Health Canada Santé Canada

Report on the Mid-Term Review of the Transfusion-Transmitted Injuries Surveillance System of Health Canada

Final Report

Presented to

Health Canada
Departmental Audit and Evaluation Committee

October 2, 2003

Canada

TRANSFUSION TRANSMITTED INJURIES SURVEILLANCE SYSTEM MID-TERM REVIEW
RESPONSE AND ACTION PLAN
APRIL 2003

Issue	Evaluation Recommendation	Program Response Current Status	Program Response Action Required	Due Date for Completion	Contact Person
What remains to be done before the TTISS is fully operational?	Obtain the participation of all provinces and territories and expand the number of sites within provinces that participate in the TTISS.	All provinces/territories are expected to be on-board by end of fiscal 2003/04.	Work with remaining provinces/territories not yet participating to develop formal plans for implementation of TTISS.	December 2003	N. McCombie, TTI
		Each province/territory is working to add to the number of hospitals each Provinces/territories are required to negotiate with hospitals to participate in the project and resources will have to be allocated in this regard. TTISS anticipates obtaining data from hospitals representing 75% of transfusions by 2004.	Work with provinces/territories to identify opportunities to expand the number of sites participating in TTISS.	December 2003	N. McCombie, TTI
		TTISS is working to install the database at the hospital level so that additional facilities can participate.	Work with provinces/territories, to identify potential sites to install database.	March 2004	N. McCombie, TTI
	Establish effective linkages with Public Health Information Networks.	A feasibility study was completed in this regard. Discussions are underway with the province of British Columbia to develop a plan that came out of the feasibility study for a pilot.	Work with British Columbia to finalize timelines to develop plan for pilot implementation.	Program exploring availability of necessary resources.	N. McCombie, TTI
	Other Gaps/Required Actions: • The need for further work on some of the forms and other tools used in the TTISS. Work is progressing on this but is not yet finished.	• The form/manual are constantly evolving and require ongoing revisions. Health Canada is working with Canadian Blood Services to communicate with hospitals to allow for a dual-use form.	Implement Version 2.0 of both manual and form. In cooperation with Canadian Blood Services, develop communication tool for hospitals.	September 2003 September 2003	N. McCombie, TTI N. McCombie, TTI

Issue	Evaluation Recommendation	Program Response Current Status	Program Response Action Required	Due Date for Completion	Contact Person
	Other Gaps/Required Actions: (cont'd) • Improvements in data on the "denominator" used in analyzing the rate of adverse reactions. In most provinces the denominator most easily available is the number of transfusions. However, the more useful denominator, according to some of those interviewed, is the number of patients.	• TTISS is working with provinces to supply the number of transfusions. It is anticipated this might be transferred in 2003 for British Columbia, Quebec and Prince Edward Island. Other provinces are working to collect utilization data, which is a provincial issue.	Work with provinces/territories to develop detailed planning to collect denominator data.	March 2004	N. McCombie, TTI
	• The need to develop data verification techniques to measure under-reporting of adverse reactions.	• Funding availability at provincial and federal levels has not allowed this to-date. Quebec is doing this but their system is mature. As such, TTISS will have to be in place for a period of time. It is anticipated this will evolve as TTISS matures.	As TTISS system matures, work with provinces/territories to include verification activities in contribution agreement activities.	Program exploring availability of necessary resources.	N. McCombie, TTI
	• The need to augment the capacity at Health Canada to conduct sophisticated epidemiological and other analysis of TTISS data. A small number of those interviewed stated that Health Canada should recruit an individual with a strong background in haematology or other blood-related specialty to enhance their analytic capabilities.	• TTISS has hired a consultant to oversee the writing of the annual report. An individual with a background in haematology or blood related specialties and epidemiological capabilities is a scare commodity. We will be actively recruiting in this regard.	Recruit individual with appropriate medical background as section chief.	September 2003	A. Giulivi, BSS&HCAID

Issue	Evaluation Recommendation	Program Response Current Status	Program Response Action Required	Due Date for Completion	Contact Person
How will the TTISS be sustained in the long run?	Funding of the TTISS on an ongoing basis is the single most important issue affecting the future sustainability of the program. It is essential that this issue be addressed and that federal and provincial governments reach agreement as to the share of required funding each will provide.	A funding extension has been received through fiscal 2003/04.	The Program is exploring the availability of necessary resources to expand the funding for program stabilization. Federal government funding for TTISS will have to be supplemented by the provinces to develop a robust system.	September 2003	A. Giulivi, BSS&HCAID
To what extent will the TTISS enhance Canada's capacity to identify and manage risks of injuries from blood transfusions?	Limitations/perceived weaknesses: • Limited effectiveness in detecting new or emerging blood-borne pathogens.	• A critical issue in this regard is data linkages. Once this component is developed, the ability to detect new/emerging pathogens will be increased.	Once the British Columbia pilot for data linkages is complete, a plan for national implementation will be completed.	Program exploring availability of necessary resources.	N. McCombie, TTI
	• Limited effectiveness in benchmarking/ interprovincial comparisons.	• The goal of the system is to provide national data. However, it will benchmark for hospitals (sized by number of beds) rather than the province due to the varying population size.	This is linked to the need for utilization data from provinces.		
	• Failure to capture minor, but potentially serious reactions.	• TTISS currently captures moderate/severe reactions. As trust increases between the provinces/territories and HealthCanada, improved communication will result and additional data will become available. The improved relationship was noted by provinces/territories (Record of Decision,TTISS Liaison Committee, November 14/2002.)			

Issue	Evaluation Recommendation	Program Response Current Status	Program Response Action Required	Due Date for Completion	Contact Person
Should TTISS incorporate transfusion error reporting from hospitals or other sites?	Data on the incidence of errors related to transfusions in hospitals and on the root causes of these errors is, in our view, a necessary complement to the existing TTISS to facilitate the development of strategies to mitigate transfusion-related risks. Due to the high costs to hospitals of implementing transfusion-related error reporting systems, implementation should be limited to a representative sample of large hospitals across the country. This should provide sufficiently robust data for the purposes of the TTISS.	Due to the successful pilot of Medical Error Reporting System (MERS) at the Sunnybrook and Women's College Hospital, a sub-group of the Core Working Group was established to implement error management with linkage to the surveillance database. A business plan is being developed to research all error management systems with recommendations, implementations and costs for sentinel sites.	It is expected a MERS pilot will run from April to August 2003 in two sites. Support materials will also be developed. This will require the approval of MERS to develop a scaled down version to be used by Health Canada. Final selection of sentinel sites to be determined.	September 2003 Program exploring availability of necessary resources.	N. McCombie, TTI
Is the TTISS model applicable to the surveillance of other phenomena of interest to the health care system, such as drug reactions or communicable disease?	Although this is an unintended impact of the TTISS and beyond the scope of the program, the TTISS model could be of value to the surveillance of drug reactions within hospitals.	A drug surveillance system is in place at Health Canada to monitor adverse reactions in drugs (through Manufactured Health Products Directorate).	Not applicable. Working closely with MHPD.		
What progress have the research projects funded under the TTISS made towards their research objectives?	Most of the six research projects were funded in two phases and most appear to have achieved their Phase 1 research objective.	TTISS is aware of the need to improve reporting from research-based projects. TTISS will continue to fund research-based projects in future due to emerging pathogens.	Follow-up on any outstanding reports from all contribution agreements. It is anticipated that funding will be given to a number of research-based projects in fiscal year 2003-2004.	Ongoing Program exploring availability of necessary resources.	M. Wotherspoon, TTI A. Giulivi, BSS&HCAID

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Consulting and Audit Canada
An Agency of Public Works and Government Services Canada

Conseils et Vérification Canada
Une agence de Travaux publics et Services gouvernementaux Canada

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Final Report

Prepared by

Consulting and Audit Canada
Project No.: 550-0813-4

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Canada

CAC CVC

Abbreviations

TTISS	Transfusion-Transmitted Injuries Surveillance System
BBP	Blood-borne pathogen
CJD	Creutzfeldt-Jakob Disease
HC	Health Canada
HCAID	Health-Care Acquired Infections Division
BSP	Health Canada's Blood Safety Program
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
LCDC	Laboratory Centre for Disease Control
SET	Surveillance and Epidemiology in Transfusions
TB	Treasury Board Secretariat

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Executive Summary

On June 2, 1998, the Government of Canada authorized $125 million in additional funding over five years to Health Canada (HC) to establish the Blood Safety Program (BSP). In 1999, Health Canada introduced the Transfusion-Transmitted Injuries Surveillance System (TTISS) component of the BSP to pilot the surveillance of adverse events, including infectious diseases and allergic and immune-mediated events, associated with the transfusion of blood products.

Recently, Health Canada requested Consulting and Audit Canada (CAC) to conduct a mid-term evaluation of the progress of the TTISS. This report contains the results of that evaluation.

The evaluation was carried out between October 2002 and January 2003. The evaluation focused on the progress of the TTISS towards implementation of a surveillance system for adverse reaction to blood transfusions in hospitals across Canada and on the progress of related research projects funded under the program. The key findings of the evaluation are summarized below.

Conclusions

Transfusion-Transmitted Injuries surveillance System

Overall, the TTISS has made a good deal of progress in terms of the number of participating provinces and territories and in terms of the coverage (number of sites and percentage of transfusions subject to TTISS) in most provinces.

Key accomplishments include:

- Development of a national database that has been adopted by all provinces;
- Development of standardized definitions, criteria, data elements and reporting protocols;
- Involvement of almost all provinces and territories on the TTISS Liaison Committee;
- Implementation on a TTISS feasibility study or pilot project in eight provinces and expected implementation in 2003/04 in two additional provinces;
- Coverage of a significant majority of blood transfusions in Canada;

To become fully operational, the TTISS needs to extend the system to those provinces and territories not yet participating in the program and to establish effective linkages with Public Health information networks. The program is making significant progress with respect to both these challenges but the time frame for their realization is not clear at this point

Funding of the TTISS on an ongoing basis is the single most important issue affecting the future sustainability of the program. It is essential that this issue be addressed and that federal and provincial governments reach agreement as to the share of required funding each will provide.

The TTISS appears to have the potential to significantly enhance Canada's ability to identify and manage risks in the post-market blood system. In the shorter term, until effective linkages are

established with Public Health information networks, this enhanced capacity will exist primarily in regard to immediate or short-term adverse reactions.

The TTISS also likely will contribute to improved identification and reporting of adverse reactions in hospitals and may contribute to a reduction in transfusion-related errors.

Data on the incidence of errors related to transfusions in hospitals and on the root causes of these errors is, in our view, a necessary complement to the existing TTISS to facilitate the development of strategies to mitigate transfusion-related risks.

Due to the high costs to hospitals of implementing transfusion-related error reporting systems, implementation should be limited to a representative sample of large hospitals across the country. This should provide sufficiently robust data for the purposes of the TTISS.

Although this is an unintended impact of the TTISS and beyond the scope of the program, the TTISS model could be of value to the electronic reporting of drug reactions within hospitals.

Research projects in Support of a Comprehensive Surveillance System

Of the six research projects reviewed, one has been completed – the Medical Event Reporting System (MERS) pilot. This project was completed successfully, met two of three research objectives and provided valuable insights into the potential benefits of transfusion error reporting.

Most of the other five projects were carried out in two phases, with the second phase not scheduled for completion until March, 2003 or March, 2004. Most appear to have achieved their Phase I research objectives and, based on interviews with the project leaders and with Health Canada officials, appear to be making good progress on their Phase II objectives. However, the rate of progress is not well documented in project files.

All of the research projects funded under the TTISS contribute, in our view, to the objectives of the program and, if successful, will make valuable contributions to the safety of the post-market blood system.

Recommendations

The following recommendations are based on the analysis of the information and data reviewed over the course of the evaluation and on the interviews with program officials and stakeholders.

