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

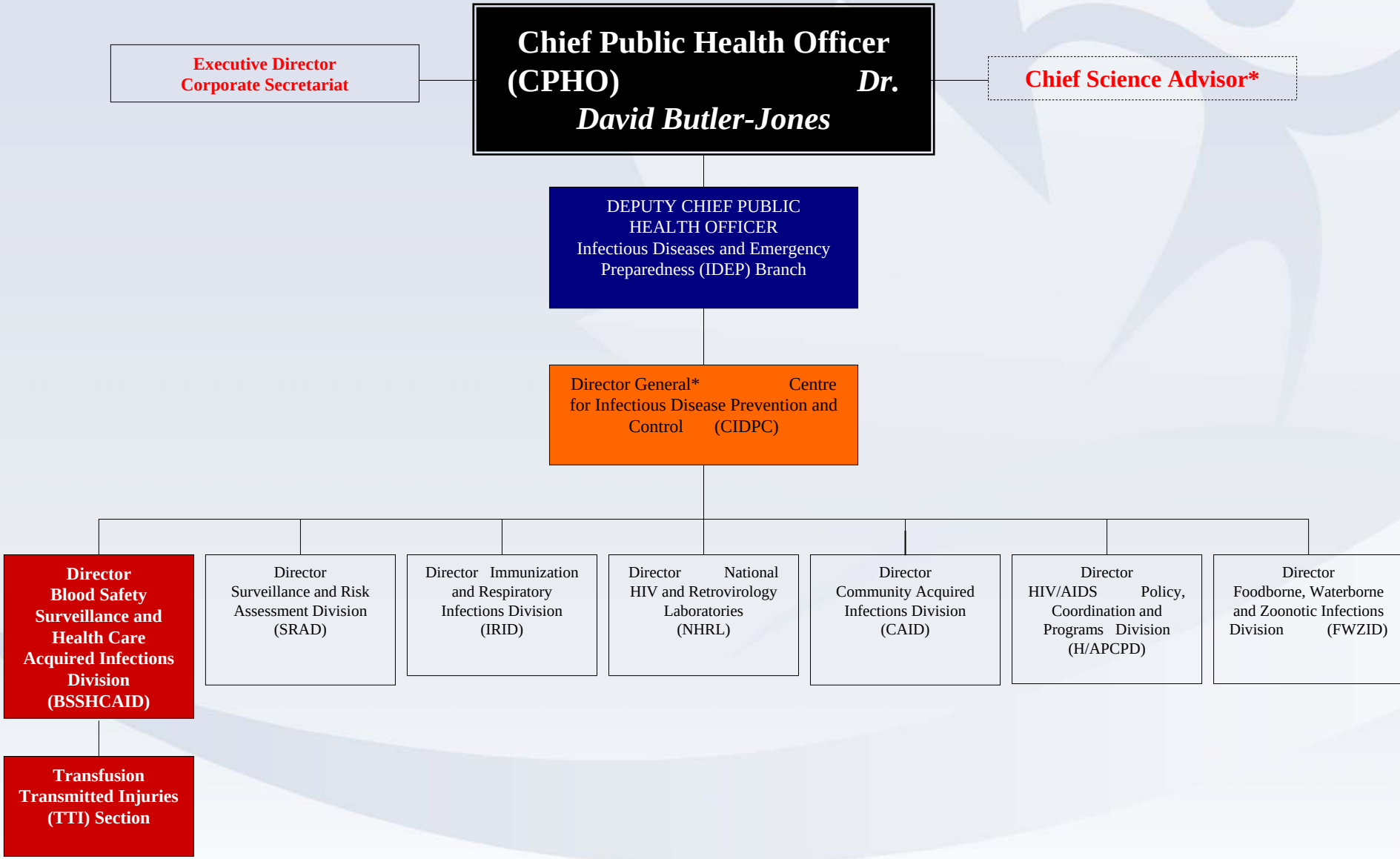
- Nancy McCombie
  - Senior Program Consultant
  - Transfusion Transmitted Injuries Section

- Jun Wu
  - Acting Associate Director
  - Transfusion Transmitted Injuries & Bloodborne Pathogens Sections

