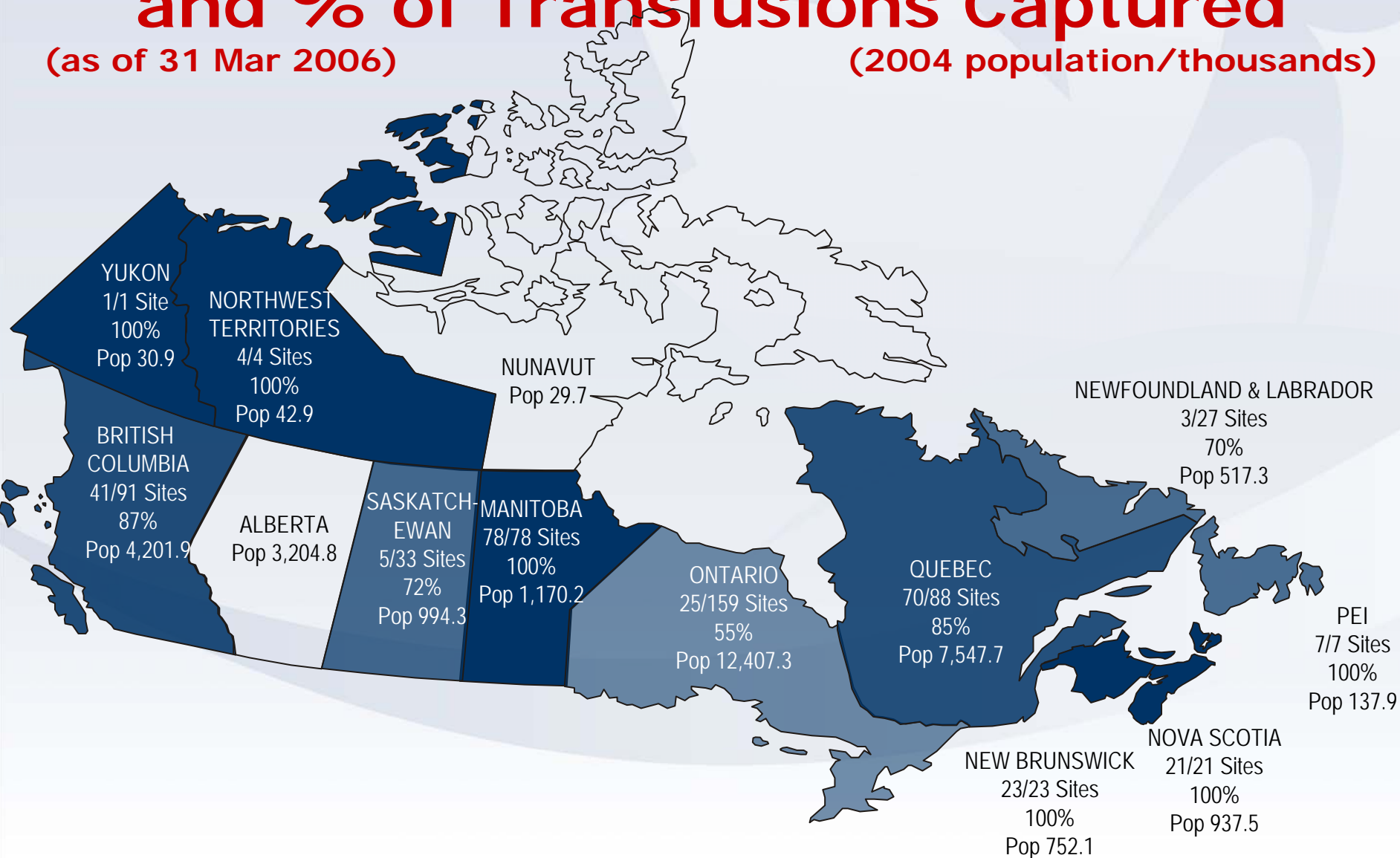
# Infrastructure for National TTISS Reporting



# Hospital Sites Participating in TTISS and % of Transfusions Captured

(as of 31 Mar 2006)

(2004 population/thousands)