- Health Canada officials should continue to work with those provinces and territories that have not yet signed contribution agreements for implementation of TTISS to determine how they can best and most cost-effectively participate in the TTISS; to determine their requirements for federal funding; and to obtain their participation.

- Health Canada officials should liaise with provinces that have completed or are carrying out pilot implementation projects to determine their funding requirements for extension of the TTISS to additional hospitals and to establish time frames for completion of this.

- Program officials should, as soon as possible, develop a strategy and action plan and preliminary funding requirements for implementing pilot projects in other provinces than BC to develop linkages with Public Health information networks.

- Program officials should attempt to determine, as soon as possible, what will be the ongoing requirements for funding of TTISS in every province and territory.

- Program officials should, in conjunction with provincial and territorial representatives on the Liaison Committee, conduct a study of the costs and benefits, and the feasibility of establishing a network of "sentinel" hospitals across Canada that would provide transfusion error reporting to Health Canada.

- The program should ensure that recipients of contributions for research projects have provided all required interim reports so that they contain sufficient information to assess progress against research objectives.

- The program should continue to support research that contributes to its objectives. In this regard, the program should develop a research plan for the next few years. The plan should identify priority areas for research; identify specific research projects that are required and estimate funding requirements.

1. Introduction

On June 2, 1998, the Government of Canada authorized $125 million in additional funding over five years to Health Canada (HC) to establish strong regulatory and surveillance programs for the blood system. As part of this Blood Safety Program (BSP), a contribution program was introduced by HC in 1999 to pilot the surveillance of adverse events, including infectious diseases and allergic and immune-mediated events, associated with the transfusion of blood products.

As requested by the Government, HC conducted an interim review in 2001-02 of Health Canada's Blood Safety Program (BSP). This review was a broadly based review of the entire surveillance program. However, in 2002, at the same time as this review was proceeding, the Auditor General, in her 2002 Status Report[1] expressed concern about the adequacy of progress towards the goal of having a national Transfusion-Transmitted Injuries Surveillance System (TTISS) in place in 2003. Partially in response to those concerns, Health Canada requested Consulting and Audit Canada (CAC) to conduct a mid-term evaluation of the progress of the TTISS and related research projects funded under the Adverse Event Surveillance Contribution Program (TTISS). This report contains the results of that evaluation.

The department also plans to conduct a final summative evaluation of the Blood Safety Program in 2003-04.

1.1 Structure of the Report

This report is comprised of two main components. The first component presents the program profile of the TTISS. The profile includes a description of the origin and history of the TTISS; its objectives and requirements; a description of the activities, outputs and outcomes, with accompanying logic model; and a brief description of the governance structure, resources and program stakeholders.

The second component presents the evaluation framework and findings of the interim evaluation of the TTISS. It includes the evaluation issues and questions and indicators against which the issues were assessed as well as the methodologies used to collect and analyse data for the evaluation. Finally, this component presents a discussion of the evaluation findings and recommendations.

[1] *Report of the Auditor General of Canada – 2002 Status report – Chapter 2,* Auditor General of Canada

2. Program Profile

2.1 Origins and Rationale

The Federal government has two key roles in regards to the country's blood system: a regulatory function under the *Food and Drugs Act* and a national disease surveillance function under the *Canada Health Act*. Although the blood supply was safer than it had ever been, a number of safety issues remained unresolved. In the early 1980's, delays in implementing safety measures related to testing blood and blood products for infectious diseases were partly to blame for the tragic consequences that ensued. Over 1,200 haemophiliacs and transfusion recipients became infected with the Human Immunodeficiency Virus (HIV). Similarly, between 1986 and 1990, approximately 16,000 Canadians were infected with the Hepatitis C Virus (HCV) through blood transfusions.

The Krever Commission was established in October 1993 to review all aspects of the blood system in Canada. Its mandate was to assess the mandate, organization, management, operations, financing and regulation of all Canadian blood system activities. An interim report released in February 1995 was focused on recommendations for immediate actions to address current shortcomings. The report identified over 300 flaws in the system. By mid-1996 the federal and provincial governments had already begun working towards immediate changes to improve and safeguard Canada's blood supply.

The final report of the Commission of Inquiry, released in November 1997, was focused on ensuring an efficient and effective blood system in Canada for the future. Of the 50 recommendations in the final report, 17 were specifically aimed at strengthening Health Canada's blood regulatory program while 5 were aimed at strengthening public health programs through enhanced blood-borne surveillance activities. The recommendations that emphasize the importance of surveillance and tracking of blood and blood products are:

Recommendation #21
It is recommended that a national integrated database be created to store and manage information about donors, donations and recipients.

Recommendation #22
It is recommended that there be an effective exchange of information between the national blood service and all hospitals that supply blood components and blood products.

Recommendation #23
It is recommended that the national blood service make it a condition of supplying blood components and blood products to hospitals that they maintain adequate records and that the blood service's standards for storing blood components and blood products be observed.

Recommendation #40
It is recommended that there be an active program of post-market surveillance for blood components and blood products.

Recommendation #48
It is recommended that the governing bodies of physicians and surgeons in the provinces and territories make it a standard of practice that physicians report adverse reactions from the transfusion of blood components to the national blood service and adverse reactions from the infusion of blood products to the national blood service and the manufacturers of blood products.

In March 1998, Health Canada's Laboratory Centre for Disease Control (LCDC) created the Surveillance and Epidemiology in Transfusions (SET) Working Group to develop a plan and design a program for a comprehensive blood surveillance system for Canada. Membership in this group included staff of the LCDC, the Bureau of Biologics and Radiopharmaceuticals, provincial and territorial public health organizations, and experts in the areas of transfusion medicine and epidemiology. Based on their findings[2], the SET Working Group made thirteen recommendations, which describe the content and structure of a comprehensive, national surveillance system for blood and blood products[3] including a list of the essential data elements, how the system should be managed, and priorities for implementation. Some of the recommendations were focused on collecting adverse reaction data that is a crucial element of an overall surveillance system. Given the various stakeholders involved in different aspects of blood and blood management, the working group considered it essential that workable governance mechanisms and a stable funding arrangement be established.

In 1998, Treasury Board approved funding in the amount of $17.5M, and an increase to HC's future year reference levels to establish strong blood regulatory and surveillance programs within the department. The TB submission also established a class of contributions to support provincial/territorial transfusion/transplantation adverse event surveillance activities as suggested in the final report from the SET Working Group. This contributions program is described in the following section.

2.2 Transfusion-Transmitted Injuries Surveillance System (TTISS)

In order to effectively monitor the blood system and assess the safety of blood and blood products, there must be means by which to assess the rate of adverse reactions resulting from its administration. Information must be collected in a reliable and standardized way in order to assure that the rates are accurate. It is on the basis of the rates of adverse reactions that corrective policies and actions are taken.

The purpose of the class of contributions established in the 1998 Treasury Board submission is to support provincial/territorial transfusion/transplantation adverse event surveillance activities.

[2] *The Surveillance and Epidemiology of Transfusion Working Group Final Report*, Chair: Dr. Steven Kleinman, February 28, 1999.

[3] Blood and blood products are only one aspect of the larger field of transplantation. The Working Group did not address surveillance of transplantation of cells, tissues and organs.

Recipients of funding from this contribution program are responsible for monitoring adverse events associated with transfusion of blood products and organ/tissue transplantation, including infectious diseases and allergic and immune-mediated events. The resources provided are to be used to increase and enhance surveillance and targeted research activities in order to identify and define risks associated with use of blood products, organs and tissues. As part of the Contribution Agreement, recipients are required to report these adverse events and outcomes to HC. "The capability to monitor these events and receive reports in a timely manner will enhance HC's ability to detect and prevent transfusion and transplantation-associated adverse events and to develop appropriate management strategies for managing these risks."[4]

2.2.1 TTISS Objectives and Goals

Since the TTISS is part of the larger Blood Safety Program, it must ultimately contribute to the long-term objectives identified for the BSP. The objectives of the BSP were derived from the 17 recommendations related to HC from Justice Krever's report. In response to the recommendations, Cabinet and subsequently TBS, provided additional funding to HC to ensure that the following two critical objectives of the BSP could be met:

- to protect the people of Canada against current and emerging health threats arising from the therapeutic use of blood, tissues and organs; and,
- to be on par, in general, with blood regulatory and surveillance programs in other leading industrialized nations, such as the United Kingdom, Australia and Germany.[5]

The 1998 TB submission established four (4) general goals concerning the blood surveillance program to respond to the BSP objectives. These are:

1. Develop linkages with public health information systems in order to strengthen public health responses to blood-borne pathogen (BBP) threats.

2. Develop linkages with appropriate organizations so that the statistical integration of CIDPC databases with other external databases can be implemented.

3. Acquire the professional and staffing resources for statistical analysis, policy development & appropriate follow-up action to develop analytic and response capacities within.

4. Establish co-coordinated research thrusts into new potential blood-borne threats, including prion diseases, which include the human form of "mad-cow disease" known as Creutzfeldt-Jakob Disease (CJD).[6]

[4] *Treasury Board Submission #826634*, Health Canada, October 8, 1998.
[5] Ibid.
[6] Ibid.

Of these four (4) objectives, only three are directly aimed at by the projects funded through TTISS contributions. These are Objectives 1, 2 and 4, above. Objective 3, while essential for the success of the TTISS, focuses on strengthening the internal analytic capacity of HC and the activities being carried out within Health-Care Acquired Infections Division (HCAID) and is in this regard part of the broader surveillance program. Consequently, these activities were viewed as being outside the scope of this evaluation.

The 1998 TB submission also included an accountability framework which outlines the increased capacities needed for effective program delivery, the planned actions, and resources required to deliver these activities. The framework identifies fourteen (14) specific requirements aimed at strengthening the regulatory and surveillance programs. For the three (3) general goals for blood surveillance listed above, four (4) requirements and activities/projects directly correspond to the TTISS.

Requirement #1: Capacity to create a blood surveillance system based on a mandated post-market surveillance and CBS data base management system

Requirement #3: Capacity to study most vulnerable populations and to conduct outbreak investigations

Requirement #5: Capacity to conduct public health investigation of emerging BBPs

Requirement #7: Capacity to link with public health information networks

Table 2.1, below, illustrate how the initiatives funded under the TTISS are linked to these requirements and objectives.

Table 2.1
Objectives & Requirements
Adverse Events Reporting System Contributions Program

Requirements	**Objective 1** Develop Linkages with public health information systems	**Objective 2** Develop linkages with appropriate partner organizations	**Objective 3** Develop analytic and response capacities within LCDC	**Objective 4**: Establish coordinated research thrusts into new potential BB threats
Reqt. #1: Blood Surveillance System based on post-market surveillance	•	•	•	•
Reqt.#3: Capacity to study most vulnerable populations	•	•	•	•
Reqt. #5: Capacity to investigate emerging BBPs	•	•	•	•
Reqt. #7: Capacity to link with public health information networks	•	•	•	•

It is important to note that the TTISS is not the only program in place to fulfill these requirements and objectives. The TTISS is only one component of a broader surveillance program being carried out by the HCAID and other divisions of the Population and Public Health Branch of Health Canada, in particular the National Microbiology Laboratory and the Bureau for HIV/AIDS, STDs and TB. This broader program includes the following activities:

- surveillance of a donor database;
- the conduct of public health investigations;
- risk assessment, risk management and risk communication of blood safety and injuries, including hepatitis, other blood-borne pathogens and prions;
- improved surveillance of and conduct of epidemiological research on HIV/AIDS and to identify, conduct risk assessment and develop strategies to address emerging retroviruses;
- development of new laboratory tools for detecting retroviral and other blood contaminants; and
- provision of laboratory science, reference services and surveillance support in connection with threats to blood safety other than retroviruses.