PHAC Mission and Vision

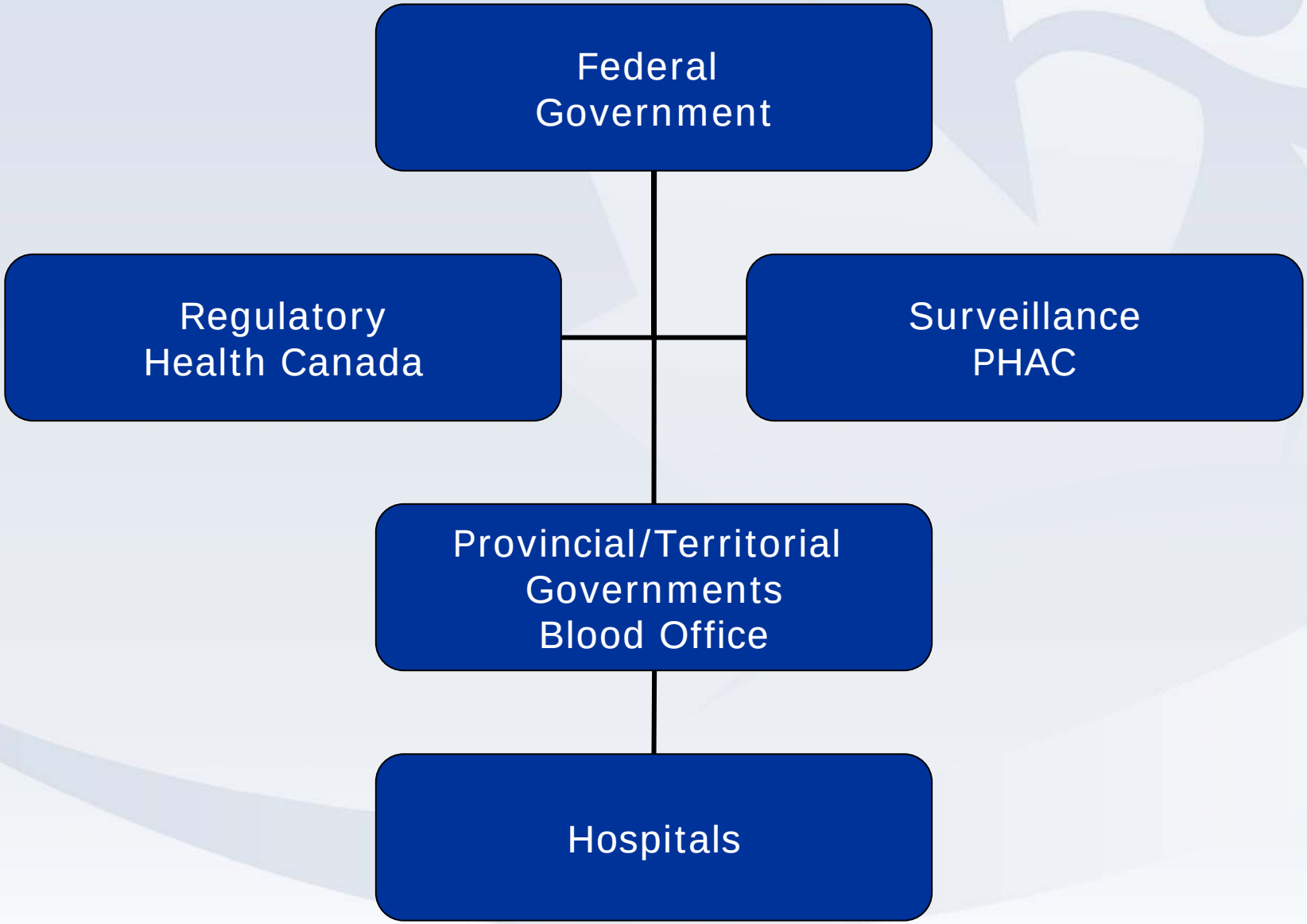
- **Mission**:
  To promote and protect the health of Canadians through leadership, partnership, innovation and action in public health

