

**Organ and Tissue Donation and Transplantation  
Tissue Expert Committee Meeting  
January 13, 2010  
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	Dr. Hassan Moghadam
Ms. Mary Gatien	Dr. Jutta Preiksaitis
Dr. Michael Gross	Mr. Christopher Snow
Dr. Frank Hohn	Ms. Janet MacLean

**Regrets:**

Dr. Sarvesh Logsetty

**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. Mathias Haun, Director, Strategic Planning (Tissues)  
Ms. Sylvia Torrance, Director, Strategic Planning  
Mr. Jim Mohr, Senior Program Advisor, Tissues  
Ms. Tracy Brand, Director, Organs and Tissues

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**1. Presentation by Dr. John Kearney (Conference call)**

Locksley welcomed all the Committee members to the meeting. He then introduced Dr. John Kearney, the Lead Scientist and Head of Tissue Services from UK NHS Blood and Transplant. Dr. Kearney began his presentation by providing background on NHSBT Tissue Services. He then reviewed the organization and functions of the three Tissue Services departments: Operations, Clinical Development and Research and Development. Discussion followed the presentation, with Dr. Kearney answering questions from the Committee. Locksley and Graham both thanked Dr. Kearney for his presentation.

**2. Follow-Up on Action Items**

Locksley welcomed the Committee Members and reviewed the meeting objectives and agenda for the day. As follow-up on action items, Locksley informed the group that the results of the ocular survey will be sent to them shortly, and that the report on the comprehensive Canadian tissue survey will be available for the next meeting. The public draft case for change will also be sent to the Committee for review and comments.

**3. Review of Activity to Date**

Sophie reviewed the preferred options of the Committee developed at the previous meeting, along with the initial feedback received as a result of the public and expert stakeholder consultations. At the public dialogues in London and Vancouver, participants were presented with the case for change and then discussed principles and actions that should be taken to improve the OTDT system. At the expert consultation in Saskatchewan, participants discussed the case for change as well as the initial options preferred by the Committee. Generally, there was endorsement of the case for change and support for the preferred options presented. Specific suggestions and comments were given on specific topics. An analysis will be done as more input is obtained, and this will be presented to the Committee at a future meeting.

**4. Quality Systems Presentation**

At the previous meeting, the Committee endorsed the principle of national quality standards for the tissue system. In response to a request for further information, Dr. Christian Choquet, Vice-President of Quality Assurance and Regulatory Affairs at Canadian Blood Services, presented what is involved in implementing and maintaining a national quality system. Key messages included:

- Quality includes safety, as well as continuous improvement and customer satisfaction. Regulatory agencies only consider whether the manufacturer meets its claims and whether products are safe. They are not responsible for looking at customer satisfaction and continuous improvement.
- The national system will need to define the appropriate level of standardization/customization. It was noted that the more centralized an organization is, the easier it is to standardize.
- Audit was only one tool in determining whether quality requirements are met.
- System wide quality indicators are built into the Canadian Blood Services' Balanced Scorecard and are reviewed quarterly.
- Economies of scale (staff for example) can be achieved to a certain extent with centralization; however, a base level is still required to conduct quality activities.
- Reporting requirements for cells, tissue and organs are complicated and unclear, there are many relationships with many organizations to manage, and there are multiple points of contact even with Health Canada.
- Reporting is a small part of surveillance. Canadian Blood Services has additional activities such as monitoring emerging pathogens to support this.

Given the challenges of implementing a comprehensive quality program, especially in a hospital environment, the group discussed the potential to use Canadian Blood Services' quality infrastructure to support tissue banks and felt this could be a viable option.