2.2.2 TTISS Activities, Outputs and Outcomes

The activities carried out under the TTISS are:

- funding of pilot projects in provinces and territories across Canada aimed at developing transfusion-transmitted injuries surveillance systems (TTISS);
- coordinating the work of the Federal/Provincial/Territorial Liaison Committee to promote a national TTISS and to develop national standards and tools;
- supporting research and communication designed to improve linkages between public health authorities and other partners across Canada and to promote sharing of information valuable for transfusion-related surveillance; and
- supporting research aimed at developing national registries for highly vulnerable populations and at assessing and managing risks associated with transfusions and related processes, such as transplantation of blood products.

There are two main intended outputs of these activities:

- development of a national transfusion transmitted injuries surveillance system for both immediate and delayed adverse reactions; and
- development of enhanced capacity to survey and develop risk mitigations strategies with respect to highly vulnerable populations and emerging blood-borne pathogens.

Achievement of these outputs is expected to lead, in turn, to a number of outcomes. However, as other initiatives of Health Canada and of provincial governments also contribute to these outcomes, their achievement will not be solely due to the program. Nor, of course are they necessarily assured by the conjunction of federal and provincial initiatives. These outcomes are:

Short-term Outcome

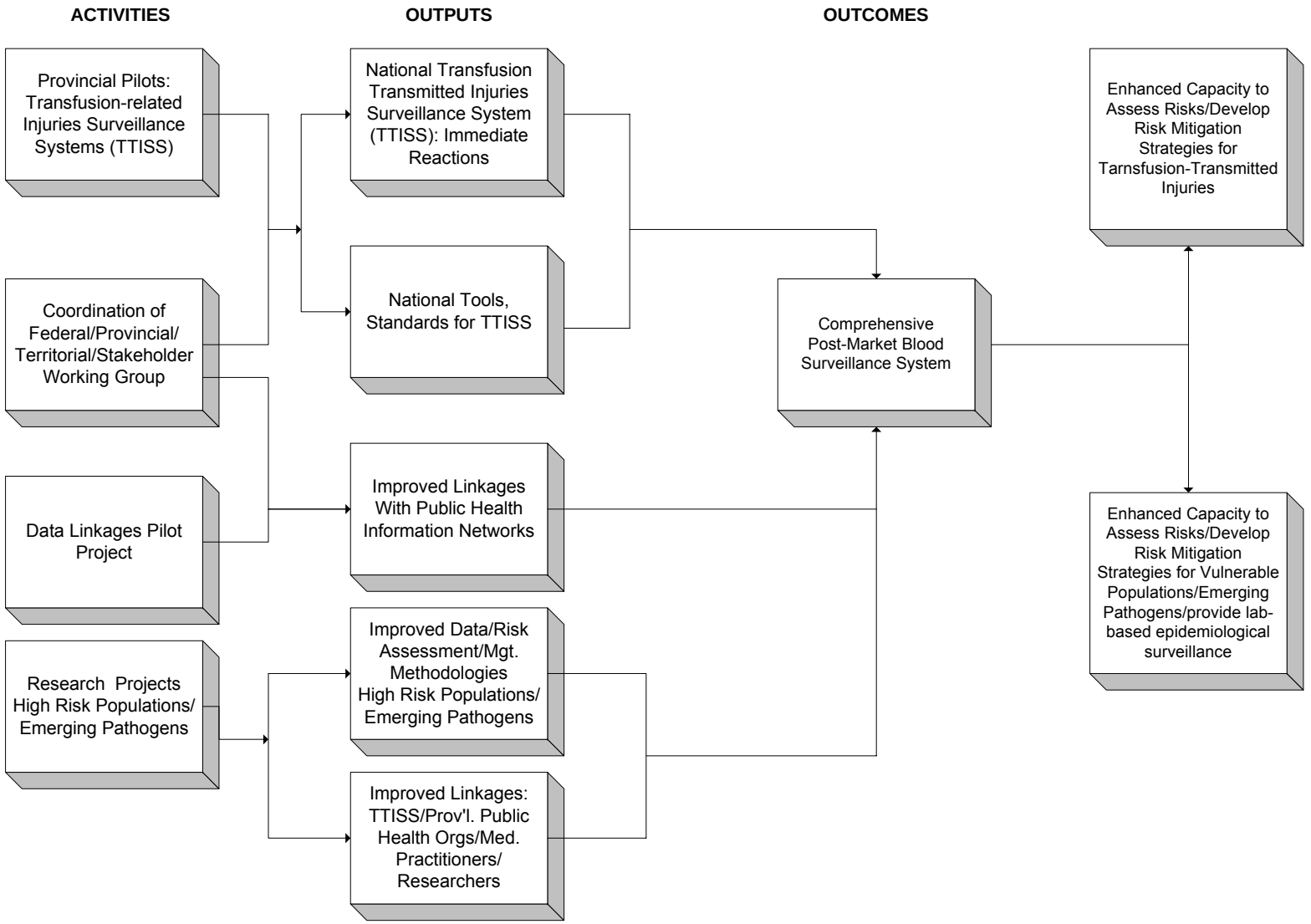
- Establishment, on an ongoing basis, of a comprehensive post-market surveillance system for blood and blood products.

Long-term Outcomes

- An enhanced capacity, within Canada, to identify and assess the risks of, and develop risk mitigation strategies for, adverse reactions to blood transfusions;
- An enhanced capacity to identify and assess risks, and to develop risk mitigation strategies for populations that are highly vulnerable to adverse reactions from blood transfusions or the administration or transplantation of blood products; and
- An enhanced capacity to identify and assess the risks to the blood system of new and emerging blood-borne pathogens; and to develop strategies to mitigate these risks.

The linkages between these activities, outputs and outcomes are summarized in Figure 2.1, the program logic model.

Transfusion-Transmitted Injuries Surveillance System
Program Logic Model



2.3 Management and Governance Structure

The TTISS is the responsibility of the Health-Care Acquired Infections Division (HCAID) of the Centre for Infectious Diseases Prevention and Control (CIDPC), Population and Public Health Branch (PPHB) of Health Canada. The HCAID provides funding for the pilot and research projects and manages most projects funded under the TTISS. Two other units in HC also manage research projects. The Hepatitis C Division of the CIDPC manages the Canadian Viral Hepatitis Network Project. The National Microbiology Laboratory (NML), Canadian Science Centre for Human and Animal Health (CSCHAH) manages the Haemophilia Genetic Mutations Project.

A Federal/Provincial/Territorial Liaison Committee currently co-chaired by Health Canada and the representative from the Yukon Territories carries out the task of coordinating the effort to develop a national TTISS. This committee includes representatives from every province and territory in Canada, Health Canada (Surveillance and Regulatory) blood manufacturers and a hospital transfusion medical expert.

2.4 Eligible Recipients

Eligible recipients are not-for profit organizations, designated transfusion/transplantation centres, and agencies/groups designated by provincial/territorial ministries of health to do surveillance for blood/tissues/organ associated adverse events.

2.5 Funded Projects/Initiatives

Since its inception the TTISS has funded sixteen projects, with thirteen of these still underway and one, with the Government of Alberta, just beginning. Of the sixteen projects, eight are in support of the implementation of the TTISS to cover each province and territory across Canada. Projects with the Governments of Saskatchewan and Newfoundland are expected for this fiscal year.

The other initiatives are categorized as research projects. The Data Linkages project is aimed at assessing the feasibility of establishing linkages between the TTISS and Public Health information networks in order to permit the incorporation into the national TTISS database of data on delayed transfusion injuries. The Medical Event Reporting System (MERS) pilot, now completed, was aimed at assessing the feasibility and usefulness of implementing transfusion error reporting in a large teaching hospital. The remaining research projects are aimed at developing national registries of information and/or serum or tissue samples for populations that are at high risk of adverse reactions to transfusions, such as haemophiliacs and viral hepatitis patients or assessing the level of risk of transmission of blood-borne pathogens in vulnerable populations.

As per the 1998 TB submission, the maximum term for each contribution was not to exceed two (2) fiscal years including any time elapsed within the fiscal year in which the contribution was signed. The maximum payment amount payable to any one recipient in any one fiscal year was set at $600,000. The following table shows disbursements against budgets from 1998-2002 as well as projected disbursements to the end of fiscal year 2002-03.

Table 2.2
Summary of TTISS Contribution Agreements

Title/Recipient	Fiscal Year	Value
Medical Error Reporting System for Transfusion Medicine	June 1, 2000 - March 31, 2002	$140,000
Data Linkage Feasibility Study	January 1, 2001 – January 31, 2003	$60,000
AERS - Quebec	Sept 1, 1999 - March 31, 2001 (Phase I) April 1, 2001 – March 31, 2003 (Phase II)	$700,000 $800,000
AERS - British Columbia	June 1, 1999 – March 31, 2001 (Phase I) April 1, 2001-March 31, 2003 (Phase II)	$510,000 $800,000
AERS - Prince Edward Island	June 1, 1999 – March 31, 2001 April 1, 2001 – March 31, 2003	$175,000 $80,000
AERS - Nova Scotia	June 15, 2000 -March 31, 2002 April 1, 2002-March 31, 2004	$200,000 $200,000
AERS – Ontario	January 1, 2002 – March 31, 2003	$188,500
AERS - Manitoba	March 1, 2002- March 31, 2003	$70,000
AERS - New Brunswick	April 1, 2002 – March 31, 2003	$40,000
AERS - Alberta	2002/03 - 2003/04	$150,000
Aphaeresis Study – Canadian Aphaeresis Group	January 4, 2000 - March 2001(Phase I) July 1, 2001-March 31, 2003 (Phase II)	$135,000 $190,000
Haemophilia Surveillance	June, 2000 – March, 2002 (Phase I) April 1, 2002 – March 31, 2004 (Phase II)	$110,00 $440,000
Haemophilia Genetic Mutation	June, 2000 to March, 2002 April 1, 2002 – March 31, 2004 (Phase II)	$125,000 $250,000
Bone Marrow Transplantation	2001/02 2002/03	$50,000 $90,000
Canadian Viral Hepatitis Network	February, 2001 – December, 2001 January, 2002 – March, 2003	$200,000 $135,500
Working Group for the International Society of Blood Transfusion	2002/03	$80,000

2.6 Resources

Health Canada officials were not able to provide an accurate estimate of the human and O&M resources allocated to the program. This is partly because some of the HCAID staff that work on the TTISS have other responsibilities and because other HC units manage two of the research projects. However, in addition to the time of the Director (1 full FTE), in 2002/03 the program resources included a Program Manager (.6 FTE) and a Program Officer (.6FTE). The Contributions budget in 2002/03 was $1.65 million. This was a reduction from the originally authorized budget of $1.9 million, as $.25 million was re-allocated to other priorities within Health Canada. The program has distributed $5.9 million in contributions since its inception.

3. Evaluation Framework and Findings

3.1 Introduction

This chapter contains a description of the evaluation framework used for the evaluation of the TTISS. This framework includes the evaluation issues and questions that were addressed, the indicators used to assess the TTISS in relation to these issues and the data sources used in the evaluation.

Subsequently, this chapter contains the findings derived from the data collection phase of the mid-term evaluation of the TTISS.

3.2 Evaluation Framework

The framework includes the evaluation issues we determined to be the most relevant to a mid-term evaluation, the indicators appropriate to those questions, and the data sources from which information was acquired for the evaluation.

3.2.1 Evaluation Issues and Indicators

The development of issues and questions for this evaluation was influenced heavily by two considerations.

Firstly, the TTISS Logic Model (Chapter 2) identifies three key outcomes of the TTISS:

Short-term Outcome

- Establishment of a comprehensive post-market blood surveillance system in Canada (the direct or short-term outcome).

Long-term Outcomes

- Enhanced capacity to assess and manage risks from transfusion-related adverse reactions – both immediate and delayed.
- Enhanced capacity to identify, assess and manage risks related to highly vulnerable populations (Haemophiliacs, Aphaeresis patients) and blood-borne pathogens.