# National TTISS Working Group (NTTISSWG)

## Membership

- All provinces/territories represented
- Blood manufacturers (CBS & Héma-Québec)
- Health Canada's regulatory branches (MHPD & BGTD)

## Terms of Reference

- Identify and address issues related to a national surveillance program to determine the risk of transmission of infections and injuries by blood transfusions
- Recommend future directions, quality, efficacy and effectiveness of the TTISS as a national surveillance program

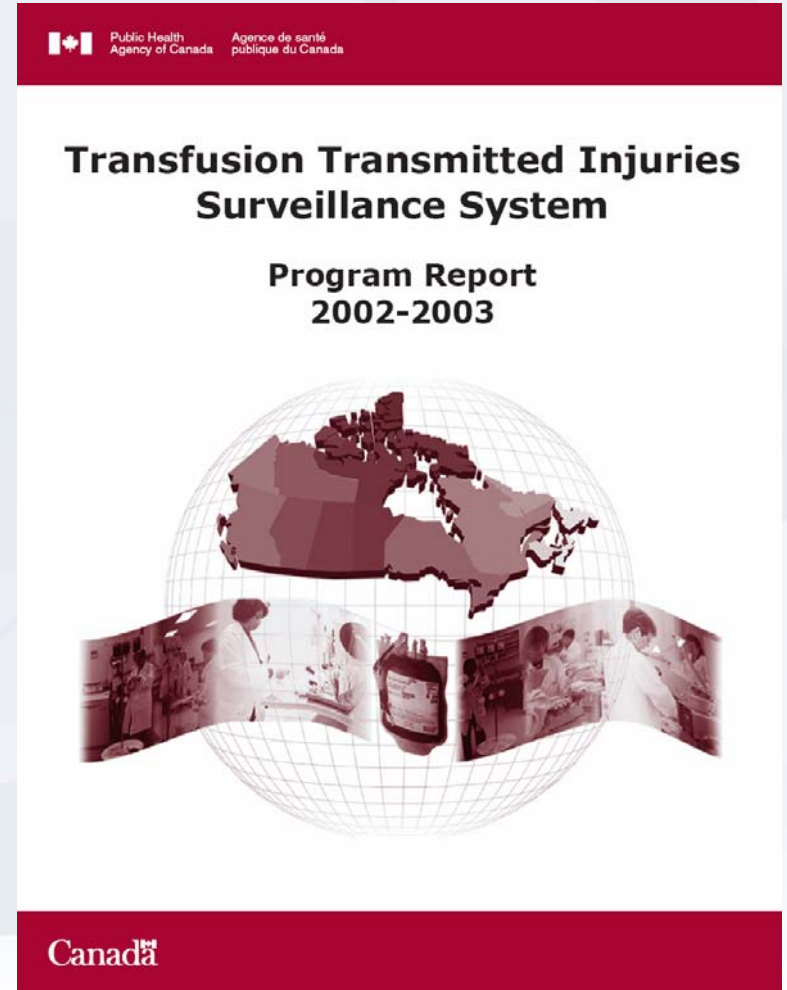
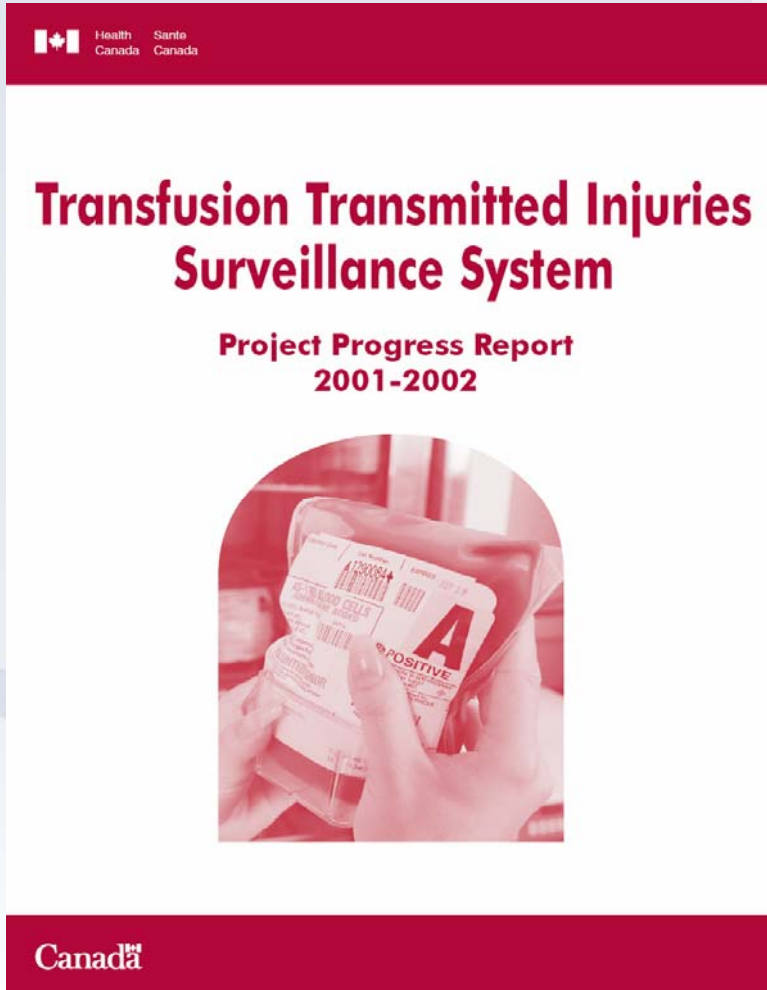