**5. Increasing Tissue Donation**

Mathias provided a summary of the information from the paper that had been sent to Committee members (*"How can tissue donation be increased in Canada?"*). The Committee then divided into breakout groups to discuss the issues of improving donor

## Tissue Expert Committee January 13, 2010 Meeting Minutes

identification and referral, family consent rate, and tissue recovery. The Committee came to the following conclusions:

### ***Identification and Referral:***

- The most viable tissue donors are external to the intensive care unit environment. Donor identification and referral initiatives should reflect this.
- Tissue donors should be identified and referred both from hospitals and from medical examiner/coroner offices outside the hospital, to increase the pool of potential tissue donors.
- Support is needed for medical examiners and coroners, to help them become part of the tissue donation system.
- Front-line hospital staff can play a key role in identifying potential donors.
- Referrals should be made to a central call centre.
- All provinces should have mandatory donor referral legislation.
- There should be nationally standardized practices.

### ***Consent:***

- Professional, trained requestors who use proven processes/best practices should be used to obtain family consent for donation. Front-line health care workers who may be in contact with families often have little time or training or are uncomfortable about making the donation request. A separate requestor also counteracts any perception of conflict of interest.
- Trained, dedicated requestors should be available 24/7 to support donation. This can be achieved by providing the service by telephone, which has been shown to be as effective as in-person requesting. Phone requesting also allows for efficient initial screening and eligibility, and allows better targeting of who should be approached.
- Trained, dedicated requestors should also provide bereavement support to donor families and follow-up support.
- Trained, dedicated requestors who provide support for organ donation can also provide services for tissue donation and this synergy should be supported when possible.
- Intent/consent registries for potential donors should also be considered, in order to improve consent rates. The information regarding the donor's wishes on the registry should be available to the requestor.

### ***Tissue Recovery:***

- Tissue recovery should be done by trained recovery teams, focused geographically, and multiple tissues should be recovered. These recovery teams could include physicians.
- A standard Canadian training program should be developed for tissue recovery and processing. Currently, there is only in-house training which differs from tissue bank to tissue bank. While there is training through the AATB in the US, this is only classroom training and does not include hands-on training. EBAA does have a hands-on component, but this addresses only eye tissue.

## Tissue Expert Committee January 13, 2010 Meeting Minutes

- Tissue procurement must be linked to demand and must be efficient. Not all locations in Canada will have tissue recovery and some areas may be tissue specific (e.g. ocular tissue). Location and logistics will determine whether the donor is moved to a central recovery site, or whether recovery takes place in a hospital OR.

### 6. Canadian Production of Tissue Allografts

Mathias provided a summary of the information from the papers that had been sent to Committee members (“*What role should surgical bone have in the Canadian tissue system?*” and “*What is the role of Canadian allograft processing in the future?*”). The Committee then divided into breakout groups to discuss what tissue types Canada should recover and process, and what tissue types should be imported or sent to the US for processing. The Committee came to the following conclusions:

#### *Surgical Bone:*

- It is expected that bone products based on new technologies (strips, pastes, injectables) as well as increased cadaver yields will gradually replace surgical bone as the product of choice for surgeons, and that surgical bone banking will phase out over time.
- The national strategic plan should not focus on surgical bone banking. However, it was noted that where banks continue to exist, they will need to meet the required standards and regulations.
- One TEC member expressed the view that surgical bone is considered safer than deceased donor bone, however there was no consensus on this issue.

#### *Skin Tissue:*

- As with surgical bone, it is expected that products based on new technology will gradually replace use of skin. However, Canadian tissue banks should recover and process as much skin as surgeons demand.
- Fresh skin is considered the “gold standard” by surgeons, but requires coordination of recovery and surgery.
- A supply of skin should be kept in inventory as emergency stock, in case of a natural disaster or other catastrophe.
- We should also consider sending skin to the US for processing into advanced products, according to supply and demand.

#### *Ocular Tissue:*

- The current funding model is a barrier to sharing tissue inventory across provinces.
- Benchmark wait times need to be established for cornea transplant patients.
- Canada needs to build ocular processing capacity to support the increasing demand for advanced corneal grafts; specifically partial thickness grafts. Processing centres should be centralized to ensure competence and efficiencies. The number of sites needs to be determined based on the shelf-life for corneas and the need to ship within short time frames.

