Canadian Blood Services
it's in you to give

Background Paper for the Tissue Expert Committee:

How can the proposed system ensure the traceability of tissue products?

Contents

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1. Introduction

A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, ***Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians***, can be found at organsandtissues.ca, along with the other background documents in this series.

Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.
- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the ***Call to Action*** report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.

For more information on these documents or the ***Call to Action*** report, please contact:

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2. Scope

How can the proposed system ensure the traceability of tissue products?

This question has propelled discussion about tissue donation and transplantation in Canada; specifically, about ways to ensure traceability of tissue products. This document describes the current state of tissue-product traceability and explores options and mechanisms that may lead to better traceability within the proposed system.

Though surveillance is an important adjunct to system traceability, this document does not address details of the surveillance process.

3. Current State

A. Current State

Tissue recalls in Canada

Over the past several years, Canadian patients have been affected by a number of high-profile recalls of tissue products sourced nationally and imported from the United States. Although there has been no evidence of disease transmissions from these products, some patients implanted with recalled product were required to undertake transmissible-disease testing. See Appendix A for recall details.

Current regulatory requirements in Canada

Health Canada administers federal cell, tissue and organ (CTO) regulations.[1] In relation to traceability, the department details the following requirements:

- Source establishments must be able to trace allografts from the originating donor to transplant establishments and vice versa.
- Transplant establishments must be able to trace allografts from the source establishment to the recipient and vice versa.
- Both source and transplant establishments must conduct surveillance for adverse events potentially related to the allograft. These establishments must also report such events promptly and appropriately to ensure control measures are triggered in response.
- Informed consent must be secured in the case of exceptional release.

Source establishments are licensed and inspected by Health Canada. Transplant establishments, however, are not licensed by Health Canada, and there is no regulatory requirement for these facilities to undergo traceability-compliance inspections and audits.

Organ and tissue donation standards, including traceability requirements,[2] are being drafted by Accreditation Canada. Under the proposed standards, healthcare institutions seeking accreditation will have to demonstrate compliance through inspection and audit; however, the process will be voluntary.

Health Canada, in collaboration with the Public Health Agency of Canada (PHAC), monitors biologic adverse events, investigates complaints and

[1] Health Canada. Guidance Document for Cell, Tissue and Organ Establishments, Safety of Human Cells, Tissues and Organs for Transplantation, Health Products and Foods Branch, April 6, 2009.

[2] Accreditation Canada. Accreditation Canada's Qmentum Program: Service Excellence, Draft Organ and Tissue Donation Standards Version 1.4, March 2009.

problem reports, maintains post-approval surveillance and manages recalls.[3]

The surveillance of cells, tissues, organs and assisted reproduction for adverse events and disease transmissions falls within PHAC's mandate.[4] PHAC has developed and is piloting the Cell, Tissue and Organ Surveillance System (CTOSS) within transplant establishments to track identified adverse events, accidents and errors. If an event is identified, Health Canada manages the response, which may include tissue quarantine and recall, as well as the implementation of appropriate prevention and control measures.

Traceability in Canadian tissue banks

A 2009 Canadian Blood Services environmental scan of Canadian tissue banks identified significant variation in traceability practices.

When it comes to allograft identification, there is little commonality or coordination nationally or within provinces. Coding systems are unique to each bank and, where distinct eye, tissue and organ programs may obtain tissues from a common donor, they may each use a different donor identification number.

Neither the traceability practices of, nor the communication protocols between programs that procure tissues from common donors are well defined. In fact, this holds true for both organ and tissue programs that procure from common donors. A 1997 cross-Canada spread of methicillin-resistant staphylococcus aureus (MRSA) provides one example. In this case, and at the time of its transplant, culture from a corneal rim identified MRSA, but notification of the organ recipients' institutions was delayed. Both organ recipients subsequently became blood-culture positive for MRSA.[5]

Where traceability practices do exist, they are often supported by in-house information systems that vary significantly in scope and sophistication, from paper trails to electronic inventory management frameworks. These systems are isolated, with limited integration into broader information systems and none with other tissue programs. Furthermore, no Canadian tissue program has yet implemented barcoding, a basic technology that reduces transcription errors and facilitates traceability.

