# A Canadian Call to Action: Saving Hemovigilance

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CSTM SCMT 2025
Annual Conference | Congrès annuel
ST. JOHN'S May 29–June 1 / 29 mai – 1er juin
Newfoundland and Labrador • Terre-Neuve-et-Labrador
No Lab is an Island • Aucun labo n'est une île

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# Presenter Disclosure

CSTM SCMT
Canadian Society for Transfusion Medicine
Société Canadienne de Médecine Transfusionnelle

**Presenter:** Andrew Shih

**Relationships with financial sponsors:**

- **Grants/Research Support:** Canadian Blood Services, Canadian Institutes of Health Research, CSL Behring, Grifols Canada, Hemerus Medical LLC, Octapharma Canada, Thermo-Fisher
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- **Consulting Fees:** BC Emergency Health Services, CDA-ADC, HealthConsult Australia, National Advisory Committee for Blood and Blood Products
- **Patents:** None

# Objectives

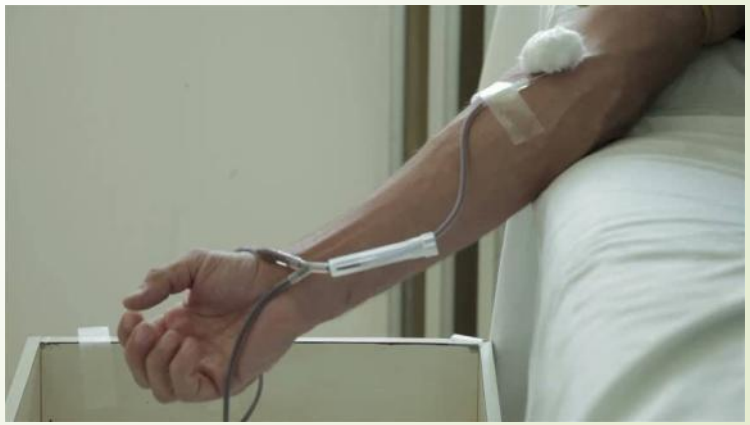
- To expand on the development and role of hemovigilance in Canada
- To discuss the current challenges of the Blood Safety Contribution Program sunsetting
- To discuss potential next steps for hemovigilance in Canada

**The following presentation is informed by the views of others, but is not representative of the views of the organizations I am affiliated with**

- Also recognition of bias for jurisdictions I've worked / are working in (BC/ON)

# Hemovigilance In Canada

# Transfusion Medicine is to Ensure Safety and Appropriateness from Vein to Vein



Wikipedia
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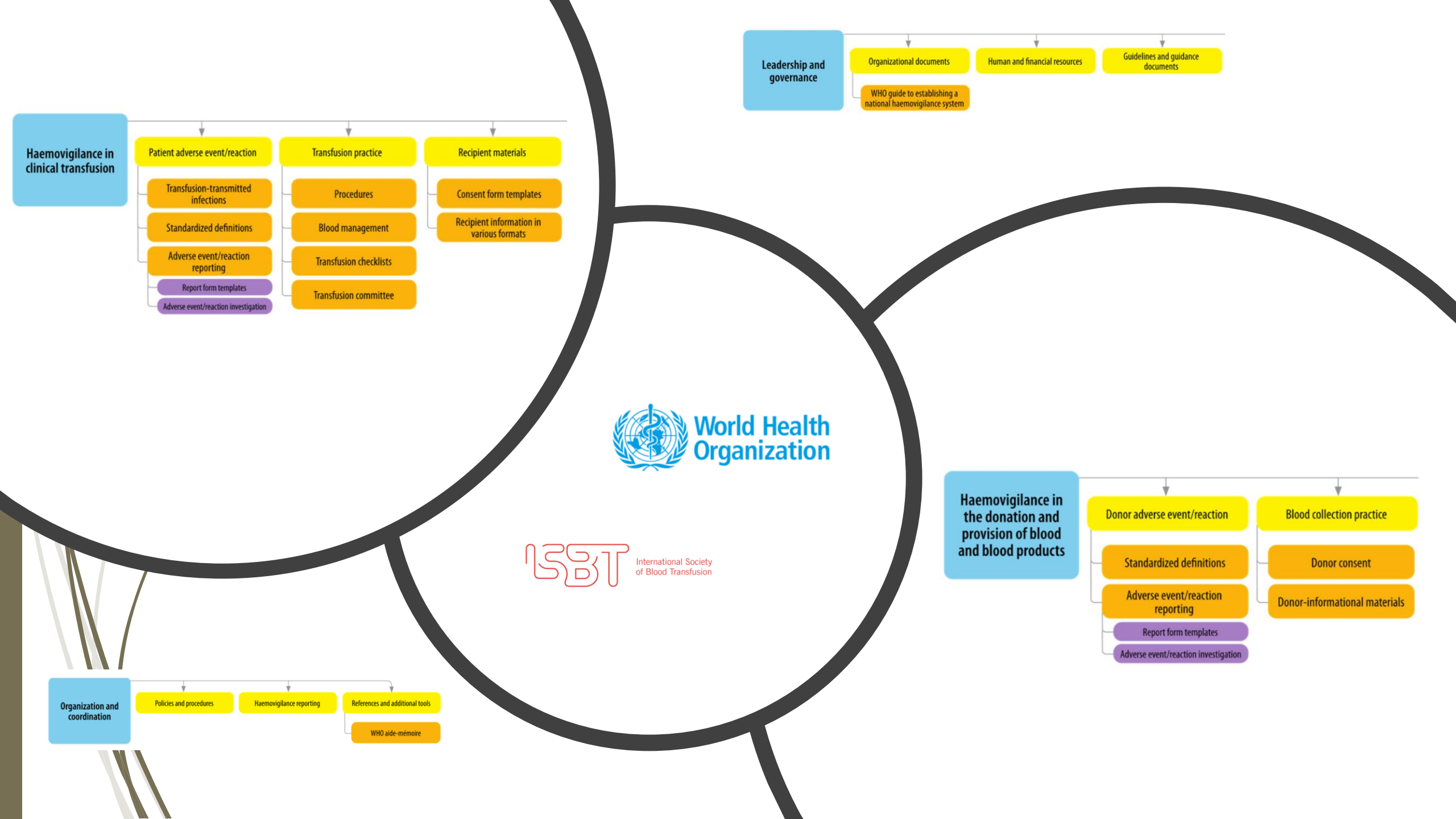
# What is Hemovigilance?

