

# **TISSUE EXPERT COMMITTEE: HOW CAN THE SYSTEM ENSURE THE TRACEABILITY OF TISSUE PRODUCTS? (DRAFT SOLUTION DESIGN PAPER)**

## **CONTENTS**

<b>1. Scope</b> .....	<b>3</b>
<b>2. Current State</b> .....	<b>4</b>
A. Current State.....	4
B. Current Community Thinking .....	7
C. Other Models.....	10
<b>3. Analysis</b> .....	<b>14</b>
A. Analysis Approach .....	14
B. Findings.....	14
<b>4. Options and Considerations</b> .....	<b>16</b>
A. Options.....	16
B. Considerations .....	20
<b>APPENDIX A</b> .....	<b>22</b>
<b>APPENDIX B</b> .....	<b>23</b>

# 1. Scope

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HOW CAN THE SYSTEM ENSURE THE TRACEABILITY OF TISSUE PRODUCTS?

This question will inform the discussion of tissue Donation and transplantation in Canada, specifically how to improve traceability in the system. This document will describe the current state as a foundation to inform discussions and will explore different options and mechanisms that may improve traceability within the system.

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

## 2. Current State

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### 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 both nationally and imported from the United States. See appendix A for recall details.

#### **Current Regulatory Requirements in Canada**

In Canada, Health Canada administers cells, tissues and organs (CTO) regulations.<sup>1</sup> In relation to traceability, Health Canada details the following requirements.

- Source establishments must be able to trace allografts from the originating donor to distribution 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 establishments and transplant establishments are required to undertake surveillance for adverse events potentially related to the allograft and communicate events promptly and appropriately to ensure control measures are initiated.
- A requirement for informed consent in the case of exceptional release.

Health Canada licenses source establishments and is developing a regulatory inspection and audit process. Transplant establishments are not licensed by Health Canada and as such, there are no audit or regulatory processes to gauge compliance for traceability

Accreditation Canada supports a voluntary accreditation process directed at Canadian healthcare institutions. It is currently drafting organ and tissue donation standards, including traceability requirements.<sup>2</sup> Demonstration of compliance through inspection and audit will be required to obtain institutional accreditation.

Health Canada, in collaboration with the Public Health Agency of Canada, monitors biologic adverse events, investigates complaints and problem reports, maintains post-approval surveillance, and manages recalls, as required.<sup>3</sup>

The surveillance of cells, tissues and organs and assisted reproduction for adverse events and disease transmissions falls within the mandate of the Public Health Agency of Canada (PHAC).<sup>4</sup> PHAC has developed and is piloting the Tissue and Organs Surveillance System to track identified adverse events, accidents or errors. If an event is

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<sup>1</sup> 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.

<sup>2</sup> Accreditation Canada. Accreditation Canada's Qmentum Program: Service Excellence, Draft Organ and Tissue Donation Standards Version 1.4, March 2009.

<sup>3</sup> Health Canada. Retrieved from <http://www.hc-sc.gc.ca/dhp-mps/brgtherap/index-eng.php> on August 14, 2009.

<sup>4</sup> 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.

identified, PHAC collaborates with Health Canada to work with traceability systems at individual source and transplant establishments to implement 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.

Firstly, 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.

At the same time, traceability practices and communication between tissue programs procuring tissues from a common donor are not well defined. This holds true in situations where organ and tissue programs procure from a common donor. This was evidenced in the case of a cross-Canada spread of methicillin-resistant staphylococcus aureus (MRSA) in 1997. In this case, culture of the corneal rim at the time of its transplant identified MRSA, yet there was delay in notifying the organ recipient's institutions. Both organ recipients subsequently became blood culture positive for MRSA.<sup>5</sup>

Where traceability practices do exist, they are often supported by institutional in-house information systems which vary significantly in scope and sophistication, from paper trails to electronic inventory management systems. Where these systems exist, there is little integration within hospital information systems and no integration between tissue programs. Bar-coding, a basic technology which reduces transcription errors and facilitates traceability, has not been implemented by any Canadian tissue program.