The environmental scan also revealed that while some tissue banks play a role in managing allograft sourced from outside their facilities, they generally play little or no role in the traceability of these products.

Tissue banks do often request recipient identification information from transplant establishments as a measure towards traceability; however, compliance with these requests varies significantly. Close to one third of the 47 tissue banks surveyed by the AATB in 2007 received recipient identification information on less than 50 percent of their requests.[6]

Despite the lack of advanced traceability systems, Canadian tissue banks identified no significant concerns in their ability to trace grafts they produce to end user facilities.

Traceability in Canadian hospitals and dental practices

At the end-user level, traceability is supported at individual institutions by processes and systems that not only vary in scope and sophistication, but are also isolated without provincial or national integration.

Some of the underlying challenges related to traceability were revealed in a 2009 pilot survey of three Canadian tissue banks. The banks were asked to coordinate with their operating rooms to indicate the quantity of allografts implanted during the 2008 calendar year. Two of the three organizations were unable to readily produce the

[3] Health Canada. http://www.hc-sc.gc.ca/dhp-mps/brgtherap/index-eng.php (August 2009)

[4] Cindy Hyson (2007), Public Health Agency of Canada, Canada's Transfusion Transmitted Injuries Surveillance System, Presentation to the CCDT Workshop on Tissue Surveillance, Montreal, Quebec April 28, 2007.

[5] L Johnston. 1997, Clinical Infectious Diseases, 1999;29:819-23.

[6] Robert Rigney. Report on the 2007 Annual Survey, American Association of Tissue Banks 13th Annual Spring Meeting, March 29. 2009.

figures. This inability to quantify tissue use suggests that the ability to trace tissues may also be compromised.

The story is much different when centralized tissue-sourcing is available and traceability can be conducted through a single entity such as a tissue coordinator or within a tissue or blood bank. One health region indicated that, prior to centralization, it took two weeks to trace and identify recipients associated with a recall. The same process took only two hours after centralization.[7]

Tissue recalls in U.S.

Between 1994 and 2007, the U.S. Food and Drug Administration (FDA) recalled 61,607 tissue allografts, of which more than 96 percent were musculoskeletal grafts. Healthcare facilities in the United States are routinely challenged to identify the disposition of tissues when informed of such recalls. In a 2005 Biomedical Tissues Services recall that included tissues distributed in Canada, more than 2,000 grafts from approximately 26,000 tissues could not be traced.[8]

Emergence of a transfusion services role in allograft traceability

Having identified tissue as a priority, the American Association of Blood Banks (AABB) created a tissue task force to investigate the appropriate role of hospital blood banks in the tissue system. Results from a 2005 web-based survey conducted among all 904 hospital AABB members indicated that blood banks (n=164) were second only to departments of surgery (n=245) in having responsibility for tissue use. Findings further indicate blood banks have tracking and monitoring experience that could help hospitals undertake tissue responsibilities and maintain oversight to ensure patient safety.[9] To leverage this tracking and monitoring experience and mitigate legal, financial and regulatory liability, AABB-member hospital administrators and blood banks are considering one model in which tissue banks and services would be centralized under hospital transfusion services.

A 2009 environmental scan conducted by Canadian Blood Services identified a number of Canadian facilities where the blood transfusion service played a role in tissue management, including tissue traceability.

Emergence of risk-based considerations for traceability systems

The U.S.-based Tissue Transplantation Sentinel Network (TTSN) is an organs and tissues surveillance and traceability system. The TTSN is considering the level of surveillance and traceability required for different types of grafts, specifically in relation to the variance in disease-transmission risk between minimally manipulated frozen grafts and highly processed lyophilized grafts.

The vast majority of allograft products created in the United States undergo processes to qualify as sterile or to significantly reduce bioburden. These processes include irradiation, chemical sterilization, patented processes and lyophilization.

