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AND VITALITY WITH
SOMEONE IN NEED



Adverse Health Event Management: Some Lessons from the Krever Inquiry

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Canadian Blood Services

NF Provincial Forum on Adverse Health Event Management

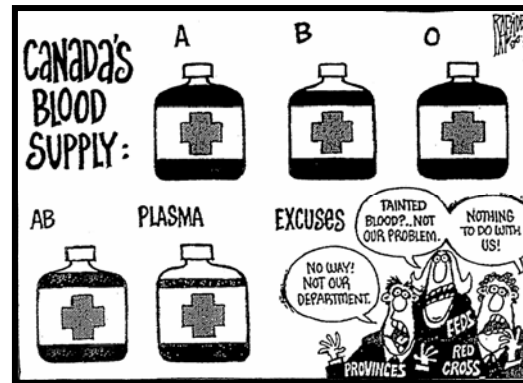
St. John's NL

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

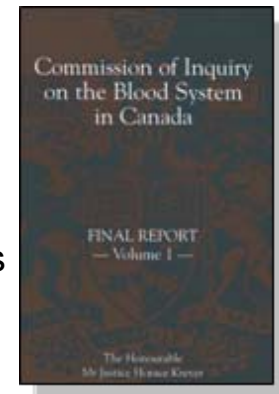
- to review and report on the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada

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 Affected***	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

<i>Date</i>	<i>Event</i>	<i>Comment</i>
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	1 st 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

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

HIV/WNV Comparisons

	<i>HIV</i>	<i>WNV</i>
<i>Communication among health care players</i>	Very limited	Fairly well developed
<i>Precautionary principle</i>		
<i>Public and stakeholder expectations</i>		
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<i>Public scrutiny</i>	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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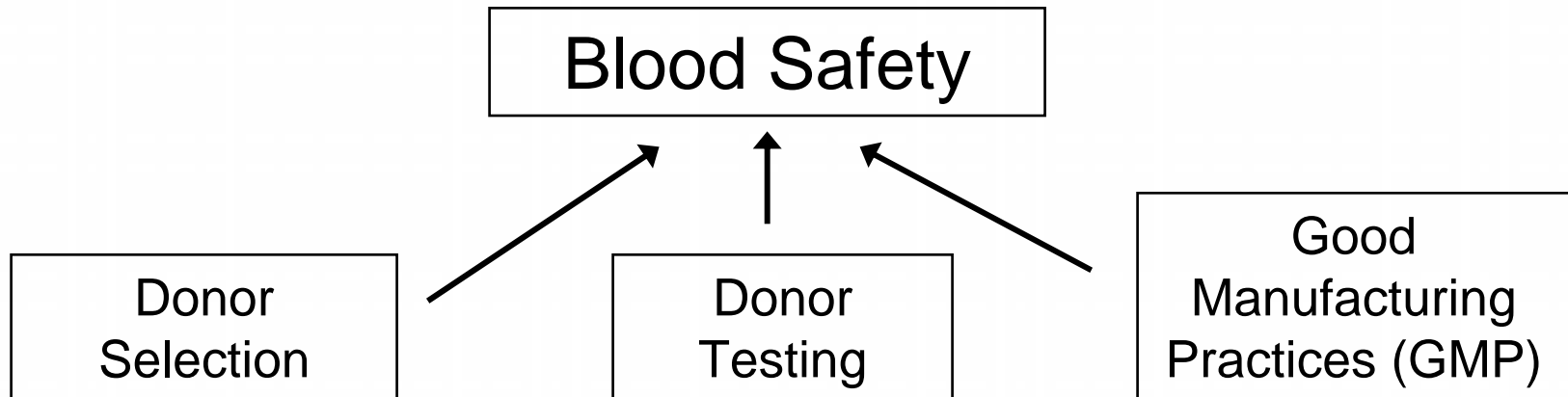
Canadian Blood Services' Advisory Committees