- **Vision**:
  Healthy Canadians and communities in a healthier world

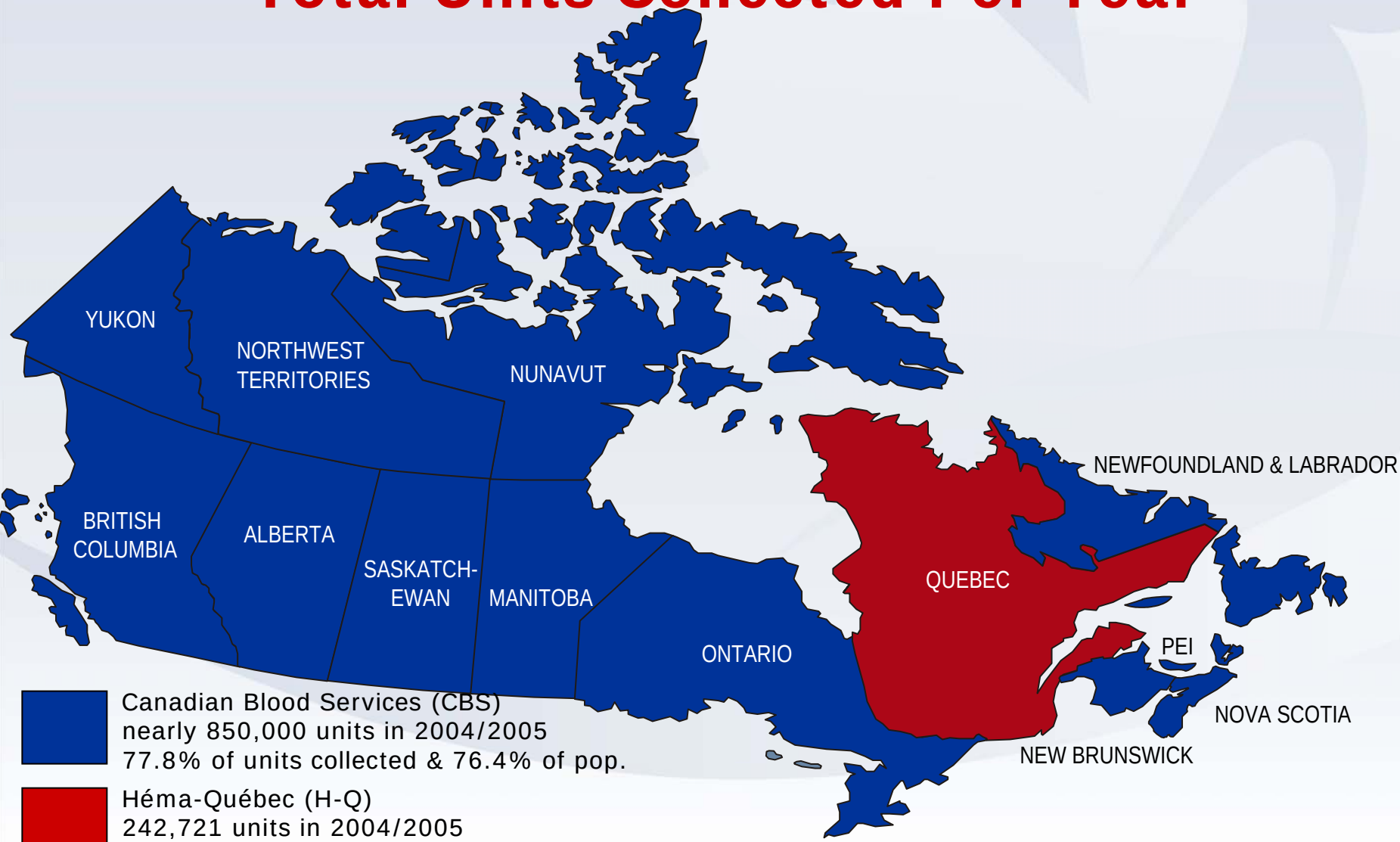


***Notes:**

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


Federal Government
Regulatory Health Canada
Surveillance PHAC
Provincial/Territorial Governments Blood Office
Hospitals

Blood Manufacturers
Total Units Collected Per Year



Canadian Blood Services (CBS)
nearly 850,000 units in 2004/2005
77.8% of units collected & 76.4% of pop.

Héma-Québec (H-Q)
242,721 units in 2004/2005
22.2% of units collected & 23.6% of pop.

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)

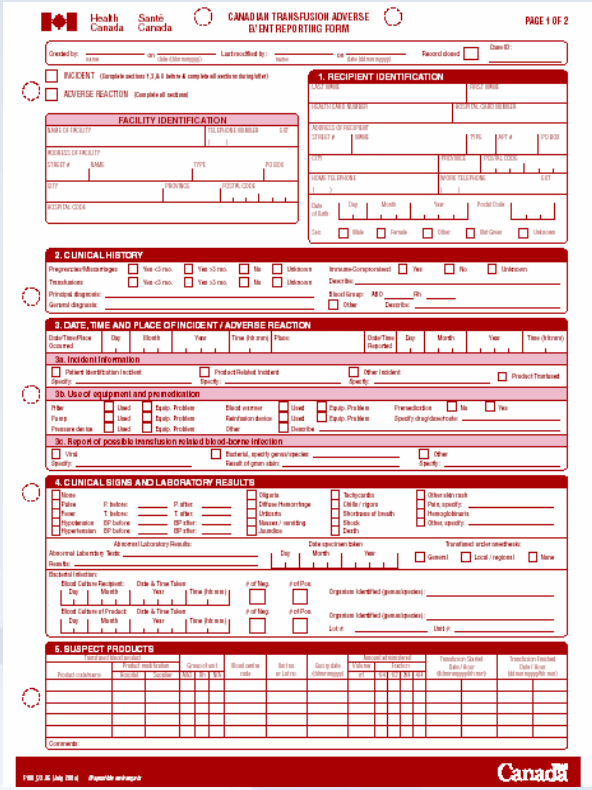
- Four Provinces:
  - British Columbia
  - Québec
  - Nova Scotia
  - PEI
- Health Canada Regulatory
- Blood Manufacturers

TTISS Project Agreements

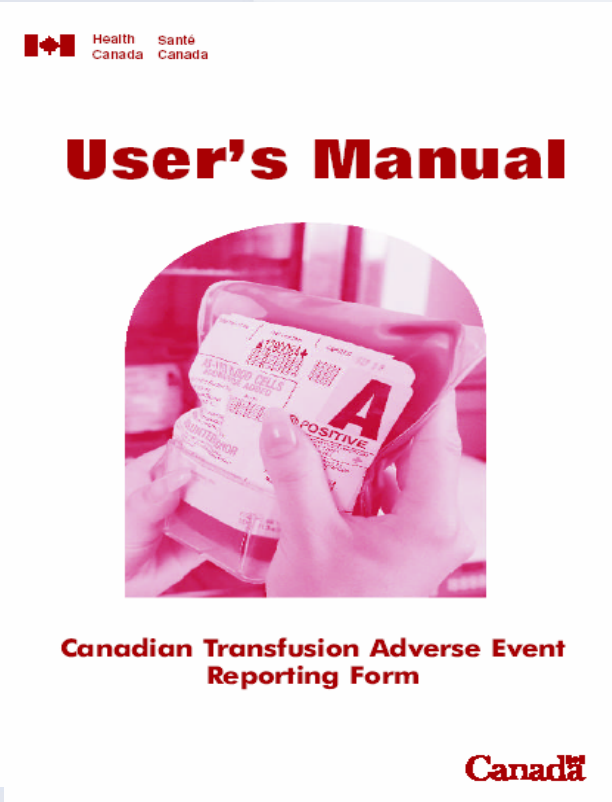
- Standardized reporting form
- Standardized definitions
- User's Manual
- Data elements exported to the Public Health Agency of Canada (non-nominal, aggregated)
- The conditions for reporting of National Data
- TTISS system to be used for reporting to Health Canada's regulatory branch & CBS
- Database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