Historically, disease transmissions have occurred in products that have not undergone intensive processing and bioburden reduction processes.

Although system traceability to the transplant establishment would be a component of the system for all grafts, a risk-management approach is being considered in which intensive traceability to and surveillance of the recipient would target only graft types at the highest risk for disease transmission.[10]

[7] Dermot Kelly. Environmental Scan of the Canadian Tissue Community, Vancouver Coast Health Region Tissue Distribution Service, Interview August 28, 2009.

[8] M. Joyce, M Strong, S Brubaker. Tracking and Tracing of Allograft Tissue Based on a Common Universal Donor Number are Lacking: Progress and Obstacles for a Transplantation Transmission Sentinel Network (TTSN) 2008.

[9] Christopher Hillyer. Editorial; Tissue Oversight in Hospitals: the Role of Transfusion Services, Transfusion 2007;47:185-187.

[10] Scott Brubaker. Interview with Scott Brubaker, Chief Policy Officer, American Association of Tissue Banks, September 21,2009

B. Current Community Thinking

Reports and Papers

Environmental Scan for the Tissues and Organs Surveillance System Core Steering Committee, 2007[11]

The Canadian Council for Donation and Transplantation (CCDT) surveyed Canadian organ procurement organizations, tissue banks, eye banks and organ transplant programs to better understand current practices in traceability and surveillance. With a response rate of 60 percent (n=43), the survey included the following observations:

- 42 percent of respondents indicated there were lapses in their traceability data,
- 28 percent indicated some concerns regarding successful communication of adverse events between organ and tissue programs in cases of common donors,
- 77 percent believe a coordinated traceability, surveillance and communication system would improve the safety of cells, tissues and organs, and
- 63 percent identified health privacy legislation as a barrier to share recipient traceability and surveillance data between source establishments and transplant programs.

[11] Canadian Council for Donation and Transplantation. An Environmental Scan for the Tissues and Organs Surveillance System Core Steering Committee, February 2008.

The European Union Cell and Tissue Directive, 2004[12]

This directive recommends a common approach for EU countries in relation to the tissue industry. It states, "An adequate system to ensure the traceability of human tissues and cells should be established. This would also make it possible to verify compliance with quality and safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures as well as record maintenance and an appropriate labelling system.

The directive requires tissue establishments to have effective and accurate systems to uniquely identify and label cells and tissues received and distributed. It also mandates the establishment of a single European coding system for all tissue products.

[12] European Parliament and Council. Directive 2004/23/EC, Official Journal of the European Union, March 31, 2004.

Forums

National Consultation: Organ and Tissue Donation and Transplantation (Canadian Blood Services) September 22–24, 2008, Gatineau, Quebec[13]

This consultation between Canadian Blood Services and 130 stakeholders was part of an initial step in planning for an integrated system. Traceability-related recommendations include:

- All tissue products must be traceable,
- Enforcement and governance is required to ensure compliance,
- Patients must be notified when they are about to receive tissue,

[13] Canadian Blood Services (2008), Executive Summary National Consultation, Organ and Tissue Donation and Transplantation, September 22-24, 2008.

- Successful traceability at the national level is not possible without a common system, and
- Successful traceability at the national level is not possible without aligned inventory coding.

Organs and Tissue Safety Workshop: Advances and Challenges
(American Society of Transplant, American Academy of Orthopedic Surgeons, United Network for Organ Sharing, Chiron Foundation)
June 5–6, 2007, Reston, Virginia, United States[14]

Workshop participants assessed progress made in organ and tissue safety and identified priorities for future interventions. Attendees included representatives from the U.S. tissue community, as well as Health Canada, the Public Health Agency of Canada and the Canadian Council for Donation and Transplantation. The following conclusions were made:

- Improved coordination among stakeholders (including organ procurement organizations, eye and tissue banks, infection disease experts and regulatory organizations) is needed in the reporting and investigation of possible donor-derived transmission events;
- Algorithms for traceability should be developed;
- Coordination of information regarding disease transmission will serve public health and healthcare providers;
- There are currently many systems for eye, organ and tissue tracking that are unique to individual procurement organizations and tissue banks. Strong consideration was given to the benefits of a unified tracking and reporting system for all allografts; and
- The Transplantation Transmission Sentinel Network (TTSN), a secure internet-based system that supports traceability and surveillance, is under development to address communication gaps and maintain data.

