CANADIAN COUNCIL FOR DONATION AND TRANSPLANTATION



CCDT CONSEIL CANADIEN POUR LE DON ET LA TRANSPLANTATION

# Enhancing Tissue Banking in Canada Phase II: Surveillance and Traceability in Tissue Transplantation

# Enhancing Tissue Banking in Canada

Phase II: Surveillance and Traceability in Tissue Transplantation

**Consultation Report from the Meeting** 

April 27-28, 2007 Montréal QC

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# Introduction

The Canadian Council for Donation and Transplantation (CCDT) was established in October 2001 as a key component of a coordinated federal/provincial/territorial strategy to improve organ and tissue donation and transplantation in Canada. An independent, not-for-profit corporation, it is mandated to provide advice to the Conference of Deputy Ministers of Health (CDM) in support of efforts to coordinate activities relating to organ and tissue donation and transplantation.

On November 23-24, 2006, 30 experts from across Canada attended the first in a series of task force meetings on Enhancing Tissue Banking (ETB) in Canada. The focus of the meeting was sustainability, with other key issues identified for future consideration being traceability, accreditation, and emerging technologies.

The second in this series of meetings was held in Montréal on April 27-28, 2007. Attended by 34 participants from across Canada, the United States, and Europe, its purpose was to consult with stakeholders in the tissue transplant community regarding possible future options for surveillance and traceability, and to provide this input to the CCDT and to stakeholders committed to change and implementation. This report describes the results of that meeting.

The surveillance and traceability workshop took place immediately following the Québec Hémovigilance Public Forum, which was held to explore the optimal means of ensuring the traceability of tissue from donor to recipients and the surveillance of adverse events related to tissue transplantation. The Forum provided important background information for task force discussions, and a summary of the key points made by its presenters was provided to task force participants.

## **Opening Remarks**

Kimberly Young, Chief Executive Officer of the CCDT, welcomed participants and thanked Dr. Marc Germain, Chair of the CCDT Tissue Committee, and Mr. Mark Vimr, Chair of the CCDT Surveillance and Traceability in Tissue Transplantation Planning Committee, for the leadership and expertise they and their members have brought to this initiative. She called the second ETB meeting an exciting and invigorating opportunity to address some of the challenges highlighted at the Québec Hémovigilance Public Forum and a vital starting point for ongoing discussions on surveillance and traceability in tissue transplantation.

In touching on the CCDT's mandate to provide recommendations for a pan-Canadian strategy to the federal/provincial/territorial Deputy Ministers of Health, Ms. Young noted the importance of bringing together national and international expertise to learn more about how the complex issues of traceability and surveillance are handled in Canada and around the world. She stressed further collaboration and communication as essential to increasing knowledge, staying current, focusing on new solutions, and thinking beyond our borders.

Dr. Jun Wu, Acting Director of the Blood Safety Surveillance and Health Care Acquired Infections Division at the Public Health Agency of Canada (PHAC), echoed Ms. Young's thanks and reiterated the need to work together, both nationally and internationally, on the issue of surveillance and

traceability. He added that the support of all task force participants is needed to help PHAC move forward in its mandate to protect the health of Canadians.

Mr. Vimr thanked Dr. Tremblay and the Québec Hémovigilance Committee for inviting the CCDT to take part in its forum and emphasized the need to improve confidence in the tissue banking system overall. He noted that the task force meeting was particularly timely, given the new Health Canada regulations that will soon come into effect and the complementary and evolving relationship between PHAC and the CCDT, whose respective mandates include surveillance and traceability.

