

**Organ and Tissue Donation and Transplantation
Tissue Expert Committee Meeting
April 19, 2010
Sheraton Gateway Hotel, Toronto**

Minutes

Attendees:

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

Regrets:

Dr. Sarvesh Logsetty
Dr. Hassan Moghadam

Canadian Blood Services Observers:

Dr. Graham Sher, Chief Executive Officer
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. Lorna Tessier, Director, Public Affairs
Ms. PJ Vankoughnett-Olson, Senior Program Manager, Organs and Tissues
Mr. Paul Derksen, Program Manager, Tissues

1. Welcome and Follow-Up on Action Items

Locksley McGann welcomed the Committee Members and reviewed the meeting objectives and agenda for the day.

2. Kelvin Brockbank – President and Chief Science Officer, Cells & Tissue Systems

The presentation explored the evolution of the tissue industry and innovation in products and processes. Key items noted during the presentation included:

- The allogeneic tissue market is being impacted by new methods for allografts and new regenerative medicine technologies.

- Bone and demineralized bone matrix is already impacted with the introduction of Bone Morphogenic Proteins. These new products (recombinant BMPs) will revolutionize orthopaedics.
- Decellularization has major impact on skin and may have an impact on valves and vessels.
- In the opinion of the speaker, there are still significant opportunities for new allograft tissue processes for cartilages, vascular grafts and heart valves for specific segments of the heart valve market.

Key messages from the discussion following the presentation included:

- The overall time to get an advanced tissue product to market can be up to ten years with research and development work and the regulatory process.
- Government support has been an important enabler for Cell and Tissue Systems' work although they are also supported by commercial companies.
- It is not feasible to perform HLA typing or to provide patients with immunosuppressants for allografts where cells are present (e.g. heart valves). However, for older children and adults, the risk of immune response is not as significant.
- The speaker thought that the impact of xenografts on the market for allografts would be minimal. In general, he felt that the use of other materials is a larger threat. (e.g. more mouldable materials, composites, recombinant BMPs)
- There are currently cost barriers to development of regenerative medicine products (e.g. regulatory approval process). It was thought that these barriers will be overcome for musculoskeletal products as there is a large market and extensive efforts to bring these products to market. The cardiovascular and cartilage markets are smaller and the cost barriers will not be as easily overcome.
- It was noted that there may be multiple factors contributing to the current surplus of tissue in the US including the efficiency of donation processes. Regardless of the factors, stricter donor criteria will reduce the number of tissue donors but will improve the quality of allografts.

3. Review of Activity to Date

Sophie provided a summary of the activity to date. There was some discussion on the importance of clinical data and allograft utilization data to inform disease prevention strategies and how this was captured in the Case for Change. It was noted that disease prevention was outside the scope of the system design work. However, there will be a minor revision to the Case for Change to highlight that “within the current system, there are no mechanisms to understand utilization for demand forecasting or to inform health or disease prevention strategies”. The Case for Change was then endorsed by the committee.

Graham summarized the system principles that are the foundation for the system strategy and system design. There was some discussion on the exclusion of “innovation” from the list of system principles; however, the majority of the group agreed that while innovation was important to achieve the strategy, it was not an end in itself and should not be a

separate principle. It was noted that the Safety principle should be viewed as “Quality and Safety” based on the premise that quality includes safety as well as continuous improvement and customer satisfaction.

4. System Strategy

Mathias reviewed the strategy management tools as well as the draft destination and strategy map. The destination statement and strategy map were recognized by the committee as a good framework upon which to build. The discussion highlighted the following items:

- The strategy map is for the entire tissue system and is not a “Canadian Blood Services” strategy map.
- The roles and responsibilities of the organizations involved in specific processes are not defined at the strategy map level;
- The strategy map helps to focus measures, targets and initiatives. In reality, there are overlaps and linkages between the system processes (e.g. ensuring traceability is linked with the effective management of imports);
- While utilization management was an important consideration for the strategy map, it was felt to be necessary to first obtain comprehensive data on product use before analyzing utilization.

The following changes were recommended to the map:

- In the system process “Partner with industry and research to understand innovations in product and practice.”, the word “understand” could be changed to “leverage” to communicate that the appropriate action would be taken upon identification of innovative products or practices.
- The word “safe” was added to the system process: “Ensure safe and effective tissue product consistent with specifications”.

5. System Design

Mathias introduced the approach to developing the system design, through validating the system requirements and elements, and answering open questions. The TEC was provided with system requirements based on the committee’s earlier recommendation. Feedback from the public dialogues and expert engagement activities was also provided for reference for each topic.

The following feedback was provided on the system requirements that were provided.