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 at all 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 per cent of their requests.<sup>6</sup>

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.

<sup>5</sup> L Johnston. 1997, Clinical Infectious Diseases, 1999;29:819-23.

<sup>6</sup> Robert Rigney. Report on the 2007 Annual Survey, American Association of Tissue Banks 13<sup>th</sup> Annual Spring Meeting, March 29, 2009.

### **Traceability in Canadian Hospitals and Dental Practices**

At the end-user level, traceability is supported by individual institutional processes and systems which vary significantly in scope and sophistication, from paper trails to electronic inventory management systems. These systems are 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. These banks were asked to coordinate with their operating rooms to identify the quantity of allografts implanted in their organizations for the 2008 calendar year. Two of the three organizations were unable to readily quantify allograft utilization within their institutions. This inability to track utilization inherently leads to an inability to trace tissues used.

Where centralized tissue-sourcing is available and traceability within a single entity such as a tissue coordinator or within a tissue or blood bank exists, the story is much different. One health region indicated that prior to centralization, it took two weeks to trace and identify recipients associated with a recall; in comparison to a post-centralization recall that took only two-hours to trace and identify recipients.<sup>7</sup>

Within blood system operations at Canadian hospitals, best practice includes the provision of documentation to the transfusion recipient of their transfusion event, often including the product identification numbers, making donor to patient traceability more direct.<sup>8</sup> This provision of documentation to allograft recipients of their implantation does not appear to be a common practice in tissue transplantation in Canadian hospitals.

### **Tissue recalls in U.S.**

In the United States, between 1994 and 2007 the U.S. Food and Drug Administration (FDA) recalled 61,607 tissue allografts of which more than 96 per cent were musculoskeletal grafts. Given that healthcare facilities in the United States are routinely challenged to identify the disposition of tissues when informed of a recall, we can extrapolate that a significant number of allografts are not traceable posing a variety of risks. In one instance, a 2005 Biomedical Tissues Services recall involving approximately 26,000 tissues, more than 2,000 tissue grafts could not be traced.<sup>9</sup> This recall included tissues distributed in Canada

### **Emergence of a Transfusion Services Role in Allograft Traceability**

The American Association of Blood Banks (AABB) has identified “tissue” as a priority, creating a tissue task force to investigate the appropriate role of the hospital blood bank in the tissue arena. Hospital administrators and blood banks are considering the centralization of tissue banks or tissue services under the auspices of hospital

<sup>7</sup> Dermot Kelly. Environmental Scan of the Canadian Tissue Community, Vancouver Coast Health Region Tissue Distribution Service, Interview August 28, 2009.

<sup>8</sup> Irene Dines. Interview with Irene Dines, Manager Look Back Trace Back, Canadian Blood Services, September 2, 2009.

<sup>9</sup> 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.

transfusion services to leverage existing tracking and monitoring processes as a means of mitigating legal, financial and regulatory liability.

For instance, a 2005 web-based survey distributed to all 904 hospital AABB institutional members, indicated the department of surgery (e.g. Operating room, n=245) most often had responsibility for tissue use, followed by the blood bank (n=164). Findings indicate blood banks have an opportunity to assist their hospitals in planning for assigned tissue responsibilities and oversight to ensure patient safety because they have experience in tracking and monitoring.<sup>10</sup> 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 Transplantation Sentinel Network (TSN) is an organs and tissues surveillance and traceability system. Following a development and pilot further consideration is being given to the level of surveillance and traceability required for different types of grafts and more specifically in relation to the variance in disease transmission risk between minimally manipulated / frozen grafts and the more highly processed / lyophilized grafts.

The vast majority of allograft products produced in the United States under-go processes which qualify the products as sterile or significantly reduce bioburden. These processes include irradiation, chemical sterilization, patented processes and lyophilization.

Historically, disease transmissions have been related to products which have not undergone the intensive processing and bioburden reduction processes.