[14] Jay Fishman, D. Michael Strong, Matthew Kuenhert . Organ and Tissue Safety Workshop 2007: Advances and Challenges. Cell Tissue Bank (2009) 10:271-280.

Enhancing Tissue Banking in Canada—Phase 11: Surveillance and Traceability in Tissue Transplantation
(Canadian Council for Donation and Transplantation)
April 27-28, 2007, Montreal, Quebec[15]

Thirty-four participants from Canada, the U.S. and Europe convened to identify options for tissue-transplantation surveillance and traceability. Participants agreed on the following points related to the development of a pan-Canadian system for transplantation surveillance and traceability:

- There should be a centralized national surveillance system;
- End-user traceability systems need to be enhanced;
- Provincial traceability systems should be used in the short term and built on in coming years during the move to a centralized national system;
- Surveillance and traceability systems should be strategically linked; and
- Further study should examine the advantages to a surveillance and traceability system that builds on existing blood systems.

[15] Canadian Council for Donation and Transplantation . Enhancing Tissue Banking in Canada – Phase II: Surveillance and Traceability in Tissue Transplantation, Consultation Report from the Meeting, June 19, 2007.

C. Other Models

Traceability models are closely linked, and therefore named in this section according to their corresponding business and distribution models.

Centralized: Sole Distributor

In some models and jurisdictions, tissue distribution is undertaken by a single organization. In this centralized scenario, the distributor uses one identification and labeling system. The examples of Héma-Québec and Canadian Blood Services illustrate and elaborate on this model.

a. **Provincial — Héma-Québec**

In Quebec, tissue and tissue products are centralized in a sole-source distribution system operated by Héma-Québec. Its inventory of both provincially produced and imported products is centralized, and the organization is developing a single identification and labeling system through ISBT 128. Traceability from source to transplant establishments is also centralized, while traceability to recipients remains the responsibility of the transplant establishment.[16]

b. **National — Canadian Blood Services**

This model centralizes production and distribution of blood products within a single organization. A common identification and labeling system is in place (ISBT 128), and traceability functions are centralized. An integrated information system provides:[17]

- One consolidated donor database,
- A real-time national view of product inventory, and
- Traceability data on every blood donation made to the receiving hospital.

This model supports two traceability functions: 1) Look Back—the process whereby a donor's infectious disease is identified and traceability occurs to identify products issued and patients affected, and 2) Trace Back—the process whereby a recipient's disease is identified and traceability occurs to establish if the blood product was the source of the event.

In Canadian Blood Services' model, traceability to the recipient is the responsibility of the transfusion establishment—in each case, a hospital blood bank. Blood-product distribution is centralized within each hospital, and the information systems that support traceability to recipients are specific to the hospital.

Centralized: Multi-distributor

In some jurisdictional models—such as the UK example described below—a single major tissue distributor competes for end-user market share with a number of independent source establishments located in and outside the jurisdiction. Traceability of products to transplant establishments is maintained by each distributor, whether the major provider or an independent source.

a. **U.K. National Tissue Services**

National Health Service Blood and Transplant (NHSBT) was formed by the merger of the National Blood Service and UK Transplant to achieve operational synergies and economies of scale. The National Tissue Service within NHSBT is the UK's major provider of human tissue for transplant; however, NTS competes for market share with other UK tissue banks and international providers. Working in the blood-operations environment, NTS operates the same quality system and ensures traceability of tissues from donors to recipient hospitals. ISBT 128 has been implemented to support a single coding and labelling system. Traceability to the recipient is the responsibility of each transplant establishment,

[16] Canadian Blood Services. Héma-Québec Site Visit and Interview, Summary of Key Learnings, February 21, 2008.
[17] Irene Dines. Interview with Irene Dines, Manager Look Back Trace Back, Canadian Blood Services, September 2, 2009.