- World Health Organization (2016)

**What is haemovigilance?**

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

**"Vein to vein" accountability within the blood system**

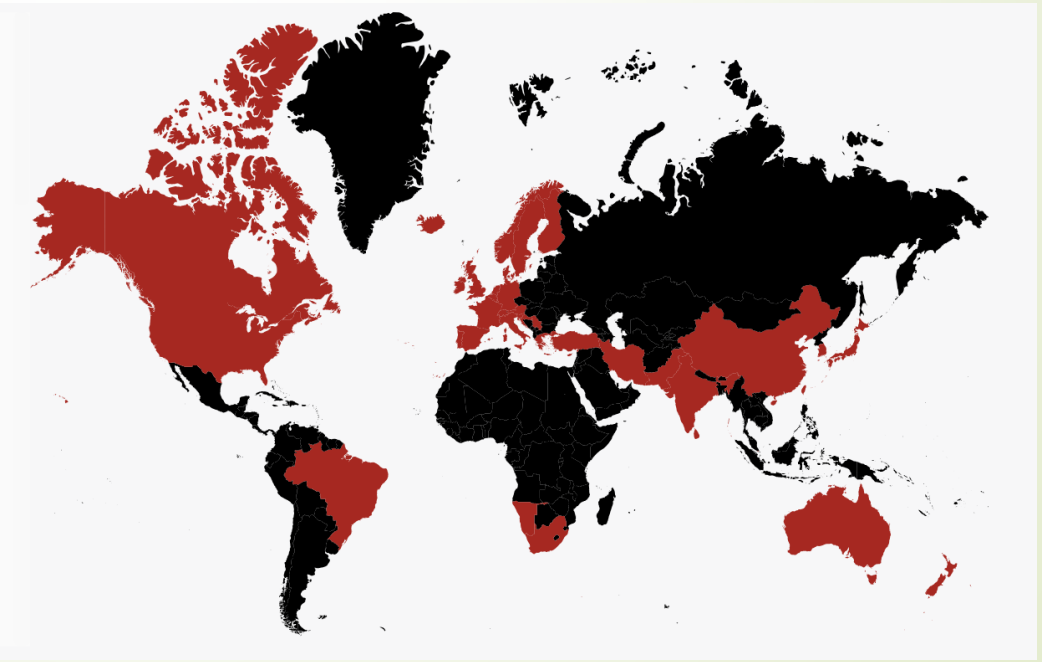

Leadership and governance
Organizational documents
Human and financial resources
Guidelines and guidance documents
WHO guide to establishing a national haemovigilance system
Haemovigilance in clinical transfusion
Patient adverse event/reaction
Transfusion practice
Recipient materials
Transfusion-transmitted infections
Standardized definitions
Adverse event/reaction reporting
Report form templates
Adverse event/reaction investigation
Procedures
Blood management
Transfusion checklists
Transfusion committee
Consent form templates
Recipient information in various formats
World Health Organization
ISBT International Society of Blood Transfusion
Haemovigilance in the donation and provision of blood and blood products
Donor adverse event/reaction
Blood collection practice
Standardized definitions
Adverse event/reaction reporting
Report form templates
Adverse event/reaction investigation
Donor consent
Donor-informational materials
Organization and coordination
Policies and procedures
Haemovigilance reporting
References and additional tools
WHO aide-mémoire

SHOT Serious Hazards of Transfusion

TRIP Hemo- en biovigilantie

CDC National Healthcare Safety Network (NHSN)

IHN International Haemovigilance Network



# Krever Inquiry (The "Tainted Blood Scandal")

- Largely considered Canada's worst preventable public health crisis
  - Led to >30,000 infections
  - Need for national blood policy to ensure safety
    - Basis for Health Canada Standards
  - Arms length from federal government
- Led to the Blood Safety Contribution Program
  - Transfusion Transmitted **Injury Surveillance System**
  - Transfusion **Error Surveillance System**

# Hemovigilance In Canada

- Health Canada - Canada Vigilance Program - Mandatory

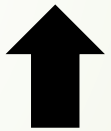
- Canadian Blood suppliers (CBS/HQ) and manufacturers of plasma derivatives