TTISS Standardized Materials

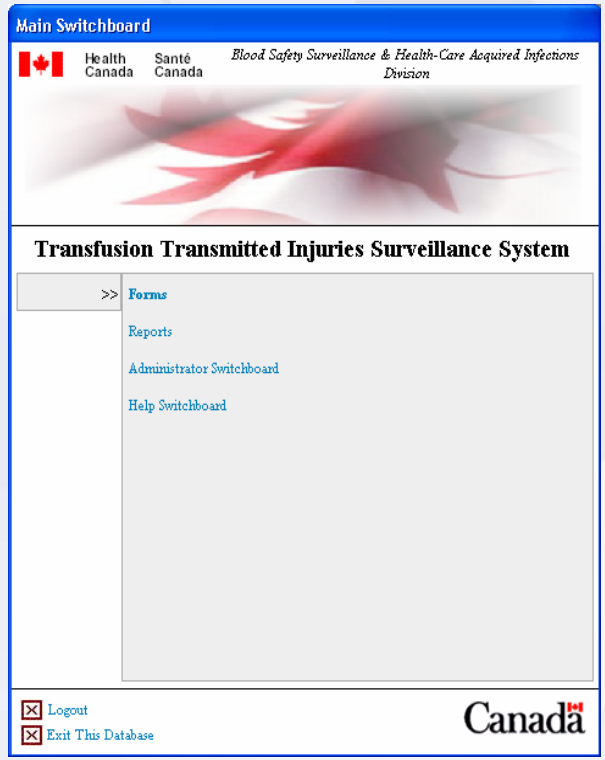
TTISS Reporting Form



TTISS User's Manual



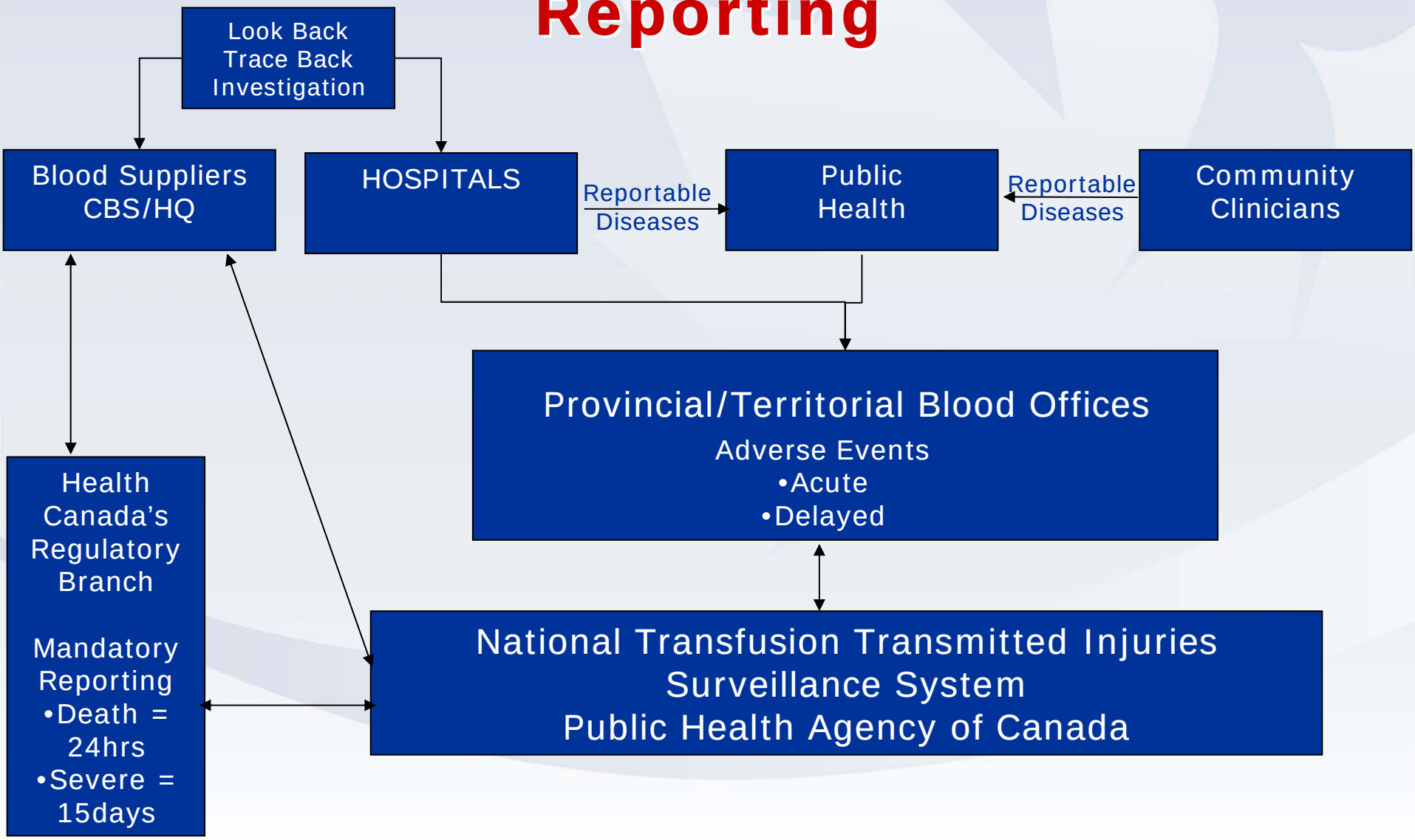
TTISS Database



TTISS Database

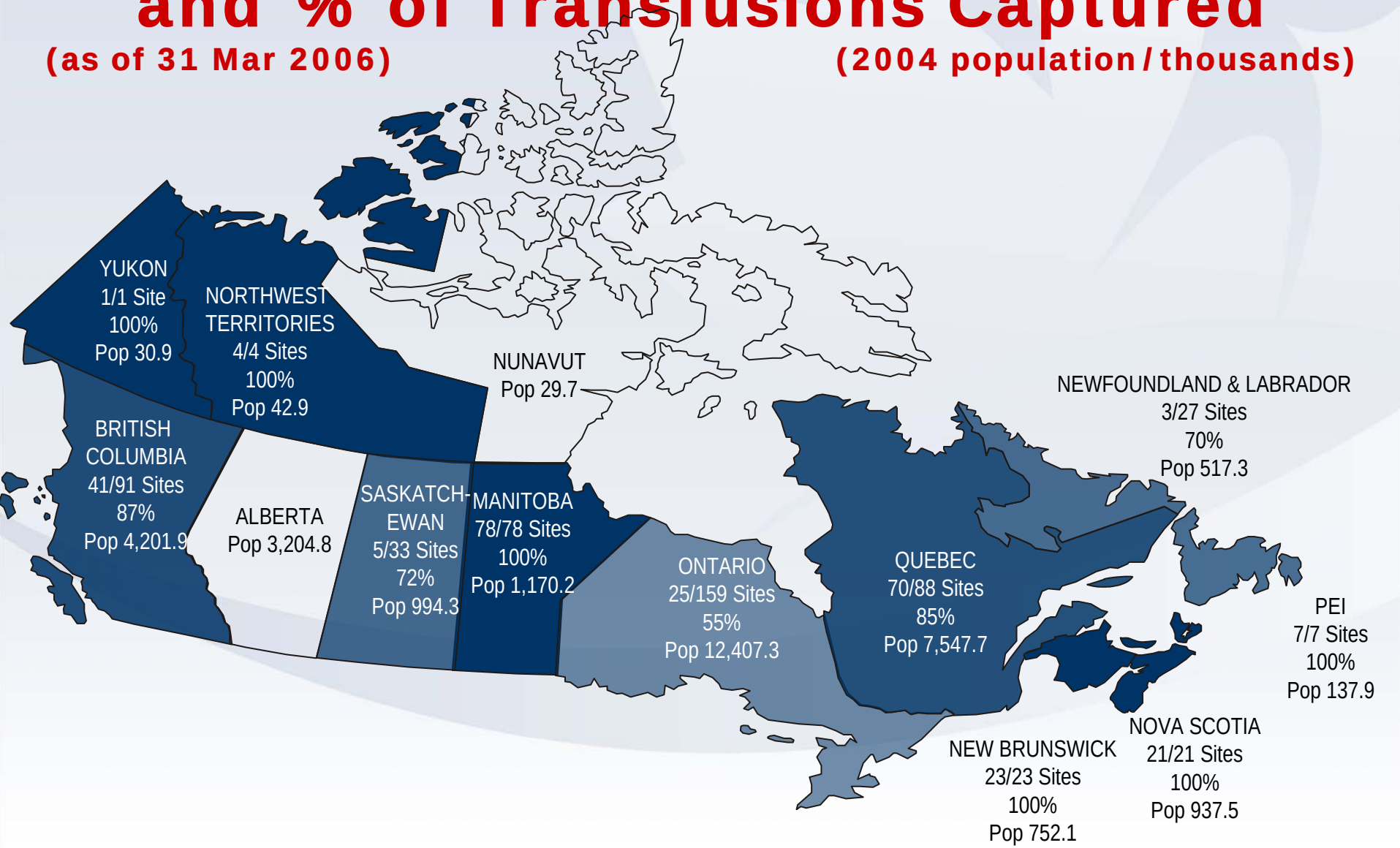
- Developed & maintained by PHAC
- MS Access Database
  - web based next version
- Provincial Blood Coordinating Offices (PBCO) export encrypted non-nominal data to PHAC quarterly