Recovery and Inventory:

- “Recovery facilities” should be included as a component

Identification, Referral, Consent and Screening:

- The first two system requirements can be merged into one statement : “Establish a consistent approach for the identification and referral of potential living donors and deaths from hospitals and settings outside the hospital environment (e.g. ME and coroner offices).”

- The requirements for family support and bereavement support should be added.
- “Legal framework for consent/donation” should be included as a component.

Other:

- Testing laboratories should be added as a system design component to the appropriate section.

The following questions were discussed in breakout groups. The final recommendations and the level of consensus within the TEC are noted below.

a. What is the scope of a single, standardized quality program?

Final Recommendation:

A single, standardized quality program should ensure a single set of quality standards, product specifications, processes, and tools will be developed and consistently implemented by all processors and recovery organizations in Canada.

Rationale:

- Required for true national standardization.
- Increase the trust that the public and end-users will have in the system.
- If product or process improvements are made, the changes will benefit the entire system.
- Introduction of standardized processes will be cost effective (e.g. for the validation program - validation protocols can be standardized, design and evaluation of processes can be done once instead of multiple times using varied approaches).
- Aligns with public and expert feedback.

It was noted that the quality program would need to be responsive and allow for innovation and change.

Level of Consensus:

Ten TEC members indicated their support for the recommendation. There were no TEC members who indicated they did not support the recommendation.

b. Should there be centralized accountability and authority for ensuring a secure supply of tissue in Canada?

Final Recommendation:

There should be a central agency that has the authority to manage domestic processing and importation of tissue based on a formal supply plan. The central agency would be accountable to implement the supply plan. It was noted that the scope of the authority of the central agency included supply chain management from processing to distribution.

Rationale:

- Provides a framework for tissues to be managed as a shared resource and to address the wide variation in regional donation rates.

Level of Consensus:

Ten TEC members indicated their support for the recommendation. There were no TEC members who indicated they did not support the recommendation.

c. If there is a single, central supply planning agency, what is the relationship between supply planning and processing?

Final Recommendation:

The central supply planning agency should control all processing either by integration and/or by contractual agreements. A business case would be required to establish whether integrating or contracting processors would be more cost effective and to evaluate the impacts of each option (e.g. effect on security of supply).

Rationale:

- Integration of processing activities would provide more control however contracted processors may be able to meet the needs of the central supply planning agency and still be able to innovate.

Level of Consensus:

Ten TEC members indicated their support for the recommendation. There were no TEC members who indicated they did not support the recommendation.

d. What is the relationship between processors and recovery organizations?

Final Recommendation:

A single agency with national scope should operate a recovery organization. Some recovery work may be able to be contracted out to other organizations at the discretion of the central recovery agency.

Rationale:

- Control over supply with the ability to align recovery with demand.
- Consistent standards and quality.

It was noted that if the recovery organizations are accountable to the central planning agency, but processors are contracted by the central planning agency (vs. integrated) the overall accountability could be complicated.

Level of Consensus:

Nine TEC members indicated their support for the recommendation. There were no TEC members who indicated they did not support the recommendation.

e. What product is available from the single tissue inventory?

Final Recommendation:

All domestically produced and imported tissues and tissue products (including those classified as medical devices) should be available from a single tissue inventory and

subject to a central authority. This approach may need to be phased in with the goal of having all tissue and tissue products in the single inventory by 2016.

Rationale:

- Supports the principle of cost effectiveness: The bulk purchasing of imported products may provide cost savings.
- Supports the principle of fairness: Not all patients currently have access to products they need as the availability is sometimes subject to the budget constraints of the local hospital or the inventory of the local tissue bank.
- Supports the principle of accountability through review of the effectiveness of products, especially new products and technologies.
- Allows for better traceability;
- Increases assurance that products comply to current standards;
- Provides some control over suppliers and will improve security of supply and mitigate risk.

Level of Consensus:

Nine TEC members indicated their support for the recommendation. There were no TEC members who indicated they did not support the recommendation.

f. How should referral centre(s) be organized?

Final Recommendation:

There should be a single set of standards for referral, consent and screening. Ideally, a single agency with national scope should manage referral centre(s). However, the legislative barriers related to interprovincial sharing of health information would need to be assessed to understand the feasibility of a single agency managing the referral centre(s). Implementation may require maintenance of existing referral centres in the short term or long term depending on the results of the assessment. It is recognized that a phased in approach may be necessary to implement the recommendation.

Rationale:

- Consistent standards and approach will improve quality;
- Cost effectiveness through economies of scale.

Level of Consensus:

Nine TEC members indicated their support for the recommendation. One member noted that the link with the organ referral process should be considered. There were no TEC members who indicated they did not support the recommendation

6. Wrap-Up and Next Steps

Locksley noted that the strategy map would be updated and that draft measures would be prepared for the June meeting. The next committee meeting will be on June 18th.

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