- **Purpose:** Monitors Adverse Transfusion Events (ATEs) related to the blood supply to ensure the safety of the blood product

- Public Health Agency of Canada (PHAC) via **Blood Safety Contribution Program (BSCP)** - Voluntary

- PHAC TTISS and TESS Programs

- Provincial Coordinating Programs



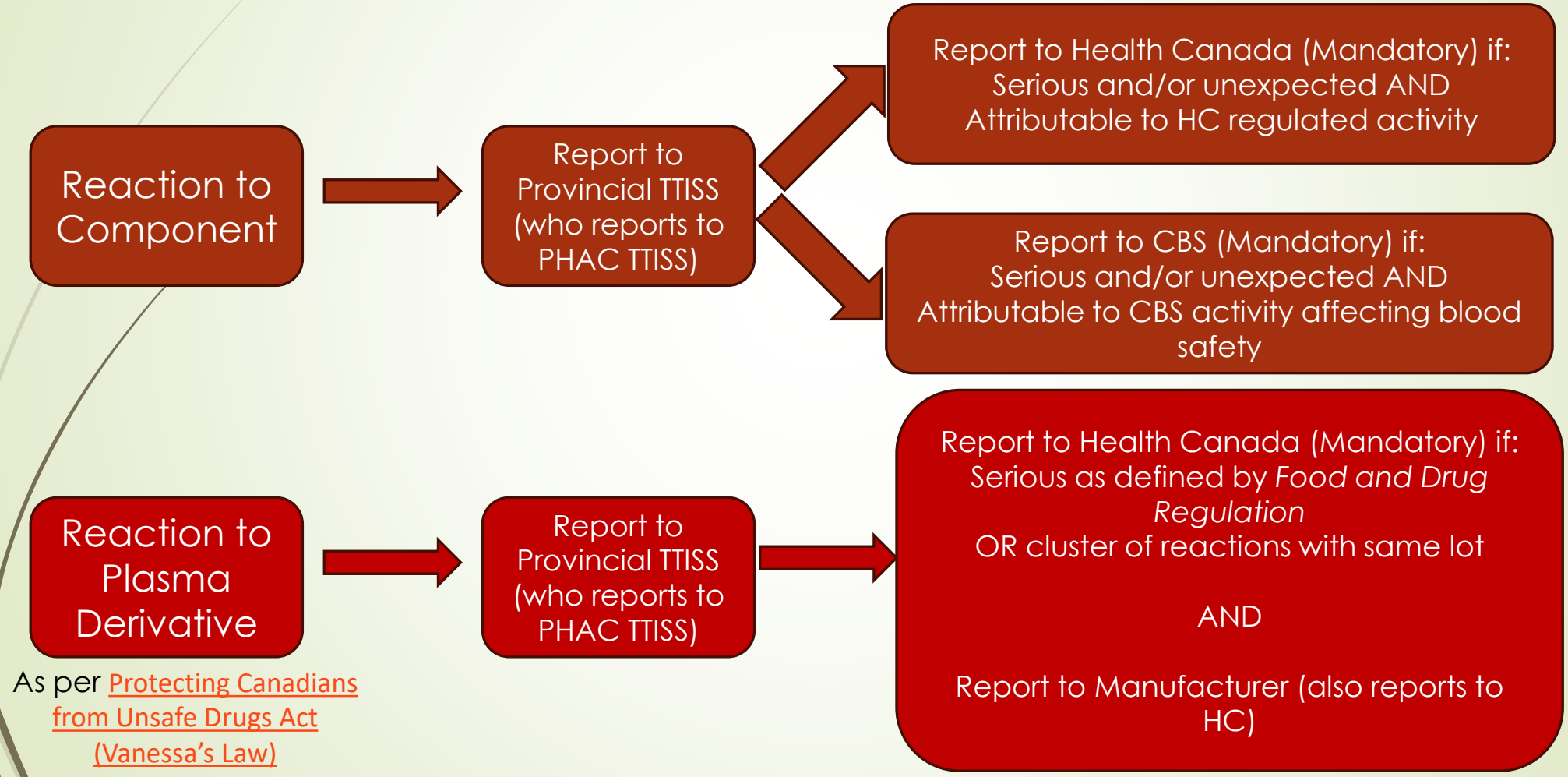
- **Purpose:** Monitors all moderate to severe ATE's for surveillance and risks (related or unrelated to the blood product)
- Created in 2001 in response to Krever report
- **TTISS – "Injuries"**
- **TESS - Errors**

# Why Report?

- Protects the blood supply
  - Recall of co-components
    - ie asymptomatic bacteremia from unaware donor
  - Donor notification, investigation, and/or deferral
- Recipient notification

- Tracking and trending new complications, known complications, and known systems factors leading to error
  - TRALI risk from multiparous female plasma → was the highest mortality until surveillance data led to intervention
  - Wrong blood in tube / wrong blood given → highly preventable
  - TACO mitigation strategies → highest mortality associated with transfusions
  - Uncertainty of emerging infectious agents

# Summary Pathway for Reporting Transfusion Reactions in the Transfusion Medicine Lab




As per Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

Adapted from https://professionaleducation.blood.ca/en/guide-reporting-adverse-transfusion-reactions