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

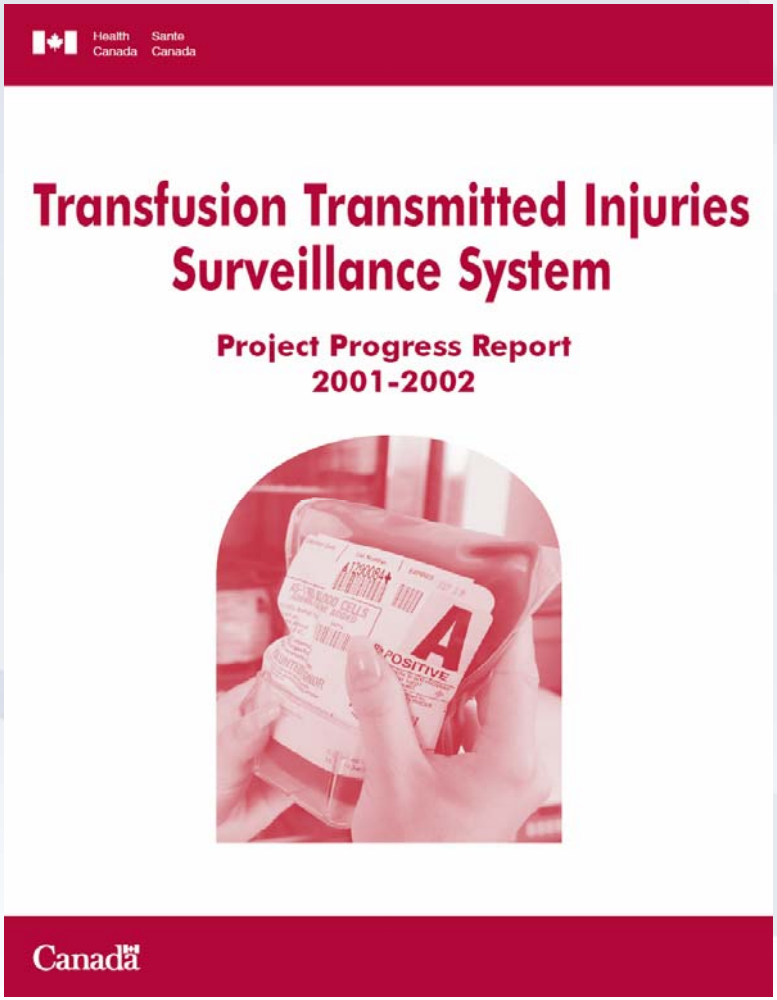
- Identify and address issues related to a national surveillance program to determine the risk of transmission of infections and injuries by blood transfusions
- Recommend future directions, quality, efficacy and effectiveness of the TTISS as a national surveillance program