## **Participant Introductions**

As participants introduced themselves, they were asked to identify one desirable outcome of the second task force meeting on ETB. Responses included the following:

- an opportunity to learn from one another
- a surveillance and traceability model that makes sense for Canada and other countries
- a database or other way of communicating and sharing information, knowledge, and wisdom
- a strategy that begins with tissues that are easy to monitor (e.g., dental)
- an accreditation program for Canada
- a defined starting point for action and momentum to keep it going
- a process that is user-friendly for both large and small tissue banks
- a standardized protocol for ensuring a safe supply of tissue for all Canadians
- a strategy that is embraced by all provincial and territorial jurisdictions
- a means of strengthening the capacity for multiple gifts of life
- the opportunity to see issues from different perspectives
- the ability to stay focused and come up with a strategy that is simple
- consensus on priority items
- realistic expectations related to surveillance, including a concrete definition of what to survey
- realization by hospitals of the need to take action on traceability
- a means of addressing the issues
- a pan-Canadian, cost-effective surveillance and traceability system

### **Purpose and Objectives**

The purpose of this workshop was to consult with stakeholders in the transplant community regarding possible future options for surveillance and traceability in tissue transplantation in Canada. Its objectives were to

- identify and explore how key learnings from the Québec Hémovigilance public forum could apply to the purpose of the workshop,
- understand Health Canada's regulatory requirements and responsibilities with respect to errors/accidents and adverse reactions involving cells, tissues, and organs (CTO),

- understand the role of the Public Health Agency of Canada in public health and in tissue traceability and surveillance within their mandate and responsibilities,
- identify potential benefits, deliverables, and challenges in the development of a coordinated pan-Canadian surveillance and traceability system, and
- identify potential options for consideration in the development of a coordinated pan-Canadian surveillance and traceability system.

The scope of discussions included all tissue grafts from deceased and living donors transplanted in hospitals, dental clinics, and other clinics within Canada, including grafts imported from outside the country. Tissue classified as medical devices (e.g., dura mater, heavily manipulated demineralised bone) was excluded, as it is covered by other Health Canada regulations. Heart valves are a possible exception, as they will be regulated under phase II of the CTO regulations.

# **Core Assumptions**

Core assumptions are the agreed-upon "givens" that provided a common starting point for reflection, discussion, and decision making at this consultation. They outline the perspective within which the process unfolds and help to ensure that everyone involved is focused on a common purpose and objective. The assumptions underlying this initiative are:

- Health privacy legislation is perceived as a barrier to the exchange of recipient information between end users and tissue banks.
- The utilization of information technology within Canadian tissue surveillance and traceability is limited and uncoordinated.
- Participation of end users in the provision of recipient information to tissue banks varies significantly.
- Tissue bank practices in requesting recipient information from end users vary significantly.
- There is a lack of identification and under-reporting of potential adverse events.
- A lack of common terminology, education and guidelines in relation to adverse-event surveillance is a barrier to the identification and reporting of events.
- Identification and reporting of adverse events varies among end-user groups.

## **Key Considerations**

The following important circumstances, facts, data, and concerns were taken into account due to their potential impact on the success of this tissue-banking initiative:

- There is preference for real-time surveillance that incorporates the analysis and reporting of aggregate data in a timely fashion.
- The national Transfusion Transmitted Injuries Surveillance System (TTISS) is a potential model for the tissue surveillance system.
- Clarity on the development of "alert" features and processes related to the identification of adverse events is required.

- Consideration should be given to incorporating organs and cells in the development of a unified surveillance system.
- The focus should be on a user-friendly system that engenders end-user compliance.
- The role of ISBT 128 (the global standard for the identification, labeling and information processing of human blood, tissue and organ products) in the identification/coding of tissue products should be considered.
- Provincial and territorial privacy legislation creates challenges in the exchange of patient information; aggregate national data for surveillance and trend analysis could be shared by excluding patient identifier information.