# NTTISS

## Yearly Data Quality Meeting

- **Attendees**
  - All provinces/territories represented
  - Blood manufacturers (CBS & Héma-Québec)
  - Health Canada's regulatory branches (MHPD & BGTD)
  
- **Goals**
  - Discuss quality of data
    - Included/Excluded
    - Validation
    - Adherence to definitions
  - Identify changes for the
    - Definitions
    - Form
    - Manual
    - Database

# TTISS Program Reports



# PHAC Responsibilities

- Funding to Provinces/Territories
- Communication - Provinces/Territories
- TTISS WG
- Data Agreements
- National Data Validation and Analysis
- Data Quality Meetings
- Database
- Communication – NWPDR
- Annual Report

# Provincial/Territorial Responsibilities

## Contribution Agreement

- Proposal
- Deliverables
- Invoices
- Cash flow forecast
- Reports

## Provincial/Territorial Responsibilities

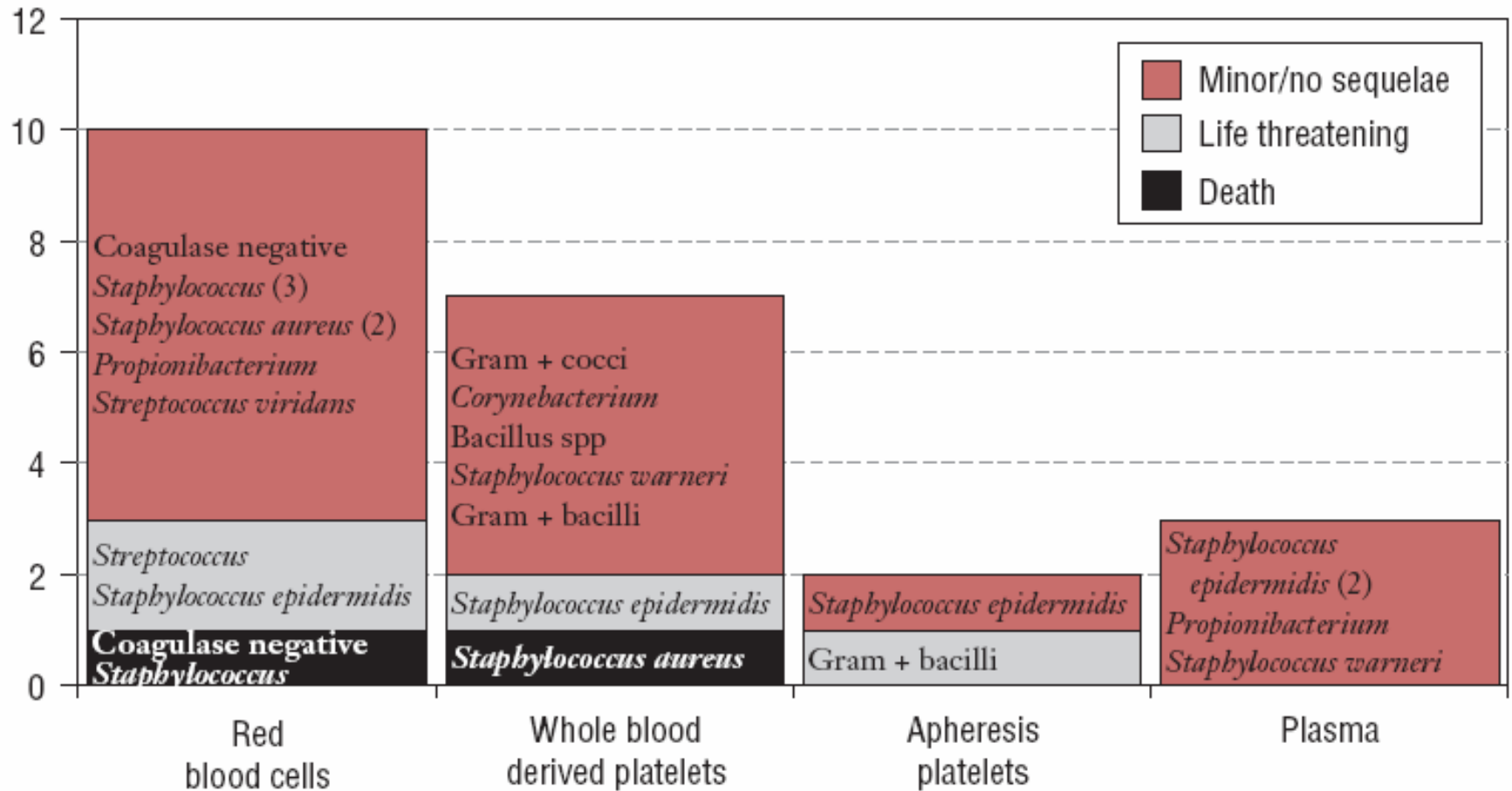
- Member of TTISS WG
- Attend Data Quality Meetings
- Data Agreements between P/T & PHAC
- Communication – Hospitals
- Training
- Data input, validation & analysis
- Export of data to PHAC
- Communication – PHAC
- Feedback/publications to P/T stakeholders