While system traceability for all grafts to the transplant establishment would remain a component of the system consideration is being given to a risk management approach where intensive traceability and surveillance to the recipient would be targeted only to those graft types of the highest risk for disease transmission.<sup>11</sup>

## **B. Current Community Thinking**

### **I. Reports and Papers**

#### **Environmental Scan for the Tissues and Organs Surveillance System Core Steering Committee, 2007<sup>12</sup>**

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 per cent (n43), observations, including the following, were made:

<sup>10</sup> Christopher Hillyer. Editorial; Tissue Oversight in Hospitals: the Role of Transfusion Services, *Transfusion* 2007;47:185-187.

<sup>11</sup> Scott Brubaker. Interview with Scott Brubaker, Chief Policy Officer, American Association of Tissue Banks, September 21, 2009

<sup>12</sup> Canadian Council for Donation and Transplantation. An Environmental Scan for the Tissues and Organs Surveillance System Core Steering Committee, February 2008.

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

**The European Union Cell and Tissue Directive, 2004<sup>13</sup>**

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 labeling system."

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

## II. Forums

**National Consultation: Organ and Tissue Donation and Transplantation  
(Canadian Blood Services)**

**September 22-24, 2008, Gatineau, Quebec<sup>14</sup>**

A September 2008 consultation between Canadian Blood Services and a group of 130 stakeholders as part of an initial step in planning for an integrated system, yielded a number of recommendations in relation to traceability including:

- All tissue products must be traceable;
- Enforcement and governance is required to ensure compliance;
- The patient always gets notified when they are about to receive tissue;
- 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.

<sup>13</sup> European Parliament and Council. Directive 2004/23/EC, Official Journal of the European Union, March 31, 2004.

<sup>14</sup> Canadian Blood Services (2008), Executive Summary National Consultation, Organ and Tissue Donation and Transplantation, September 22-24, 2008.

**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<sup>15</sup>**

The workshop assessed progress made in organ and tissue safety and identified priorities for future interventions. This workshop included broad representation from the U.S. tissue community as well as representation from 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 is needed in the reporting and investigation of possible donor-derived transmission events including organ procurement organizations, eye and tissue banks, infection disease experts and regulatory organizations;
- 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 supporting traceability and surveillance is under development to address communication gaps and maintain data.

**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<sup>16</sup>**

Thirty-four participants from Canada, the United States and Europe convened to identify possible future options for surveillance and traceability in tissue transplantation. The participants agreed in plenary on the following points related to the development of a pan-Canadian system for surveillance and traceability in 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; and

<sup>15</sup> Jay Fishman, D. Michael Strong, Matthew Kuenhert . Organ and Tissue Safety Workshop 2007: Advances and Challenges. Cell Tissue Bank (2009) 10:271-280.

<sup>16</sup> 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.

- There are advantages to a surveillance and traceability system that builds on the existing blood systems and this requires further study.

## C. Other Models

In any system, the traceability function is closely linked to the system's business and distribution model. Consequently, the types of traceability models presented below are named in reference to their business and distribution model.

### I. Centralized: Sole Distributor

In some models, tissue distribution within a given jurisdiction is restricted to a single distributor. In this scenario, a single identification and labeling system is in place with traceability centralized in that single distributor. The examples of Héma-Québec and Canadian Blood Services will be used to illustrate and elaborate upon this model.

#### a) Provincial - Héma-Québec

In Quebec, tissue and tissue products have been centralized provincially in a sole-source distribution model. An inventory of provincially produced products as well as imported products is centralized through the sole distributor (Héma-Québec) to support end-user needs. A single identification and labeling system is being pursued through ISBT 128. Traceability from the source establishment to the transplant establishment is centralized. Traceability to the recipient remains the responsibility of the transfusion establishment.<sup>17</sup>

#### 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 (ISBT128) and traceability functions are centralized. The organization supports traceability from the donor to the transfusion establishment and vice-versa. An integrated information system provides:<sup>18</sup>

- One consolidated donor database
- A national / real-time view of product inventory
- 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 transmission

<sup>17</sup> Canadian Blood Services. Héma-Québec Site Visit and Interview, Summary of Key Learnings, February 21, 2008.

<sup>18</sup> Irene Dines. Interview with Irene Dines, Manager Look Back Trace Back, Canadian Blood Services, September 2, 2009.

is identified and traceability occurs to establish if the blood product was the source of the event.