However, as was noted in Chapter 2, the TTISS is only one among a number of initiatives aimed enhancing the capacity of Health Canada and its various partners to identify and manage risks in Canada's blood system. The achievement of the above outcomes will be a function of the success of all of these initiatives, not just of the TTISS.

Secondly, this is a mid-term evaluation of the TTISS. Funding for this program began only in 1998. Initially, four provinces participated in pilot initiatives; the other provincial participants have come on board only in the last year or two. As well, many of the research projects are still in progress.

In light of these considerations, it was concluded that it would be inappropriate in this evaluation to attempt to address, in any detailed way, the extent to which the TTISS has achieved its intended outcomes. These will most likely be addressed in a planned future summative evaluation of the entire Blood Safety Program.

Consequently, in this evaluation the focus has been on the extent to which the TTISS has achieved its intended outputs, as described in Chapter 2. These two outputs are:

1. development of a national transfusion transmitted injuries surveillance system for both immediate and delayed adverse reactions; and

2. development of enhanced capacity to survey and develop risk mitigations strategies with respect to highly vulnerable populations and emerging blood-borne pathogens.

However, the evaluation has also addressed, in a limited, qualitative fashion, the prospective question as to the extent to which the TTISS and the research projects currently being funded under the TTISS will enhance Canada's capacity to identify, assess and mitigate risks in the post-market blood system. As well, the question of whether the TTISS model had applicability to other aspects of the health care system was also addressed.

The following identifies the questions addressed in the evaluation, indicators to assess the issues, as well as an explanation as to why these issues should be examined..

1. TRANSFUSION-TRANSMITTED INJURIES SURVEILLANCE SYSTEM

1.1 What progress has been made towards implementation of a national transfusion-transmitted injuries surveillance system for short-term adverse reactions?

When Treasury Board approved funding to strengthen Canada's Blood Safety program in 1998, it provided funding through to 2002/03 for enhancement of Canada's capacity to create a post-market blood surveillance system. The vast majority of blood transfusions in Canada are administered in a relatively small number of large, tertiary care hospitals. Participation of hospitals is essential for effective surveillance of reactions to blood transfusions that occur immediately or a short time after the transfusion. Consequently, it was essential for the success of this initiative to have the cooperation of provincial governments who are responsible for the health care systems in their jurisdictions.

The primary indicators and measures of this progress are the number of provinces that have implemented TTISS pilots; how many have completed their pilots; the number of sites (hospitals) out of those eligible, that are participating in the TTISS; and the proportion of the total annual volume of blood transfusions that are captured by the TTISS. The development of national standards and tools and the acceptance of these by provincial and territorial governments were critical to the success of the TTISS. Thus, progress in this area is also an important indicator of the success of the TTISS.

1.2 How long will it be before the TTISS is fully operational?

Originally, the TTISS was to be in place by 2003. It now appears that, although that deadline will not be met, considerable progress has been made. Funding for the TTISS has been extended through fiscal year 2003/04; however, the program will terminate at that time unless a case can be made for an extension. It will be important for Health Canada management and central agencies to have a clear understanding of such things as when the TTISS is likely to be fully operational; what are the major obstacles remaining; how many additional sites/provinces must participate before the TTISS can be viewed as being fully operational; and what will be the expected number of sites participating when the provincial pilots are completed.

The in-hospital TTISS will track immediate or short-term adverse reactions to transfusions. However, adverse reactions can also occur or become evident days or months after the transfusions. Linkages with Public Health networks that monitor incidences of communicable diseases will, therefore, be important to the ability of the TTISS to provide comprehensive coverage.

1.3 How will the TTISS be sustained in the long run?

Health Canada provided seed funding for the TTISS pilot projects. However, the TTISS is intended to be an on-going initiative of federal, provincial and territorial governments. This raises the important question of how the initiative will be sustained in the long run. Key indicators here are whether provincial governments would have funded post-market surveillance systems on their own if the TTISS had not been implemented; the views of federal, provincial and territorial officials as to the necessary and sufficient conditions of sustainability; and the extent to which there are commitments at the federal or provincial level for sustained funding.

1.4 To what extent will the TTISS enhance Canada's capacity to identify and manage risks of injuries from blood transfusions?

The TTISS ultimately is of value only if provides data that will enhance the ability of federal and provincial officials to identify, assess and manage risks of adverse reactions related to blood transfusions. A key issue, then, is whether the main stakeholders in the program are of the view that the system can currently do this now or, if not now, when fully operational.

1.5 Should TTISS incorporate transfusion error reporting from hospitals or other sites?

The TTISS system will capture data on adverse errors and includes a data element for identifying cases where the reaction is due to an error in the transfusion process in the hospital. The TTISS data on errors provides very little detail and cannot help in determining how or why the mistake occurred or what, if anything, can be done to reduce incidences of the error in the future. One of the research projects funded under the TTISS was a pilot in-hospital error reporting system for transfusion-related errors. An important question for the future is whether error reporting should be incorporated into the TTISS to enhance its ability to develop strategies to reduce risks.

1.6 Is the TTISS model applicable to the surveillance of other phenomena of interest to the health care system, such as drug reactions or communicable disease?

The TTISS provides a model that, in principle, could be applied to other issues of concern to the health care system in Canada, such as rates of communicable diseases or adverse reactions to drugs. Given this, the mid-term review is an opportunity to obtain the views of professionals intimately involved with the development and the implementation of the TTISS as to whether this is, in fact, the case.

2. RESEARCH CAPACITY IN SUPPORT OF SURVEILLANCE

2.1 What progress have the research projects funded under the TTISS made towards their research objectives?

The various research projects funded under the TTISS are aimed at improving Canada's understanding of the risks faced by populations, such as Haemophiliacs and individuals on whom Aphaeresis[7] is performed, that receive much higher volumes of blood products than is the case for the general population.

Research projects are also focused on developing improved data to support identification of individuals at risk and to identify trends with respect to high-risk populations through, for example, development of a blood transfusion archive for Haemophiliacs. Other projects are aimed improving knowledge related to specific risk factors such as genetic mutation in the case of Haemophiliacs.

Key indicators of progress will documented progress against work plans; the proportion of projects completed successfully and the improvements in data, knowledge, or research methodologies that would enhance the ability to identify, assess and manage risks faced by vulnerable populations or associated with merging blood-borne pathogens.

[7] Aphaeresis involves the withdrawal of blood temporarily from an individual in order to separate out and remove the individual's blood components and the subsequent return of the withdrawn blood into the individual's circulatory system. Aphaeresis may be performed on blood donors, in order to obtain specific blood components for donation or on patients as part of a treatment program.

2.2 Will the research projects, if successful, contribute to improved post-market surveillance?

While it is important to know if the TTISS-supported research projects are making progress in terms of their research objectives, as important is the question of whether the projects, if successful will enhance Canada's ability to identify, assess and manage risks in the post-market component of the blood system. Key indicators here will be whether the projects will improve data on, or understanding of the risks faced by the most vulnerable populations or whether they will improve the ability to identify and assess risks associated with new or emerging blood-borne pathogens.

3.2.2 Information Sources

In carrying out the evaluation we made use of the following sources of data and other information:

Documents and Data Reviewed

Appendix B to this report contains a comprehensive list of documents reviewed in the course of this evaluation. Key among these documents were the following:

Program Documents

The TB Submission and related documents seeking Government approval for the TTISS contained a good deal of descriptive information as to the planned surveillance activities; the goals and requirements of the Surveillance Component of the Blood System; and the timeframes for achieving those goals. Extensive use was made of this information in developing the program profile, in particular, the program logic model; the identification of potential evaluation issues and indicators; and the development of evaluation questions.

We also reviewed a number of presentations and reports prepared by program staff over the last few years that outlined the overall approach to surveillance of Canada's blood system; clarified how the TTISS initiatives, especially the TTISS fit within this broader initiative; and reported on the progress of TTISS initiatives.

An evaluation framework prepared for the Blood Safety Program in 2001 and a report on a mid-term evaluation of the BSP, carried out in 2002 were also reviewed. These documents also provided useful information on the objectives and activities of the TTISS in the context of the broader surveillance program and assisted in the formulation of evaluation issues and questions.

Contribution Project Documents

Health Canada's files on the contribution projects contained copies of the original proposals from recipients, contribution agreements, interim and final reports and correspondence between health Canada officials relating to proposals, agreements or the administration of the agreements.

The evaluation team made extensive use of this material to identify the specific objectives of projects; the nature and scope of the projects; and timeframes and deliverables. These documents were also extremely useful in assessing progress of the projects and to develop interview questions for recipients and Health Canada officials.

Other documents and data reviewed included the Evaluation Framework of the Blood Safety Program (2001); a report on a Review of the Health Canada Blood Safety Program (2002); and a number of presentations on the TTISS, the Blood Surveillance Program and related issues prepared by HCAID officials over the last two years. HCAID officials also provided budgetary information on the TTISS.

Interviews

Interviews were conducted with Health Canada officials within HCAID who are responsible for the TTISS and who participate on the TTISS Liaison Committee; other Health Canada officials responsible for managing individual research projects funded under the TTISS; provincial government officials who have received contributions funds under the TTISS to establish pilot TTISS initiatives in their province and who participate on the Liaison Committee; researchers who are leading research projects funded under the TTISS; and the representative of Canadian Blood Services on the Liaison Committee. Appendix A to this report contains a list of all persons interviewed.

3.2.3 Evaluation Matrix

Figure 3.1, below, provides an overview of the evaluation issues and questions, the indicators for each, the data sources, and methods of data collection.

EVALUATION ISSUES/QUESTIONS	INDICATORS	DATA SOURCES
I. Transfusion- Transmitted Injuries Surveillance System.		
1.1 What progress has been made towards implementation of a national transfusion-transmitted injuries surveillance system for short-term adverse reactions?	• No. of provinces that have implemented/completed pilot initiatives • Proportion of provinces/sites reporting TTISS data: currently and by completion of projects • Proportion of blood transfusions captured: currently & by Project completion • Development of national standards and tools	• Project Proposals/Interim & Final Reports • Program Documents • Interviews • Provincial Data
1.2 What remains to be done before the TTISS is fully operational?	• Additional Sites/Provinces/Territories Required • Adequacy of linkages to Public Health information networks • Obstacles • Expected Timeframe	• Interviews • Program Documents • Project Interim/Final reports
1.3 How will the TTISS be sustained in the long run?	• Perceptions of participants as to conditions for sustainability • Provincial funding commitments: past/future	• Interviews
1.4 To what extent will the TTISS enhance Canada's capacity to identify and manage risks of injuries from blood transfusions?	• Perceived benefits of TTISS (Participants) • Perceived risks of not implementing (Participants) • Perceived limitations in system	• Interviews
1.5 Should TTISS incorporate transfusion error reporting from hospitals or other sites?	• Lessons Learned from MERS Pilot project • Perceptions of TTISS participants	• MERS project final report • Interviews
1.6 Is the TTISS model applicable to the surveillance of other phenomena of interest to the health care system, such as drug reactions or communicable disease?	• Perceptions of TTISS participants/other Liaison Committee members/Health Canada officials	• Interviews
II. Research Capacity in Support of Comprehensive Surveillance System		
2.1 What progress have the research projects funded under the TTISS made towards their research objectives?	• Progress of projects against work plans/deliverables • Proportion of projects completed successfully • Knowledge gained/data collections systems established	• Project Proposals, Agreements, Interim & Final reports • Interviews
2.2 Will the research projects, if successful, contribute to the enhancement of Canada's post-market surveillance system?	• Comparison of project objectives with goals/objectives of surveillance program	• Interviews • Project Documents

3.3 Evaluation Findings

3.3.1 Achievement of Objectives

1. TRANSFUSION-TRANSMITTED INJURIES SURVEILLANCE SYSTEM

1.1 What progress has been made towards implementation of a national transfusion-transmitted injuries surveillance system for short-term adverse reactions?

