

**Organ and Tissue Donation and Transplantation  
Tissue Expert Committee Meeting  
October 29, 2009  
Sheraton Gateway Hotel, Toronto**

**Minutes**

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**Attendees:**

Dr. Locksley McGann (Chair)	Dr. David Howarth
Mr. Mike Bentley	Mr. Dermot Kelly
Dr. Brian Berry	Mr. Sean Margueratt
Mr. Scott Brubaker	Mr. Christopher Snow
Ms. Mary Gatien	Ms. Janet MacLean
Dr. Michael Gross	

**Regrets:**

Dr. Frank Hohn	Dr. Hassan Moghadam
Dr. Sarvesh Logsetty	Dr. Jutta Preiksaitis

**Canadian Blood Services Observers:**

Ms. Sophie de Villers, Vice-President, Strategy Management  
Dr. Christian Choquet, Vice President, Quality and Regulatory Affairs  
Ms. Kimberly Young, Executive Director, Organs and Tissues  
Mr. David Howe, Executive Director, Product and Hospital Services  
Ms. Lorna Tessier, Director, Public Relations  
Mr. Mathias Haun, Director, Plasma Products and Services  
Mr. Jim Mohr, Senior Program Advisor, Tissues  
Ms. PJ Vankoughnett-Olson, Senior Manager, Organs and Tissues

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**1. Welcome and Administrative Items**

- Locksley McGann welcomed the Committee Members and reviewed the meeting objectives and agenda for the day.
- Minutes from the Committee's June 30, 2009 meeting were approved.
- It was noted that the number of eye banks in Canada is incorrect in the Case for Change. The document will be revised accordingly.

**2. Review of Preliminary OTDT System Principles**

Sophie de Villers provided a summary of the discussions from the OTDT Steering Committee on principles to guide the design and development of the national system. She

indicated that the Steering Committee had not completed their deliberations, but their preliminary discussions focused on the following areas:

- **Safety:** Safety has to be a driver for system design but it is important that the scope be broad. While risk can be reduced to as low as reasonably achievable, zero-risk is not possible. A risk based approach can be used to balance safety benefit and cost.
- **Privacy:** Individual privacy should be protected but should not be a barrier to collaboration and development of Canadian, inter-provincial systems, especially registries. The consideration of the Steering Committee is that privacy should not be a barrier to collaboration and exchange of information in the system.
- **Equity/Fairness/Access/Utility:** Access should encompass both opportunity to donate as well as access to transplantations. There was extensive debate at the Steering Committee on what equity means across provincial boundaries. The majority of the Committee agreed that the system should strive for equitable access for all Canadians, recognizing that geography and need may impact allocation, and recognizing that a national donation strategy needs to be in place to ensure that all regions are equal contributors for organs.
- **Adequacy:** The Steering Committee recognized that while fulfilling 100% of the organ demand was not possible, the tissue system should be capable of meeting all needs for Canadian patients. It will be important to understand the capacity of the system.
- **System Efficiency and Effectiveness:** Given the economic situation, the system should optimize resources and outcomes to be as efficient and effective as possible.

There were several principles that required further deliberations by the Steering Committee, including collaborative approach and interdependencies, accountability, transparency, and autonomy of individuals. The Committee also noted that gaps in legislation should not impede the development of the system or the inclusion of a principle.

The Tissue Expert Committee noted some points for the Steering Committee's consideration:

- It will be important to define collaboration and what it means with such a complex group of players
- Integration should be a prominent principle
- Innovation is important and should be added to the principles

### 3. Overview of Canadian Blood Services programs

David Howe provided an overview of Canadian Blood Services programs including a comparison between Canadian Blood Services programs and tissue systems to understand areas of commonality. He reviewed the governance and system structures of Canadian Blood Services including the supply chain and supporting infrastructure.

There was some discussion in areas that Canadian Blood Services experience and infrastructure may be applicable to tissues including implementation of ISBT 128 labelling, centralization of a contact centre and management of a national inventory.

### 4. Review of Tissue Survey

Kimberly Young provided an overview of the preliminary results of the recent tissue survey. The scope of the survey included an environmental scan of national tissue programs to

understand the current supply of tissues and existing infrastructure; a review of current data on the demand for allograft tissues within Canadian hospitals including the number imported from the United States and; an environmental scan of international programs to understand options for a national framework. Kim asked the Committee Members for input on where to find additional data and some other areas for further investigation were suggested:

- There is a need to better understand what is happening in the United States
- Reporting on the systems that are working well would provide useful insight
- Add performance and efficiencies
- The committee would like more information on the funding/costing
- Further information on missed referrals and where they are missed may be useful
- There has to be a universality of financial support of the tissue system

Further work is being done and additional information will be communicated to the Committee as it is available.

## 5. Introduction to Design Discussions

Sophie de Villers began the presentation by reminding Committee Members of the OTDT system design process. The first phase involved identifying what needed to be fixed and documenting this through the Case for Change. Phase 2 involves exploring the critical issues and discussing options to solve the problems. The four background papers provided to the Committee outline options for discussion at today's meeting. The next phases involve development of measures and targets and look at implementation approaches.