whether it receives product from NTS or an independent source. NTS audits compliance with each transplant centre annually. [18]

Decentralized — Coordinated

In these models, product distribution is provided within a jurisdiction by multiple independent source establishments in a network scenario. Systems processes are established to coordinate traceability practices through a single shared information system or through information standards. Two examples help elaborate on this model.

a. **Australia Organ and Tissue Donation and Transplant Authority (OTDTA)**
In Australia, tissue banks are state-based and function independently as a network. For example, the National Eye and Tissue Donation and Transplant Network (currently in development by the OTDTA) will deliver a coordinated, accountable, national tissue transplantation service. The network will also develop tissue data-collection, analysis and reporting requirements, including a national eye and tissue donor database and national eye and tissue outcome registries.[19] Specific traceability processes are yet to be determined.

b. **United States — National Transplantation Sentinel Network**
The Centers for Disease Control and Prevention (CDC) and the United Network for Organ Sharing (UNOS) are developing the Tissue Transplantation Sentinel Network (TTSN), a combined traceability and surveillance system for detecting, communicating, tracking and preventing the transmission of infections from organ, tissue and ocular donors to transplant recipients. Traceability functions for both source and transplant establishments will be provided through a web-based format. The system will:[20]

- Develop a communication network to serve all groups involved in allograft transplantation,
- Enhance and develop unique donor identification systems to facilitate the tracking of organs, tissues and eyes,
- Develop specific processes for adverse event and reaction reporting by healthcare facilities and professionals,
- Improve information dissemination to clinicians, health professionals and patients,
- Develop a notification algorithm for trace-back and trace-forward tracking to optimize collaboration between the clinical community and public health authorities, and
- Enable continuous improvement of outcome and public safety measures.

In follow-up to TTSN's development and pilot, the CDC has recently issued a Request for Information to solicit interest from potential vendors and partners in moving TTSN to full implementation.[21]

Consideration is ongoing regarding the expectations and or viability of the support and use of TTSN by transplant establishments and end-users outside the U.S. Further consideration is being given to the level of surveillance and traceability required for different types of grafts; specifically in relation to the variance in disease-transmission risk between minimally manipulated frozen grafts and the highly processed lyophilized grafts.[22] .

[18] National Health Service Blood and Transplant (NHSBT). NHSBT Service Strategy 2006-2010, November 28, 2006.
[19] Australia Government Department of Health and Ageing. A Worlds Best Practice Approach to Organ and Tissue Donation for Australia: Overview, Retrieved from www.health.gov.au on August 15, 2009.
[20] United Network for Organ Sharing. Year Two Annual Update of Cooperative Agreement Progress – Sentinel Network for Detecting Emerging Infections Among Allograft Donors and Recipients (2008).
[21] Centres for Disease Control. Request for Information. National Transplantation Sentinel Network, September 21, 2009
[22] Scott Brubaker. Interview with Scott Brubaker, Chief Policy Officer, American Association of Tissue Banks, September 21,2009

4. Analysis

A. Analysis Approach

This document was prepared following:

- An environmental scan of the Canadian tissue community and a thorough analysis of existing research and opinion papers, and
- Consultation with members of the Tissue Expert Committee, along with Canadian tissue banks, end-users and leaders in traceability processes.

The views of those consulted are reflected throughout this document. A high-level SWOT analysis of current traceability models is available in Appendix B.

An analysis of the current state will then be used to compare options for traceability models. The comparison will map out specific strengths, weaknesses and challenges, and highlight the outcomes that can potentially be achieved by implementing each option.

The following assumptions have been made in evaluating the options:

- Regulatory requirements for traceability are unchanged,
- Traceability processes are required for all allograft products implanted in Canada independent of the source establishment's country of origin,
- The development of Canadian traceability systems will include consideration of the methodology proposed for the U.S. Sentinel Networks to support traceability of grafts produced in the U.S. and implanted in Canada, and
- The final decision must integrate with other elements of the tissue system strategy.

