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# Adverse Health Event Management: Some Lessons from the Krever Inquiry

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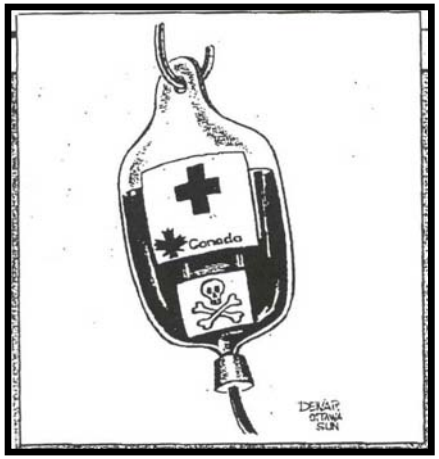
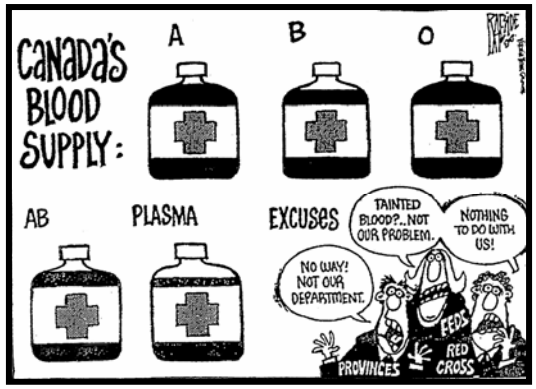
*NF Provincial Forum on Adverse Health Event Management*
*St. John's NL*
*May 26, 2008*

Canadian Blood Services
it's in you to give

# Legacy - born in an environment of failure and scandal




# The Commission of Inquiry on the Blood System in Canada

Federal government determines need for a commission of inquiry

Justice Horace Krever, appointed by Order in Council, October 4th 1993

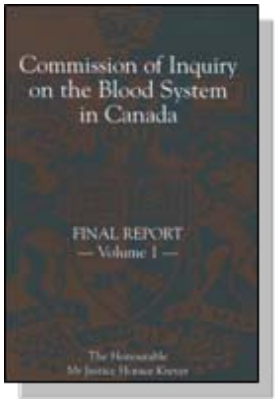
- to review and report on the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada

Justice Krever tables an Interim Report

- February 15th 1995
- 43 recommendations focused on operational, technical and clinical aspects of blood system at the time

Work on final report continues

- 247 days of hearings from 474 individuals
- phase I – input from those infected with HIV or HCV
- phase II – national issues concerning historical actions and relationships
- phase III – organization of the blood system at the time
- appeals under *Section 13 of the Inquiries Act* caused significant delays
- final report released November 26th, 1997



# Canadian Blood Services

- In September 1998, Canadian Blood Services and Héma-Québec established
- Canadian Blood Services operates in 9 provinces and all 3 territories
  - Population served ~25,000,000  (HQ ~7,700,000)
  - Collect ~880,000 units/year
  - Must recruit ~86,000 new donors each year
  - Support ~750 health care facilities
- Funded by provincial/territorial MOH (excluding QC)
  - Operations occur at “arms-length” from funders
- Independent Board of Directors
  - Members appointed by the provincial MOH

# Quotes from Krever - Foreword

- “In the pages that follow, an account is given of a public health disaster that was unprecedented in Canada, and if we have learned from it, one that will never occur again.”

# Quotes from Krever – Precautionary Principle

- “When there was reasonable evidence that serious infectious diseases could be transmitted by blood, the principal actors in the blood supply system in Canada refrained from taking essential preventative measures until causation had been proved with scientific certainty. The result was a national public health disaster.”

# Quotes from Krever – Balancing risks & benefits and partial measures

- “The balancing of the risks and benefits of taking action should be dependent not only on the likelihood of the risk materializing but also on the severity of the effect if the risk does materialize, on the number of persons who could be affected, and on the ease of implementing protective or preventative measures. The more severe the potential effect, the lower the threshold should be for taking action. . .. If there are no measures that will entirely prevent the harm, measures that may only partially prevent transmission should be undertaken.”