In this model, traceability to the recipient is the responsibility of the transfusion establishment. Transfusion establishments centralize all distribution of products within their institution to the transfusion service. Information systems to support transfusion centre traceability are institution- specific.

## II. Centralized: Multi-Distributor

In some models, distribution of products produced in a defined jurisdiction is restricted to a single major provider. As such, traceability functions to the transplant establishment are centralized in one organization. However, external source establishments compete with the major provider for end-user market share and traceability of their products to the transplant establishment remains linked to their abilities. The example of UK National Tissue Services within NHSBT will be used to elaborate upon this model.

### 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. NHSBT Tissue Services is the U.K.'s major provider of human tissue for transplant and competes with other U.K. tissue banks and international providers for market share. It works within the environment of blood operations, operates the same quality system and ensures traceability of tissues from donor to recipient hospital. ISBT 128 has been implemented to support a single coding and labelling system. Traceability to the recipient is the responsibility of the transplant establishment. The National Tissue Service contractually requires all transplant establishments it supports to provide traceability of NHSBT product to the recipient. The service audits compliance with each transplant centre annually.<sup>19</sup>

## III. Decentralized - Coordinated

In these models distribution of products within a jurisdiction is supported by multiple independent source establishments in a network scenario. Systems processes are established to coordinate traceability practices through a single information system or through information standards. The examples of Australia and the United States will be used to elaborate upon this model.

<sup>19</sup> National Health Service Blood and Transplant (NHSBT). NHSBT Service Strategy 2006-2010, November 28, 2006.

**a) Australia-Organ and Tissue Donation and Transplant Authority**

In this scenario, tissue banks are state-based and function independently. The Australian Organ and Tissue Donation and Transplant Authority is developing a National Eye and Tissue Donation and Transplant Network. This network will deliver a coordinated, accountable, national tissue transplantation service and will develop the data collection, analysis and reporting requirements for tissue including a national eye and tissue donor database and national eye and tissue outcome registries.<sup>20</sup> As this system is in development, 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 Transplantation Sentinel Network (TSN), 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:<sup>21</sup>

- 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/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.
- Continuous improvement of transplant recipient and public safety measures.

In follow-up to its development and pilot, the CDC has recently released a Request for Information to solicit interest and insight from potential vendors and partners in moving TSN to development and implementation.<sup>22</sup>

Consideration is ongoing regarding the expectations and or viability of the support and use of TSN by transplant establishments and end-users

<sup>20</sup> 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](http://www.health.gov.au) on August 15, 2009.

<sup>21</sup> 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).

<sup>22</sup> Centres for Disease Control. Request for Information. National Transplantation Sentinel Network, September 21, 2009

external to the US. Further consideration is being given to the level of surveillance and traceability required for different types of grafts and more specifically in relation to the variance in disease transmission risk between minimally manipulated/frozen grafts and the more highly processed / lyophilized grafts<sup>23</sup>

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<sup>23</sup> Scott Brubaker. Interview with Scott Brubaker, Chief Policy Officer, American Association of Tissue Banks, September 21,2009

## 3. Analysis

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### A. Analysis Approach

An environmental scan of the Canadian tissue community and a thorough analysis of existing research and opinion papers have been conducted to provide the basis for this document. Members of the Tissue Expert Committee, Canadian tissue banks, end-users and leaders in traceability processes have been consulted and their views are reflected within this report. A high level SWOT analysis of current models for traceability is available in appendix B.

An analysis of the current state will then be used in the options comparison to assess the status quo and potential options for each of the questions. This comparison will map out the strengths, weaknesses and challenges. The outcomes achieved by implementing each option will also be highlighted.

In evaluation of the options, the following assumptions are made:

- Regulatory requirements for traceability are unchanged;
- Traceability processes are required for all allograft products implanted in Canada independent of the country of origin of the source establishment;
- The development of Canadian traceability systems will include a consideration of the developing US Sentinel Networks proposed methodology to support traceability of grafts produced in the U.S. and implanted in Canada; and
- The final decision will have to integrate with the other elements of the Tissue System strategy.

