

**Organ and Tissue Donation and Transplantation  
Tissue Expert Committee Meeting  
November 15th, 2010  
Hilton Garden Inn, Ottawa Airport  
Minutes**

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**Attendees:**

Dr. Locksley McGann (Chair)	Dr. Michael Gross
Mr. Mike Bentley	Dr. Frank Hohn
Dr. Brian Berry	Mr. Sean Margueratt
Mr. Scott Brubaker	Dr. Jutta Preiksaitis
Ms. Mary Gatien	

**Regrets:**

Dr. Hassan Moghadam  
Mr. Dermot Kelly  
Dr. David Howarth  
Dr. Sarvesh Logsetty  
Mr. Christopher Snow  
Ms. Janet MacLean

**Canadian Blood Services Observers:**

Dr. Christian Choquet, Vice President, Quality and Regulatory Affairs  
Mr. Mathias Haun, Director, Strategic Planning (Tissues)  
Mr. Jim Mohr, Senior Program Advisor, Tissues  
Ms. Christina Parsons, Program Manager, Tissues  
Mr. Paul Derksen, Program Manager, Tissues  
Ms. Lorna Tessier, Director, Public Relations

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**1. Welcome and Opening Remarks**

Graham welcomed the members of all three OTDT committees to today's joint committee meeting. He thanked the participants for their efforts, and noted that he would be presenting the preliminary recommendations to the federal/provincial/territorial Deputy Ministers of Health at their December 9, 2011 meeting. Graham also indicated that while this was the last formal meeting of the committees, Canadian Blood Services would continue working with many of them.

**2. Context and Objectives for the Meeting**

Graham then presented the agenda for the day. He noted that the meeting would focus on reviewing and endorsing the system strategy and design, and discussing remaining challenges and implementation options. He also provided an update on the activities since the June meetings. In addition to advancing the work on system strategy and system design, there were several meetings with expert stakeholders, the patient partner groups, and government officials, to inform and seek input. He indicated that there would be continued consultation throughout the winter with the OTDT community to help finalize the recommendations. These would then be submitted to the Deputy Ministers in the spring of 2011, followed up with another meeting in June 2011 to receive

the decision of the Deputy Ministers. The participants then adjourned to their individual committee sessions.

### **3. System Strategy – Strategy Map**

Locksley welcomed the Tissue Expert Committee Members and reviewed the meeting objectives and agenda for the day. Mathias reviewed the strategy map and outlined the adjustments that were made based on input from the committee. There was some discussion on the need to be able to assess effectiveness of allografts or to track transplant outcomes. It was determined that the wording of objective P8 would be adjusted to address this concern. There was agreement that systems to collect data would need to be in place prior to being able to assess effectiveness or track outcomes. End-users would be an integral part of determining effectiveness by providing data and conducting analysis.

### **4. System Strategy – Measures**

Jim Mohr provided an overview of the draft key measures and targets. Due to the lack of data availability, it is not feasible to set targets for all measures at this time. Targets have been chosen for specific tissue types base on large gaps between supply and demand or the need for emergency planning. The following feedback was provided:

- Increase the target for tendon allografts and overall production. The suggestion was to increase the current production by 100%.
- Add a new measure related to the processing of advanced tissue products. It was suggested that Demineralized Bone Matrix (DBM) products could be produced with the target of providing 10% of the DBM market demand in Year 5. It is understood that the forward looking system would examine opportunities to expand tissue production on an on-going basis; this measure is a draft measure and would require further refinement.
- There was some discussion about the development of clinical guidelines to support appropriate utilization of allografts. It was noted that it is hard to develop this type of guideline and that it would have to be done carefully. This type of effort would be related to the use of more advanced products and would not be as applicable to the tissue allografts currently produced domestically. The measure regarding hospital's requirement to have surveillance and traceability procedures in place will be expanded to encompass ensuring proper utilization of tissues and tracking clinical outcomes.
- Suggestion was made to partner with Health Canada to ensure a unified approach to tissue traceability and surveillance.

### **5. System Design – Recap and Checkpoint**

Mathias provided a summary of the system design work to date and the design recommendations. It was suggested that a recipient registry for tissue should also be examined. It was noted that this specific element was not previously highlighted and that there were some barriers to this type of system (e.g., issues with privacy and provincial data sharing). This is an additional option that could be considered to improve traceability as well as supply planning. To make a registry of this type useful, compliance would need to be 100%.

### **6. System Design – Processing Rationalization**

Comments included:

- To ensure that a geographic location is not inferred, the term rationalization should be used instead of centralization.