## Process

Several background documents were provided by the Planning Committee in advance of the meeting. The issue of surveillance and traceability was addressed using the following process:

- Expert presentations were followed by a question-and-answer period. Participants then worked in small groups to address key challenge questions. Each group selected a facilitator to keep discussions on track and a recorder to reflect agreement by group members and prepare a brief plenary report.
- Small group discussions focused on specific questions related to surveillance and traceability in tissue transplantation. The following questions were addressed:
  - potential benefits and opportunities of a coordinated, pan-Canadian system
  - potential challenges of a coordinated, pan-Canadian system
  - possible options and rationale for the development of a surveillance and traceability system for tissue
- After the results of these discussions were presented in plenary, participants compiled a list of key points about a surveillance and traceability system for tissue transplantation in Canada upon which they agreed and provided their expert advice to the CCDT on implementing such a system.
- Participants' comments and suggestions were recorded by the report writer and facilitator.

# **Presentations and Background Information**

Three presentations and several background documents provided a shared information base for participants at this meeting.

## Presentations

#### 1. Models in Other Countries: Lessons for Canada

Dr. Marc Germain, Chair of the CCDT Tissue Committee, provided an overview of the key points covered during the eight presentations made at the Québec Hémovigilance Public Forum on April 27, 2007. Presenters at the Forum provided a review of surveillance and traceability systems in jurisdictions ranging from hospitals to countries. This overview highlighted strengths, challenges,

and lessons learned from the previous day's presentations. This provided participants with valuable information on best practices in various parts of Canada (Quebec, Halifax, and Toronto) and the rest of the world (the United States, Belgium, Europe, France, and internationally with the World Health Organization). After the presentation, the floor was opened for a question-and-answer period, during which the following points were made.

### **Discussion Points**

- We need ways to convince surgeons to provide the necessary information (e.g., side effects, complications)—either through mandatory compliance or a voluntary system (e.g., reward-based, as in Belgium).
- There is no legislation in place to allow information to flow among provinces/territories and nationally, and changing legislation is difficult.
- It is important to move forward as a country on a pan-Canadian system. There is a risk of fractioning if some provinces are willing to move forward and others aren't.
- It is essential to test a system before implementing it; perhaps by piloting it in a few jurisdictions.
- Soft tissue, such as tendons, may be a good place to start as it is not as extensively processed as other tissue.
- Since the United States is developing the Transplantation Transmission Sentinel Network (TTSN) to cover the traceability of material processed in the U.S., Canada should perhaps begin by focusing on material produced at home.

### 2. Safety of Human Cells, Tissues, and Organs for Transplantation Regulations— Error/Accident and Adverse Reaction Regulatory Requirements

Gita Nayeri and Susanne Reid, of Health Canada, provided an overview of the Cells, Organs, and Tissues (CTO) regulatory framework, the responsibilities of CTO establishments, and error and accident and adverse reaction reporting and investigation.

#### **Discussion Points:**

- It would be very helpful if Health Canada did something with the data they collect in terms of collation, dissemination, and analysis.
- A Health Canada vigilance database is being developed/implemented that will provide people with greater access to statistics.

# 3. Transfusion Transmitted Injuries Surveillance System: The Building of a Solid Foundation

Ms. Cindy Hyson, of the Public Health Agency of Canada (PHAC), provided an overview of Canada's TTISS, including its background, objectives, development, current users, methods, data, results, future directions, and relevance to tissues and organs.

She noted that data from the first TTISS report (2002-03) were too scarce to make any recommendations; however, the second report (2004-05), which will come out later this year, will be sufficiently detailed to suggest some areas for improvement. PHAC is also looking at the feasibility

of incorporating data on transfusion errors and currently has a pilot program in place on transfusion-related errors.

## **Background Documents**

Participants were provided with three background documents and a list of key terms and acronyms in advance of the meeting. This material served as the basis for discussions in small groups and plenary:

- James Mohr in collaboration with the workshop planning committee. Surveillance and Traceability in Tissue Transplantation: Discussion Paper (Draft), April 2007.
- CCDT. Enhancing Tissue Banking in Canada Task Force: Chronology April 2007.
- CCDT. Summary Notes from Québec Hémovigilance Public Forum held on April 27, 2007 (not for further distribution).