## **Tissue Expert Committee January 13, 2010 Meeting Minutes**

- Canada needs to increase cornea donation, especially in areas with low donation rates.
- Investigation is needed into how to improve accessibility to hospital ORs, where this is a limiting factor for performing cornea transplants.

### ***Cardiac Tissue:***

- The number of Canadian cardiac processing facilities (n=4) exceeds the US cardiac processing facilities (n=3). It is estimated that the 3 programs external to Quebec produce small volumes totalling less than 100 grafts annually. Depending on the exact number, consideration should be given to consolidating production, sending to the US for processing or eliminating collection and processing altogether.
- A significant portion of recovered valves go unutilized as the majority of demand is for the smallest valves (paediatric population). Awareness initiatives and procurement should be targeted to increase the recovery of pediatric hearts.

### ***Musculoskeletal Tissue:***

- Recovery and capacity for basic processing of MSK tissue should be expanded.
- A cost-benefit analysis should be conducted to determine whether advanced processing of MSK tissue should be performed in Canada.
- Centralization of processing of MSK tissue should be considered, to take advantage of potential economies of scale, with a national distribution system for MSK (and all tissue)
- Processing of MSK tissue would best be supported in a facility outside the hospital environment.

### ***Tendons and Soft Tissue:***

- Canada needs to increase recovery and production of tendons and soft tissues. These products are expensive for Canadian hospitals to import and they are often in short supply.
- Increased Canadian supply will allow patient need to be met, as well as allowing for clinical outcome studies and structural investigations to assess what practices and products work best.
- There is a need to increase processing capacity in Canada; however, depending on the amount of tissue recovered, processing some of this tissue in the US should be considered.

### ***Demineralized Bone Matrix and Machined Graft Products:***

- DBM and machined graft products could be produced in Canada, though a business case is needed to determine whether it is feasible from a financial point of view.

### ***General Comments:***

- There is a need to address issues of access to surgeons and hospital ORs where this is a limiting factor for transplantation.
- Centralized processing is needed, if cost-efficiency is to be achieved.

## **Tissue Expert Committee January 13, 2010 Meeting Minutes**

- Good Manufacturing Practices are best supported outside of the hospital healthcare delivery environment.
- Processing of some tissues by US processors is likely to be an ongoing requirement if advanced products are to be made from Canadian tissue.

### **7. Costing and Data Gaps**

Mathias introduced the presentation for costing to the Committee. A costing project was undertaken by Canadian Blood Services in order to understand current OTDT costs and funding. The project was needed to identify critical gaps in costing data, as well as to assist in the development of budgets for implementation of the strategic plan. Mathias introduced Mhezbin Dharssi who then went through the project methodology and assumptions. While data was provided for tissue donation and cornea transplantation, limitations of the data were reviewed. Discussion then took place on the data and potential next steps for the project.

Discussion and suggestions followed on what can be done to fill information gaps:

- Canadian Blood Services will hire a market research company to investigate and estimate amount of tissue imports.
- Surgeons will be surveyed on skin and cardiac usage and importation.
- Skin and soft tissue for dental are small volumes and won't be a priority for investigation.
- It was suggested that current or recent unit costing data be obtained from comprehensive tissue banks, if they were willing to share the data.
- R&D costs should be investigated.
- It was suggested that infrastructure costs could be calculated as a percentage of operating costs.

Work on costing will continue and further information will be presented at a future meeting.

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

Locksley asked the Committee whether they found the conference calls held between meetings useful, given the low attendance rate. There was a suggestion that updates could be distributed through a general e-mail.

Locksley informed the Committee that the meeting set for March would be moved to April 19 to allow time for input from the public and expert consultations and to prepare for the next meeting. An additional meeting is being scheduled for June 18.

Kim provided more information on the international speakers series, and noted that members from all the OTDT Committees were welcome to join. The next talk will be on January 20<sup>th</sup> with Dr. Luc Noel from the World Health Organization. Conversations will be taped and posted on the Committee website, so that members can listen to them at their convenience.

Locksley thanked the members for their attendance and adjourned the meeting.