Health Canada Santé Canada

Canada

The Canadian National Transfusion Transmitted Injuries Surveillance System (TTISS)

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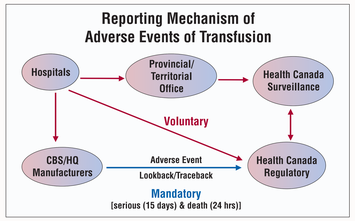
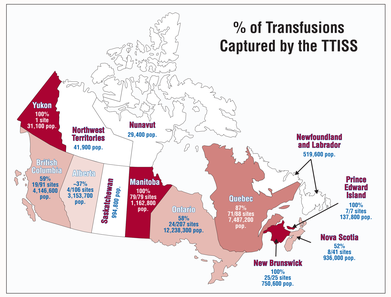
A collaborative project of the Division of Blood Safety Surveillance and Health Care Acquired Infections[1], Marketed Health Products Directorate[2], Biologics and Genetic Therapies Directorate[2], Health Canada, Ottawa, Ontario; Provincial/Territorial Blood Surveillance Offices[2] and Canadian Blood Manufacturers[2]

Background

- Transfusion of blood components and plasma derivatives may occasionally pose a risk of adverse events.
- In Canada, serious transfusion related adverse events must be reported to the regulatory branch of Health Canada by the Blood Manufacturers [Canadian Blood Services (CBS) and HÉMA-QUÉBEC (HQ)].
- However, these establishments rely on voluntary reporting of these adverse events from Hospitals and Health Care Professionals.



- To improve reporting of adverse events, a pilot Transfusion Transmitted Injuries Surveillance System (TTISS) was developed and implemented in 1999 in 4 Canadian provinces: British Columbia, Quebec, Nova Scotia and Prince Edward Island.
- The system was then expanded to other provinces and territories and now for the first time Canada has a national surveillance system for monitoring adverse events of transfusion.



Objective

- To describe the adverse events of transfusion reported to Health Canada for the period 1 Apr 2001 to 30 Jun 2003.

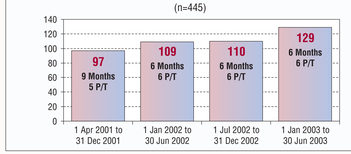
Methods

- Standardized case definitions, data elements, a reporting form and a database were developed to collect the adverse events.
- After transfer from hospitals to a provincial/territorial (P/T) office, validated, non nominal adverse events that met TTISS requirements were reported electronically on a quarterly basis to Health Canada for analyses, with an ongoing review of the data.

Results

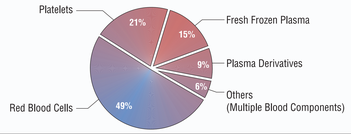
Transfusion Related Cases Reported to Health Canada

(n=445)



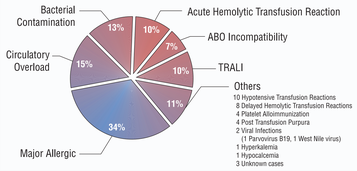
Blood Products Implicated in the Adverse Events of Transfusion Reported to Health Canada

(1 Apr 2001 - 30 Jun 2003) (n=317)



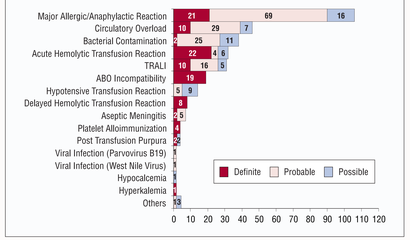
Types of Adverse Events Associated with Administration of Blood Components Reported to Health Canada

(1 Apr 2001 - 30 Jun 2003) (n=290)



Distribution of Adverse Events of Transfusion Reported to Health Canada

(1 Apr 2001 - 30 Jun 2003) (n=317)



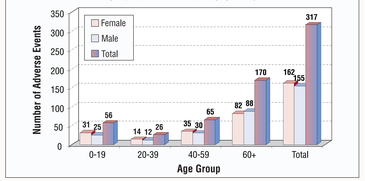
Definite and Probable Adverse Events of Transfusion by Severity of Outcome

(1 Apr 2001 - 30 Jun 2003) (n=257)

Adverse Events	Death	Life-threatening	Long-term	Minor/ No Sequelae	Not determined	Total
Major Allergic /Anaphylactic Reaction	1	51	–	38	–	90
Circulatory Overload	–	39	–	–	–	39
Bacterial Contamination	3	7	–	17	–	27
Acute Hemolytic Transfusion Reaction	1	12	2	11	–	26
TRALI	3	19	–	4	–	26
ABO Incompatibility	–	3	1	13	2	19
Delayed Hemolytic Transfusion Reaction	–	4	4	–	–	8
Aseptic Meningitis	–	–	–	6	1	7
Hypotensive Transfusion Reaction	–	5	–	–	–	5
Platelet Alloimmunization	–	–	4	–	–	4
Post Transfusion Purpura	2	–	–	–	–	2
Viral Infection (Parvovirus B19)	–	–	–	1	–	1
Viral Infection (West Nile Virus)	1	–	–	–	–	1
Hyperkalemia	–	1	–	–	–	1
Others	1	–	–	–	–	1
TOTAL #	12	141	11	90	3	257
TOTAL %	4.7%	54.9%	4.3%	35.0%	1.2%	100.0%

Distribution of Adverse Events of Transfusion by Age and Gender

(1 Apr 2001 - 30 Jun 2003) (n=317)



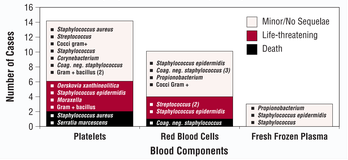
Fatal Adverse Events of Transfusion Reported to Health Canada

(1 Apr 2001 - 30 Jun 2003) (n=11)

Adverse Events	Relationship to Transfusion		
	Definite	Probable	Total
Anaphylactic Reaction	–	1	1
Acute Hemolytic Transfusion Reaction	1	–	1
Bacterial Contamination	1	2	3
Post Transfusion Purpura	1	1	2
TRALI	1	2	3
Other (Severe Hypertension)	–	1	1
TOTAL #	4	7	11

Definite and Probable Cases of Bacterial Contamination

(1 Apr 2001 - 30 Jun 2003) (n=27)



Conclusions

- The TTISS has been successfully implemented in Canada. Since then the voluntary reporting of adverse events has increased. This is the first national system implemented in Canada.
- This collaborative project has provided the opportunity for the development of a standardized infrastructure for reporting transfusion related adverse events to all stakeholders.
- To enhance the system:
  - Denominator data will be provided by the provinces/territories for the calculation of risks of adverse events per products transfused.
  - An error surveillance system to capture near misses and transfusion errors will be implemented in the current year.
  - Methods to capture delayed adverse events related to transfusion are being addressed.

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Transfusion Transmitted Injuries Section's Website

http://www.hc-sc.gc.ca/pphb-dgspsp/hcai-iamss/tti-it/index.html

TTISS
Transfusion Transmitted Injuries Surveillance System
SSIT
Système de surveillance des incidents transfusionnels

May 2004