# Strategic Issues Related to a Pan-Canadian System

Participants convened in six small discussion groups to address questions on a pan-Canadian surveillance and traceability system for tissue. The first step in this task involved identifying benefits/opportunities and challenges related to such a system. A summary of their responses is provided below and this list is not intended to be definitive.

## **Benefits and Opportunities**

- Ability to define scope, type, minimum/maximum, and quantity/quality of data
- Application to all CTO
- Avoid duplication
- Build on existing systems (e.g., TTISS, Canadian Blood Services) and on expertise and experience of hospital blood banks
- Contribute to aggregate data
- Coordination at a national level avoids fragmentation
- Defined and transparent structure
- Easy to use
- Enhanced surveillance and traceability of all tissues, including imports
- Estimate risks of transplantation
- Greater coherence
- Improved knowledge and data for decision-making (e.g., adverse events)
- Improved responsiveness (look-backs, recalls)
- Increased public trust and enhanced confidence in product
- Meet Health Canada regulations
- Model for other countries

- No conflict with existing systems
- Partner in global network
- Standardized labelling (e.g., ISBT 128 bar-coding system) and standardized donor ID number
- Standardized nomenclature
- Timely patient care, reduced patient risk and increased safety
- Development of TTSN electronic system
- Uses of system could be extended in future (e.g., to track outcomes)
- Web-based, real-time, barcode scanned

### Challenges

- Achieving consensus on minimum data requirements and developing standard definitions
- Assigning responsibility for traceability
- Balancing population health and individual patient safety
- · Centralized receiving/distribution records
- Creating a system that is end-user friendly
- Clarification of jurisdictions (Health Canada, PHAC, hospitals, provinces, private clinics)
- Compliance by end users (particularly private)
- Diversity of products
- Education, experience, and knowledge of staff
- Enforcement
- Ensuring consistency of data collection
- Establishing national ID number (no national oversight)
- Fragmented system
- Funding and human resources as well as IT infrastructure/management
- Identifying object of surveillance and data elements
- Implementing a surveillance system at a national level
- Inter-provincial cooperation
- Lack of data on current situation
- Loss of control of supplier for private clinics
- Major practice change for surgeons
- Multiple suppliers and drop points in hospitals and clinics
- Patient tracking
- Privacy legislation and issues related to confidentiality and information-sharing
- Reporting to end users
- · Sensitizing clinicians to adverse events identification and reporting
- Streamlining the flow of information
- Traceability and reporting from hospital to recipient

# **Possible Options and Rationales**

The discussion groups were then asked to discuss possible options and rationales for a pan-Canadian surveillance and traceability system for tissue transplantation. These options were then presented in plenary. They represent the best thoughts of the participants; the feasibility of proposed options within the Canadian context has not been explored and the options are presented in no particular order.

Following is a summary of the six options outlined:

## Option 1: centralized surveillance, decentralized but linked traceability

In this option, surveillance is centralized and traceability is decentralized but linkable. The two systems have separate purposes and may involve separate parties. The rationale for centralized surveillance of adverse transplantation events is that it would be less cumbersome than separate, decentralized systems and would standardize the objects of surveillance, data elements for recording, and case definitions. National centralization was not deemed necessary for tracing tissue from donor to recipient, as it can be achieved as easily using a decentralized system. The establishment of a national registry for this purpose would be hampered by provincial privacy legislation and the need to create a unique patient identification number—both of which would require many years to achieve agreement.

## Option 2: centralized national surveillance and traceability

In this option, surveillance and traceability are centralized nationally to ensure greater control over the system, data sharing, and Canada's role as a partner in a global network. Such a system would improve patient safety and create an important link between donation/transplantation and surveillance/traceability—thereby increasing safety, transparency, and confidence. Although linking the tissue system with the existing blood system would be financially effective, it was felt that end users might respond negatively to a system that is further removed from national organ and tissue governance. A centralized system, including a national register, is essential to tracking both material transferred across Canada and the large volume of tissue imported from outside the country. It would also be useful in situations where global rapid alert is important.