## Diagnosis of adverse transfusion events related to blood components

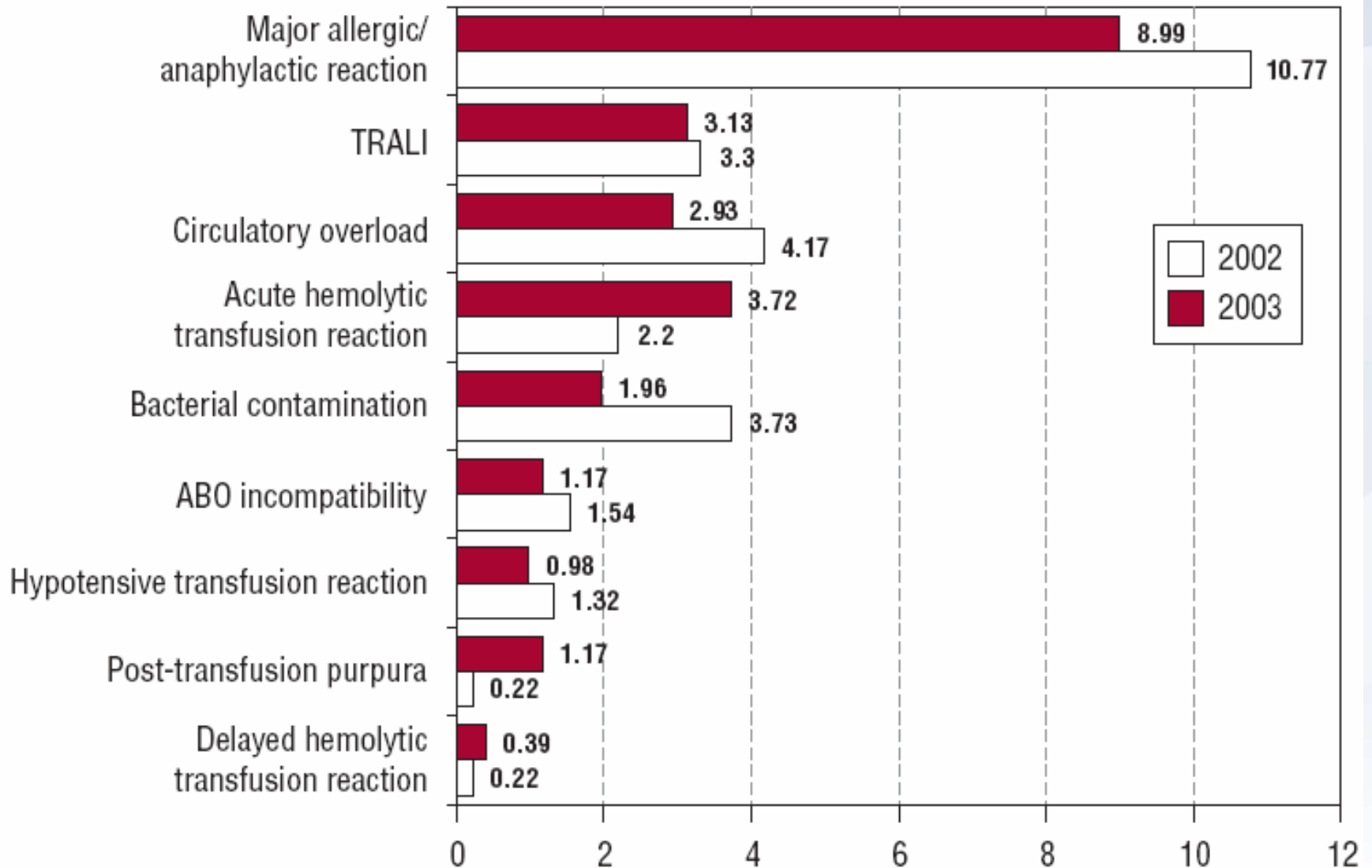
Adverse transfusion event	Red blood cells			Whole blood derived platelets			Apheresis platelets			Plasma			Total <sup>a</sup>			
	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002	2003	Total	
Major allergic / anaphylactic reaction	21 (28.0)	14 (20.3)	35 (24.3)	16 (51.6)	8 (53.3)	24 (52.2)	1 (50.0)	5 (71.4)	6 (66.7)	11 (50.0)	16 (57.1)	27 (54.0)	50 (36.2)	46 (35.7)	96 (36.0)	
TRALI	10 (13.3)	8 (11.6)	18 (12.5)	1 (3.2)	2 (13.3)	3 (6.5)	-	-	-	2 (9.1)	5 (17.9)	7 (14.0)	18 (13.0)	17 (13.2)	35 (13.1)	
Circulatory overload	14 (18.7)	10 (14.5)	24 (16.7)	1 (3.2)	-	1 (2.2)	-	-	-	4 (18.2)	3 (10.7)	7 (14.0)	19 (13.8)	15 (11.6)	34 (12.7)	
Acute hemolytic transfusion reaction	12 (16.0)	18 (26.1)	30 (20.8)	-	1 (6.7)	1 (2.2)	-	-	-	-	-	-	12 (8.7)	19 (14.7)	31 (11.6)	
Bacterial contamination	5 (6.7)	5 (7.2)	10 (6.9)	9 (29.0)	1 (6.7)	10 (21.7)	-	2 (28.6)	2 (22.2)	3 (13.6)	2 (7.1)	5 (10.0)	17 (12.3)	10 (7.8)	27 (10.1)	
