

**Organ and Tissue Donation and Transplantation
Tissue Expert Committee Meeting
June 18th, 2010
Sheraton Gateway Hotel, Toronto**

Minutes

Attendees:

| | |
|-----------------------------|-----------------------|
| Dr. Locksley McGann (Chair) | Dr. Sarvesh Logsetty |
| Mr. Mike Bentley | Mr. Sean Margueratt |
| Dr. Brian Berry | Dr. Jutta Preiksaitis |
| Mr. Scott Brubaker | Mr. Christopher Snow |
| Ms. Mary Gatien | Ms. Janet MacLean |
| Dr. David Howarth | |
| Mr. Dermot Kelly | |

Regrets:

Dr. Hassan Moghadam
Dr. Frank Hohn
Dr. Michael Gross

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. PJ Vankoughnett-Olson, Senior Program Manager, Organs and Tissues
Mr. Paul Derksen, Program Manager, Tissues

1. Welcome and Follow-Up on Action Items

- Locksley welcomed the Committee Members and reviewed the meeting objectives and agenda for the day.
- Suggested corrections to meeting minutes:
 - The “referral of potential donors” would be more accurately captured as “referral of deaths”. Referrals may be for living donors or for deceased donors so the text will be updated to “referral of potential living donors and deaths”.

2. Activity to Date

Sophie reviewed the activity to date and indicated that the entire draft plan would be presented to all three expert and steering committees in October (tentative date October 4th). Graham provided an update on his meeting with the Deputy Ministers and noted their request not to release the Case for Change prior to the release of the strategic plan.

3. Case for Change Update

Mathias provided a summary of Health Canada's concerns on the tissue donation and transplantation Case for Change. There was an extensive discussion about the suggestion to remove "safety" from the introductory statement on the "safety and quality" of tissue. It was determined that the term safety would not be removed because there still remains inconsistent application of the regulations. Specific areas of safety concern that were mentioned included transmissible disease testing and the implementation of NAT and the validation and implementation of bio-burden reduction practices for tissue processing.

The committee supported all other proposed changes to the document and agreed to the proposal not to incorporate some of the feedback from Health Canada (slides 16 and 17).

4. Public Opinion on OTDT

Kim provided an overview of the public opinion pool that was conducted in March 2010.

5. Results of Tissue Demand Studies

Mathias provided an overview of the two studies examining the demand for tissue in Canada. The gap between the supply and demand for "non-proprietary" or "base" tissue products is less than earlier reports had indicated.

6. Changes to the System Strategy Map

- There was some discussion re: the applicability of the strategy map to the dental market. It was noted that a portion of the allografts used in dental market (e.g. trauma cases) would be used within the hospital surgical environment and be a part of the "health care system" identified in S3. However, a large portion of the imported allografts in the dental market are used in the private clinic setting. Mathias noted that the most significant concerns raised related to the use of allograft in the private clinic setting were informed consent and traceability, and that the Canadian Dental Association was addressing these issues with its membership.
- Re: the term "physician" in P8 - It was noted that the broader term "clinician" has been used by AATB instead of "end-user" or "physician". The term clinician would include surgeons and individuals involved with follow-up activities (e.g., adverse reaction reporting) in both the surgical and dental markets.

7. Systems Measures and Targets

Draft measures for the system were discussed in breakout groups. General agreement or disagreement, and comments on the draft measures were captured for each system objective and are documented in the following tables:

Quality and Safety

| | Measure | Yes/No? | Comments |
|--|---|--|--|
| S1 – Ensure Safety and quality | End-user satisfaction (with safety and quality of product) | Yes | -Consider including another measure for patient outcomes. -Consider including another measure to track recall events -The existing measure is focused on the final product/service delivered –measures relating to donation could be considered (this may be covered under other objectives) |
| | P3 – Ensure effective and safe tissue product consistent with specifications | % of allografts with standardized product specifications defined | Yes |
| | % of product discarded for non-conformity | Yes | -This is more of an effectiveness and efficiency measure but does provide insight on process control. |
| P2- Enhance surveillance and assure 100% traceability | % traceability (in audit exercises) | Yes | |
| | % of transplant establishments with surveillance and adverse event reporting in place | Yes | -Surveillance encompasses “adverse event reporting.” -Essentially we are trying to evaluate whether or not hospitals have basic surveillance processes established |
| P1 – Operate an effective quality management system | % of source establishments that have implemented the national quality program | Yes | |
| | Audit results of each establishment’s quality program. | Yes | -This might be linked or combined with % of source establishments that have implemented the national quality program. -Audits may focus on specific elements or areas of high risk. |
| | # of observations from Health Canada inspections. | Yes | -Observations from other external assessments or inspections (AATB, EBAA) may be included in this measure. -It may be helpful to classify observations based on risk |