# Option 3: combined national surveillance and traceability in a provincially/territorially centralized system

In this option, surveillance and traceability are part of a combined system that is provincially centralized and nationally integrated. The system is supportable within the existing health-care system and would be relatively easy to implement. It recognizes the unique differences in tissue needs among provinces/territories and emphasizes interaction among jurisdictions. IT resources and systems in each province/territory communicate with each other, and tools and resources are shared among key players. Aggregate data and provincial databases feed into a national database, which serves as an additional step toward vigilance and increases transparency, control, and product safety. Feeding into a national system would enable trends analyses.

# Option 4: centralized surveillance and decentralized traceability linked to a national system

In this option, surveillance is centralized and traceability is decentralized but linked to a national IT system and database. The rationale for this option is that it minimizes the initial human- and financial-resource outlay and reduces disruption, since accountability for traceability still lies with the end user and functioning traceability systems remain in place. These feed into a national system that is accessible to all end users. Centralized surveillance sidesteps the issue of privacy legislation and intra-provincial jurisdictions, thereby allowing for a diversity of products and end users, improving the potential for alerts, increasing patient safety, and enhancing the ability to quantify this segment of Canada's health sector. The biggest challenge under this option is to educate the end user on how the system works and to encourage compliance.

# Option 5: combined centralized-decentralized system with uniform data collection

This option advocates a combined centralized-decentralized system in which information collected is uniform across the system and feeds into traceability and surveillance. The provincial system for traceability would remain intact, with reciprocal agreements possibly put in place between provinces/territories and nationally—thereby improving responsiveness and recalls. Centralized surveillance would increase transparency, accountability, public trust, and responsiveness through the issuance of standardized reports. The potential would exist to collect information on outcomes at the same time.

# Option 6: combined, centralized national system for surveillance and traceability

This option advocates a combined, centralized national system for surveillance and traceability. The rationale for this option is that it would standardize the use of tissues through the use of universal ID numbers; would be aligned with international directions; and would be transparent, thereby providing both a level of verification that surveillance and traceability is occurring and an opportunity for benchmarking. The latter could be used to compare adverse outcomes among provinces or regions, which could be helpful in developing best practices. The use of a scanner and barcode would also make it easier for doctors and surgeons to maintain records.

### **Discussion Point**

• Should not expect hospitals to be any better at reporting than they are now until a standardized system and software exist; if left to their own procedures, some will do it well and others will not. Some companies have already developed such systems for implants.

# **Conclusion and Closing Words**

# Conclusions

As a final step in the meeting, and to synthesize the results of the discussions held over the course of the two days, participants agreed in plenary on the following points related to the development of a pan-Canadian system for surveillance and traceability in tissue transplantation:

- There should be a centralized national surveillance system.
- End-user traceability systems need to be enhanced.
- Provincial systems for traceability should be used in the short term, with an eye to building on these systems in coming years and possibly moving toward a centralized national system for traceability over the longer term.
- Surveillance and traceability systems should be strategically linked.
- There are advantages to a surveillance and traceability system that builds on the existing blood system; however, given the unique nature of cells, tissues, and organs, this requires further study.
- The need for a national registry should be explored further, as there are many challenges involved—including privacy and voluntary patient participation.