ABO incompatibility	6 (8.0)	3 (4.3)	9 (6.3)	-	2 (13.3)	2 (4.3)	1 (50.0)	-	1 (11.1)	1 (4.5)	1 (3.6)	2 (4.0)	8 (5.8)	6 (4.7)	14 (5.2)	
Hypotensive transfusion reaction	4 (5.3)	3 (4.3)	7 (4.9)	2 (6.5)	-	2 (4.3)	-	-	-	-	1 (3.6)	1 (2.0)	6 (4.3)	5 (3.9)	11 (4.1)	
Post-transfusion purpura	-	3 (4.3)	3 (2.1)	-	1 (6.7)	1 (2.2)	-	-	-	-	-	-	1 (0.7)	6 (4.7)	7 (2.6)	
Delayed hemolytic transfusion reaction	1 (1.3)	2 (2.9)	3 (2.1)	-	-	-	-	-	-	-	-	-	1 (0.7)	2 (1.6)	3 (1.1)	
Viral infection <sup>c</sup>	-	-	-	-	-	-	-	-	-	-	-	-	1 (0.7)	-	1 (0.4)	
Other <sup>d</sup>	2 (2.7)	3 (4.3)	5 (3.5)	2 (6.5)	-	2 (4.3)	-	-	-	1 (4.5)	-	1 (2.0)	5 (3.6)	3 (2.3)	8 (3.0)	
<b>Total</b>	<b>N</b>	<b>75</b>	<b>69</b>	<b>144</b>	<b>31</b>	<b>15</b>	<b>46</b>	<b>2</b>	<b>7</b>	<b>9</b>	<b>22</b>	<b>28</b>	<b>50</b>	<b>138</b>	<b>129</b>	<b>267</b>
	<b>%<sup>e</sup></b>	<b>(54.3)</b>	<b>(53.5)</b>	<b>(53.9)</b>	<b>(22.5)</b>	<b>(11.6)</b>	<b>(17.2)</b>	<b>(1.4)</b>	<b>(5.4)</b>	<b>(3.4)</b>	<b>(15.9)</b>	<b>(21.7)</b>	<b>(18.7)</b>	<b>(51.7)</b>	<b>(48.3)</b>	<b>(100.0)</b>

