Health Canada Santé Canada

Canada

Development of the Transfusion Transmitted Injuries Surveillance System (TTISS) in Canada

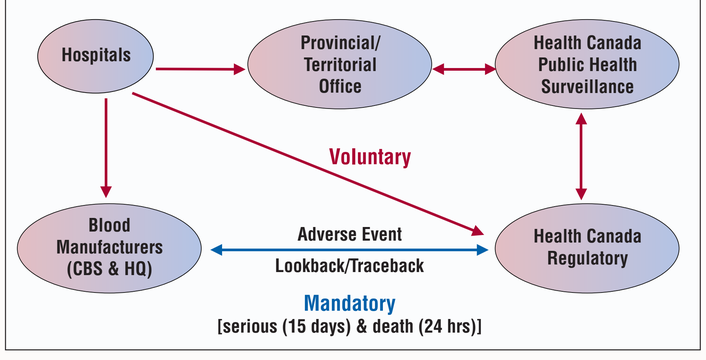
N. McCombie[1], M. Cator[1], J. Egan[1], M. Wotherspoon[1], N. Karitisiotis[1], A. Giulivi[1], and the Members of the National TTISS Working Group[2]

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

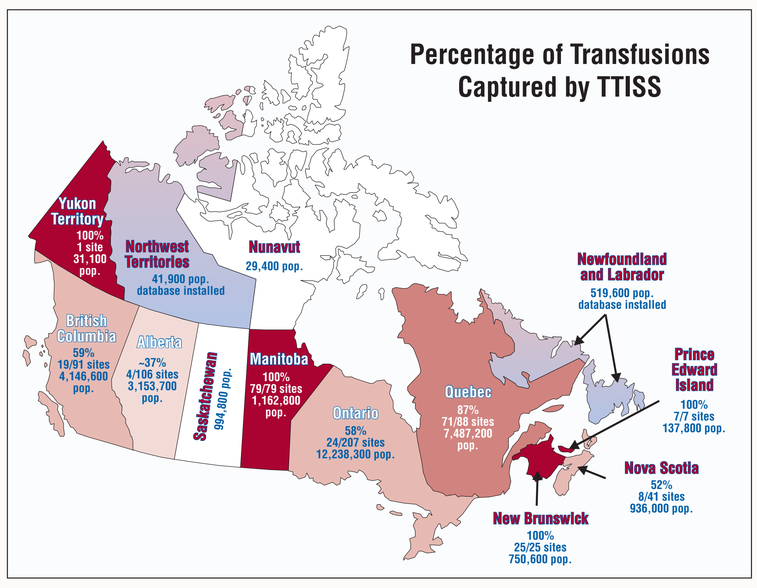
- In Canada, Blood Manufacturers [Canadian Blood Services (CBS) and Héma-Québec (HQ)] must report serious transfusion related events to the regulatory branch of Health Canada.
- CBS and HQ however rely on voluntary reporting of severe adverse events from hospitals and health care professionals.
- Therefore, a National Surveillance System to report adverse events associated with the transfusion of blood components and plasma derivatives is essential to monitor known and potential risks.

Reporting Mechanism of Adverse Events of Transfusion



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

Percentage of Transfusions Captured by TTISS



Aim

The goals of the TTISS are to:

- Monitor the trends in known risks
- Monitor the effectiveness of actions taken to reduce the risks
- Provide a network for national (Public Health, Health Canada Regulators and Blood Manufacturers) and international groups to collaborate on new and emerging transfusion risks
- Provide data for policy decisions

Methods

- Data is collected at the hospitals and voluntarily reported to the provinces/territories.
- The provincial/territorial surveillance offices analyse their data and report back to the hospitals.
- Non-nominal, validated data that meet the TTISS requirements are transferred from the provincial/territorial surveillance offices to Health Canada quarterly.
- Health Canada:
  - analyses the national data
  - reviews the data with the working groups
  - provides recommendations for risk management
  - publishes annual programme reports