B. Analysis Findings

There is consensus in the tissue community that tissue traceability is essential to the control and prevention of allograft-related adverse events.

In the Canadian tissue system, incomplete traceability poses risks for both Canadian source establishments and internal source establishments importing tissue into Canada. There are significant risks associated with incomplete traceability at Canadian transplant establishments, both in the current lack of traceability oversight and accountability, and in the provision of informed consent to allograft recipients. No less significant are the risks associated with the current status of audit processes for traceability compliance by source and transplant establishments.

Yet to be determined are:

- The impact on traceability in Canada of the developing U.S. Sentinel network,
- Potential synergies with the Sentinel network, and
- The risk of duplication of efforts and the possibility of transplant establishments being required to support separate systems.

Analysis suggests that the following mechanisms are critical to the advancement of traceability:

- The standardization of product coding and labeling. Labeling standards exist for blood and blood products, and are used consistently in all Canadian jurisdictions. The lack of a common coding standard in tissues may contribute to tracking and traceability problems.[23]
- Integrated information systems, which enable rapid tracking of allografts to

[23] Michael Strong (2009), Cells and Tissue Traceability and ISBT 128, In Press: GxP Lifeline (www.mastercontrol.com/newsletter/).

recipients, and vice versa. The lack of integrated data systems could lead to public health risks and weaken the ability to identify and, if necessary, treat allograft recipients.[24]

- Assigned oversight and accountability for the acquisition and distribution of tissues within transplant establishments.[25]
- Audit processes to validate compliance with regulatory requirements.

[24] M. Joyce, M Strong, S Brubaker (2008). Tracking and Tracing of Allograft Tissue Based on a Common Universal Donor Number are Lacking: Progress and Obstacles for a Transplantation Transmission Sentinel Network (TTSN).

[25] Joint Commission (2008). The Joint Commission Accreditation Program: Hospital Transplant Safety (2008).

5. Options and Considerations

A. Options

Traceability has two distinct streams: source establishment and transplant establishment. The final recommended solution may treat these streams similarly or differently, depending on the specific component or mechanism. The set of options presented below is intended as a starting point for discussing and identifying the final solution.

What is the best strategy to support the regulatory requirements for traceability and enhance tissue safety?

Status quo at source and transplant establishments

In this case, the status quo refers to uncoordinated independent source and transplant establishment traceability practices. The committee may discuss solutions that involve status quo enhancements that are not manifested in the other solution options.

	Strengths	Weaknesses
Source Establishment Status Quo	▪ No net new resource requirements ▪ No change management	▪ No traceability oversight ▪ Potential negative public reaction during recall events ▪ Traceability variation among multiple independent systems ▪ Uncoordinated response to traceability incidents ▪ No common coding or labeling ▪ Non-responsive to community direction ▪ Heightened risk for legal and financial liability in the event of traceability failures
Transplant Establishment Status Quo	▪ Few resource requirements ▪ Minimal change management	▪ Uncoordinated response to traceability incidents ▪ Potential negative public reaction during recall events ▪ Inconsistent traceability oversight and accountability in transplant establishments ▪ Traceability variance among multiple independent systems ▪ Patients may be unaware of their tissue implant

Barriers to implementation
▪ Compliance Management

Critical mechanisms	Source Establishment Status Quo	Transplant Establishment Status Quo
Common coding and labeling	No	No
Integrated information systems	No	No
Informed-consent processes	No	No
Transplant establishment oversight and accountability	No	No
Audit processes	The efficacy of the Health Canada inspection process has yet to be determined	No

Coordinated source and transplant establishment traceability systems

This case refers to the development of integrated information systems to support traceability functions at Canadian source and transplant establishments. In this scenario:

- All Canadian source establishments would be required to manage traceability data using a common coding structure and other information standards.
- At transplant establishments, traceability oversight responsibilities, accountability requirements and informed-consent processes would be documented.
- Traceability would be audited at the source and transplant establishments.
- For the transplant sector, particularly dental establishments, a new auditing solution would need to be developed.