# Bacterial Contamination

Organisms identified in blood product culture



## Comparative rates of adverse transfusion events per 100,000 units of blood components transfused





## Diagnosis of adverse transfusion events related to plasma derivatives and recombinant products

Adverse transfusion event	Plasma derivatives and recombinant products											
	IVIg			Anti-D			Albumin			Total <sup>a</sup>		
	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002 <sup>b</sup>	2003 <sup>b</sup>	Total <sup>b</sup>	2002	2003	Total
Major allergic/ anaphylactic reaction	1 (11.1)	3 (27.3)	4 (20.0)	2 (100.0)	-	2 (100.0)	-	3 (100.0)	3 (100.0)	6 (42.9)	7 (46.7)	13 (44.8)
Aseptic meningitis	3 (33.3)	3 (27.3)	6 (30.0)	-	-	-	-	-	-	3 (21.4)	3 (20.0)	6 (20.7)
Hypotensive transfusion reaction	3 (33.3)	1 (9.1)	4 (20.0)	-	-	-	-	-	-	3 (21.4)	1 (6.7)	4 (13.8)
TRALI	-	1 (9.1)	1 (5.0)	-	-	-	-	-	-	-	1 (6.7)	1 (3.5)
Cerebrovascular accident	-	2 (18.2)	2 (10.0)	-	-	-	-	-	-	-	2 (13.3)	2 (6.9)
Other <sup>c</sup>	2 (22.2)	1 (9.1)	3 (15.0)	-	-	-	-	-	-	2 (14.3)	1 (6.7)	3 (10.3)
<b>Total</b>	<b>N</b>	<b>9</b>	<b>11</b>	<b>20</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>14</b>	<b>15</b>	<b>29</b>	<b>29</b>
	<b>(%)<sup>d</sup></b>	<b>(64.3)</b>	<b>(73.3)</b>	<b>(69.0)</b>	<b>(14.3)</b>	<b>(6.9)</b>	<b>(20.0)</b>	<b>(10.3)</b>	<b>(48.3)</b>	<b>(51.7)</b>	<b>(100.0)</b>	<b>(100.0)</b>