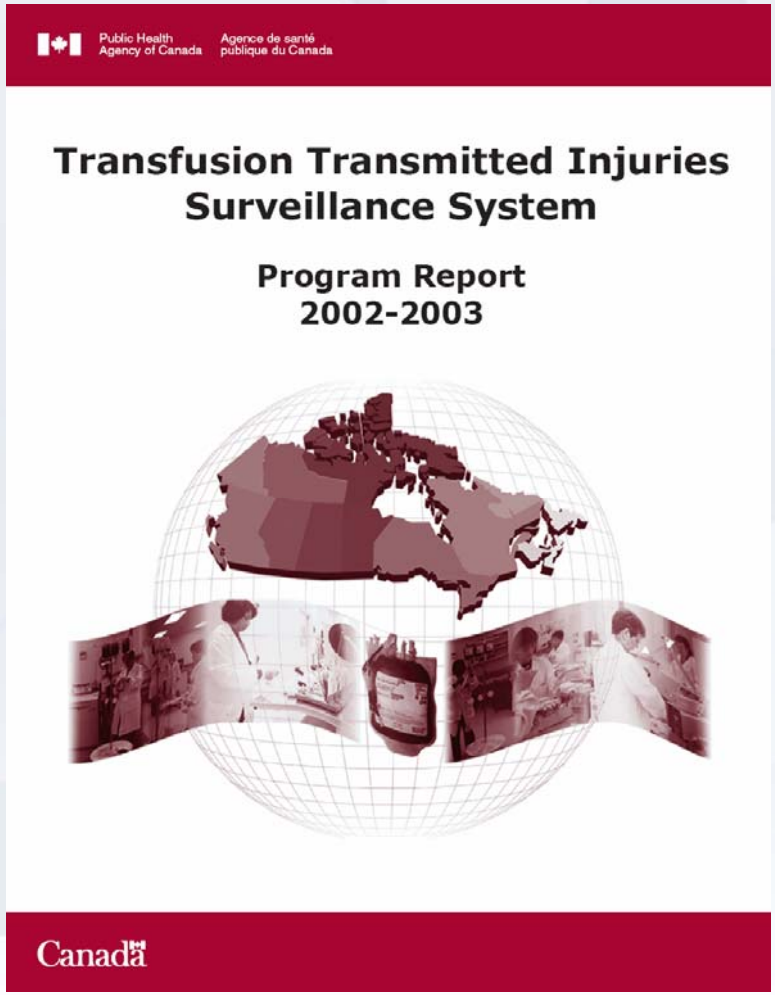
NTTISS
Yearly Data Quality Meeting

- **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

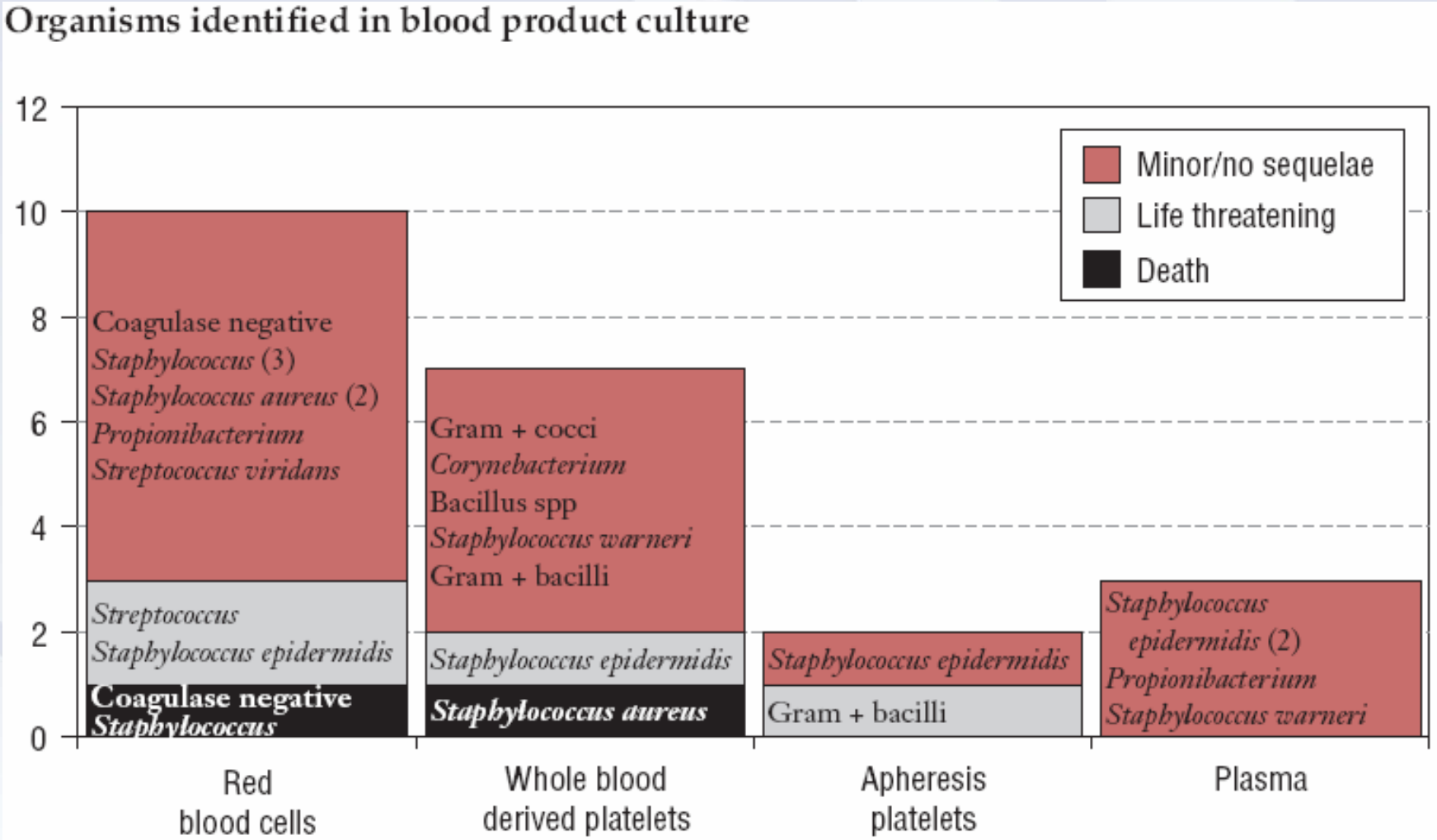
Provincial / Territorial Responsibilities