## 6. Design Discussions

The Committee then worked in breakout groups to discuss the following questions:

- How can the Canadian tissues system best ensure consistent safety and quality?
- What is the best strategy to achieve the regulatory requirements for traceability?
- For recovery and processing, what is the best balance between domestic and imported tissue?
- How can the system best ensure that supply is aligned with demand?

### **How can the Canadian tissues system best ensure consistent safety and quality?**

Options Discussed:

- Solutions for source establishments
  - National standardized quality program
  - Centrally supported, independently operated quality programs
- Solutions for transplant establishments
  - Update Accreditation Canada standards

Preferred Options:

- There is support for a nationally standardized quality program at source although “quality program” needs to be defined
- Acknowledgement that a standardized quality program could have some customization at the regional/local level.
  - requires rationale to address the gaps in quality and safety

- economy of scale that can be achieved would lower the cost of quality
- quality would ensure equitability across Canada
- Further research is required on transplant establishments and where boundaries exist with current standards
- There is support for a national quality system for transplant establishments

**What is the best strategy to achieve the regulatory requirements for traceability?**

Options discussed:

- Solutions for source and transplant establishments
  - Common coding and labeling system
  - Information standards and sharing
  - Single, integrated information platform
  - Informed consent
  - Audit and accountability

Preferred Options:

- It was agreed that traceability is an essential aspect of the system and that status quo is not an option
- There is a need to have accountability and audit for traceability which should also cover imported tissues
- Recommendation for standardized packaging and labelling including coding, ISBT 128, unique donor numbers, real time integrated information system which will allow for urgent issues and lookbacks as part of a centralized facility
- An information platform is needed that would hold different data including donor, recipient, medical devices and tissues
- Need standard guidelines for the information a recipient receives (informed consent) but flexibility in how the information is given.
- Accreditation and audit should be a requirement
- Centralized distribution would allow cost savings through bulk buying - a centralized facility would help
- A call centre that would support tissue donation would improve access to potential tissue donors

**For recovery and processing, what is the best balance between domestic and imported tissue?**

Options discussed:

- 100% domestic self-sufficiency of donation and processing
- 100% importation of product and processing
- 100% domestic self-sufficiency of donation; processing in Canada and US

Preferred Options:

- Tissue is a national resource, donation is not a right but there is a need to look at principles of access
- 100% importation is not a valid option
- Recommend a combination of dependence on both Canadian and American donor source and processing
- Security of supply of donation can be approached separately from security of supply of processing
  - Both elements should target a mix of domestic and imported
- Innovation will be critical to prepare for the future although more discussion is needed
- Security of supply management will have to be responsive to external stimuli, including economic changes and changes in demand and supply

### **How can the system best ensure that supply is aligned with demand?**

#### Options Discussed:

- National or Provincial approaches to:
  - End User Relationship Management
  - Demand Forecasting
  - Production Flexibility
  - Inventory Management

#### Preferred options:

- There should be the capacity/motivation for a Canadian supply side to take advantage of innovation and new technologies that would grow out of the demand in Canada.
- Although supply and demand are different, a nationally organized program with regional or provincial hubs is recommended
  - supply could be regionally based to take advantage of efficiencies
- End user relationship management is important to align supply with demand
  - There has to be an intimate relationship with the users both from demand and supply point of view. This could be at a national/regional level or the individual user level.
- Appropriate medical utilization management needs to be part of the strategy, this will be important to securing funder support
- Demand forecasting should be driven by the end-user relationship strategy and technology

### **7. Review of Design Discussions**

The group reviewed the outcomes from the design discussions. There was agreement that the summary report was reflective of the discussions. Additional suggestions were noted:

- It is important that we capitalize on what is in existence already
- Registration of intent to donate needs more discussion although it was recognized that the Organ Expert Committee is looking at this

- It is a shift to move to a business model, there was a lot of discussion about a manufacturing facility
- We need to consider the actual costs of the programs and identify any potential savings

#### **8. Wrap Up and Next Steps**

- Locksley provided some information on the upcoming International Speakers conference calls. Dates will be provided when finalized and members were encouraged to participate in calls. He also noted that the first Public Dialogue took place in London on October 24, 2009.
  - It was noted that there is only one Public Dialogue planned in Atlantic Canada, in Halifax. Sophie explained that Canadian Blood Services is looking at other options to engage the public who are unable to attend the dialogues because of geography.
- Canadian Blood Services will begin working on follow up items from the design discussions in preparation for the next meeting.
- Canadian Blood Services will prepare material (briefing notes, presentations, etc) that can be used by Committee members to inform their colleagues about Committee activities. Canadian Blood Services will also plan further outreach to groups such as The Canadian Society of Transplantation.
- It was noted that the background documents were very helpful in preparing for the meeting

Draft minutes will be circulated by Nov. 19<sup>th</sup>. Next in person meeting is January 13/10. Some conference calls will also be arranged.

#### **9. Meeting Adjournment**

Locksley thanked the Committee Members for their participation in the meeting. The next meeting will be held on January 13, 2010.