## Fatal events definitely, probably or possibly related to transfusion

Fatal events	Relationship to transfusion			
	Definite	Probable	Possible	Total
Events related to blood components				
Bacterial contamination	1	2	1	4
TRALI	-	1	1	2
Post-transfusion purpura	1	1	-	2
Circulatory overload	-	1	-	1
Anaphylactic reaction	-	1	-	1
Events related to plasma derivatives and recombinant products				
Cerebrovascular accident	-	1	-	1
<b>Total</b>	<b>2</b>	<b>7</b>	<b>2</b>	<b>11</b>

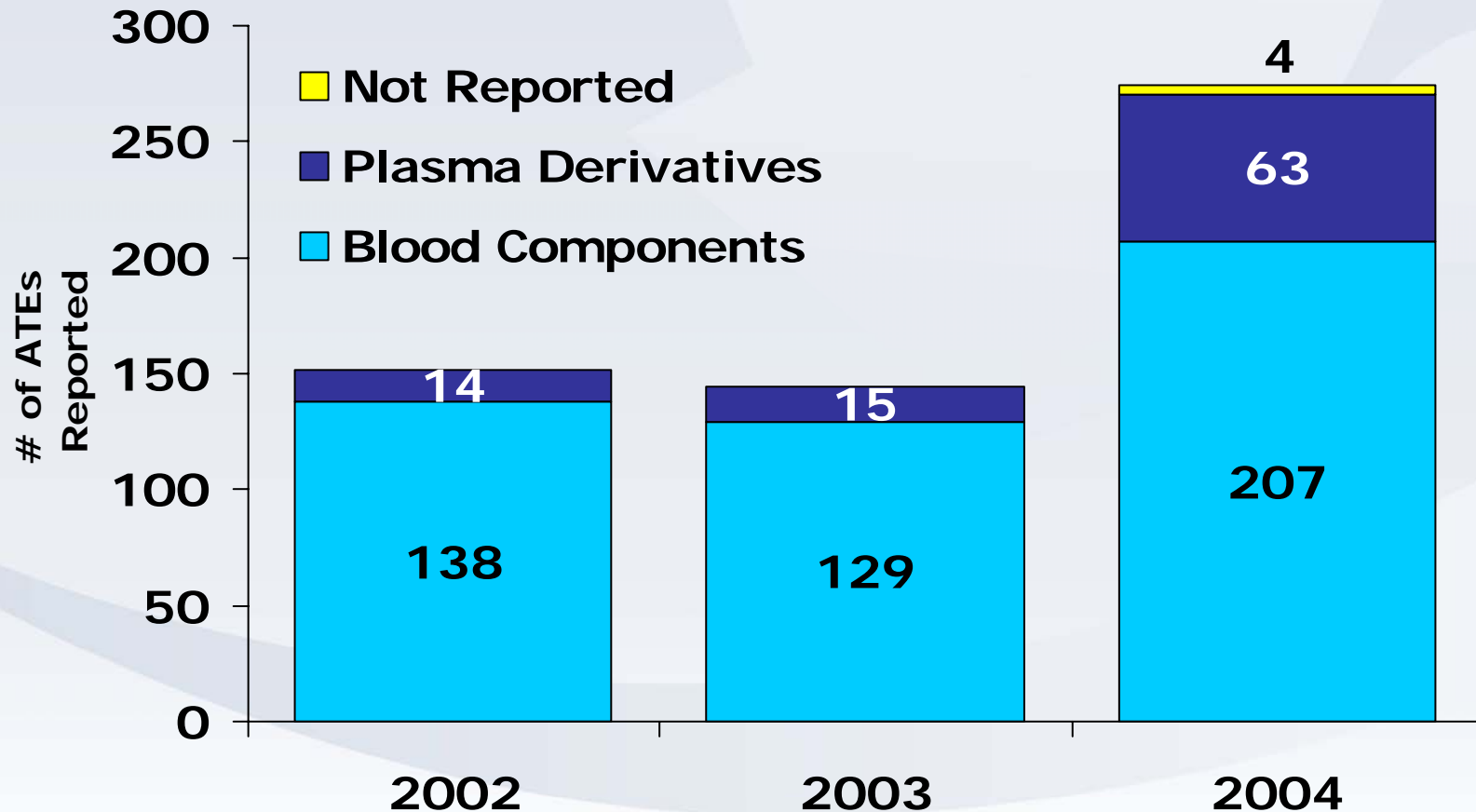
# Incidence of fatal events definitely, probably and possibly related to transfusion of blood components