The small discussion groups reconvened briefly before providing the following "best advice" to the CCDT on implementing a pan-Canadian surveillance and traceability system:

- Ensure that collaborative discussions on these issues continue on a national level, through whatever mechanisms necessary.
- Improve education and awareness among dentists, surgeons, and other end-users; if they don't buy in, we won't have a good product.
- Keep the system simple, so that everyone understands and is able to take part in it. Do not burden end users with a complicated system.
- Explore the feasibility of building the tissue system on the blood system, taking into account the impracticalities raised at this consultation.
- Consider all aspects of transplantation (cells, organs, and tissues) in developing a pan-Canadian system.
- Make a centralized system the first priority and encourage a joint task force (CCDT, PHAC) to pilot it—possibly in a province that already has a solid foundation in this area.
- Ensure that the system supports compliance of the enacted regulations.
- Approach organizations for accreditation in order to encourage consensus building.
- Study the extent of traceability in hospitals and possible solutions.

## **Closing Words**

Dr. Luc Noel, of the World Health Organization, thanked the CCDT for inviting him to take part in the meeting, adding that the concern participants have shown for patients is an example for the rest of the world. Dr. Vimr closed the meeting by thanking all participants for their ongoing contributions to this effort.

A briefing note was provided to all participants the week after the meeting, and all were encouraged to customize and distribute it widely in support of timely communication about the Task Force's discussions. All meeting attendees will receive a copy of the final report and will be kept informed of discussions and decisions, particularly with respect to the commencement of work on a coordinated surveillance and traceability system.

# **Appendix A: Participants**

#### Simon Avis MD

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#### Jean-Marie Berthelot

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#### **Tracy Brand**

Director of Initiatives CCDT Edmonton AB

#### **Scott Brubaker** Chief Policy Officer American Association of Tissue Banks McLean VA

#### Penny Clarke-Richardson

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#### **Beverley Curtis**

Managing Director, Initiatives CCDT Edmonton AB

#### Mary Gatien

Executive Director New Brunswick Eye Bank President, Canadian Association of Eye and Tissue Banks Saint John NB

#### Michel Giroux

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#### George Herrera

Vice President, Donor Services Musculoskeletal Transplant Foundation Edison NJ

#### **Cindy Hyson**

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#### Marc Jacquin

Canadian Council for Health Services Accreditation Ottawa ON

#### Brendan Lewis MD

President Canadian Orthopaedic Association Ottawa ON

# Jackie Mace

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#### Lisa MacIsaac

Tissue Donation Advisor Trillium Gift of Life Network Toronto ON

#### **Sean Margueratt** Manager Regional Tissue Bank

Halifax NS

#### Marc Germain MD Vice President, Human Tissues Héma-Québec Sainte-Foy QC

#### Liz Anne Gillham-Eisen

Senior Policy Analyst/Project Manager Cells, Tissues and Organs, Health Canada Ottawa ON

#### Hassan Moghadam DDS

Oral and Maxillofacial Surgeon, Canadian Association of Oral and Maxillofacial Surgeons Ottawa ON

#### Gita Nayeri

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#### **Doris Neurath**

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#### Pierre Robillard MD

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#### **Christina Rogers**

Director of Initiatives CCDT Edmonton AB

### Linda Socha

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#### Michael Strong PhD

Executive Vice President, Operations Puget Sound Blood Centre/Northwest Tissue Centre Seattle WA

#### Euan Swan DDS

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### Robert Turcotte MD

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#### Mark Vimr

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## Jun Wu PhD

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## **Kimberly Young**

Chief Executive Officer CCDT Edmonton AB

# **Appendix B: Meeting Agenda**

# Friday, April 27, 2007

18:00	Workshop Registration
18:30	Welcome and Greetings
	<ul> <li>Welcome</li> <li>Ms. Kimberly Young, Chief Executive Officer</li> <li>Canadian Council for Donation and Transplantation</li> </ul>
	• Greetings
	Dr. Jun Wu, Director
18:40	Public Health Agency of Canada
19:00	Opening Remarks     Mr. Mark Vimr, Chair     CCDT Surveillance and Traceability in Tissue     Transplantation Subcommittee
	Workshop Process and Procedures     Ms. Dorothy Strachan, Strachan-Tomlinson
Saturda	y, April 28, 2007
08:00	Agenda: Review/Preview
	Discussion Paper $Q $ & A
08:30	Part I: Yesterday Worldwide
	Models in Other Countries: Lessons for Canada
	Dr. Marc Germain, Chair, CCDT Tissue Committee
09:00	$Q  \mathcal{C} A$
09:30	Part II: Today in Canada
	a) "Safety of Human Cells, Tissues and Organs for Transplantation Regulations-Error/Accident and Adverse Reaction Regulatory Requirements"
	Ms. Gita Nayeri and Ms. Susanne Reid, Health Canada