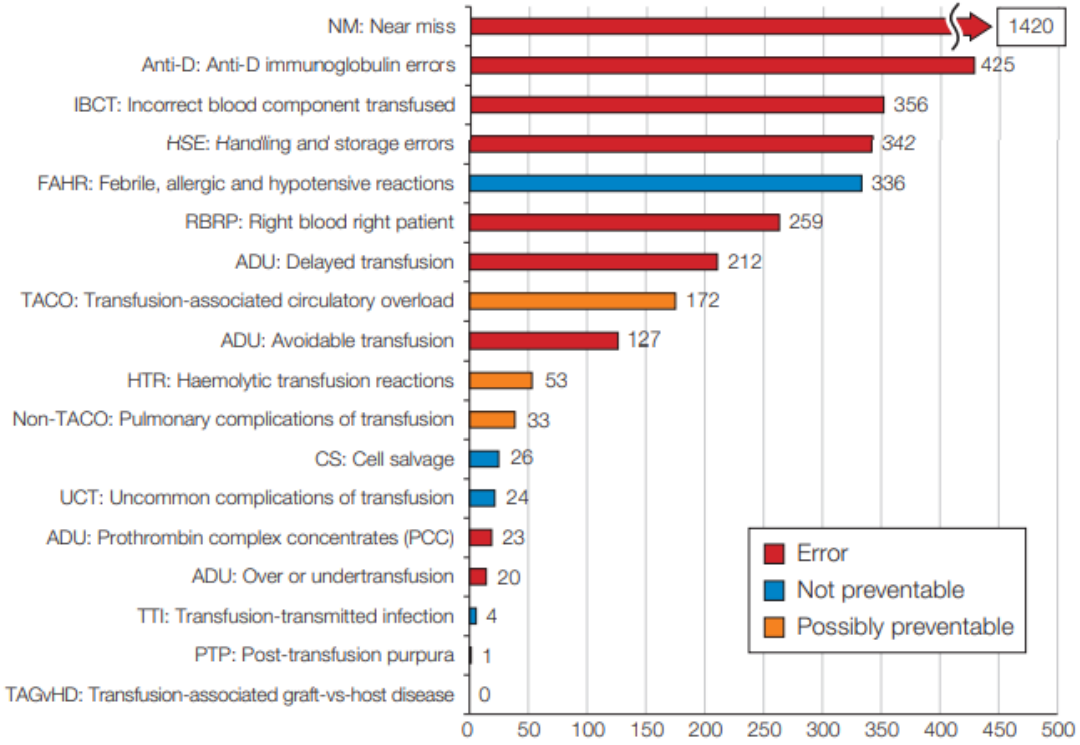
# Error Reporting

## ANNUAL SHOT REPORT 2023

SHOT is affiliated to the Royal College of Pathologists
This report is produced by SHOT working with MHRA

MHRA SHOT Serious Hazards of Transfusion

**Summary data for 2023, all categories (includes RBRP and NM) (n=3833)**





Transfusion Error Surveillance System (TESS) 2012-2016 Report
Slide adapted from Dr. Akash Gupta

# www.nacblood.ca

## OVERVIEW OF ADVERSE TRANSFUSION REACTION REPORTING FOR HOSPITALS IN CANADA:

## A NAC and Québec Hemovigilance System Collaborative Initiative

National Advisory Committee on Blood and Blood Products | Comité consultatif national sur le sang et les produits sanguins

### ADVERSE TRANSFUSION REACTION SUBCOMMITTEE

**Adverse Transfusion Reaction Subcommittee Members:**

Oksana Prokopchuk-Gauk, MD; Chair
Alan Tinmouth, MD
Lakshmi Rajappannair, MD
Lucinda Whitman, MD

*Ad hoc members:*
Mohammad Afzal (PHAC)
Maria Faraci, MD (Health Canada)
Gilles Lambert, MD (QHS/INSPQ)
Marianne Lavoie, MD (QHS/INSPQ)
Jessica Leung, PharmD (Health Canada)
Pierre-Aurèle Morin, MD (CCNMT)
Joanne Nixon (TTISS Ontario)
Andréanne Trottier (CCNMT, MSSS)
Jun Wu, MD, PhD (PHAC)
Matthew Yan, MD (CBS)