### B. 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, there are risks associated with incomplete traceability 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 recipient. Also significant are the risks associated with current status of audit processes for traceability compliance of source and transplant establishments.

The impact of the developing US Sentinel network on traceability in Canada (including possible synergies) has yet to be determined. Risk of duplication of efforts and the potential of transplant establishments being required to support separate systems have yet to be determined.

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

1. The **standardization of product coding and labeling** is critical for traceability. Labeling standards exist for blood and blood products and are utilized consistently through all Canadian jurisdictions. The lack of a common coding standard in tissues may contribute to the problems of tracking and traceability.<sup>24</sup>
2. **Integrated information systems** which provide ability to rapidly track allografts to recipients, and vice versa are critical to traceability. The lack of integrated developed data systems creates vulnerability to identification and treatment of allograft recipients and public health risks.<sup>25</sup>
3. **Assigned oversight and accountability** for the acquisition and distribution of tissues within a transplant establishment is critical to traceability.<sup>26</sup>
4. **Audit processes** to validate compliance with regulatory requirements.

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<sup>24</sup> Michael Strong (2009), Cells and Tissue Traceability and ISBT 128, In Press: GxP Lifeline ([www.mastercontrol.com/newsletter/](http://www.mastercontrol.com/newsletter/)).

<sup>25</sup> 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).

<sup>26</sup> Joint Commission (2008). The Joint Commission Accreditation Program: Hospital Transplant Safety (2008).

## 4. 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 that final solution.

- I. What is the best strategy to support the regulatory requirements for traceability and enhance the safety of tissues?

#### a) Status Quo at Source and Transplant Establishments

In this case, the status quo refers to uncoordinated independent source and transplant establishment traceability practices. Though the analysis tables below refer to the as-is status quo, the committee may also discuss solutions that involve enhancements to the status quo that are not manifested in the other solution options.

	<b>Strengths</b>	<b>Weaknesses</b>
Source Establishment Status Quo	<ul style="list-style-type: none"> <li>▪ No net new resource requirements</li> <li>▪ No change management</li> </ul>	<ul style="list-style-type: none"> <li>▪ No traceability oversight</li> <li>▪ Potential negative public reaction during recall events</li> <li>▪ Traceability variation in multiple independent systems</li> <li>▪ Uncoordinated response to traceability incidents</li> <li>▪ No common coding or labeling</li> <li>▪ Non responsive to community direction</li> </ul>

**TISSUE EXPERT COMMITTEE:  
HOW CAN THE SYSTEM ENSURE THE  
TRACEABILITY OF TISSUE PRODUCTS?**

Transplant Establishment Status Quo	<ul style="list-style-type: none"> <li>▪ Few resource requirements</li> <li>▪ Little change management</li> </ul>	<ul style="list-style-type: none"> <li>▪ Uncoordinated response to traceability incidents</li> <li>▪ Potential negative public reaction during recall events</li> <li>▪ Inconsistent traceability oversight and accountability in transplant establishments</li> <li>▪ Traceability variance in multiple independent systems</li> <li>▪ Patients may be unaware of their tissue implant</li> </ul>
<b>Barriers to implementation</b>		
<ul style="list-style-type: none"> <li>▪ Compliance Management</li> </ul>		

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

**b) Coordinated Source and Transplant Establishment Traceability Systems**

This case refers to the development of integrated information systems to support traceability functions of 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.

In this option, traceability would be audited at the source and transplant establishments. For the transplant sector, particularly the dental establishments, a new auditing solution would need to be developed.

