Health Canada Santé Canada

Reporting of Transfusion Adverse Events in Canada

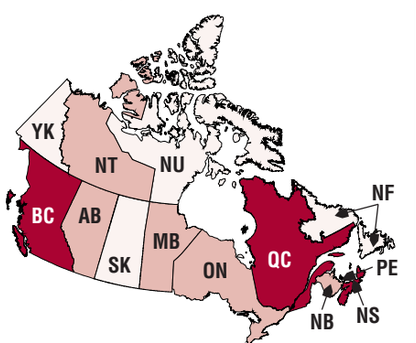
Canada

Development of the Transfusion Transmitted Injuries Surveillance System (TTISS)

Blood transfusions are life saving treatments that can carry some risks for the recipient. As part of Health Canada's mandate, helping the Canadian people maintain and improve their health, a surveillance system to capture adverse events related to the transfusion of blood/blood products and plasma derivatives was implemented in Canada. This surveillance system is invaluable in assessing the potential risks associated with blood transfusions, and assisting in the development and implementation of strategies to minimize the risks against current and emerging health threats arising from the use of blood/blood products and plasma derivatives.

The TTISS is a voluntary reporting system that started in 1999 as a pilot project in four provinces (British Columbia, Quebec, Prince Edward Island and Nova Scotia). The TTISS has since grown into a national system as a collaborative, voluntary effort between hospitals, provinces/territories, blood manufacturers and Health Canada.

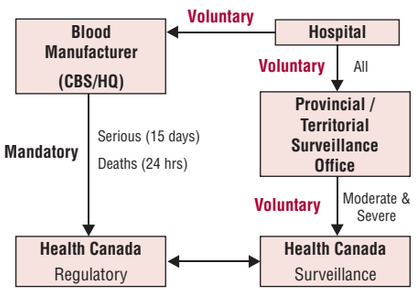
Implementation Dates



How TTISS works

The reporting of adverse events of transfusion flows from the hospitals to the provinces/territories and subsequently on to Health Canada. Reporting is done using a standard form and database developed by Health Canada and supported by a user's manual containing specific directions and standardized definitions for reporting of adverse events. Only non-nominal data on moderate and severe adverse events are electronically transferred on a quarterly basis to Health Canada in adherence with all federal/provincial privacy legislation.

Reporting Mechanism for Transfusion Adverse Events

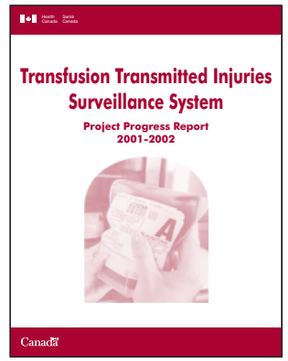


The TTISS is supported through two working groups set up by Health Canada.

The National TTISS Working Group meets 3 to 4 times per year to discuss ways of improving the system through upgrades to the manual, form, definitions and data transfer methods. Unexpected adverse events and unusual events are identified by this group and given to the national data review group for analysis.

The National Data Review Group, with experts in fields related to transfusion medicine, has been instituted to review the data twice a year, make recommendations for enhancing the system, and provide suggestions on any major issues identified.

Health Canada analyses the data and produces annual reports to monitor the progress of the TTISS and to make information available to stakeholders and Canadians.



Achievements

The funding provided by Health Canada in support of TTISS activities has allowed for the development of training and educational initiatives targeted at health professionals regarding transfusion adverse events. This is a critical element in facilitating the reporting and surveillance of adverse events related to transfusion.

The introduction of the TTISS across Canada results in a single system for reporting of adverse events following blood transfusion therapy. The single form used by hospitals includes copies for the hospitals, provinces/territories, blood manufacturers and Health Canada regulators. Canada is one of the few nations with a truly national surveillance program related to transfusion.

The TTISS captures adverse events of transfusion and works towards minimizing such events in an effort to maintain and improve the health of the Canadian population.

Future Initiatives

Error management

Data linkage for the capture of delayed transfusion adverse events

Acknowledgements

- **Canadian hospitals**
- **Provinces/Territories**
  - British Columbia [BC], Alberta [AB], Saskatchewan [SK], Manitoba [MB], Ontario [ON], Quebec [QC], New Brunswick [NB], Prince Edward Island [PE], Nova Scotia [NS], Newfoundland and Labrador [NF], Yukon Territory [YT], Northwest Territories [NT], Nunavut [NU]
- **Blood Manufacturers**
  - Canadian Blood Services [CBS] http://www.bloodservices.ca/
  - HÉMA-QUÉBEC [HQ] http://www.hema-quebec.qc.ca/
- **Health Canada Regulators**
  - Biologics and Genetic Therapies Directorate [BGTD] http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/index_e.html
  - Marketed Health Products Directorate [MHPD] http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/about-mhpd_e.html

More Information

- **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

Our mission is to help the people of Canada maintain and improve their health.
Health Canada

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