- 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

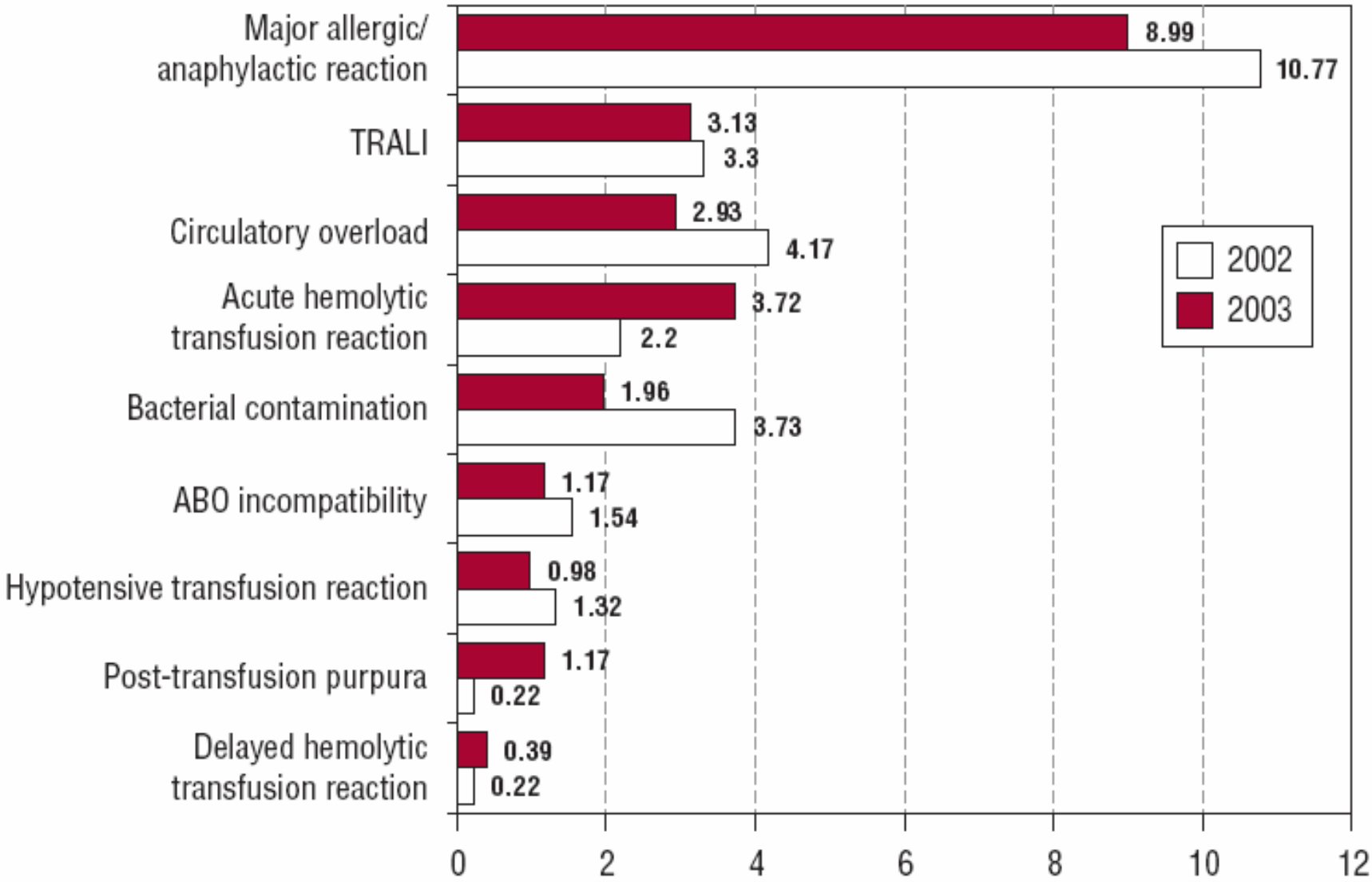
Diagnosis of adverse transfusion events related to blood components

Adverse transfusion event	Red blood cells			Whole blood derived platelets			Apheresis platelets			Plasma			Total[a]		
	2002[b]	2003[b]	Total[b]	2002[b]	2003[b]	Total[b]	2002[b]	2003[b]	Total[b]	2002[b]	2003[b]	Total[b]	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[c]	-	-	-	-	-	-	-	-	-	-	-	-	1 (0.7)	-	1 (0.4)
Other[d]	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)
Total N	75	69	144	31	15	46	2	7	9	22	28	50	138	129	267
Total %[e]	(54.3)	(53.5)	(53.9)	(22.5)	(11.6)	(17.2)	(1.4)	(5.4)	(3.4)	(15.9)	(21.7)	(18.7)	(51.7)	(48.3)	(100.0)