**TISSUE EXPERT COMMITTEE:  
HOW CAN THE SYSTEM ENSURE THE  
TRACEABILITY OF TISSUE PRODUCTS?**

	<b>Strengths</b>	<b>Weaknesses</b>
Coordinated Source Establishments	<ul style="list-style-type: none"> <li>▪ Adequate traceability to the transplant establishment</li> <li>▪ Increased traceability response through centralized information system</li> <li>▪ Common coding and labeling</li> <li>▪ Tissue community support</li> <li>▪ Facilitates audit processes</li> <li>▪ A national approach</li> </ul>	<ul style="list-style-type: none"> <li>▪ Resource requirements</li> <li>▪ Does not address traceability of foreign sourced tissue</li> </ul>
Coordinated Transplant Establishments	<ul style="list-style-type: none"> <li>▪ Control over traceability to the recipient</li> <li>▪ Traceability of all products including imported</li> <li>▪ Facilitates audit processes</li> <li>▪ A national approach</li> </ul>	<ul style="list-style-type: none"> <li>▪ Resource requirements</li> <li>▪ Multiple stakeholders</li> <li>▪ Potential duplication in relation to US TSN</li> </ul>
<b>Barriers to implementation</b>		
<ul style="list-style-type: none"> <li>• Support and participation of all eye and tissue banks would be required</li> <li>• Change management – this solution would impact many individuals at many establishments</li> <li>• Compliance management – this solution would require new approach(es) to auditing at the transplant layer</li> </ul>		

<b>Critical Mechanisms</b>	<b>Coordinated Source Establishments</b>	<b>Coordinated Transplant Establishments</b>
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

**c) Coordinated Source / Status Quo Transplant Establishment Traceability Systems**

This case is a “hybrid” approach in which traceability systems at Canadian source establishments reflect the changes in “Option B” but traceability at the transplant establishment level remains in the status quo.

## TISSUE EXPERT COMMITTEE: HOW CAN THE SYSTEM ENSURE THE TRACEABILITY OF TISSUE PRODUCTS?

This option is intended to illustrate how different combinations of mechanisms at source and transplant establishments can be combined into a single solution.

	Strengths	Weaknesses
Coordinated Source Establishments	<ul style="list-style-type: none"> <li>Adequate traceability to the transplant establishment</li> <li>Increased traceability response through centralized information system</li> <li>Common coding and labeling</li> <li>Tissue community support</li> <li>Facilitates audit processes</li> <li>A national approach</li> </ul>	<ul style="list-style-type: none"> <li>Resource requirements</li> <li>Does not address traceability of foreign sourced tissue</li> </ul>
Transplant Establishment Status Quo	<ul style="list-style-type: none"> <li>Few resource requirements</li> <li>Little change management</li> </ul>	<ul style="list-style-type: none"> <li>May lose benefits of coordinated traceability at source establishments</li> <li>Uncoordinated response to traceability incidents</li> <li>Potential negative public reaction during recall events</li> <li>Inconsistent traceability oversight and accountability in transplant establishments</li> <li>Traceability variance in multiple independent systems</li> <li>Patients may be unaware of their tissue implant</li> </ul>
<b>Barriers to implementation</b>		
<ul style="list-style-type: none"> <li>Support and participation of all eye and tissue banks would be required</li> <li>Change management – this solution would impact many individuals at many establishments</li> </ul>		

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

## II. What are strategies to support traceability critical mechanisms?

The purpose of the table below is to support the solution discussions in two ways: by supporting discussion of which mechanisms are most critical to traceability and by providing example strategies of how these mechanisms could be implemented.

Critical Mechanisms	Strategies
Common coding and labeling	<ul style="list-style-type: none"> <li>▪ Implementation of a common coding a labeling system in all banks</li> <li>▪ A unique product identifier generated via existing banks codes</li> </ul>
Integrated information systems	<ul style="list-style-type: none"> <li>▪ Implementation of a common inventory distribution and traceability system in all banks</li> <li>▪ Development of common system populated remotely by individual banks</li> <li>▪ Collaboration with the US Transplantation Transmission Sentinel Network</li> </ul>
Informed consent processes	<ul style="list-style-type: none"> <li>▪ Amendment of standards and regulations to include this requirement</li> <li>▪ Inclusion of requirement within Accreditation Canada requirements</li> </ul>
Transplant establishment oversight and accountability	<ul style="list-style-type: none"> <li>▪ Amendment of standards and regulations to include this requirement</li> <li>▪ Inclusion of requirement within Accreditation Canada requirements</li> <li>▪ Consideration of transfusion services role in oversight</li> </ul>
Audit processes	<ul style="list-style-type: none"> <li>▪ Within centralization internal audits from governing organization</li> <li>▪ Health Canada</li> <li>▪ Accreditation Canada</li> </ul>

## 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; hospital versus dental.
- There can be different strategies for different tissue grafts in relation to risk of disease transmission; frozen versus processed lyophilized products.

