Health Canada Santé Canada

Canada

Adverse Events of Transfusion Reported to the Transfusion Transmitted Injuries Surveillance System in Canada

1 April 2001-30 June 2002

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A collaborative project of the Division of Blood Safety Surveillance and Health Care Acquired Infections, Health Canada, Ottawa, ON[1];
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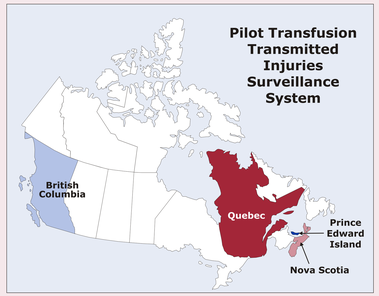
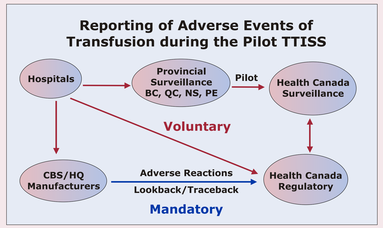
Background

- Transfusion of blood and blood products exposes patients to some risks, which may vary greatly in severity despite all precautions taken.
- In Canada, the blood establishments, Canadian Blood Services (CBS) and HEMA-QUEBEC (HQ) have a mandatory obligation to report serious adverse events of transfusion to Health Canada.
- However, these blood establishments rely on voluntary reporting of these adverse events by hospitals and health care professionals.
- To improve the reporting of adverse events, in March 1999, Health Canada requested participation of Canadian provinces/territories in the Pilot Transfusion Transmitted Injuries Surveillance System (TTISS) project to serve as a model for a national surveillance system to increase blood safety in Canada.



- Four Canadian provinces:
British Columbia (BC), Quebec (QC), Nova Scotia (NS) and Prince Edward Island (PE) participated in this surveillance project.



Objective

To describe the adverse events of transfusion reported to Health Canada by the Pilot Provinces for the period April 1, 2001 to June 30, 2002.

Methods

- Data were derived from 56 hospitals participating in the Pilot TTISS project, and representing about 46% of transfusion activity in these provinces. Reported adverse events were related to blood components and plasma derivatives.
- Standardized case definitions, data elements, data validation techniques, reporting tools (form and database) and reporting protocols, were used to ensure comparability of the reported data across the pilot sites.
- Data collected from each site were sent to a provincial office and then transferred electronically on a bi-annual basis to Health Canada for analysis.

Causality assessment of adverse events of transfusion was defined as follows:

- **Definite**
If the event occurred within a time period consistent with the administration of the blood product and was proven by investigation to have been caused by transfusion.
- **Probable**
If the event occurred within a time period consistent with the administration of the blood product and did not seem to be explainable by any other cause.
- **Possible**
If the event occurred within a time period consistent with the administration of the blood product but could be explained by a concurrent disease or by the administration of a drug or other agent.

Causality was established at the hospital level.

Results

Figure 1. Total Number of Adverse Events of Transfusion by Causality Reported to Health Canada (1 April 2001 – 30 June 2002) (n=99)

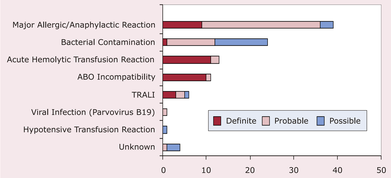


Figure 2. Total Number of Adverse Events of Transfusion by Age and Gender Reported to Health Canada (1 April 2001 – 30 June 2002) (n=99)

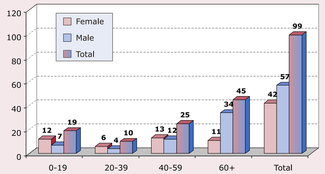


Figure 3. Blood Products Implicated in the Adverse Events of Transfusion Reported to Health Canada (1 April 2001 – 30 June 2002) (n=99)

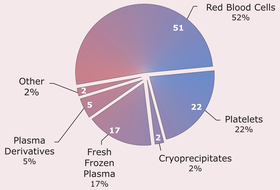
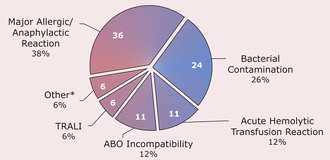


Figure 4. Types of Adverse Events Associated with Administration of Blood Components Reported to Health Canada (1 April 2001 – 30 June 2002) (n=94)



* Includes 1 hypotensive reaction, 1 viral infection (Parvovirus B19), 4 unknown cases

Table 1. Definite and Probable Adverse Events of Transfusion by Severity of Outcome Reported to Health Canada (1 April 2001 – 30 June 2002) (n=68)

Adverse Events	Life-threatening	Long-term Sequelae	Minor/ No Sequelae	Total
Major Allergic/Anaphylactic Reaction	15	-	18	33
ABO Incompatibility	1	1	9	11
Acute Hemolytic Transfusion Reaction	5	-	3	8
Viral Infection (Parvovirus B19)	-	-	1	1
Bacterial Contamination	3	-	8	11
TRALI	2	-	2	4
TOTAL #	**26**	**1**	**41**	**68**
TOTAL %	**38%**	**2%**	**60%**	**100%**

Table 2. Fatal Adverse Events of Transfusion Reported to Health Canada (1 April 2001 – 30 June 2002) (n=5)

Adverse Events	Relationship to Transfusion		
	Definite	Probable	Total
Major Allergic/Anaphylactic Reaction	-	1	1
Acute Hemolytic Tranfusion Reaction	1	-	1
Bacterial Contamination	1	-	1
TRALI	-	1	1
Unknown *	-	1	1
TOTAL #	**2**	**3**	**5**

* Severe hypertension

Definite and Probable Cases of Bacterial Contamination Reported to Health Canada (1 April 2001 – 30 June 2002) (n=12)

- A total of 24 cases of bacterial contamination were reported to Health Canada.
- Half of them (12) were definitely or probably associated with transfusion.
- The blood component implicated in two thirds of these cases was Platelets; one of these cases was fatal.
- A variety of bacteria was isolated in the blood product culture with predominance of skin contaminants.

Conclusions

- This Pilot Transfusion Transmitted Injuries Surveillance project has shown the feasibility of a National TTISS.
- Results presented here should be interpreted with caution because of the pilot nature of the project and probable underreporting.
- Nationally accepted methods for uniform reporting, including a reporting form and a User's Manual have been developed at low cost.
- The TTISS has been implemented in almost all Canadian provinces and is now a national system.
- To enhance the system, denominator data will be collected for estimation of risks and methods to capture viral infections are being addressed.

Website

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

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