Bacterial Contamination



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[a]		
	2002[b]	2003[b]	Total[b]	2002[b]	2003[b]	Total[b]	2002[b]	2003[b]	Total[b]	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[c]	2 (22.2)	1 (9.1)	3 (15.0)	-	-	-	-	-	-	2 (14.3)	1 (6.7)	3 (10.3)
Total N (%)[d]	9 (64.3)	11 (73.3)	20 (69.0)	2 (14.3)	-	2 (6.9)	-	3 (20.0)	3 (10.3)	14 (48.3)	15 (51.7)	29 (100.0)

Fatal events definitely, probably or possibly related to transfusion

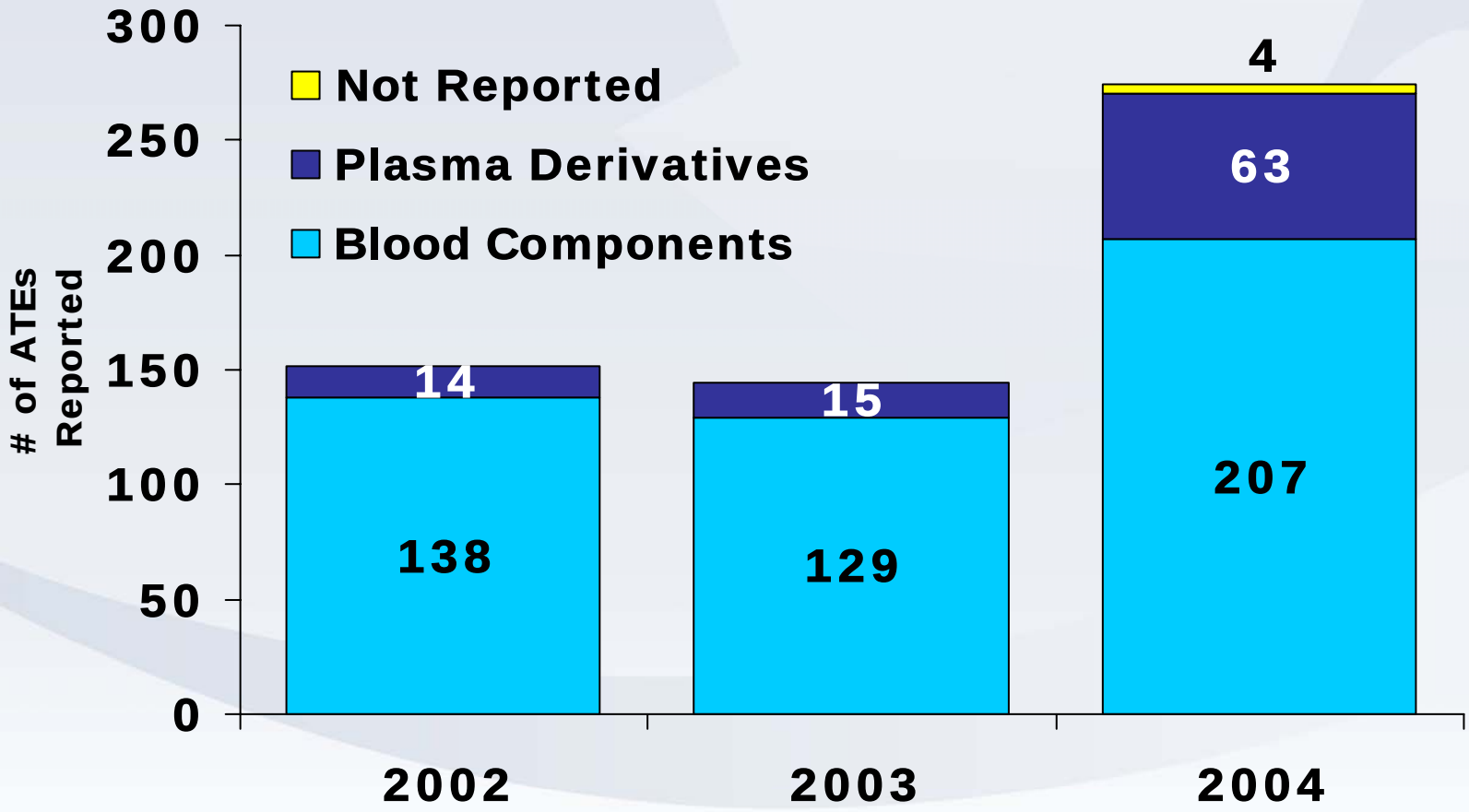
Fatal events	Relationship to transfusion			
	Definite	Probable	Possible	Total
Events related to blood components				
Bacterial contamination	1	2	1	4
TRALI	-	1	1	2
Post-transfusion purpura	1	1	-	2
Circulatory overload	-	1	-	1
Anaphylactic reaction	-	1	-	1
Events related to plasma derivatives and recombinant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

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

Fatal events	Red blood cells (616,309)		Whole blood derived platelets Pools (5) (61,447)		Cryoprecipitate (58,239)		Plasma (182,329)		All products[a] (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[b]**
Major allergic/ anaphylactic reaction	-	-	-	-	-	-	1	1:182,329	**1**	**1:966,490**
Circulatory overload	-	-	-	-	-	-	1	1:182,329	**1**	**1:966,490**
Total	**3**	**1:205,634**	**3**	**1:20,482**	**1**	**1:58,239**	**2**	**1:91,165**	**10**	**1:96,649**

[a] Includes whole blood, apheresis platelets, cryosupernatant, and granulocytes.
[b] 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