**Table 1: Submission Forms for Reporting Authorities**

| Reporting Authority | Form |
|---|---|
| **PHAC-TTISS**<br>- ATRs with sign-symptoms along with relationship/ severity/outcome during or after blood transfusions. | Fax the a de-identified provincial/jurisdictional ATR report form or a completed Canadian Transfusion Adverse Event Reporting Form (CTAERF) to your local or P/T TTISS designate for data entry into CNPHI.<br>• CNPHI is a web-based online system with access granted to individuals in each province/territory to directly enter or upload their TTISS data. The system is password protected. The TTISS annual data of all provinces/territories is exported to other software for internal reports and analysis.<br>• Hospitals in Québec report all ATRs to the QHS using the REIAT Form (not directly to the TTISS). |
| **Health Canada – CVP**<br>- Serious or unexpected ATRs related to quality/ safety of blood component. | **To report serious or unexpected ATRs related to quality/safety of blood component:**<br>• Fax a provincial/jurisdictional ATR report form[1] or completed CTAERF to 1-866-678-6789. |
| **Health Canada – CVP**<br>- Trends/clusters of non-serious (minor) ATRs to blood products. | **To report trends/clusters of non-serious (minor) ATRs to blood products:**<br>• Submit a voluntary online Report a Side Effect Form[2];<br>• Call 1-866-234-2345 (toll-free); or,<br>• Fax the Side Effect Reporting Form to 1-866-678-6789.<br>Note: for general blood-related inquiries or if you suspect lot-associated issues (such as potential clusters of serious and non-serious reactions), you may wish to notify canada.vigilance.blood-sang@hc-sc.gc.ca prior to submitting the report form(s). Please do not send copies of completed reports containing patient information to this email address. |
| **Health Canada – CVP**<br>- Serious ATR to blood product;<br>- Medical Device Incidents (MDIs). | **To report serious ATRs to blood product and MDIs:**<br>• Submit online using the:<br>  ○ Serious adverse drug reaction (for hospitals); or<br>  ○ Medical device problem (for healthcare professionals).<br>• Fax either of the below to 1-866-678-6789:<br>  ○ Serious Adverse Drug Reaction Reporting Form for Hospitals; or<br>  ○ Medical Device Problem Report Form for Health Care Professionals. |

# Blood Safety Contribution Program Sunsetting

# Hemovigilance is…

- **A direct requirement of the Krever Commission**
  - Recommendations #2, #46, #47, and #48
- **A Federal Responsibility**
  - Minister of Health (Canada) is responsible based on the MoU from the Krever Commission:
    - The administration of the Food and Drugs Act with respect to the national blood system
    - Conduct of national surveillance activities and an effective national system for the surveillance of blood-borne pathogens in cooperating with blood authorities
- **Required for True Vein-to-Vein Safety**
  - Increased safety of blood through CBS and HQ (which mitigates risks) is complementary to hemovigilance (which detects risks) → required for true vein-to-vein safety

# Background

- Through the voluntary Blood Safety Contribution Program (BSCP), the Public Health Agency of Canada (PHAC) currently provides a total of $2.19M annually for the function of TTISS and TESS
  - Established in follow-up to the publication of the Krever Report in 1997
  - Supports **provincial and territorial systems** that monitor adverse events
  - Federal funding originally $4 million - ↓ in ~$2 million unaccounted for over years
- BSCP Sunsetting announced in August 2024 to end funding in March 2026
- The Evaluation of the PHAC BSCP report was published in February 2023, which was undertaken internally with selected external consultation, which highlighted some challenges with the existing BSCP

# Evaluation of the Public Health Agency of Canada's Blood Safety Contribution Program 2017-18 to 2021-22

Prepared by the Office of Audit and Evaluation
Health Canada and the Public Health Agency of Canada
February 2023

## Key findings

As the need and use of blood, blood products, and CTOs in transfusion and transplantation activities continues to increase in Canada, there is an elevated risk of adverse events related to transfusion and transplantation. Monitoring adverse events will allow for a quicker reaction in the event of a new or previously unknown blood and CTO safety issue or threat.

Surveillance data generated by provinces and territories was appropriate and is being used within their respective jurisdictions. However, national information provided by PHAC is not timely for users and has not been used to further inform planning and decision making within provinces and territories. In some cases, provinces and territories are undertaking some level of multi-jurisdictional analysis themselves which they feel should be PHAC's role.

## Recommendations

The evaluation evidence discussed in this report led to the development of the following recommendations.

**Recommendation 1**: Clearly define and communicate PHAC's role, responsibilities, and priorities, in collaboration with all partners, with respect to:

- financially supporting surveillance systems monitoring adverse events and errors associated with the transfusion of blood, blood products and cell, organ and tissue transplantation in Canada; and
- monitoring, analyzing and reporting adverse events and errors linked to transfusion and transplantation activities in Canada.

**Recommendation 2:** Based on the outcome of the first recommendation, determine the necessary structures to ensure the timely release of BSCP surveillance information.

***Rather than addressing key recommendations and investing in the BSCP, PHAC has chosen to <u>sunset</u> the BSCP instead.***

# Rationale for Sunsetting

- In follow-up to Evaluation of the PHAC BSCP report published in February 2023, PHAC has decided to phase-out the BSCP following the end date of existing contribution agreements on March 31, 2026, stating the following rationales:
  1. *"objectives of the BSCP do not align with PHAC's mandate and priorities,"*
  2. the BSCP is voluntary and supplements existing PT surveillance activities,
  3. data collection and synthesis is not reported in a timely fashion,
  4. all mandatory reporting for unexpected and severe outcomes are reported to blood operators under the regulatory oversight of Health Canada.