Much has been done in Canada in the last five-to-six years to improve the safety of the blood supply through extensive screening of blood donors and through the testing of blood donations for pathogens known to be transmitted through the blood system. However, the capacity to monitor the safety of the blood supply "post-market" (i.e. downstream of the blood donation) is as important as this "pre-market" surveillance. Post-market surveillance, if sufficiently representative, can provide a means of identifying unusual patterns or rates in adverse reactions. This result in investigations that could lead to new or modified blood testing of blood donations for new or emerging blood-borne pathogens; it could also lead to changes in procedures followed by staff manufacturing and administering blood transfusions.

In 1998, there was no formal system in place to identify and report on adverse reactions to blood transfusions in these hospitals or in other institutions with high volumes of blood transfusions. The TTISS attempted to address this gap through the provision of federal contributions to projects in each province and territory to establish systems to track and report on these adverse reactions. In this section we attempt to determine the extent to which the TTISS has made progress in establishing a national transfusion-transmitted injuries surveillance system.

Based on the review of a substantial number of program documents and on interviews with the pilot project leaders in provinces and with other members of the Liaison Committee, it appears that considerable progress has been made towards the establishment of a national TTISS, especially in the last one and one-half years.

Initially, four provinces (Quebec, Nova Scotia, Prince Edward Island and British Columbia) participated in TTISS developmental pilot projects that took place over the period from June 1999 to March 2002. At the beginning of the process, according to those interviewed, the initiative faced a number of challenges, the key ones being:

- Reaching agreement on the database to be used as the basis for the system; ultimately, the four core provinces agreed to develop a national system based on a system under development in Quebec, which was modeled on a system in France; the other provinces also agreed to adopt this system;
- The lack of standard definitions, criteria, data elements to be reported and other system parameters;
- a considerable degree of skepticism, initially, among the representatives on the Federal/Provincial/Territorial Liaison Committee; it took some time before all members "came on side" and participated fully in the work of the committee.

Despite these challenges, these four "core" provinces worked cooperatively to reach agreement with each other and with Health Canada on:

- standardized reporting forms;
- standardized definitions;
- data elements to be reported to Health Canada;
- Frequency of reporting;
- Conditions for reporting national data
- Use of TTISS to report to Health Canada's regulatory program.

Each of the four core provinces also established Phase I pilot projects in their respective jurisdictions. These Phase I pilots focused on the design (in conjunction with other provinces and Health Canada) of the TTISS and the planning and implementation of pilot initiatives at a number of major transfusion sites within their jurisdictions. Quebec, British Columbia and Prince Edward Island completed their Phase I pilot by March, 2001, Nova Scotia by March, 2002.

Beginning in 2002, other provinces began pilot TTISS projects. Different provinces have taken different approaches to these pilots. Some have elected to begin with feasibility studies to determine how best to implement the TTISS within their health care system while others have moved straight to pilot implementation projects.

The status of the TTISS initiative in each province/territory is as follows:

British Columbia

- BC has implemented the TTISS in 6 tertiary hospitals. In Phase II they will be extending the TTISS to 15-20 lower volume community hospitals who will report manually rather than on-line due to cost considerations.

Alberta

- Alberta has signed a contribution agreement with Health Canada. They are expected to begin a pilot by March 2003.

Saskatchewan

- Saskatchewan expects to submit a proposal to Health Canada for a pilot initiative by March 2003. The pilot will involve implementing TTISS at 4 tertiary care hospitals.

Manitoba

- Manitoba began implementing a pilot in March 2002 and is being assisted by BC. By March 2003, it will have implemented TTISS in its 2 largest hospitals representing 85% of transfusions. Ultimately it hopes to have a province-wide system.

Ontario

- Ontario has had a pilot project in place since January 2002. The pilot involves six (6) hospitals. The project has been delayed due to difficulties coordinating the TTISS project with the province's own blood surveillance initiative, which is intended to track blood through to the end user. Health Canada has installed the TTISS database directly into the six hospitals while the province builds the infrastructure for the provincial Blood Coordinating Office. This will not delay data transfer from these hospitals. Ontario is behind schedule on their administrative requirements, such as invoices and report submissions.

Quebec

- Quebec will have implemented TTISS in 34 tertiary hospitals and 20 associated hospitals by March 2003. This will represent 75-80% of blood transfusions in the province. In the future, they also intend to capture data from 4 haemophiliac clinics and from a number of municipal and mobile clinics, as well as to establish linkages with public health authorities.

Nova Scotia

- Nova Scotia has completed a Phase I pilot involving the implementation of TTISS at 2 tertiary hospitals and one other major health centre. They are in the process of extending the system to 6 district hospitals in the Capital District. Ultimately, they intend to roll out the system to all hospital districts. However, as TTISS is linked to the Meditech information system, timing of the roll out is dependent on the roll out of Meditech.

New Brunswick

- New Brunswick is conducting a feasibility study at its 3 largest tertiary care hospitals prior to implementing TTISS. This study was to be completed by March 2003. However, since the work was delayed in starting, its completion will also likely be delayed.

PEI

- PEI has implemented TTISS in all 5 hospitals and has implemented a Phase II project, to be completed by March 2003 to improve linkages, address issues regarding reporting forms and resolve technical issues re the TTISS database.

Other Provinces and Territories

- Newfoundland has been an active participant in the liaison committee but has not been able to implement a pilot due to a lack of resources. There is ongoing communication with Newfoundland and Health Canada expects them to participate in 2003.

Nunavut will likely report their data through Manitoba's system. The Yukon Territories will be reporting through BC's TTISS. The Northwest Territories will have the TTISS database installed in 2003. In any case, they all involve very small numbers.

Table 3.2 provides a synopsis of the current and expected coverage of TTISS in terms of number of sites and percentage of blood transfusions in each province that will be subject to the reporting system.

Table 3.2
Coverage of TTISS by Province/Territory

Province/ Territory	Coverage of Current TTISS Pilot		Expected Coverage on Full Implementation		Expected Date: Full Implementation
	No. Of Sites	% Of All Transfusions	No. Of Hospitals	% Of All Transfusions	
British Columbia	6	75-80%	21-26	90-95%	
Alberta	0	0	Not available	Not available	Not available
Saskatchewan	0	0	4	75%	Unknown
Manitoba	2	85%	2	85%	March, 2004
Ontario	6	80%	Unknown	80%+	Unknown
Quebec	54	75-80%	54 hospitals 4 Haemophiliac Clinics Other clinics	80%+	Unknown
Nova Scotia	9	75%	Unknown	Close to 100%	4-5 years
New Brunswick	0	0	Unknown	Unknown	Unknown
PEI	5	100%	5	100%	March, 2003
Newfoundland	0	0	Unknown	Unknown	Unknown
Nunavut	Unknown	Unknown	Unknown	Unknown	Unknown
NWT	0	0	1	100%	2003
Yukon	0	0	1	100%	Unknown

As is clear from this table, the TTISS has been implemented, at least on a pilot basis, in six (6) provinces, including Ontario and Quebec, the two provinces representing the majority of blood transfusions in Canada. In most of these provinces, the TTISS already covers a high percentage of blood transfusions and coverage in most provinces is expected to be at or close to 100% in the next few years. One other province (New Brunswick) is completing a feasibility study and two other provinces (Alberta and Saskatchewan) are about to begin implementation projects. Two of the three territories, although they have very small volumes of transfusions, are working with other provinces to determine how they can "piggy-back" on provincial reporting systems. The Northwest Territories will install the database this year.

In terms of the number of blood transfusions that would be covered under the TTISS at present, the program has been quite successful, based on the anecdotal evidence of interviewees. Most respondents were able to provide only a rough estimate of the number of blood transfusions in their province that would be covered under the TTISS at present and most did not know what percentage of all transfusions in Canada this estimate represented. However, it would appear, based on the estimates contained in Table 3.2, that currently the TTISS covers somewhere between 70-75% of all blood transfusions in Canada.

Conclusions

Overall, the TTISS has made a good deal of progress in terms of the number of participating provinces and territories and in terms of the coverage (number of sites and percentage of transfusions subject to TTISS) in most provinces.

Key accomplishments include:

- Development of a national database that has been adopted by all provinces;
- Development of standardized definitions, criteria, data elements and reporting protocols;
- Involvement of almost all provinces and territories on the TTISS Liaison Committee;
- Implementation on a pilot or fully operational basis in eight provinces representing a significant proportion of blood transfusions in Canada and plans for implementation pilots in five other provinces or territories.

1.2 What remains to be done before the TTISS is fully operational?

Based on our interviews with program officials, provincial pilot project leaders, research and other committee members, although significant progress has been made, there is still considerable work to do before the TTISS is fully operational, Interviewees were asked what obstacles to, and gaps in, a national TTISS remain They were also asked to identify what additional steps need to be taken to fully implement the TTISS. The challenges remaining most frequently cited by those interviewed are the following:

Obtain the participation of all provinces and territories and expand the number of sites within provinces that participate in the TTISS

A significant majority of those interviewed indicated that the most important next step is to bring on board those provinces and territories - Newfoundland, Saskatchewan, and the three territories – that have not yet implemented TTISS in their respective jurisdictions. In fact, as noted above, all of these jurisdictions are either about to start implementation pilots or are in discussions with provinces that have implemented TTISS to “piggy-back” on the latter’s’ systems to report TTISS data.

A significant number of interviewees also indicated that it is imperative that the TTISS be extended to additional hospitals within those provinces that are currently participating in the program. There are two main reasons for this:

i) firstly, adverse reactions can be regionally based, as demonstrated in the case of the West Nile virus which is a problem in central Canada but not yet in western Canada; because of this, ideally the TTISS should be analyzing data from all regions of Canada and, in the cases of large provinces especially, from all regions within the province;

ii) secondly, it is possible that different types of hospitals may experience different rates of adverse reactions: for example, it may be that hospitals with trauma units, where staff are working at high speed in life or death situations, may have a higher rate of reactions due to errors than a Haemophiliac clinic where staff can take more time to avoid error. In light of these sorts of possibilities, it could be important to have data from a range of different types of institutions.

Considerations of cost and efficiency must be juxtaposed against these reasons. In most provinces a relatively small number of hospitals account for the vast majority of blood transfusions. The small amount of additional data obtained by extending the system to other, low volume hospitals and clinics may not justify the costs involved. On the other hand, in some cases, (e.g. Haemophiliac clinics) the site may provide services mostly or exclusively to highly vulnerable populations in respect of whom it may be important to have as much data as possible.

A high proportion of transfusions in each province is required, for the reasons noted above, to ensure the data is sufficiently robust; however, the TTISS does not need 100% coverage of transfusions to be effective. It will be important for the sustainability of the program that Health Canada work closely with provincial officials to identify the most cost-effective means of obtaining adequate data from each province. Based on our interviews, both federal and provincial officials are well aware of this and have this issue in hand.

Establish effective linkages with Public Health Information Networks

The focus of the work of Health Canada officials and their provincial partners in the first years of the TTISS has been primarily on the development of the TTISS tools and standards and on implementation of the in-hospital surveillance system. The in-hospital TTISS, however, captures only immediate reactions to blood transfusions. To capture data on delayed reactions – reactions that occur days or months after the fact, the TTISS database needs to be linked to Public Health Information Systems where information is collected on communicable diseases and other disorders that, by law, must be reported by private practitioners and community health service agencies.

Establishing these linkages, while essential for the TTISS to be able to capture both immediate and delayed reactions will not be easy. There are a number of issues that must be resolved, including technical issues that will differ from province-to-province; differences between the TTISS system and Public Health systems with respect to terminology, criteria, and definitions; privacy issues that will also vary from province-to-province; and the identification of the data elements required by the TTISS.

Health Canada has taken a significant first step to deal with these issues by funding a Data Linkages feasibility study in British Columbia. This study is addressing the above and other issues. The project began in January, 2002 and has just recently been completed.