# The Commission of Inquiry on the Blood System in Canada

- Final report (Nov 1997) – 50 recommendations

| | |
|---|---|
| #1 | Compensation |
| #2 | The Canadian blood system – basic principles |
| #3-28 | The operator: a national blood service |
| #29-45 | The regulator: the health protection branch |
| #46-50 | Public health |

# Krever recommendation # 6

- …that the blood supply system be operated in an open and accessible manner.
  - …the current lack of confidence in the blood system…results, in no small measure, from the absence of public participation in the decision-making process that, until now, has characterized the system."

# Krever recommendation # 14

- …..that…the following standing committees be created to facilitate the work of the national blood service:
  - a safety committee
  - a technical and scientific committee
  - a liaison committee

  *All committees should have as member representatives from consumer groups and the public.*

# Krever recommendation # 22

- …that there be an effective exchange of information between the national blood service and all hospitals that supply blood components and blood products

# Krever recommendation # 28

- …that, on learning of potential risks to the safety of blood components or blood products, the national blood service cause recipients to be informed.

# Krever recommendation # 40

- …that there be  an active program of post-market surveillance for blood components and blood products

# Krever recommendation # 28

- …that, on learning of potential risks to the safety of blood components or blood products, the national blood service cause recipients to be informed.

# Definitions – Lookback

- Lookback - The process of identifying and initiating testing of recipients who received blood components from a donor who, on subsequent testing, is confirmed positive for a transfusion-transmissible infectious agent.
  - from a regulatory point of view is similar to a recall

# Definitions – Traceback

- Traceback - The process of investigating donors who contributed blood component(s) for a transfusion to a patient who developed a blood-transmissible infection.
  - from a regulatory point of view is similar to an adverse reaction
  - reporting requirement for adverse reactions
    - 24 hr if life-threatening or fatal
    - 15 days for all others

# Difficulties with lookback & resolving those difficulties

- Not begun in a timely manner
- Poor records – lack of ‘traceability”
- Many patients did not know that they had received a transfusion
- Policies/SOPs/resources
  - Blood supply, hospitals
- Requirement for tracking “vein to vein”
- Patient information
  - Informed consent
  - Notification of transfusion

**Canadian Blood Services**

**ENHANCED LOOKBACK OUTCOMES ON COMPLETED INVESTIGATIONS**

**From: 1985-01-01 To: 2007-11-30**

| | HIV | | HTLV | | HCV | | HBV | |
|---|---|---|---|---|---|---|---|---|
| **Total Cases** | **717** | | **386** | | **10521** | | **296** | |
| | # | % | # | % | # | % | # | % |
| Initiated through Centre Screening | 430 | 60.0% | 370 | 95.9% | 6108 | 58.1% | 230 | 77.7% |
| Initiated through Traceback | 67 | 9.3% | 4 | 1.0% | 751 | 7.1% | 9 | 3.0% |
| Initiated through Other* | 219 | 30.5% | 12 | 3.1% | 2721 | 25.9% | 57 | 19.3% |
| Initiated through SSP** | 1 | 0.1% | 0 | 0.0% | 941 | 8.9% | 0 | 0.0% |
| **Cases Open** | **10** | **1.4%** | **7** | **1.8%** | **288** | **2.7%** | **29** | **9.8%** |
| **Cases Completed** | **707** | **98.6%** | **379** | **98.2%** | **10233** | **97.3%** | **267** | **90.2%** |
| First-time Donors | 259 | 36.6% | 194 | 51.2% | 4091 | 40.0% | 126 | 47.2% |
| Repeated Donors | 400 | 56.6% | 146 | 38.5% | 4336 | 42.4% | 59 | 22.1% |
| Not available | 46 | 6.5% | 36 | 9.5% | 1704 | 16.7% | 79 | 29.6% |
| Total # of Recipients Afftected*** | 1559 | 217.4% | 685 | 177.5% | 26171 | 248.8% | 324 | 109.5% |
| Recipients (+) | 251 | 35.0% | 28 | 7.3% | 5758 | 54.7% | 27 | 9.1% |
| Recipients (-) | 373 | 52.0% | 162 | 42.0% | 2031 | 19.3% | 76 | 25.7% |
| Recipients Not Found; Status Unknown | 935 | 130.4% | 495 | 128.2% | 18382 | 174.7% | 221 | 74.7% |