# Assessment – Rationale 1

- ***"Objectives of the BSCP do not align with PHAC's mandate and priorities"*** – this statement is in opposition to the posted PHAC Mandate:

## Mandate

The role of the Public Health Agency of Canada is to:

- promote health
- prevent and control chronic diseases and injuries
- prevent and control infectious diseases
- prepare for and respond to public health emergencies

We serve as a central point for sharing Canada's expertise with the rest of the world. As such, our role is also to:

- strengthen public health collaboration between governments
- facilitate national approaches to public health policy and planning
- apply international research and development to Canada's public health programs

# Assessment – Rationales 2 and 3

- **Untimely data collection and synthesis, without federal accountability:**
  - Last PHAC TTISS summary results from 2016-2020, one-page infographics since
  - Not a reason to redirect federal funding away from hemovigilance

- **The Program is voluntary and supplements existing PT surveillance activities, without the BSCP:**
  - Loss of national program: facilitates resources and reach for local surveillance
  - Loss of avenue for PT hospital accreditation: Reporting to hemovigilance required
  - Loss of power to detect threats: PTs depend on collective data and comparisons

# Assessment – Rationale 3

- **Examples: Canadian Standards Association – Z902-20**

**14.8 Adverse events**

The facility's operating procedures shall include provisions for documenting, reporting, evaluation, and follow-up of all adverse events relating to the blood products it handles, including the necessary notifications of the distributor, manufacturer, and regulatory authorities. These procedures should be developed in consultation with the facility's pharmacy.

**18.2.2**

Following notification of an unexpected or serious adverse event, the transfusion service shall conduct investigations, including laboratory tests, to determine the probable cause. Reports shall be submitted to the appropriate authorities in accordance with applicable requirements.

**At the hospital level, <u>who</u> is to complete associated chart reviews and reports?**

→ This is currently the role of Transfusion Safety Officers (personnel funded by BSCP dollars)

**<u>What database</u> is to be utilized to track provincial adverse transfusion reaction data?**

→ This is currently completed in partnership with the TTISS program utilizing the CTAER Form and the database (with provincial profiles) within CNPHI maintained by PHAC

# Assessment – Rationale 4

- **All mandatory reporting for unexpected and severe outcomes are reported to blood operators under the regulatory oversight of Health Canada, but Health Canada/CBS-HQ not solely adequate:**
  - HC does not capture all transfusion reactions
    - Emerging threats begin in subtle fashion, pathogen reduction not universal
  - HC/CBS-HQ only capture reactions associated with blood quality
  - HC does not provide surveillance data reports for PTs to interpret and analyze

# Impact

- **What does loss of the BSCP mean for patients and the public?**
  - Public now vulnerable to emerging threats and signals of harm
    - Blood transfusion is ubiquitous, life-saving, and has different risks compared to pharmaceuticals which have minimal variability.
    - If harm occurs, it will be impossible to regain public trust and health care systems across PTs will feel the most burden
  - Canada will be the only industrialized nation without a comprehensive hemovigilance program
  - Budgets mostly used for highly-skilled personnel
  - Blood safety in relation to the role of error capture and inappropriate practice will be completely lost → now seen as the largest risk of blood

# Potential Next Steps for Hemovigilance?

The following slides are my own opinion

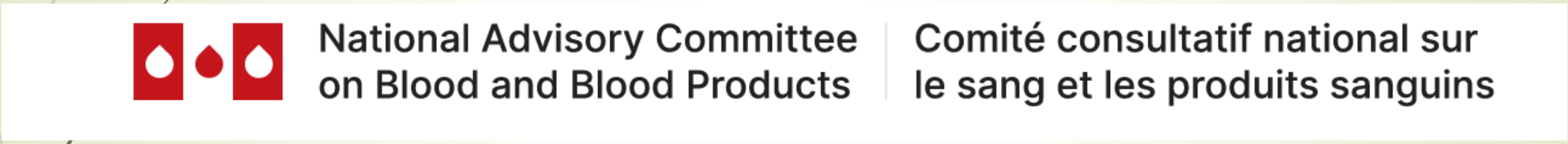
Need for engagement for “Hemovigilance 2.0”


Canadian
Blood
Services
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES


HÉMA-QUÉBEC


Canadian Hemophilia Society
Help Stop the Bleeding


HAE|AOH
CANADA


National Advisory Committee
on Blood and Blood Products
Comité consultatif national sur
le sang et les produits sanguins


ORBCoN
Ontario Regional Blood Coordinating Network


Québec
INSPQ


CSTM
Canadian Society
for Transfusion Medicine
SCMT
Société canadienne
de médecine transfusionnelle

# Recommendations

1. Engage PHAC to retract its withdrawal of funding and discuss redirection of federal dollars
   - Nationwide surveillance and safety is a federal responsibility → allows for centralization, harmonization, and economies of scale
     - Data from the PHAC National Database (CNPHI) must be preserved and made accessible

2. Engage federal government to understand BSCP defunding and eventual discontinuation
   - Federal funding began at $4 million, with multiple staff working at federal office

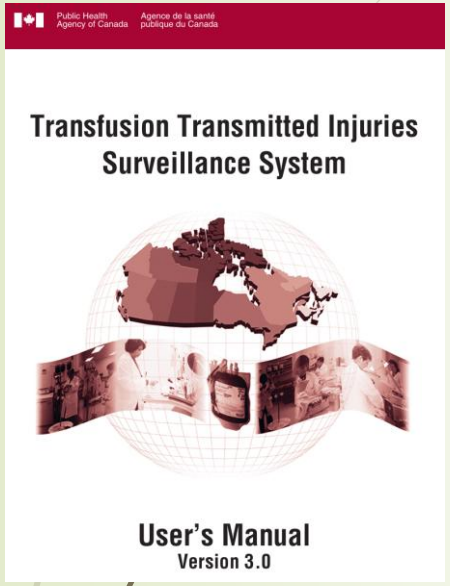
3. Reform the Canadian hemovigilance system to ensure PT involvement
   - New system must be timely, accountable, comprehensive, forward-thinking
     - Regular reports & recommendations co-created, collecting all reactions (with right level of detail), leverage technology & modern approaches to maximize efficiency for dollars spent
   - Independent body, funded majorly federally
   - Engagement and representation of PT stakeholders involved – across all PTs