Fatal events	Red blood cells		Whole blood derived platelets Pools (5)		Cryoprecipitate		Plasma		All products <sup>a</sup>	
	(616,309)		(61,447)		(58,239)		(182,329)		(966,490)	
	N	Ratio	N	Ratio	N	Ratio	N	Ratio	N	Ratio
Bacterial contamination	1	1:616,309	3	1:20,482	-	-	-	-	4	1:241,623
TRALI	1	1:616,309	-	-	1	1:58,239	-	-	2	1:483,245
Post-transfusion purpura	1	1:616,309	-	-	-	-	-	-	2	1:483,245 <sup>b</sup>
Major allergic/anaphylactic reaction	-	-	-	-	-	-	1	1:182,329	1	1:966,490
Circulatory overload	-	-	-	-	-	-	1	1:182,329	1	1:966,490
<b>Total</b>	<b>3</b>	<b>1:205,634</b>	<b>3</b>	<b>1:20,482</b>	<b>1</b>	<b>1:58,239</b>	<b>2</b>	<b>1:91,165</b>	<b>10</b>	<b>1:96,649</b>

<sup>a</sup> Includes whole blood, apheresis platelets, cryosupernatant, and granulocytes.

<sup>b</sup> Includes ATEs to multiple blood components not shown in the table.

# Total # of ATEs Reported (2002-2004)



# Summary

- **TTISS is an evolving surveillance system**
  - More provinces/territories and more hospital sites will be providing data in the future
  - It will take some years to estimate trends in the incidence of adverse transfusion events in Canada
- **TTISS is not an alert system**
  - TTISS is not a substitute to reporting to the blood manufacturers and to the Health Canada Regulatory for action to be taken on products
  - Data that are transferred to TTISS are six months old thus being useful only for surveillance purposes
- **Canada is actively involved in international standardization of definitions of adverse transfusion events and of reporting tools**
  - Standardization will allow for better comparisons between different countries and settings and may help identify the optimal transfusion practices for improvement of blood safety in Canada and elsewhere

# Transfusion Error Surveillance System (TESS) Overview

- Pilot Project underway in 4 provinces:
  - British Columbia, Ontario, Nova Scotia, Quebec
- Voluntary & non-punitive
- Non-nominal data exported to PHAC
- Web based database developed by PHAC to collect data & provide reports
- Exports to PHAC quarterly based on high severity cases
- Data Element Agreement and Reporting Agreement with pilot provinces (similar to TTISS)
- Over 3500 cases entered as of December 2005 (all levels of severity)

# TESS Working Group

## Membership

- Four pilot provinces represented
- PHAC

## Terms of Reference

- Develop and implement a Transfusion Error Surveillance System
- Inform and consult the National TTISS WG on issues related to progress and implementation of TESS

# National Working Party for Data Review

## Membership

- Members are selected for their individual medical/scientific expertise in the fields of:
  - public health
  - infectious diseases
  - epidemiology
  - transfusion medicine
  - cells, tissues and organs
- Ex-officio representatives are from BSSHCAID, BGTD, MHPD, H-Q & CBS
- Liaison and Adhoc (invited by the co-chairs)

## Terms of Reference

- Review and evaluation of surveillance based epidemiological data
- Develop research questions and hypotheses for investigation purposes
- Identify signals or unusual events that should be investigated further



# Partnerships & Collaborations

- Hospitals & Transfusion Physicians
- All Provinces / Territories
- Health Canada Regulatory
  - BGTD / MHPD
- Blood Manufacturers
  - Canadian Blood Services / Hema Québec

# Our Website

- Where you can find:
  - Reports
  - Form
  - Manual
  - Posters
  - Links
  - Variety of information
- <http://www.phac-aspc.gc.ca/hcai-iamss/tti-it>