**TISSUE EXPERT COMMITTEE:  
HOW CAN THE SYSTEM ENSURE THE  
TRACEABILITY OF TISSUE PRODUCTS?**

- Options may be evaluated according to their practicality, sustainability, achievability, and the availability of strategies to overcome implementation barriers, among other criteria.

# APPENDIX A

Company/ Product	Year	Description
Tutoplast Dura	2002	<ul style="list-style-type: none"> <li>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.</li> <li>In 2003, a case of classical CJD was confirmed in a Canadian patient who received a graft in 1992.</li> </ul>
Cryolife, Inc. (U.S.)	2002	<ul style="list-style-type: none"> <li>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 having been 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.</li> </ul>
B.C. Ear Bank	2003	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul>
Biomedical Tissue Services Limited (BTS) (U.S.)	2005	<ul style="list-style-type: none"> <li>In October of 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.</li> <li>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.</li> </ul>
Donor Referral Services (DRS) (U.S.)	2006	<ul style="list-style-type: none"> <li>In 2006 DRS, located in Raleigh, NC, 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.</li> <li>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.</li> </ul>

# APPENDIX B

## Model Strengths-Weaknesses-Opportunities Analysis

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

	<b>Status Quo</b>	<b>Model 1</b>	<b>Model 2</b>	<b>Model 3</b>
<b>Description</b>	Decentralized Uncoordinated	Centralized Sole Distributor	Centralized Multi Distributor	Decentralized Coordinated
<b>Strengths</b>	<ul style="list-style-type: none"> <li>▪ No additional resources</li> <li>▪ No change management</li> </ul>	<ul style="list-style-type: none"> <li>▪ Traceability of entire source and imported inventory</li> <li>▪ Transplant establishment traceability compliance more easily managed</li> <li>▪ Common coding and labeling</li> <li>▪ Single traceability system and processes</li> <li>▪ Enhanced audit ability</li> </ul>	<ul style="list-style-type: none"> <li>▪ Traceability of domestically sourced inventory</li> <li>▪ Integrated systems and processes for domestic products</li> <li>▪ Enhanced audit ability</li> </ul>	<ul style="list-style-type: none"> <li>▪ Traceability of entire source inventory</li> <li>▪ Traceability of all Transplant establishments</li> <li>▪ Single system identifier</li> <li>▪ Integrated system and processes</li> </ul>
<b>Weaknesses</b>	<ul style="list-style-type: none"> <li>▪ Traceability risk</li> <li>▪ No common coding and labeling</li> <li>▪ Multiple independent traceability systems</li> <li>▪ Current audit processes</li> <li>▪ No requirement for informed consent</li> </ul>	<ul style="list-style-type: none"> <li>▪ Complexity</li> <li>▪ Does not assure informed consent</li> </ul>	<ul style="list-style-type: none"> <li>▪ No common coding or labeling</li> <li>▪ Traceability of import source inventory not assured</li> <li>▪ Does not assure informed consent</li> </ul>	<ul style="list-style-type: none"> <li>▪ Complexity</li> <li>▪ The U.S.- based international Sentinel network may duplicate national processes</li> <li>▪ Does not assure informed consent</li> <li>▪ Audit processes</li> </ul>
<b>Opportunity</b>	<ul style="list-style-type: none"> <li>▪ No improvement opportunities in status quo</li> </ul>	<ul style="list-style-type: none"> <li>▪ Enhanced traceability, especially at source establishments</li> </ul>	<ul style="list-style-type: none"> <li>▪ Enhanced traceability – complete for domestic inventory</li> </ul>	<ul style="list-style-type: none"> <li>▪ End-to-end traceability</li> </ul>