	Strengths	Weaknesses
Coordinated Source Establishments	▪ Adequate traceability to the transplant establishment ▪ Increased traceability response through centralized information system ▪ Common coding and labeling ▪ Tissue community support ▪ Facilitates audit processes ▪ A national approach	▪ Resource requirements ▪ Does not address traceability of foreign sourced tissue

How can the proposed system ensure the traceability of tissue products?

Coordinated Transplant Establishments	▪ Control over traceability to the recipient ▪ Traceability of all products including imported ▪ Facilitates audit processes ▪ A national approach	▪ Resource requirements ▪ Multiple stakeholders ▪ Potential duplication in relation to U.S. TSN

Barriers to implementation

- Support and participation of all eye and tissue banks would be required
- Change management: this solution would impact many individuals at many establishments
- Compliance management: this solution would require new approaches to auditing at the transplant layer

Critical Mechanisms	Coordinated Source Establishments	Coordinated Transplant Establishments
Common coding and labeling	Yes	Dependent on source establishment strategy
Integrated information systems	Yes	Yes
Informed consent processes	No	Yes
Transplant establishment oversight and accountability	No	Yes
Audit processes	Yes	Yes

Coordinated source and status quo transplant establishment traceability systems

This is a hybrid approach in which traceability systems at Canadian source establishments include the changes in Option B, but traceability at the transplant establishment level remains in the status quo. This option is intended to illustrate how different combinations of mechanisms at source and transplant establishments can be combined in a single solution.

	Strengths	Weaknesses
Coordinated Source Establishments	▪ Adequate traceability to the transplant establishment ▪ Increased traceability response through centralized information system ▪ Common coding and labeling ▪ Tissue community support ▪ Facilitates audit processes ▪ A national approach	▪ Resource requirements ▪ Does not address traceability of foreign sourced tissue
Transplant Establishment Status Quo	▪ Few resource requirements ▪ Minimal change management	▪ May lose benefits of coordinated traceability at source establishments ▪ Uncoordinated response to traceability incidents ▪ Potential negative public reaction during recall events ▪ Inconsistent traceability oversight and accountability in transplant establishments ▪ Traceability variance among multiple independent systems ▪ Patients may be unaware of their tissue implant

Barriers to implementation
▪ Support and participation of all eye and tissue banks would be required ▪ Change management: this solution would impact many individuals at many establishments

Critical Mechanisms	Coordinated Source Establishments	Status Quo Transplant Establishments
Common coding and labeling	Yes	No
Integrated information systems	Yes	No
Informed-consent processes	No	No
Transplant establishment oversight and accountability	No	No
Audit processes	Yes	No

What are strategies to support critical traceability mechanisms?

The table below supports the solution discussion with information about the mechanisms most critical to traceability, and by providing examples of how these mechanisms could be implemented.

Critical Mechanisms	Strategies
Common coding and labeling	▪ Implementation of a common coding and labeling system in all banks ▪ A unique product identifier generated via existing bank codes
Integrated information systems	▪ Implementation of a common inventory distribution and traceability system in all banks ▪ Development of a common system that is populated remotely by individual banks ▪ Collaboration with the U.S. Transplantation Transmission Sentinel Network
Informed-consent processes	▪ Amendment of standards and regulations to include this requirement ▪ Adoption of requirement by Accreditation Canada
Transplant establishment oversight and accountability	▪ Amendment of standards and regulations to include this requirement ▪ Adoption of requirement by Accreditation Canada ▪ Consideration of transfusion services role in oversight
Audit processes	▪ Governing organization ▪ Health Canada ▪ Accreditation Canada

B. Considerations

- There can be different strategies developed for source establishments and transplant establishments.
- There can be different strategies for Canadian and international source establishments.
- There can be different strategies developed for different types of transplant establishments; for example, hospitals and dental facilities.
- There can be different strategies for different tissue grafts in relation to the risk of disease transmission; for example, frozen versus processed lyophilized products.
- Options may be evaluated according to a range of criteria, including practicality, sustainability, achievability, and the availability of strategies to overcome implementation barriers.