***Information provided by donor, donor's physician, Public Health**

****Stored Sample Project**

*****Estimated total # of transfused components = total # number of recipients affected**

# West Nile Virus (WNV) and the blood supply

- Applying lessons from Krever
  - Changes in the basic structure of the Canadian blood suppliers
  - Also a conscious effort to
    - apply the precautionary principle
    - implement partial measures
    - assure an adequate exchange of information

# Early HIV Transfusion-Related Milestones

| *Date* | *Event* | *Comment* |
|---|---|---|
| June 1981 | 5 cases of P.carinii pneumonia in homosexual men | Initial report |
| July 1982 | Initial cases in 3 persons with hemophilia | Possibility of tainted blood supply |
| Dec 1982 | Initial transfusion-related case, in an infant | Further evidence of tainted blood supply |
| May 1983 | Montagnier isolates the virus causing AIDS | Later also isolated by Gallo in the USA |
| Jan 1984 | Report of 18 cases of transfusion-related AIDS | “The debate is over...” |
| Nov 1985 | Blood donor HIV antibody screening fully implemented in Canada | In USA implemented in March 1985 |

# WNV milestones

| | |
|---|---|
| Summer 1999 | 1st documented cases of human WNV infection in North America (eastern USA) |
| Aug 2002 | Publication estimating theoretical risk of transmission of WNV through transfusion |
| Sept 2002 | WNV transmission through solid organ transplantation |
| Oct 2002 | USA CDC confirm 6 cases of transmission-transmitted WNV |
| July 2003 | Blood donor screening for WNV RNA implemented in Canada and USA |

# HIV/WNV Comparisons

| | ***HIV (1982)*** | ***WNV (2002)*** |
|---|---|---|
| *Agent* | Unknown | Known |
| *PCR technology for blood donor viral screening* | Non-existent | In place for HCV and HIV for several years |
| *Blood operator access to independent funding* | No | Yes |

# HIV/WNV Comparisons

| | ***HIV*** | ***WNV*** |
|---|---|---|
| *Communication among health care players* | Very limited | Fairly well developed |
| *Precautionary principle* | | |
| *Public and stakeholder expectations* | | |
| *Public scrutiny* | | |

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| *Public scrutiny* | Relatively limited until about 1984 | Intense media and stakeholder scrutiny |

# Precautionary Principle and Partial Measures: Inventory Management

- Dec 2002: withdrawal of frozen blood components collected in Ontario in summer 2002
- Jan-May 2003: stockpiling of frozen components for use in the summer 2003
- May-June 2003 – increased RBC collections for use in July 2003
- Sept 2003 – withdrew components collected in Saskatchewan in Aug 2003
- Summer 2003 – blood clinics were not held in areas with significant number of human WNV cases

# Communications

- Communications to hospitals
  - Frequent “Dear Colleague Letters”
  - Bulletin in the CMAJ
- Regular conference calls with stakeholders
  - 2 blood suppliers, Health Canada, provincial MOH & public health officials
- International communications
  - American colleagues
- Media
  - Nov-Dec 2002 – 106 media interviews!