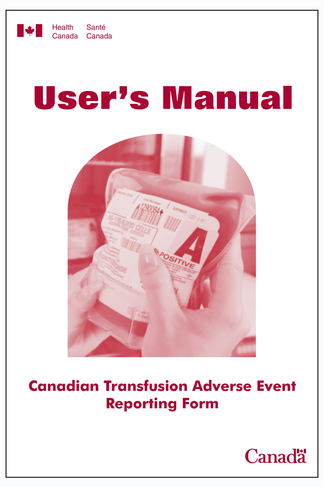
Two Working Groups have been established to ensure excellence in epidemiologic surveillance:

- The National TTISS Working Group consists of members from each participating province/territory, federal regulators, Health Canada and blood manufacturers. The group provides recommendations on future directions, quality, efficacy and effectiveness of TTISS.
- An external National Data Review Working Group includes professionals who are knowledgeable in transfusion medicine, infectious diseases, epidemiology and public health. They review and evaluate the data to identify potential risks or trends. They also provide advice on other scientific or medical issues regarding current/emerging transfusion issues.

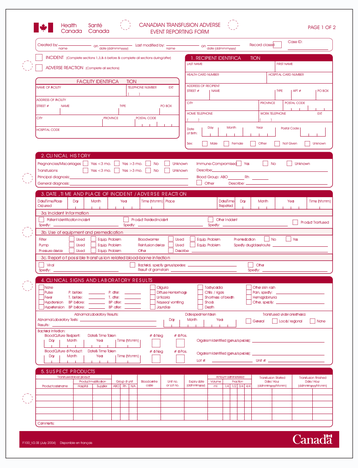
Materials

- **Standardized Reporting:**
  - Standardized reporting form
  - User's manual
  - Standardized definitions
  - Minimum required data elements
  - Rules and conditions for data reporting
  - Schedule of data reporting
- **Electronic National Database used to:**
  - Record adverse events
  - Produce and analyse data
  - Produce reports for the provinces/territories
  - Export non-nominal, encrypted data elements to Health Canada
- **Communications**
  - Working groups
  - Progress Report