# Progress

- CBS/HQ, PTs, transfusion medicine experts/clinicians, patient groups and others united in serious concern
  - All stress the importance of maintaining and improving hemovigilance
  - PT governments are discussing the issue and engagement of federal counterparts
- CBS/HQ have proposed to host a robust consensus conference as a forum for essential consultation.
  - Representation suggested to include: CBS/HQ, PHAC/Health Canada, PT ministries of health, NAC and CCNMT, international hemovigilance expertise, transfusion medicine leaders and patient groups
  - PHAC discussing with Health Canada
  - CBS has done preliminary work for such a conference

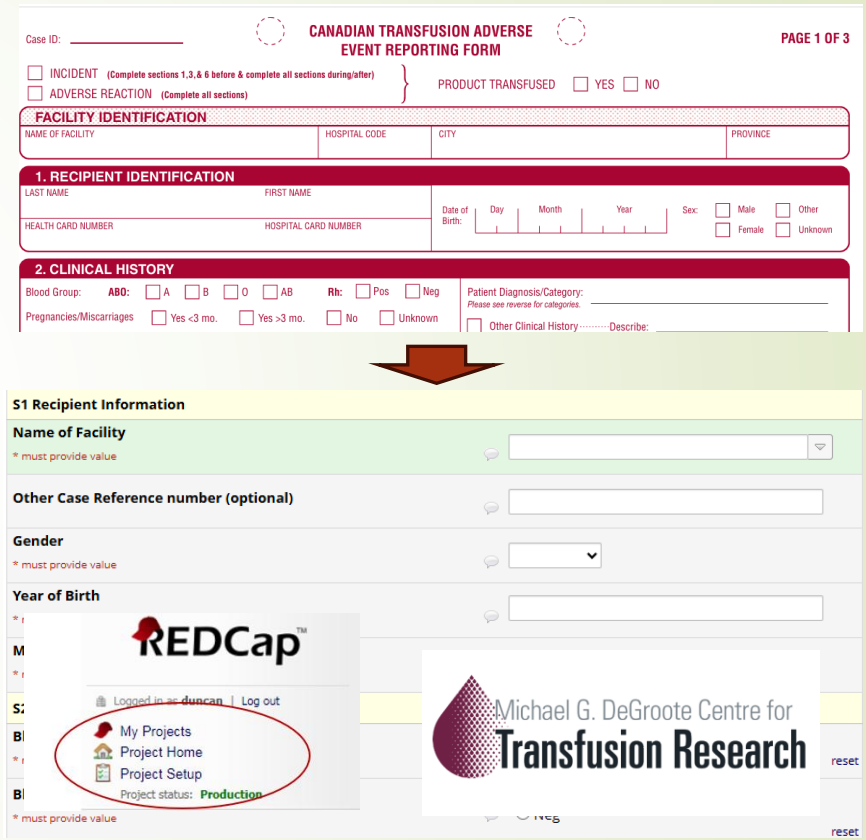
- *The central thesis/purpose: thorough analysis of current gaps, and recommendations for necessary improvements to national hemovigilance to ensure effectiveness at a critical time for blood system surveillance in Canada and the world.*

# Revision of the TTISS Manual and CTAER



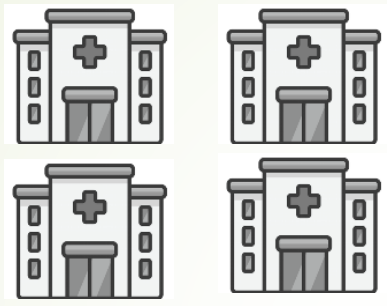


- Internationally recognized definitions and new categories
- Guidance for data collection
- Introduction of error codes?




- Electronic data entry and report generation
- Flexibility to capture emerging threats and categorizations

# Surveillance for "Cluster" Reactions



HÉMA-QUÉBEC

Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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