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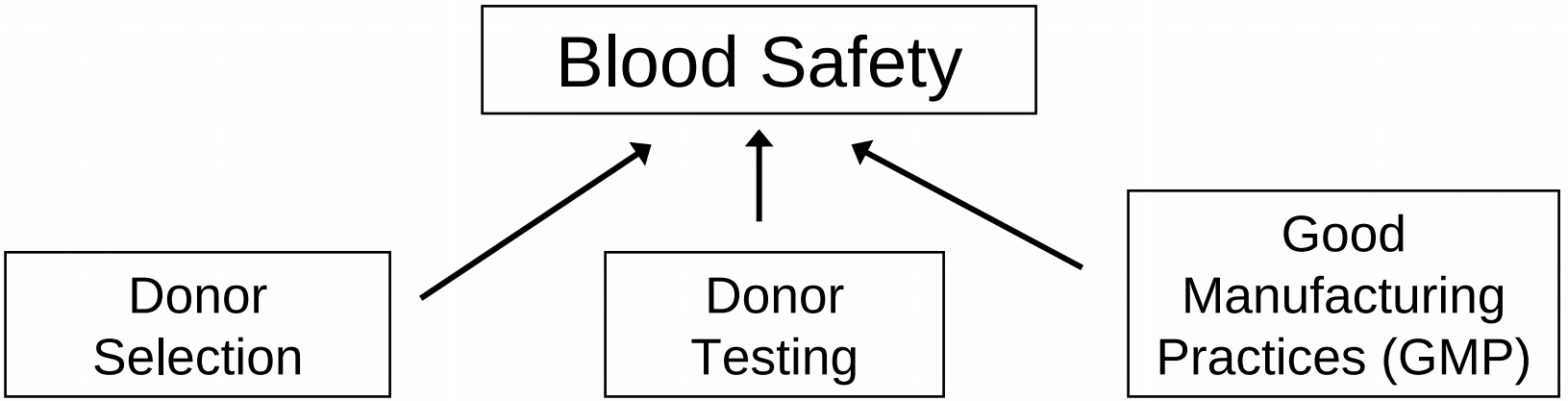
# Canadian Blood Services' Advisory Committees

- National & Regional Liaison Committees
  - NLC – representation from 16 stakeholder groups
  - RLC (7) – total of 120 members
- Hospital Advisory Panel
  - Hospital regional & functional representation
- National Advisory Committee on Blood & Blood Products
  - Medical representation from all provinces served by Canadian Blood Services
- Scientific & Research Advisory Committee
  - National & international membership

# Example of public participation in decision-making: the MSM deferral policy

# Current Donor Screening

- Each donor is asked ~85 different items related to health, medication, travel, lifestyle
- Every unit of blood collected is tested for transmissible diseases



# MSM Deferral Policy

- Men who have had sex with men (even once) since 1977 are indefinitely ineligible to donate blood
- Policy implemented in mid-1980s
  - Given the highly sensitive blood donor screening tests that we currently use to detect HIV (and the time that has passed) is this question still necessary? Could it be revised or removed?
- Decision to review the policy in 2006/07
- Two overriding principles:
  - Primary basis for donor deferral rests on the assessment and estimation of the various types of risks to health associated with donated blood
  - Any changes to existing policies on donor deferral must result in an improved or equivalent level of safety by comparison to what now exists

# Steps in determining whether or not to modify the MSM deferral criteria

- Internal medical point of view
  - literature review
  - analysis of surveillance data
- Assessment of international MSM policies
- Independent risk assessment by McLaughlin Centre for Population Health Risk Assessment
- Stakeholder consultation

# Stakeholder Consultation Strategy

- Face-to-face sessions to gather insights of student associations, equality advocates, healthcare professionals and patient groups
- Independent facilitator with a structured process and agenda
  - Presentation by Canadian Blood Services Medical, Scientific and Research Affairs
  - Presentation by the McLaughlin Centre on the risk assessment
  - Board member representatives present at meeting
- Provided opportunity for input into decision-making
  - “What would you/your organization like Canadian Blood Services to take into consideration in reviewing the MSM policy?”
- Final report communicated to participants for comment prior to submission to the Board
- Always clear that the final decision-makers would be the members of the Board of Directors

# Decision on the MSM Deferral Policy

- Canadian Blood Services will simultaneously maintain the current policy while actively gathering knowledge to close the “gaps” in information that were identified through the risk assessment and consultations:
  - Better understanding of emerging pathogens
  - Examining the risks and benefits of behavioural-based questions
  - Monitoring the experiences of blood agencies that have modified or changed their own MSM deferral policies

# Benefits of stakeholder consultations

- Decision-makers are able to make an informed decision
  - Participants provided valuable insights and input that might not otherwise have been brought to the Board
- Increases acceptance of the decision
  - No public outcry
  - Positive recognition of process
    - even from those who did not agree with the final decision
- Increases mutual understanding
  - All parties gained appreciation for each other's issues and challenges
  - Enhanced existing relationships
  - Built new relationships