APPENDIX A

Company/ Product	Year	Description
Tutoplast Dura	2002	• In April 2002, Health Canada suspended the license for Tutoplast Dura and monitored a recall of the product. This product, processed in Germany, was available in Canada between 1982 and 2002. • In 2003, a case of classical CJD was confirmed in a Canadian patient who received a graft in 1992.
Cryolife Inc. (U.S.)	2002	• In August, 2002, Health Canada issued notice of a risk of fungal and bacterial contamination of soft tissues for implantation processed and sold by CryoLife Inc. (Georgia). The FDA also initiated a recall due to infections reported with these implants and the occurrence of one confirmed death following knee allograft surgery. No cases of death or infection were reported in Canada.
B.C. Ear Bank	2003	• In February 2003, Health Canada began investigating the B.C. Ear Bank at St. Paul's Hospital, Vancouver. Their investigation revealed donor suitability and tissue processing documentation was incomplete. • All unused tissue was recalled and patients who were the recipients of bones or tissues supplied by the B.C. Ear Bank were advised to be tested for HIV, Hepatitis B and Hepatitis C. Thousands of patients across North America were affected, as the B.C. Ear Bank supplied tissue and bone to 87 hospitals and physicians across Canada, and in two cities in the United States.
Biomedical Tissue Services Limited (BTS) (U.S.)	2005	• In October 2005, Health Canada advised Canadians of a voluntary recall in the United States of tissue products used in implants and grafts that were imported into Canada. • Tissues recovered by BTS were acquired without legal consent or proper screening. Funeral home operators accepted money from the company in exchange for ignoring forged death certificates and consent forms. BTS sold these tissues to several companies, including those that exported tissue to Canada. These companies initiated voluntary recalls for all products that were produced using tissues from BTS. About 10,000 people received product from BTS. Approximately 300 tissue products were imported into Canada, though no adverse effects have been reported from Canadian patients.
Donor Referral Services (DRS) (U.S.)	2006	• In 2006, DRS, located in Raleigh, North Carolina, was ordered by the FDA to cease all manufacturing operations because of serious deficiencies in its donor screening and record keeping practices. The owner allegedly used a local consumer group to procure material from a local funeral home's unsterilized embalming room. • The companies that received their tissues initiated voluntary recalls involving 2,400 allografts. Six implicated products were imported into Canada. None were transplanted, all were returned to the U.S.

APPENDIX B

Model Strengths-Weaknesses-Opportunities Analysis

This section represents an initial analysis of example traceability models that informed the development and analysis of the options in Section 4.

	Status Quo	Model 1	Model 2	Model 3
Type	Decentralized Uncoordinated	Centralized Sole Distributor	Centralized Multi-distributor	Decentralized Coordinated
Strengths	▪ No additional resources ▪ No change management	▪ Traceability of entire source and imported inventory ▪ Easier management of transplant establishment traceability compliance ▪ Common coding and labeling ▪ Single traceability system and processes ▪ Enhanced audit ability	▪ Traceability of domestically sourced inventory ▪ Integrated systems and processes for domestic products ▪ Enhanced audit ability	▪ Traceability of entire source inventory ▪ Traceability of all Transplant establishments ▪ Single system identifier ▪ Integrated system and processes
Weaknesses	▪ Traceability risk ▪ No common coding and labeling ▪ Multiple independent traceability systems ▪ Current audit processes ▪ No requirement for informed consent	▪ Complexity ▪ Does not assure informed consent	▪ No common coding or labeling ▪ Traceability of import-source inventory not assured ▪ Does not assure informed consent	▪ Complexity ▪ The U.S.-based international Sentinel network may duplicate national processes ▪ Does not assure informed consent ▪ Audit processes
Opportunity	▪ No improvement opportunities in status quo	▪ Enhanced traceability, especially at source establishments	▪ Enhanced traceability, including complete traceability of domestic inventory	▪ End-to-end traceability