So far, the study has developed a conceptual framework for the design of a data linkage pilot; has completed a data needs analysis; conducted planning sessions to address issues, including the design of the system and the data infrastructure and legal implications.

Once this feasibility study has been completed, BC is expected to move forward with implementation of linkages with Public Health systems on a pilot basis. Other provinces will be able to take advantage of the lessons learned through BC's experience.

At the moment, no timeline has been established for the implementation of these linkages in BC or in other provinces.

Other Gaps/Required Actions

A few of those interviewed identified other gaps that will have to be addressed or actions that will be required before the TTISS is fully operational, including:

- The need for further work on some of the forms and other tools used in the TTISS. Work is progressing on this but is not yet finished.

- Improvements in data on the "denominator" used in analyzing the rate of adverse reactions. In most provinces the denominator most easily available is the number of transfusions. However, the more useful denominator, according to some of those interviewed, is the number of patients.
- The need to develop data verification techniques to measure under-reporting of adverse reactions.

- The need to augment the capacity at Health Canada to conduct sophisticated epidemiological and other analysis of TTISS data. A small number of those interviewed stated that Health Canada should recruit an individual with a strong background in haematology or other blood-related specialty to enhance their analytic capabilities.

Conclusions

To become fully operational, the TTISS needs to extend the system to those provinces and territories not yet participating in the program and to establish effective linkages with Public Health information networks. The program is making significant progress with respect to both these challenges but the time frame for their realization is not clear at this point.

1.3 How will the TTISS be sustained in the long run?

Federal funding for TTISS pilots will be ending after 2003/04. As the TTISS is intended to be an ongoing surveillance system, it is logical to ask at this time how the program will be sustained in the future. In order to address this issue, interviewees were asked several questions aimed at determining what has been the degree of commitment to the TTISS by provincial governments; to assess what the future level of commitment is likely to be; and to obtain their views as to the necessary conditions for the sustainability of the program.

Interviewees were first asked what proportion of funding for their pilot initiatives provincial governments provided. Based on their responses federal funding as a portion of total pilot costs ranged from a low of 10% in Quebec to 100% in Ontario, New Brunswick and British Columbia, with most other provinces contributing 50% or less.

These estimates are somewhat misleading, however, in that, even where the federal government provided most or all of the funding there were considerable "in-kind" contributions from provincial governments in the form of extensive time committed by professional staff to the pilot and to participation on the Liaison Committee. In addition, several provinces (PEI, BC, Ontario, Quebec) had already initiated provincial blood registry programs aimed at maintaining records on all blood transfusions in the province. These registries will provide the denominator data required by TTISS to monitor the rate of adverse reactions in each province.

In response to the question as to whether they would have proceeded with a TTISS system in the absence of federal funding, four provinces indicated that they would have. Ontario would have included the TTISS in its $1.6 million Blood Conservation and Bloodless Medicine Program. Quebec had planned to develop a TTISS capability as part of its $47 million Hemo-Vigilance program but implementation would have been delayed by at least two years, to allow for development of a comprehensive Hemo-Vigilance information system. Manitoba and Nova Scotia indicated that they likely would have proceeded with development of a TTISS-type system but that federal funding accelerated the process.

Both PEI and BC would have developed the denominator component of TTISS, as noted above, but provincial officials indicated that the province would not have gone ahead with the tracking of adverse reactions. New Brunswick indicated that they would not have proceeded with their feasibility study in the absence of federal funding. The only other province to respond to this question – Saskatchewan – has not yet implemented TTISS. The provincial representative interviewed indicated that the province would almost certainly not proceed without federal funding.

The responses to these questions indicate that, while most provinces committed time and resources to the TTISS, federal funding so far has been an essential catalyst. Given this, we asked provinces and committee members what would be required to sustain the TTISS initiative on an ongoing basis. The issue that was of paramount concern to the individuals interviewed was that of funding.

Among the six provinces that have completed or are carrying out implementation projects[8], four (Ontario, Quebec, Nova Scotia and Manitoba) indicated that they would be counting on funding from their provincial government to sustain the program. Of these provinces, however, only Nova Scotia has formally committed funding for the program ($400,00.00 over the next four years). Two provinces stated that there would likely be an expectation of at least some federal funding. No representative of Alberta was interviewed. Saskatchewan, which is expected to begin a pilot project this year, indicated that they would expect ongoing federal funding. New Brunswick, which is carrying out a feasibility study with its federal contribution and is not yet in the implementation phase, indicated that the project would likely seek provincial funding for implementation.

Both PEI and BC had implemented blood registry programs prior to the start of their TTISS initiatives and they would continue to fund these; however, in both cases provincial funding would be directed to the blood registry (the denominator of the TTISS system) and not to monitoring adverse reactions.

Based on these responses it is clear that most provincial governments are committed to the TTISS. Nevertheless, most provinces have made no formal commitment to fund the TTISS, in whole or in part, in the future. While some provincial funding is likely in most provinces, it is also likely that most, if not all, provinces and territories will expect federal funding for the program on an ongoing basis. As one interviewee put it, “If Health Canada wants the data they are going to have to pay for it.”

Given this, in our view, it is essential that Health Canada begin discussions with provincial governments to determine what is likely to be required to sustain the TTISS across Canada and to maintain the commitment of provincial governments to a national database. They also need to identify how much of this provincial governments are prepared to commit and determine federal funding requirements.

Conclusions

Funding of the TTISS on an ongoing basis is the single most important issue affecting the future sustainability of the program. It is essential that this issue be addressed and that federal and provincial governments reach agreement as to the share of required funding each will provide.

[8] We have excluded New Brunswick from this category as it is not yet in the implementation stage.

1.4 To what extent will the TTISS enhance Canada's capacity to identify and manage risks of injuries from blood transfusions?

The TTISS is intended to enhance Canada's capacity to identify and manage risks of both immediate and delayed adverse reactions to blood transfusions. Federal, provincial and territorial officials, as well as representatives from the CBS, have spent the last few years taking the TTISS from a concept to a real system operating in a number of provinces. The work of clarifying the specific objectives of the TTISS; determining the nature, scope and sources of data to be entered on the system; and identifying and overcoming the obstacles to implementation of the system has given these individuals the opportunity to develop a clear understanding of the potential of the system and its limitations.

It is, therefore, an appropriate time to ask whether the TTISS will in fact be able to do what it was originally intended to do: enhance the capacity to identify and develop strategies to deal with, ongoing or emerging risks associated with blood transfusions.

To this end, interviewees were asked what they perceived as the benefits of a national TTISS and what they felt to be the risks of not implementing such a system. While there was a range of responses to these two questions, a number of common themes emerged. Key themes are summarized below.

Ability to identify trends or patterns of adverse reactions resulting from transfusions

There was a clear consensus among those interviewed that the TTISS would give Canada the ability to identify trends (changes over time) or patterns (unusual rates of reactions in certain regions or provinces). Prior to the TTISS, there was no system in place anywhere in Canada to systematically gather data on transfusion-related incidents. TTISS fills that gap. Among the kinds of adverse events that can be identified are the following:

- Bacterial contamination
- Reactions due to errors, such administration of the wrong blood type
- Allergic reactions
- Viral infections

The TTISS in Quebec has already identified rates of bacterial contamination above what has been reported by other countries with post-market surveillance systems. Using this data, the province modified its procedures for blood donations to reduce the risk of bacterial contamination.

Ability to identify patterns or trends not detectable in smaller populations

There are several benefits to a national TTISS database as opposed to provincial databases, according to a number of those interviewed. Firstly, because the rate of adverse reactions, especially those related to viral infections, is so low, large volumes of data are necessary to enable trends or patterns to be identified. Several smaller provinces indicated that they would not be able to identify significant trends or patterns based only on their provincial data because the volume of blood transfusions is simply too small.

Ability to establish geographical or chronological boundaries to risks

Conversely, in some cases the national TTISS database will be able to determine that an emerging pathogen, such a West Nile virus, is a high risk in one area but not in another. As well, the TTISS could identify timeframes within which blood inventories may pose an unacceptably high risk. This could result in cost savings to provinces in the form of avoiding the necessity of having to dump inventory.

Improved recognition of adverse reactions/reductions of errors in hospitals in hospitals

One interviewee indicated that, in Sunnybrook Hospital, where the TTISS has been implemented, reports of adverse reactions have increased from 2/month to 20/month. The interviewee attributed this to the TTISS training which, in their view, enhanced the ability of physicians to recognize adverse reactions as such. A related benefit cited, by some interviewees, is a reduction in transfusion-related errors as a result, in part, of TTISS training. *[Some of this error reduction at Sunnybrook is likely attributable to a transfusion error reporting system being piloted at this site]*.

In summary, most interviewees felt that the TTISS had significant potential to contribute to improved safety in the post-market blood system. One individual noted that the consequences of not implementing it could include liability for adverse reactions resulting from transfusions.

Nevertheless, several limitations or perceived weaknesses of the system were cited as well, including:

Limited effectiveness in detecting new or emerging blood-borne pathogens

One individual was of the view that TTISS would not be an effective surveillance system with respect to blood-borne pathogens, as most of these involve very long-term reactions. This would appear to be a valid observation as, at the present time, the TTISS is receiving very limited information from Public Health information networks. Once the TTISS has established extensive linkages with these networks, its capacity to identify long-term reactions will be significantly enhanced.

Limited effectiveness in benchmarking/interprovincial comparisons

The TTISS may be of limited effectiveness in providing comparisons among provinces regarding rates of adverse reactions or rates of reactions among different populations. This will be most evident in the case of provinces and territories with very small populations with different demographic characteristics from other provinces (e.g. PEI has a very small population with a high proportion of rural residents compared to some other provinces).

Failure to capture minor, but potentially serious reactions

One interviewee noted that the TTISS captures only adverse reactions that meet the program criteria as "serious". He pointed out that there are some types of moderate reactions to transfusions that, in another patient, could have been serious reactions. This individual felt that the system should be capturing these moderate, but potentially serious reactions.

If the intent of the TTISS is not just to monitor adverse reactions but to assess the risk they pose and to take steps to mitigate those risks, it may well be that there is an argument for including minor reactions that do not meet the current criteria for reporting under the TTISS. For example, a transfusion error, such as administration of the wrong blood type, may result in only a very minor reaction in some patients but in others may cause a very serious reaction. If the overall rate of a particular type of reaction is high but the rate of *serious* reactions of this type is low, it might be deemed there is no need for remedial action on the basis of the latter numbers alone. Inclusion of potentially serious events could provide a stronger basis for assessing risks and the costs and benefits of remedial actions to address the risks.

Further, if data from hospital-based systems for tracking errors in the administration of transfusions is included in the TTISS database, it may be necessary for the TTISS system to capture minor reactions in order to ensure comparability of data between the two systems.

Conclusions

The TTISS appears to have the potential to significantly enhance Canada's ability to identify and manage risks in the post-market blood system. In the shorter term, until effective linkages are established with Public Health information networks, this enhanced capacity will exist primarily in regard to immediate or short-term adverse reactions.

The TTISS will also likely contribute to improved identification and reporting of adverse reactions in hospitals and may contribute to a reduction in transfusion-related errors.

1.5 Should TTISS incorporate transfusion error reporting from hospitals or other sites?

The TTISS system will capture data on adverse errors and includes a data element for identifying cases where the reaction is due to an error in the transfusion process in the hospital. The data on errors provides very little detail, however, as to how or why the mistake occurred or what, if anything, was done to reduce incidences of the error in the future. Thus, the TTISS will be of limited value, by itself, in mitigating risks related to errors.

However, one of the research projects funded under the TTISS tested the applicability of the Medical Error Reporting System (MERS) – an application developed in the U.S.A. – to the reporting of transfusions. Under the MERS system, as piloted at Sunnybrook Hospital, all transfusion errors and "near misses" (mistakes that were corrected before the transfusion) are reported on a database on which they are classified as to their severity (or potential severity in the case of near misses). Subsequently, physicians, nurses and technicians involved in the incident do a root cause analysis to identify the underlying cause of the error and recommend remedial action or modifications to transfusion processes to reduce the risk of future errors.