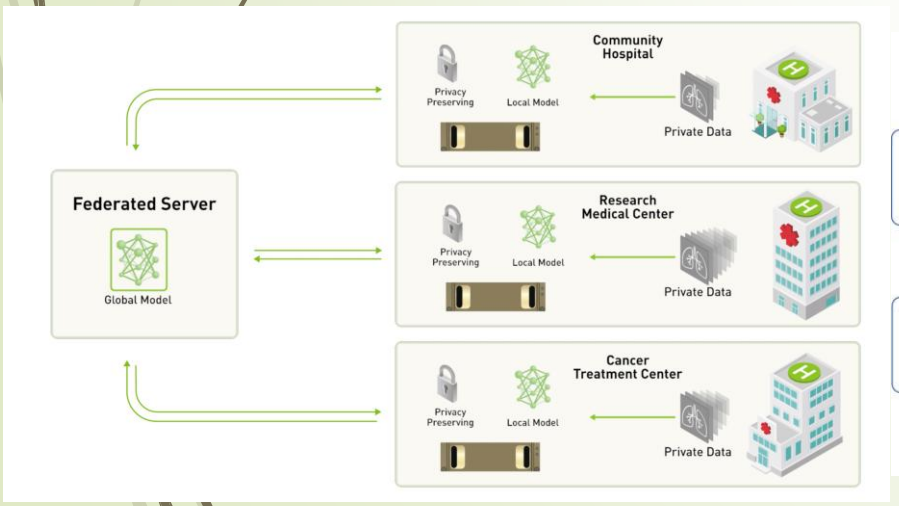
Santé Canada Health Canada

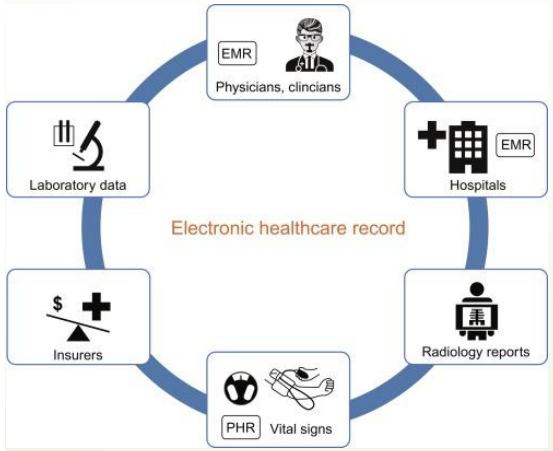
- Expertise and serendipity to recognize cluster
- Lack of process for local hospitals to communicate
- **What is a cluster and how do we monitor for it?**

- **What informs when a cluster of reactions requires action?**
  - Not all groups of reactions require action
- What P/T data and/or guidance plays a role?

Royalty-free images: **Pien Duijverman;** Toon Lambrechts on Unsplash

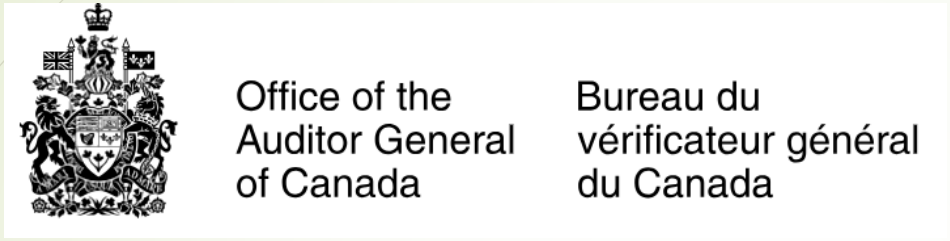
# Opportunity to Leverage Technology

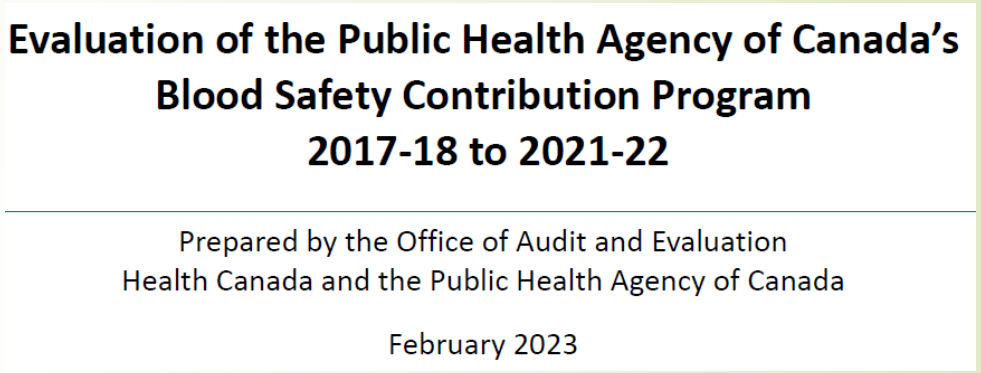




- Connection of electronic healthcare data
  - Automated data entry
  - Clinical insights
  - Active surveillance
- Canadian data frameworks already in play
- Opportunity for *AI-augmented* expert review and adjudication

# Accountability to Program Audits




- Sunsetting occurred against the recommendations of the blood system and two independent government-affiliated audits
  - OAG has a role to ensure accountability


# Questions?

- Non-exhaustive list of thanks to:
  - TTISS Manual Working Group and hemovigilance supporters
    - Dr. Christine Cserti, Dr. Pierre-Aurele Morin, Dr. Oksana Prokopchuk-Gauk, Dr. Matthew Yan, Nour Alhomsi, Crystal Brunk
  - TTISS-ON and MCTR
    - Melanie St. John, Maheen Ahmad, Joanne Nixon, Nancy Heddle, Dr. Donnie Arnold
    - TTISS-ON Educational Committee
  - Canadian Blood Services, Hema-Quebec, and the Provincial-Territorial Blood Liaison Committee
    - NAC and CCNMT
  - The CSTM Board of Directors
  - Canadian Blood Coordinating Program Collaborative (CBCPC) and ORBCoN
  - TESS
    - Sunnybrook Office: Julia Lou, Aryana Singh, TM lab, Dr. Yulia Lin, Dr. Heather VanderMeulen, and Dr. Akash Gupta
  - Transfusion Safety Officers and Transfusion Nurse Clinicians
  - **You, the transfusion medicine community of Canada**