- 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



Transfusion Transmitted Injuries Surveillance System

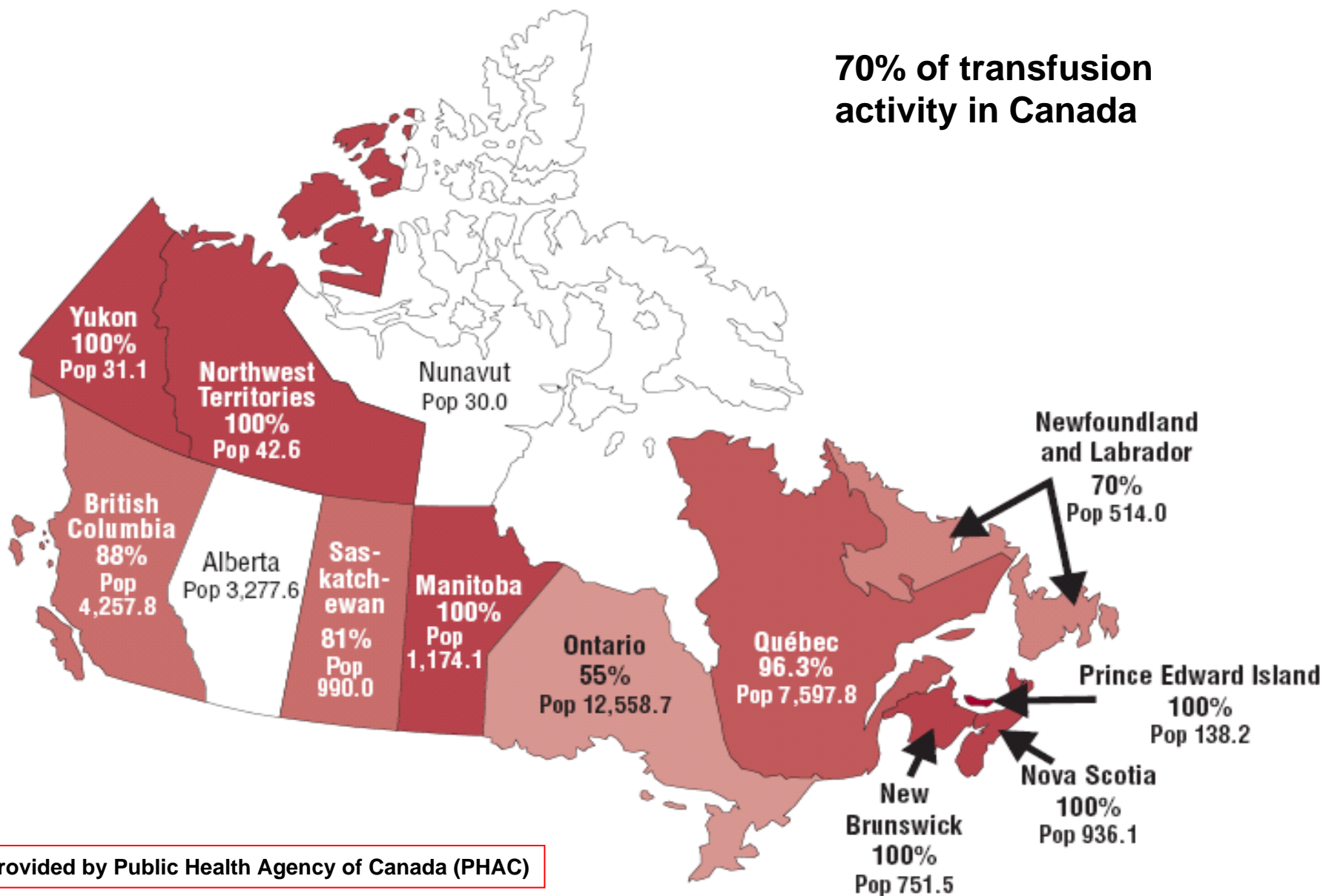
Program Report
2004-2005



Provided by Public Health Agency of Canada (PHAC)

Figure 1

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



Provided by Public Health Agency of Canada (PHAC)

Table 3

Adverse transfusion events by type of products and year of occurrence

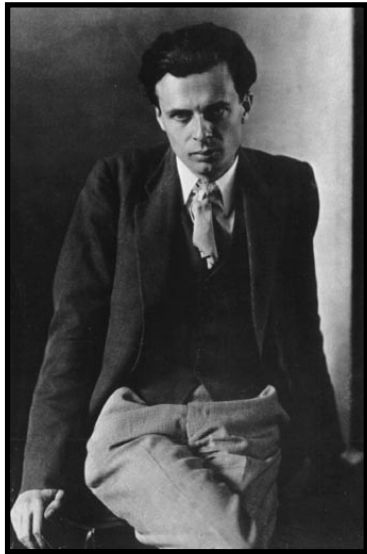
Type of products	2 004		2 005		Total	
	N	%	N	%	N	%
Plasma derivatives	53	15.1	54	13.1	107	14.0
Blood components	298	84.9	357	86.9	655	86.0
Total	351	100.0	411	100.0	762	100.0

Table 9**Type of adverse transfusion events by relationship to transfusion**

Diagnosis	Relationship to transfusion							
	Definite		Probable		Possible		Total	
	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



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

Aldous Huxley