# Krever recommendation # 40

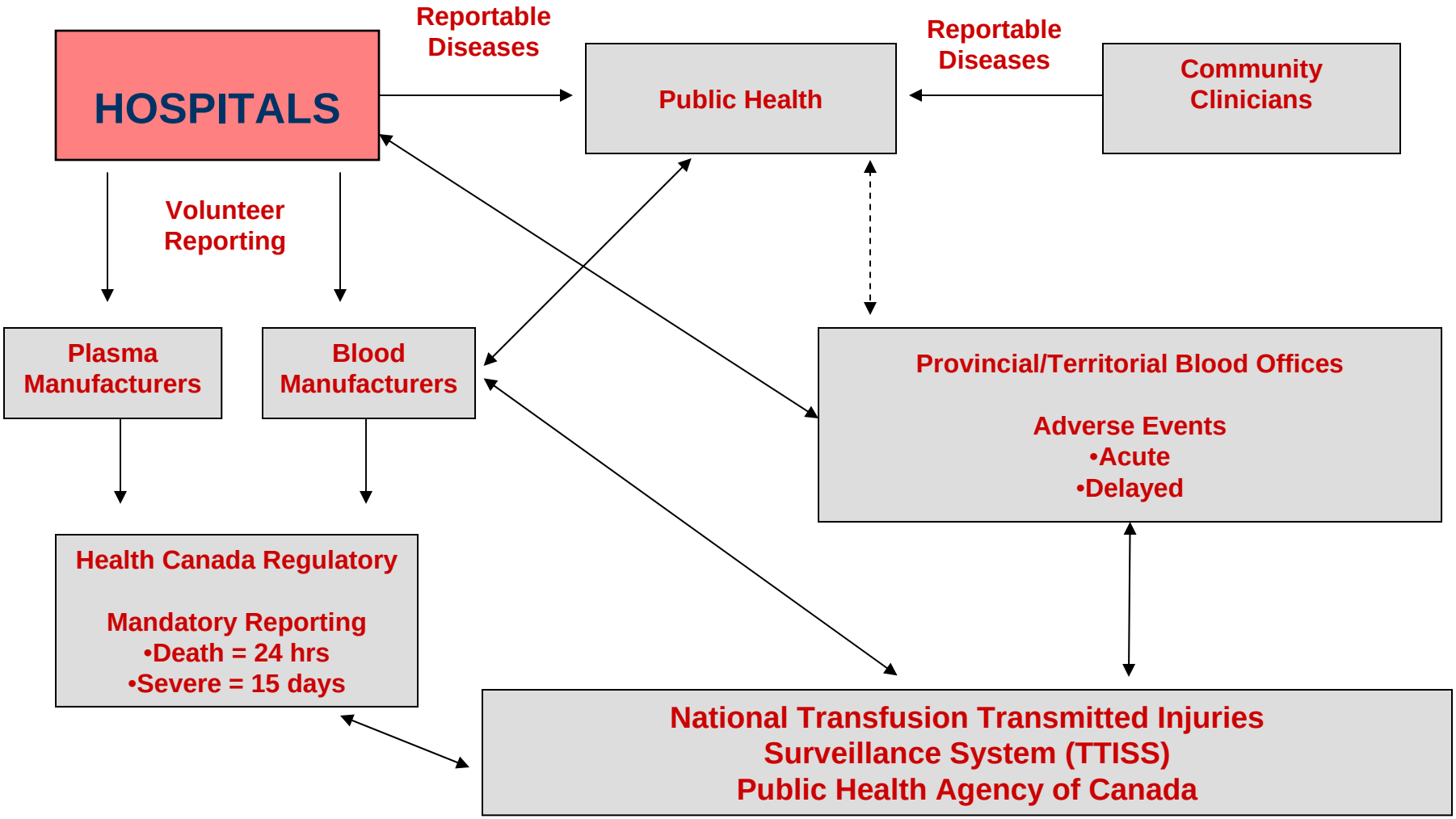
- …that there be  an active program of post-market surveillance for blood components and blood products

# Adverse Event Surveillance – Public Health Agency of Canada

- Transfusion-transmitted injury surveillance system (TTISS)
  - Voluntary surveillance system for capturing moderate and severe transfusion reactions
  - Collaboration with the blood suppliers
    - agreement on definitions of reactions, severity, imputability
    - agreement on what reactions need to be reported to the blood supplier as well as to TTISS
    - reconciliation of data reported to each agency