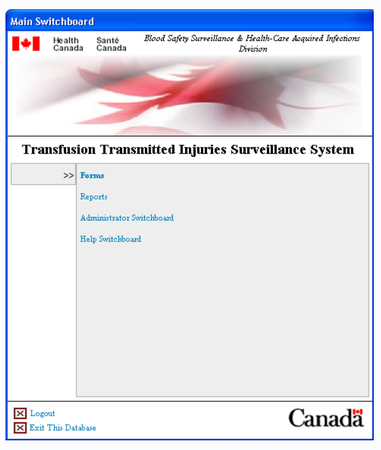
Manual



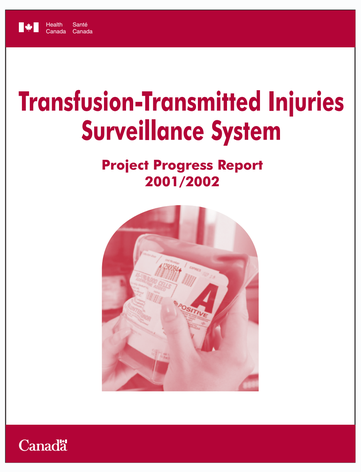
Reporting Form



Electronic Database



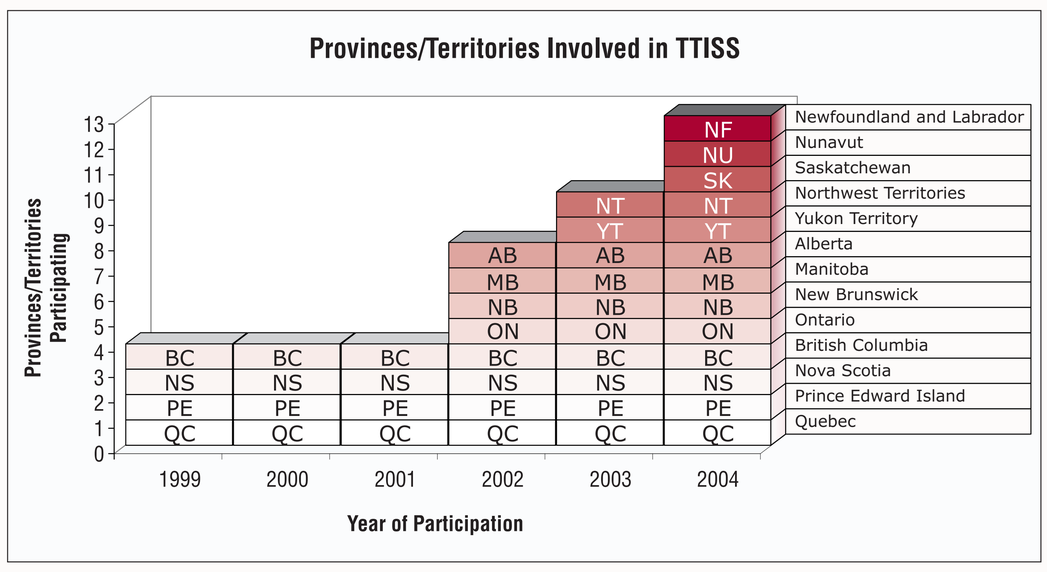
Analysis and Report



Results

- Since 1999, TTISS has been implemented in 9 of 10 provinces and 2 of 3 territories with the remaining province and territory expected in 2004.
- Data will be reported from all sites by March 2005.
- From April 2001 – September 2003, 6 sets of data reporting 608 cases of moderate and serious adverse events have been reported to Health Canada.
- This data is from 238 sites, which represents an average of 77% (with a range of approximately 40-100%) of transfusions in the participating provinces/territories.

Provinces/Territories Involved in TTISS



- The first Progress Report (1 April 2001 to 30 June 2002) was published in March 2004.
- A brochure has been developed for distribution at transfusion meetings to share the program updates.

Conclusions

- TTISS has been successfully implemented making it the Canadian national system for reporting transfusion transmitted adverse events.
- Voluntary reporting of adverse events and the quality of the data reported has improved.
- The agreement of provinces/territories, blood manufacturers and regulators to introduce TTISS across Canada provides a process with standardized tools and definitions for reporting adverse events following blood transfusion therapy.

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 piloted in the current year.
- Links are anticipated with proposed provincial/territorial transfusion recipient registries.

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

Acknowledgements

Provinces/Territories	Names
British Columbia & Yukon Territory	D. Pi**, D. Fulton*
Alberta	M. Swaters*
Northwest Territories	R. Greig*
Manitoba & Nunavut	I. Wilkinson*, C. Renner, S. Turnbull
Ontario	H. Lloyd*, G. Rock, J. Callum, D. Sutton, R. Barr, N. Heddle, J. Freedman
Quebec	A. Fortin, P. Robillard**, C. Poulin*
New Brunswick	C. Balram, G. Bolesnikov*
Nova Scotia	D. Anderson**, M. Hamilton*
Prince Edward Island	L. Van Til, H. MacMillan*
Health Canada Regulatory	**Names**
Biologics and Genetic Therapies Directorate	F. Hindieh**, A. Simniceanu*
Marketed Health Products Directorate	C. Legaré(*) (**)
Blood Manufacturers	**Names**
Canadian Blood Services	T. Alport*
Héma-Québec	G. Delage (*) (**)
Working Groups	**Names**
* National TTISS Working Group	N. McCombie (chairperson)
** National Data Review Working Group	B. Larke (chairperson), R. Dodd, J. Saldanha, R. Nair, H. Hume

July 2004