- For eye banks, the time requirements related to tissue expiry and specific transport issues (e.g., damage with transportation) should be considered. One member suggested that one eye bank per province is reasonable however, this results in a status quo approach with no rationalization.
  - An understanding of how CBS manages transport of platelets would be helpful
  - An understanding of the US Vision Share and Sightlife model, where corneas are routinely distributed over great distances, would be helpful
- Processing could occur regionally, focused around ocular transplant centres.
- The number of centres should be minimized but based on the ability to meet defined quality requirements.
- For this type of decision making, all the facts are required including costs and an assessment of all the other variables.
  - Factors and variables include: banks preparedness / ability to respond to production targets, tissue storage conditions, tissue timing requirements, logistical infrastructure, equipment requirements/access to equipment (e.g., some equipment can be shared with ophthalmologists), security of supply and risk management, expertise of staff and the ability of staff to maintain competency, donation legislation.
- Cost effectiveness is important but there is a need to ensure the appropriate redundancies are in place.
- The redundancies required for the tissue system may be minimal if the appropriate linkages with Hema-Quebec and US tissue banks are developed.
- The separation of recovery and processing activities may be helpful in planning. i.e., there would be a smaller number of processing sites but recovery activities could occur in various locations that do not process tissue.
- The trend of amalgamation of Canadian Eye Banks within Tissue programs was identified. Within the US model ocular and tissue remain distinct. No rationale for this separation was identified other than the historical evolution of programs.
- Determine location of recovery based on population.
- The difficulties regarding bringing recovery team into area where they don't normally work was highlighted. Don't remove working recovery agencies from areas. Look toward local recovery for ocular and regionalized recovery for tissue.

## 7. System Implementation

Committee members were asked to provide input on the risks and benefits to the different implementation scenarios being considered. The following is a summary of the discussions:

### Scenario 1 – Early Engagement

Benefits	Barriers to Implementation	Risks – Impact to allograft supply or quality
-Builds on existing system and uses existing processors -Less politically charged -Some changes are made in a timely manner to improve the system - Increases capacity and quality	-The move from regional or provincial supply systems to an inter-provincial inventory may be challenging -There will be political issues in specific regions (e.g., selection of suppliers)	-Suppliers cannot not meet the established standards (e.g., quality, process or product specifications) - May build more capacity than you need - Increase cost per unit with more variability in quality

quickly	- Interested processors may not have the capacity	- May be insufficient time to plan
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**Scenario 2 – Late Engagement**

Benefits	Barriers to Implementation	Risks – Impact to allograft supply or quality
<ul style="list-style-type: none"> <li>-Minimizes the risk of making a mistake</li> <li>- Costs for change are back-end loaded</li> <li>- Status quo; don't upset any parties</li> </ul>	<ul style="list-style-type: none"> <li>- Limited ability to impact change</li> </ul>	<ul style="list-style-type: none"> <li>-No obvious early wins</li> <li>-Lose inertia with the tissue community</li> <li>- Existing infrastructure under utilized</li> <li>- 5 year targets not likely to be met</li> <li>- May be more expensive</li> <li>- May not be funds available for required changes in future</li> </ul>

**Scenario 3 – Rapid Integration**

Benefits	Barriers to Implementation	Risks – Impact to allograft supply or quality
<ul style="list-style-type: none"> <li>-Moves quickly. Bigger changes earlier</li> <li>- Continues current momentum with community</li> <li>- Potential for quicker cost savings</li> <li>- Start with the end goal</li> <li>- Security of investment</li> <li>- Operational efficiencies immediately</li> <li>- Ability to leverage existing CBS infrastructure</li> </ul>	<ul style="list-style-type: none"> <li>-Political issues</li> <li>- Time required to establish system, build infrastructure and capacity</li> <li>- Complexity of change occurring all at once</li> <li>- Require a transition team</li> <li>- Funding and mandate would need to be transferred to CBS</li> </ul>	<ul style="list-style-type: none"> <li>-The planning process for this transition would be treacherous</li> <li>-Risk of losing staff and not being able to maintain the staff expertise</li> <li>- The complexity of the change may delay gains</li> <li>- Reputational risk for CBS</li> <li>- Due to size of change, security of supply could be impacted</li> </ul>

**8. Tissue Expert Committee Wrap-Up**

Locksley thanked the committee members for their contributions to the work over the past year. An update regarding the meeting with the Conference of Deputy Ministers will be sent to all members shortly after December 9, 2010. The group then rejoined the rest of the committees for the closing plenary session.

**9. Synthesis and Next Steps (Plenary)**

Graham welcomed members back to the plenary. Peter and Locksley presented the organ and tissue system strategy respectively, summarizing the system strategy and design, and identified the gaps that still needed to be worked on.