09:50

Q & A

10:20	
	b) "Transfusion Transmitted Injuries Surveillance System (TTISS): The Building of a Solid Foundation"
10:35	Ms. Cindy Hyson, Public Health Agency of Canada
10.00	$Q \phi A$
10:50	
	Surveillance and Traceability in Tissue Transplantation in Canada: Small Group Discussions
	Benefits and Opportunities
	• Drawbacks and Challenges
40.45	
13:15	Plenary Synthesis of Small Group Discussions
14:30	Part III: Tomorrow Across Canada
	Scoping the options for a Surveillance and Traceability System in Tissue Transplantation: Discussions and Conclusions
15:00	Working Break
15:30	Possible Options and Rationales
	Summary of Workshop Conclusions
15:45	Concluding Remarks: Mr. Mark Vimr
	Workshop Report
	Task Force Next Steps
16:00	Workshop Feedback
	Closing

# Appendix C: Key Terms and Acronyms

AABB	American Association of Blood Banks
AATB	American Association of Tissue Banks
AFSSAPS	French Health Products Safety Agency
Allogeneic	Taken from different individuals of the same species
AR	Adverse reactions
ASBMT	American Society for Blood and Marrow Transplantation
Autologous	Cells and tissues that are implanted in the same individual who donated them. Donor and recipient is the same individual.
CCDT	Canadian Council for Donation and Transplantation
CDC	Centers for Disease Control and Prevention
Centralized	Information and control are supported by individual establishments, institutions or regions with information centralized into a comprehensive information repository
Competent authority	EU member states must have a body to oversee compliance with the EUTCD
CSA	Canadian Standards Association
СТО	Cells, Tissues and Organs
Decentralized	Information is housed within individual establishments, institutions or regions with no centralized repository for aggregate data, information or communication
E/A	Errors and accidents
EBMT	European Group for Blood and Marrow Transplantation
ETB	Enhancing Tissue Banking in Canada Task Force
EU	European Union
EUSTITE	European Union Standards & Training For Inspection Of Tissues Establishment
EUTCD	European Union Tissues and Cells Directive
FACT	Foundation for Accreditation of Cellular Therapy (FACT
FDA	Food and Drug Administration (United States)
нс	Health Canada
HCAID	Health Care Acquired Infections Division of the PHAC
НТА	Human Tissue Authority

ICCBBA	International Council for Commonality in Blood Bank Automation
ISBT	International Society of Blood Transfusion
ISCT	International Society for Cellular Therapy
IT	Information technology
JACIE	Joint Accreditation Committee-ISCT & EBMT
ЈСАНО	Formerly referred to the Joint Commission on Accreditation of Healthcare Organisations; now called Joint Commission
NMDP	National Marrow Donor Program
РНАС	Public Health Agency of Canada
SABRE	Serious Adverse Blood Reactions & Events
Surveillance	The ongoing systematic collection, analysis, and interpretation of data on specific health events affecting a population, closely integrated with the timely dissemination of these data to those responsible for prevention and control. A feature of surveillance is the ability to identify individuals and groups of individuals for further action on prevention and treatment.
ТС	Tissue Committee of the CCDT
TC Traceability	Tissue Committee of the CCDT The ability to locate tissue during any step of its donation, collection, processing, testing, storage, distribution or disposition. It implies the capacity to identify the medical facility receiving the cells and or tissue and, at the medical or dental facility, the ability to identify the recipient. Traceability supports the trace-forward and trace-backward processes, enabling the tracking of the donor tissue to the recipient and from the recipient back to the donor.
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# **Appendix D: Committees and Support**