**Provided by Public Health Agency of Canada (PHAC)**

# Infrastructure for National TTISS Reporting

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

# Transfusion Transmitted Injuries Surveillance System

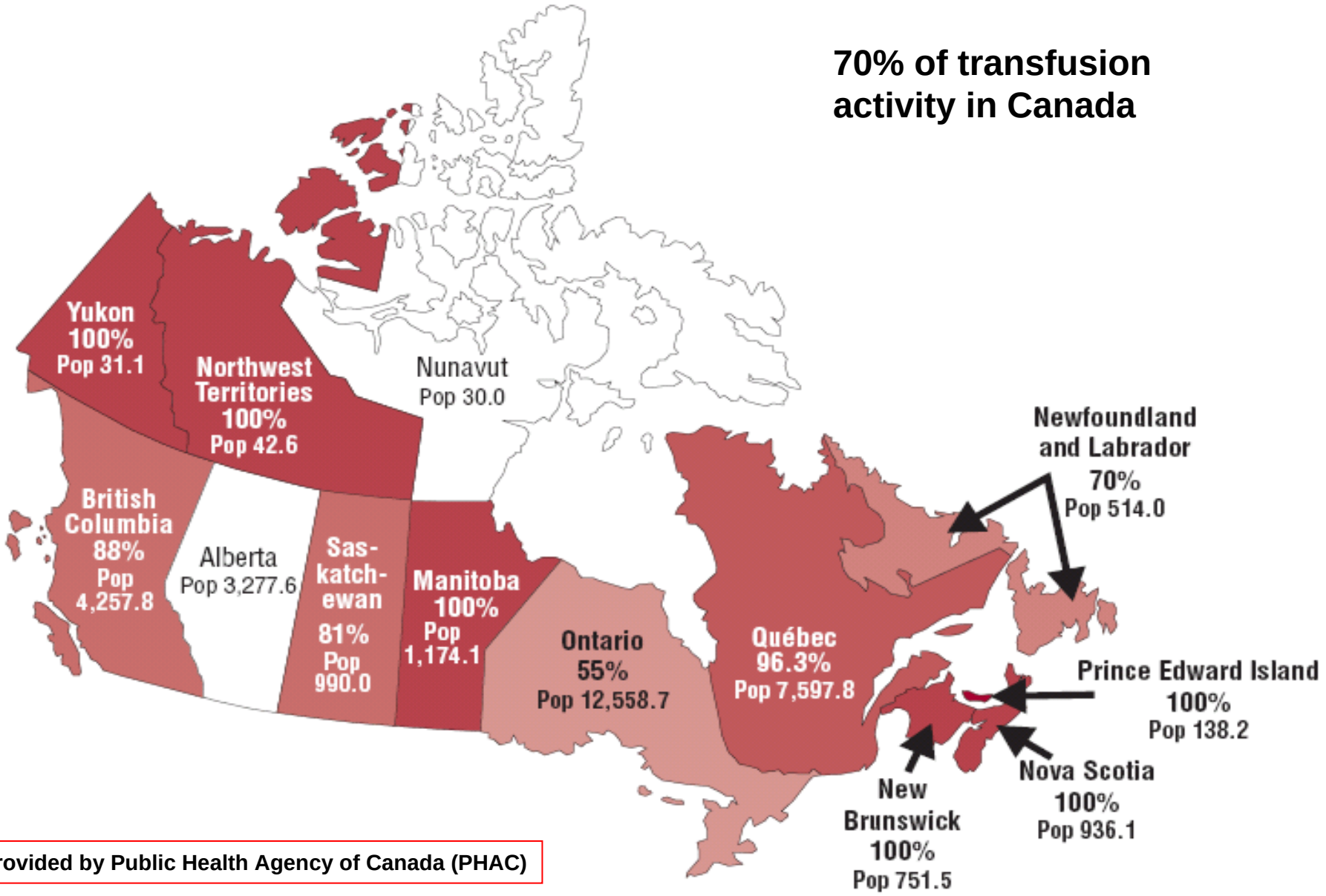
## Program Report 2004-2005

Provided by Public Health Agency of Canada (PHAC)