We discussed with the interviewees whether an error reporting system, such as MERS, is a necessary element of an effective national TTISS. While there was a range of views on this issue, a majority of those interviewed were of the view that some form of error reporting and analysis eventually should be part of the national TTISS.

According to a number of those interviewed, much has been done to improve the safety of the blood supplied to hospital blood banks. However, little has been done to reduce errors occurring within hospitals during the administration of blood transfusions. Yet these errors are far more frequently the cause of adverse reactions than the blood itself or patient characteristics that increase his or her risk of an adverse reaction.

The majority of interviewees who supported implementation of a MERS type system as a complement to the TTISS in hospitals did so for the following reasons:

- A MERS type system can provide much more detailed information about errors than does the TTISS, thus allowing for more sophisticated analysis of reactions.

- The information in MERS on the root cause analysis and remedial actions recommended or taken; and on the success of those actions, if captured on a national database, would enable lessons learned in one hospital to be passed on to other hospitals across the country.

- The more detailed data on errors provided by a MERS type system is necessary if the TTISS system is to go beyond the assessment of risks to developing risk mitigation strategies for transfusion-transmitted reactions. The inclusion of near-miss data likely would be important in respect of this objective.

Although interviewees did not specifically mention this, a national database of MERS data would be extremely valuable, as well, in testing measures aimed at reducing errors to assess their efficacy. For example, if it became evident from MERS data that the incidence of the wrong blood type being administered was unacceptably high, Health Canada, in conjunction with the CBS and participating hospitals might want to test, on a pilot basis, alternative approaches to labeling of blood and blood products (e.g. different coloured blood bags for each blood type vs. coloured labels affixed to bags). By establishing certain hospitals as experimental sites and others as control sites, the efficacy of alternatives could be examined in a rigorous fashion.

Another potentially valuable use of national data could be to identify factors that are associated with high rates of errors in particular areas (e.g. hospitals with a high volume of trauma patients may have a very different error profile than hospitals that do not have a trauma centre).

A number of interviewees were at pains to point out, nevertheless, that it is not feasible to implement a MERS type system in all hospitals in Canada. Implementation of a MERS type system is simply too costly, especially for smaller hospitals. Several individuals suggested that a more viable alternative is a national network of large "sentinel" hospitals that would provide MERS data to health Canada for analysis. In our view this approach is likely the most cost-effective approach to gathering data on errors on a national basis and is one that should be explored by Health Canada.

Conclusions

Data on the incidence of errors related to transfusions in hospitals and on the root causes of these errors is, in our view, a necessary complement to the existing TTISS to facilitate the development of strategies to mitigate transfusion-related risks.

Due to the high costs to hospitals of implementing transfusion-related error reporting systems, implementation should be limited to a representative sample of large hospitals across the country. This should provide sufficiently robust data for the purposes of the TTISS.

1.6 Is the TTISS model applicable to the surveillance of other phenomena of interest to the health care system, such as drug reactions or communicable disease?

In the course of interviews for this mid-term review, the issue arose as to whether the TTISS provides a template or model that could be used to monitor other the rates of other phenomena of concern to the health care system in Canada. Consequently, in subsequent interviews we raised this question.

Based on the feedback received there are two main candidates for application of the TTISS. One is for tracking of communicable diseases, especially those diagnosed in hospitals. Information on communicable disease rates is important to the goal of identifying local, regional or national risks to the blood supply and, thus, is data that is required by the TTISS. Based on our discussions with interviewees, while the TTISS could potentially be applied to this function, there is no need to develop a new system for this. Firstly, communicable diseases, including

those occurring in hospitals are currently being reported to Public Health authorities in most, if not all regions of Canada. Secondly, the Centre for Disease Surveillance of Health Canada is in the process of developing a national communicable disease tracking system that will capture this data. Finally, the TTISS is conducting a data linkages feasibility study in BC to examine the feasibility of, and options for acquiring data on cases of communicable diseases where the individual has either donated or received blood in the past.

Consequently, there appears to be no justification at this time for attempting to apply the TTISS to surveillance of communicable diseases.

A second potential application of the TTISS model is for the surveillance of drug reactions in hospitals. This application is of more value, according to a majority of those we interviewed. Several of the individuals we interviewed remarked that the incidence of adverse reactions to drugs is considerably higher than that of reactions to transfusions. On the other hand, surveillance of the administration of drugs takes place at many more locations within hospitals than do transfusions, so there are considerably greater technical and administrative difficulties, in implementing a TTISS type system for this purpose.

At the moment, there is a reporting system for adverse reactions to drugs administered in Canada, including those occurring in hospitals. This system is currently based on manual reporting. It may be very cost/beneficial to apply the TTISS model to electronic – as opposed to manual - reporting of in-hospital drug reactions. Electronic reporting would facilitate reporting and data analysis. It should be noted, however, that adaptation of a TTISS-type system for this purpose is outside the mandate of the TTISS program.

Conclusions

Although this is an unintended impact of the TTISS and beyond the scope of the program, the TTISS model could be of value to the surveillance of drug reactions within hospitals.

1.7 What progress have the research projects funded under the TTISS made towards their research objectives?

In addition to the Data Linkages Feasibility Study, discussed in the context of the review of the TTISS, the TTISS has funded six other research projects in support of an enhanced post-market blood system surveillance capacity. Based on a review of the project documents provided and, where possible, on interviews with individuals within Health Canada responsible for managing these projects and with the research project leaders, we reviewed the progress of these projects against their research projects and their deliverables. The results of this review are summarized below.

Medical Error Reporting System (MERS)

This research project was took place in the period June 2000 to March 2002. Health Canada provided 100% of the funding for this project, in the amount of $140,000.00. The project, which was carried out at Sunnybrook Hospital in Toronto had three main objectives:

- To gain acceptance within the hospital community and administration of an error reporting system for transfusion-related errors;
- To operate MERS for a sufficient length of time to establish a robust data set on transfusion-related errors;
- To validate the effectiveness of MERS in a large teaching hospital.

This research project was completed on time and within the budget, based on documents in the project file and according to the physician who led the project. Interim and final reports on the project were submitted.

Based on those reports and on our interview with the project leader, the project was quite successful. It achieved Objective A (the system has been implemented on a permanent basis at Sunnybrook which has assumed the costs of operating the system) and Objective B (it has a data set of over 5000 errors).

The project has been less successful with respect to Objective C. Although Level 1 errors (potentially life-threatening) have declined, the overall error rate has not yet declined. As well, staff involved in the system has had difficulty in obtaining the agreement of the hospital administration to some suggested remedial actions due to their costs. Alternative remedies have been found to be not effective so far, although they continue to seek alternative solutions.

National Program for Haemophilia Mutation Testing

This research project was funded in two phases. The objective of this project is to investigate and develop a comprehensive national database of genetic mutations among Canadians with haemophilia. Phase I, which took place from June 2000 to March, 2002 was funded in the amount of $125,000.00. This phase focused on the design of the program, recruitment of staff and the development of testing methodologies. Testing was also carried out on a number of tissue samples.

Although an interim report was provided on Phase I in March 2001, we were not provided with a final report on this Phase. However, in the proposal for Phase II of this project, the project leader summarized the Phase I accomplishments as:

- Establishment of administrative aspects of the program
- Approval obtained for ethics of the program
- Materials and supplies obtained
- Testing methodologies established
- Technical staff recruited

- Testing initiated
- Announcements circulated to all haemophilia clinics.

Health Canada approved a Phase II for this project, covering the period April 2002 to March 2004, with funding in the amount of $250,000.00. Queen's University is contributing $20,000.00. The objectives of this second phase are to:

- increase the number of haemophiliacs that have been genotyped; and
- investigate improvements in technology to enhance the efficiency of the program.

An interim report on Phase II of this project was to have been submitted to Health Canada by September, 2002. This report was not in the package of documents on this project provided by Health Canada. However, according to the project leader, the project is on schedule. In Phase II, they are primarily trying to expand the number of individuals with Haemophilia who have been genotyped. This will serve two main purposes:

- improved ability to forecast adverse events that are correlated with specific genotypes
- improved ability to correlate the efficacy of different treatments with genotypes.

Haemophiliac Surveillance

The objective of the project is to develop an archive of blood samples from patients with bleeding disorders to be kept for screening for blood-borne pathogens and for genetic pathophysiology in preparation for gene therapy. The archive is to be supported by clinical data and patient information obtained from upgrades of existing systems (the Canadian Haemophilia Assessment and Resource database (CHARMS) and the Canadian Haemophilia Registry (CHR))

Phase I took place from June, 2000 to March, 2002. It focused on the design of the system, development of the infrastructure and methodology; piloting the archiving of samples; and testing of samples for suitability for assay. Based on the final report on Phase I, this phase achieved its objectives.

Phase II involves the rollout of the archive across Canada. Health Canada is funding the initiative in the amount of $440,000.00 until March, 2004. According to the project leader, they are slightly behind schedule due to the extensive time required to obtain approval from the Boards of Ethics of participating institutions. According to the proposal for Phase II, an interim report was to be submitted in September, 2002. This report was not included in the project documents provided us by Health Canada so we are not in a position to verify that the progress of the project.

Canadian Viral Hepatitis Network (CVHN)

This project was approved in February, 2001 and was to be completed by March, 2002. In December, 2001 an amendment to the Contribution Agreement extended the project to March 31, 2003 and increased Health Canada funding from $2000,000.00 to $335,900.00.

The project aims at establishing a network of Centres of Excellence in the treatment of viral hepatitis. Specifically, the project aims at:

- establishing a national database and serum and tissue bank for patients;
- fostering viral hepatitis research across Canada;
- developing innovative ways of delivering health care to viral hepatitis patients; and
- developing educational materials to inform the public, patients, care givers and public health officials about these diseases.

The project appears to have fallen behind schedule initially. According to a letter submitted to Health Canada by the project leader at the time this was due to increased demand, subsequent to development of the national database, by centres that wanted to be included in the national network; the acceptance by the CVHN of a leadership role in developing a strategic research agenda for viral hepatitis; and additional time and resources required to complete standardization of database elements and to complete a Privacy Impact Assessment.

The copy of the Contribution Agreement provided to us did not contain any references to progress or interim reports and none were included in the project documents provided by Health Canada. We were unable to arrange interviews with the Health Canada project authority or with the project leader of this project before the cut-off date for interviews. Therefore, we are unable to assess the progress on this project.

Canadian Blood and Marrow Transplant Registry and Clinical Trials Network

This project has as its objective the development of a Canadian registry for the collection and analysis of data on patients who have received blood or marrow transplantations. The database is intended to support research on the uses and outcomes of transplant methodologies.

Phase I of this project took was to take place from November, 1999 to May, 2000 and was to assess the feasibility and usefulness of development of a National Blood and Marrow Transplantation Registry (NBMTR) through a registry pilot project. This Phase was funded by Health Canada in the amount of $75,000.00. The final report, which was submitted in March, 2001, concluded that a NBMTR was both viable and useful.

Phase II of the project appears to have started in fiscal year 2000/01, although the project documents we were provided do not contain this information. It is scheduled to be completed in March, 2003. Health Canada has provided $140,000.00 during the period 2001/02 to 2002/03 for this project. Phase II aims at developing a business plan for development of the BMTR and at obtaining ongoing funding for the Registry and the Clinical Trials network.
Two interim reports on this project have been submitted, one in March, 2001 and one in November, 2001. The latter indicates that the main activity in 2001/02 has been engage in discussions with, and obtain the support of key stakeholders and to prepare and submit applications to foundations for funding.

The project documents we were provided do not include the Contribution Agreement Phase II; consequently, we are unable to determine whether this project is on schedule. We were not able to arrange interviews with the individuals responsible for this project prior to the cut-of date for interviews.