#### Workshop Chair

*Mark Vimr* VP, Clinical Operations Chief Nursing Officer Trillium Gift of Life Network

**Sponsored by** Canadian Council for Donation and Transplantation (CCDT)

#### Management

*Christina Rogers* Director of Initiatives – CCDT

*Beverley Curtis* Managing Director – CCDT

*Kimberly Young* Chief Executive Officer - CCDT

#### In Collaboration with

Québec Hémovigilance Committee

Public Health Agency of Canada

Facilitation

**Dorothy Strachan** Strachan-Tomlinson Consulting

#### **Report Writing**

*Leslie Ebbs* Leslie Ebbs Communications

#### **Consultant Support**

*Jim Mohr* Source JM

#### **Initiative Support**

*John Harkins* Sr. Admin. Assistant - CCDT

#### **Planning Committee**

*Mark Vimr, Chair* VP, Clinical Operations Chief Nursing Officer Trillium Gift of Life Network

*Liz Anne Gillham-Eisen* Senior Policy Analyst/Project Manager for Cells, Tissues and Organs Health Canada

Sean Margueratt Quality Leader Regional Tissue Bank

*Scott Brubaker* Chief Policy Officer American Association of Tissue Banks

*Cindy Hyson* Manager, Transfusion Transmitted Injuries Section/Blood Safety Surveillance & Health Care Acquired Infections Division Public Health Agency of Canada

#### **Tissue Committee**

*Marc Germain MD, Chair* VP, Human Tissues Héma-Québec

*Mary Gatien* Executive Director New Brunswick Eye Bank President, Canadian Association of Eye and Tissue Banks

*Graham Scoles, PhD* College of Agriculture University of Saskatchewan

#### Liz Anne Gillham-Eisen

Senior Policy Analyst/ Project Manager for Cells, Tissues and Organs, Health Canada

Sean Margueratt Quality Leader Regional Tissue Bank

*Scott Brubaker* Chief Policy Officer American Association of Tissue Banks

*Linda Socha* Acting Provincial Program Manager Saskatchewan Transplant Program

# Simon Avis, MD

Chief Medical Examiner Professor of Pathology Office of the Chief Medical Examiner, NL

*Mark Vimr* VP, Clinical Operations Chief Nursing Officer Trillium Gift of Life Network

*Christopher Seamone, MD* Ophthalmology and Visual Sciences, Dalhousie University Chair, Eyebank Committee, Canadian Ophthalmological Society

*Robert Turcotte, MD* Chief, Orthopaedic Surgery McGill University Health Centre

*Kimberly Young* Chief Executive Officer Canadian Council for Donation and Transplantation

# **Appendix E: Organizations and Societies Represented**

- American Association of Tissue Banks
- British Columbia Transplant Society
- Canadian Association of Oral and Maxillofacial Surgeons
- Canadian Association of Orthopaedic Nurses
- Canadian Council for Donation and Transplantation
- Canadian Dental Association
- Canadian Orthopaedic Association
- Canadian Institute for Health Information
- Canadian Standards Association
- Capital Health Comprehensive Tissue Centre, Edmonton, Alberta
- Health Canada
- Héma-Québec
- Ministère de la Santé et Services sociaux, Québec
- Musculoskeletal Transplant Foundation, New Jersey
- New Brunswick Eye Bank
- NorthWest Tissue Centre, Washington
- Operating Room Nurses Association of Canada
- Public Health Agency of Canada
- Québec Hemovigilance Committee
- Regional Tissue Bank, Nova Scotia
- Saskatchewan Transplant Program
- The Ottawa Hospital
- Trillium Gift of Life Network, Ontario
- World Health Organisation, Switzerland