Graham then provided a summary of the steering committee discussions. They focused on governance, discussing challenges and potential solutions in dealing with the provincial governments, and the best way to position the plan for the F/P/T governments. He noted that there was agreement with OEC in emphasizing mandatory data reporting, transparency and reporting of non-compliance as effective accountability mechanisms.

Graham reviewed next steps. The meeting on the December 9 with the Deputy Ministers of Health was to present the preliminary recommendations. The Deputy Minister would then receive final recommendations with costing and implementation options in the spring of 2011. He told the group that Canadian Blood Services would send committee members the material going to the DM meeting before the meeting. Graham closed the meeting by once again thanking them for their contribution and giving a commitment to keep them informed of the progress with the DMs and the final documents.

**Addendum: Notes from December 8, 2010 Teleconference - Follow-up to November 15<sup>th</sup> Tissue Expert Committee meeting**

**Tissue Expert Committee Attendees:**

Dermot Kelly, Christopher Snow, Hassan Moghadam, Locksley McGann

**Canadian Blood Services Attendees:**

Christina Parsons, Paul Derksen, Jim Mohr, Mathias Haun

*TEC members who were unable to attend the November 15 meeting in Ottawa were invited to a one-hour conference call at 4:30 pm EST on December 8, 2010 to provide their feedback on the strategy map, measures and targets, consolidation, and implementation options.*

**Summary of Discussion:**

**A. Revisions to Strategy Map**

No concerns were raised.

**B. Key Measures and Targets**

The key measures and targets seem conservative for multi tissue and ocular donors. It seems like a long period of time to be able to get to this level of production. US processors currently get 50 allografts per donor.

Within 5 years, the national demand for corneas should be met. It was noted that the exact demand for corneas is unknown due to the number of patients on waitlists but the goal would be to meet demand for all types of corneal surgeries (PK and EK). Everyone should have access to EK tissue.

These targets are achievable but we should expect more out of the system. It was noted that large American procurement programs and processors have significant operational expertise, processing sophistication and infrastructure and could provide valued insight and knowledge to the development of the Canadian system.

It was noted that targets can be revised as the system develops.

**C. Tissue Recovery and Processing Centralization**

If the intent is to offer donation to Canadians in various regions across Canada the system would need to have recovery teams or programs located in the regions. In the development of an integrated system we need to ensure that existing procurement relationships and activities are not adversely affected.

With respect to the recovery target for multi-tissue donors, it is an extremely low number when compared to the capacity of large processors in the United States. In assessing rationalization of processing activity one should consider volume of activity. The Canadian processing targets (number of donors) are extremely low when compared to the banks in the United States. A single facility would be suitable to process the targeted numbers for the Canadian system and would still be under capacity. With the small number of donors, it is a pretty expensive approach to the system and the cost per allograft would be high.

It was noted that given the advanced US infrastructure and sophistication processing partnerships should be considered within the options for a Canadian system.

It would be important not to rely on just one facility or one country. For example, if there was ever an issue with transporting unprocessed tissue over the US- Canada border there would need to be an alternate option for meeting Canadian needs.

From an oral and maxillofacial surgical perspective, it was noted that it would be good to have one or two processing centres to provide Canadian products to end users for consistency in product and assist with traceability.

With eye banking, one variable is the recovery method. If whole eyes are recovered, there is a 12-16 hour window for processing. However, if corneas are recovered, the constraints associated with whole eye recovery are removed.

The evolution of advanced corneal processing has rapidly changed demand with the majority of corneal demand moving to these split thickness grafts. Demand will continue to change with the evolution of new procedures such as DMAEK. With the need for advanced corneal processing it was recommended to develop regional processing centres. It was suggested that three programs could be adequate to meet the needs for advanced processing techniques: western, central and east. The issues with smaller eye banks are that there is no funding for equipment and it is difficult to maintain competency of staff with small numbers of donors.

#### **D. System Implementation Scenarios**

Scenario 3 would be a good option if Canadian Blood Services had a track record in tissue banking. If you were partnering with larger US processors it may be a viable option. Otherwise, a combination of Scenario 1 and 2 may be appropriate and work to increase recovery capacity in certain areas. It is important to demonstrate cost effectiveness and to capitalize on what is working in Canada in the development of a more integrated system.

There is a staffing risk with Scenario 3 which could negatively impact donation and production numbers. A combination of Scenario 1 and 2 could be used but be implemented faster with higher targets. It would be important to keep the momentum going and not be something that is long and drawn out.

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Another option presented would be to pilot a rapid implementation approach. The risk with this approach is that Canadian Blood Services may lose credibility if the pilot does not prove to be successful.

**Call ended at 5:30 pm EST.**