Aphaeresis Research Project

This project was carried out in two phases. In Phase I, the objective was to determine the degree of risk of viral disease transmission in Canadian aphaeresis[9] patients. This project was funded by Health Canada in the amount of $135,000.00 during the period January, 2000 to March 31, 2001. The project was extended to July, 2001.

Phase I involved the development of a study protocol an patient information package; submission of protocols and patient consent to 18 hospital ethics boars and approval by 11; entry of initial patient into the trials and collection of initial samples.

Phase II of the project has essentially the same objectives and is, essentially, the continuation of clinical trials and the expansion of the number of patients participating; the analysis of data and the report on findings. Phase II was to be carried out between July, 2001 and March, 2003 with funding in the amount of $190,00.00 from Health Canada. Interim reports were to be provided in March, July and November, 2002. These reports were not included in the project documents we received. Health Canada officials indicated in interviews that this project is behind schedule, in part due to extensive difficulties and delays in obtaining the approval of ethical oversight boards.

Conclusions

Most of the six research projects were funded in two phases and most appear to have achieved their Phase I research objectives. Most of these projects are scheduled to complete Phase II by 2003 or 2004. At present there is insufficient information in the project files to assess progress against Phase II objectives. However, based on interviews with Health Canada officials and with project leaders, most appear to be making good progress. One project – the Aphaeresis project - appears to be behind schedule and Health Canada is taking steps with the project leader to accelerate progress on this project.

One project has been completed very successfully – the Medical Event Reporting System (MERS) pilot. This project met two of three research objectives and provided valuable insights into the potential benefits of transfusion error reporting.

[9] Aphaeresis is the process of withdrawing blood from an individual for the purpose of selectively removing a desired component of whole blood and then returning the whole blood to the individual's circulatory system.

1.8 Will the research projects, if successful, contribute to the enhancement of Canada's post-market blood surveillance system?

To address this issue, we examined the objectives of the research projects to see how they compared with the objectives of the TTISS. This section summarizes the results of that review.

MERS

The MERS project clearly is directly related to the objective of developing an effective TTISS in Canada. For such a system to be effective it must have the capability to assess reasons why adverse events occur and to develop appropriate mitigation strategies. The MERS project provided a valuable assessment of the feasibility and usefulness of in-hospital error reporting as one way of doing this.

National Program for Haemophilia Mutation Testing

Although not undertaken solely for surveillance purposes, this project will enable ongoing surveillance of the haemophiliac population with respect to risks of adverse reactions and their correlation to specific genetic mutations within this population.

Haemophiliac Surveillance

This project will provide a comprehensive database of information on the Haemophiliac population and will enable testing of archive blood samples where risk factors suggest this is appropriate. Thus, it contributes to the objective of improving the capacity to identify, assess and develop strategies to mitigate risks for vulnerable populations.

Canadian Viral Hepatitis Network

This project will establish a national database and a serum and tissue archive for hepatitis patients. The data can be used to identify the risk factors associated with treatment regimens for this group, including the use of blood transfusions and blood products. This is consistent with the objective of identifying and reducing risks of vulnerable populations.

Canadian Blood and Marrow Registry and Clinical Trials Network

This project will provide valuable information on adverse reactions in patients who receive blood or marrow transplants as part of their treatment. This data would not be captured through the mainstream TTISS.

Aphaeresis Research Project

This project will provide valuable information of the risks faced by another vulnerable group. As in the case of patients receiving blood or marrow transplants, this data would not be captured by the mainstream TTISS.

Conclusions

All of the research projects funded under the TTISS contribute, in our view, to the objectives of the program and, if successful will make valuable contributions to the safety of the post-market blood system.

3.4 Summary of Conclusions and Recommendations

3.4.1 Summary of Conclusions

1. TRANSFUSION-TRANSMITTED INJURIES SURVEILLANCE SYSTEM

Overall, the TTISS has made a good deal of progress in terms of the number of participating provinces and territories and in terms of the coverage (number of sites and percentage of transfusions subject to TTISS) in most provinces.

- Key accomplishments include:
- Development of a national database that has been adopted by all provinces;
- Development of standardized definitions, criteria, data elements and reporting protocols;
- Involvement of almost all provinces and territories on the TTISS Liaison Committee;
- Implementation on a TTISS feasibility study or pilot project in seven provinces and planned implementation in 2003/04 in two additional provinces representing a significant majority of blood transfusions in Canada;

To become fully operational, the TTISS needs to extend the system to those provinces and territories not yet participating in the program and to establish effective linkages with Public Health information networks. The program is making significant progress with respect to both these challenges but the time frame for their realization is not clear at this point

Funding of the TTISS on an ongoing basis is the single most important issue affecting the future sustainability of the program. It is essential that this issue be addressed and that federal and provincial governments reach agreement as to the share of required funding each will provide.

The TTISS appears to have the potential to significantly enhance Canada's ability to identify and manage risks in the post-market blood system. In the shorter term, until effective linkages are established with Public Health information networks, this enhanced capacity will exist primarily in regard to immediate or short-term adverse reactions.

The TTISS also likely will contribute to improved identification and reporting of adverse reactions in hospitals and may contribute to a reduction in transfusion-related errors.

Data on the incidence of errors related to transfusions in hospitals and on the root causes of these errors is, in our view, a necessary complement to the existing TTISS to facilitate the development of strategies to mitigate transfusion-related risks.

Due to the high costs to hospitals of implementing transfusion-related error reporting systems, implementation should be limited to a representative sample of large hospitals across the country. This should provide sufficiently robust data for the purposes of the TTISS.

Although this is an unintended impact of the TTISS and beyond the scope of the program, the TTISS model could be of value to the electronic reporting of drug reactions within hospitals.

Research projects in Support of a Comprehensive Surveillance System

Of the six research projects reviewed, one has been completed – the Medical Event Reporting System (MERS) pilot. This project was completed successfully, met two of three research objectives and provided valuable insights into the potential benefits of transfusion error reporting.

Most of the other five projects were carried out in two phases, with the second phase not scheduled for completion until March, 2003 or March, 2004. Most appear to have achieved their Phase I research objectives and, based on interviews with the project leaders and with Health Canada officials, appear to be making good progress on their Phase II objectives. However, the rate of progress is not well documented in project files.

All of the research projects funded under the TTISS contribute, in our view, to the objectives of the program and, if successful will make valuable contributions to the safety of the post-market blood system.

3.4.2 Recommendations

The following recommendations are based on the analysis of the information and data reviewed over the course of the evaluation and on the interviews with program officials and stakeholders.

- Health Canada officials should continue to work with those provinces and territories that have not yet signed contribution agreements for implementation of TTISS to determine how they can best and most cost-effectively participate in the TTISS; to determine their requirements for federal funding; and to obtain their participation.

- Health Canada officials should liaise with provinces that have completed or are carrying out pilot implementation projects to determine their funding requirements for extension of the TTISS to additional hospitals and to establish time frames for completion of this.

- Program officials should, as soon as possible, develop a strategy and action plan and preliminary funding requirements for implementing pilot projects in other provinces than BC to develop linkages with Public health information networks.

- Program officials should attempt to determine, as soon as possible, what will be the ongoing requirements for funding of TTISS in every province and territory.

- Program officials should, in conjunction with provincial and territorial representatives on the Liaison Committee, conduct a study of the costs and benefits, and the feasibility of establishing a network of "sentinel" hospitals across Canada that would provide transfusion error reporting to Health Canada.

- The program should ensure that recipients of contributions for research projects have provided all required interim reports so that they contain sufficient information to assess progress against research objectives.

- The program should continue to support research that contributes to its objectives. In this regard, the program should develop a research plan for the next few years. The plan should identify priority areas for research; identify specific research projects that are required and estimate funding requirements.

Appendix A
List of Interviewees

CONTRIBUTION RECIPIENTS			
Individuals and Contact Info	**Project**	**Individuals and Contact Info**	**Project**
Dr. Jeannie Callum & Lisa Merkle Director of Transfusion Medicine Sunnybrook and Women's College (416) 480-4045	MERS	Dr. Linda Van Til * Health and Social Services Prince Edward Island (902) 368-4964	PEI TTISS
Mr. Jack Lee Executive Director, OPHA (Project Manager) (416) 367-3313 ext 226	Ontario TTISS	David Reeleder 416-327-7382	Ontario TTISS
Dr. Pierre Robillard * Médecin-conseil Institut National de Santé Public Québec (514) 597-0769 poste 4802	Quebec TTISS	Ann Fortin * Secrétariat de système du sang Ministère de la santé & des services sociaux Québec	Quebec TTISS
Ian Wilkinson Special Consultant Blood Programs Province of Manitoba (204) 786-7196	Manitoba TTISS	Dr. Stephan Gabos Director, Health Surveillance Province of Alberta (780) 427-4419	Alberta TTISS
Dr. Bruce Ritchie Assistant Professor Clinic Hematology University of Alberta (780) 407-1369	Hemophilia Surveillance	Dr. David Lillicrap Professor Department of Pathology Queen's University (613)548-1304	Haemophilia Genetic Mutation
Dr. David Pi * Provincial Blood Coordinating Office British Columbia (604) 806-8840	British Columbia TTISS	Dr. David Anderson Associate Professor Medicine and Pathology QEII Health Sciences Centre Nova Scotia (902) 473-8562	Nova Scotia TTISS
Grlica Bolesnikov Scientific Officer Provincial Epidemiology Services Department of Health and Wellness New Brunswick (506) 453-3092	TTISS Feasibility Study		

HEALTH CANADA REPRESENTATIVES			
Individuals and Contact Info	**Position**	**Individuals and Contact Info**	**Position**
Dr. Antonio Giulivi Blood Borne Pathogens Health Care Acquired Infections Division (613) 957-1789	Associate Director	Dr. Ezzat Farzad Blood Borne Pathogens Health Care Acquired Infections Division (613) 952-8228	Medical Specialist
Nancy McCombie Blood Borne Pathogens Health Care Acquired Infections Division (613) 952-1369	Project Coordinator	Kwasi Nyarko Blood Tissues and Organs Unit Therapeutic Products Directorate (613) 946-7254	Unit Head
Nick Giannakoulis Director General's Office	Planning and Research Officer		

OTHERS			
Individuals and Contact Info	**Organization**	**Individuals and Contact Info**	**Organization**
Ted Alport ***** Medical Director Saskatchewan (306) 766-2244	Canadian Blood Services	George Peters ***** Executive Director Population Health Branch Saskatchewan (306) 787-3629	Department of Health
André Corriveau Chief Medical Officer Northwest Territories (867) 920-3231	Fort Smith Health & Social Services Board	Bryce Lark ***** Yukon Medical Health Officer Yukon (867) 667-5716	

TTISS Committee Members *

Appendix B
List of Key Documents Reviewed

Health Canada Documents

MC 1996 "Safety of Blood"
MC 1998 "Strengthening Canada's Blood System"
TB Submission (1998) Strengthening Canada's Blood System"
MC 98 Project Management Plan
Blood Surveillance and Clinical Products Outcomes Plan: 2000-01 to 2002-03
The Surveillance and Epidemiology of Transfusions Working Group: Final report (1999)
Evaluation Framework: Health Canada Blood Safety Program (2001)
Review of the Health Canada Blood Safety Program: Final Report (2002)
"Surveillance for Blood-Borne Pathogens in Canada" (PowerPoint Presentation (PPT))
"Canadian Legislation on Blood Safety Surveillance Activities" (PPT)
"Health Canada's Blood Safety Program" (PPT)
"Blood-Borne Pathogens Division: Blood Safety Program" (PPT)
"National Blood Surveillance System" (PPT)

TTISS Contribution Project Documents

Project Proposals
Contribution Agreements
Interim and Final Reports

Other Documents

Report of the Auditor General of Canada – 2002 Status Report
Material on legal motions and decisions respecting compensation for people infected with infectious diseases through the blood system