Canada

Figure 1

Proportion of Transfusion Activity captured by TTISS (as of 31 December 2005)
(2005 population/thousands)

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## Table 3

### Adverse transfusion events by type of products and year of occurrence

| | 2 004 | | 2 005 | | Total | |
|---|---|---|---|---|---|---|
| Type of products | N | % | N | % | N | % |
| Plasma derivatives | 53 | 15.1 | 54 | 13.1 | 107 | 14.0 |
| Blood components | 298 | 84.9 | 357 | 86.9 | 655 | 86.0 |
| Total | 351 | 100.0 | 411 | 100.0 | 762 | 100.0 |

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Provided by Public Health Agency of Canada (PHAC)

Table 9

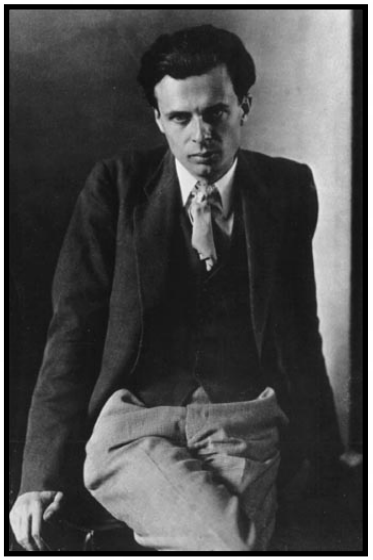
## Type of adverse transfusion events by relationship to transfusion

| | Relationship to transfusion | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Definite | | Probable | | Possible | | Total | |
| Diagnosis | N | % | N | % | N | % | N | % |
| ABO incompatibility | 17 | 100.0 | - | - | - | - | 17 | 2.6 |
| Bacterial contamination | 3 | 25.0 | 7 | 58.3 | 2 | 16.7 | 12 | 1.8 |
| TACO | 36 | 14.0 | 128 | 49.8 | 93 | 36.2 | 257 | 39.2 |
| Hemachromatosis | - | - | 1 | 100.0 | - | - | 1 | 0.2 |
| Hemolytic reaction: acute | 13 | 40.6 | 14 | 43.8 | 5 | 15.6 | 32 | 4.9 |
| Hemolytic reaction: delayed | 28 | 62.2 | 13 | 28.9 | 4 | 8.9 | 45 | 6.9 |
| Hypocalcemia | - | - | 1 | 100.0 | - | - | 1 | 0.2 |
| Hypotensive reaction | - | - | 20 | 40.0 | 30 | 60.0 | 50 | 7.6 |
| Possible TRALI | - | - | 1 | 50.0 | 1 | 50.0 | 2 | 0.3 |
| Post-transfusion purpura | 2 | 50.0 | 1 | 25.0 | 1 | 25.0 | 4 | 0.6 |
| Severe/Allergic/Anaphylactoid | 16 | 14.7 | 68 | 62.4 | 25 | 22.9 | 109 | 16.6 |
| TRAIN | 1 | 50.0 | 1 | 50.0 | - | - | 2 | 0.3 |
| TRALI | 10 | 9.5 | 37 | 35.2 | 58 | 55.2 | 105 | 16.0 |
| TAD | - | - | 1 | 12.5 | 7 | 87.5 | 8 | 1.2 |
| Other | 1 | 100.0 | - | - | 1 | 100.0 | 2 | 0.3 |
| Unknown | - | - | 4 | 50.0 | 4 | 50.0 | 8 | 1.2 |
| Total | 127 | 19.4 | 297 | 45.3 | 231 | 35.3 | 655 | 100.0 |

# Adverse Event Surveillance – Public Health Agency of Canada

- Transfusion error surveillance system (TESS)
  - pilot project in 4 provinces/11 hospitals begun in 2005
  - non-punitive, anonymous web-based reporting system of errors related to hospital-based transfusion activities
  - groundwork for a national system that can be integrated with TTISS

**Provided by Public Health Agency of Canada (PHAC)**



"That men do not learn very much from the lessons of history is the most important lesson of history"

*Aldous Huxley*