Infrastructure and Capabilities

The group did not get a chance to discuss these measures in as much detail as the quality and safety measures.

| | Measure | Yes/No? | Comments |
|---|---|---------|----------|
| C1 - Ensure the workforce is sustainable and aligned to the strategy | % of standard job classifications with defined training | Yes | |
| | % of workforce trained to standard classifications | Yes | |

| | Measure | Yes/No? | Comments |
|--|--|---------|--|
| C2 - Enable effective data and information management | % of establishments using central IT systems | Yes | |
| | % of establishments complying with data requests | - | The definition of "data request" may need to be clarified. |
| C3 - Optimize the infrastructure | Infrastructure cost per allograft | Yes | |
| | % capacity utilization | Yes | |
| C4 - Develop a funding model to ensure a sustainable system | % of system expenses covered by the original funding model established | No | This measure was unclear to the group. |

Efficient and Secure Supply

| | Measure | Yes/No? | Comments |
|--|---|---------|--|
| S2 - Ensure timely and equitable access to effective product | Wait Time For Corneas | Yes | This is a measure the deputy ministers and the public would respond to; however, the variables influencing wait times include operating room and surgeon availability as well as the supply of tissue. |
| | Order Fulfillment Rate (for products in the supply plan) | Yes | Order fulfillment rate should have two components – one to deal with quantity and the other to deal with the timeliness of availability. |
| S3 - Be an efficient part of the health care system (cont.) | Cost per Unit (by product category) | Yes | |
| | Market share (domestic production) | Yes | This measure should include both domestic and imported product. |
| | Reporting on Spending | Yes | Revise to "% of data available on spending" |
| | Reporting on Usage | Yes | Revise to "% of data available on usage". |
| P6 - Manage imports effectively and efficiently | % of importation from qualified vendors | Yes | This was considered a good measure. It was also important to clarify whether dental products would be included in this measure. |
| | Cost savings from centralized purchasing of allografts | Yes | This should be adjusted to include cost savings from contract processing as well as centralized purchasing. |
| P5 - Optimize recovery, processing, and inventory to align supply with demand | % deviation from the production plan | Yes | This should be categorized by reason for deviation. |
| | # of tissue types recovered per donor (for transplant vs. for research/education) | Yes | -This should be "yield per donor". -"Rejection rate" and "time to process" should also be added as measures. |
| | # allografts processed and released per donor | Yes | Revise to "# allografts processed, released and distributed per donor". |
| P4 - Optimize donation in acute care and non-acute care settings | Donors PMP (Ocular; Other) | Yes | It was recognized that this is an imperfect measure, but since it was a standard international measure it should be included. |
| P4 - Optimize donation in acute care and non-acute care settings (cont.) | Consent rate | Yes | Qualification rates of donors and rates of qualified donors who were recovered are two measures that should be added to either P4 or P5 to cover the screening process. |

| | | | |
|--|--|-----|---|
| | Referral rate (Acute Care; non-Acute Care) | Yes | “Non-acute care” should be changed to “out-of-hospital care”. |
| | % of adult population registered to donate | Yes | |

A Responsive, Forward-Looking System

The group felt that the measures in this theme were too narrow and should be expanded to include areas such as outcome measures, understanding and preparing for new technologies, ability to respond to emerging threats, and the availability of evidence-based clinical guidelines. Another potential measure that was discussed involved capturing deviation from clinical guidelines (for appropriate utilization of products).

| | Measure | Yes/No? | Comments |
|--|---|---------|---|
| P9 - Ensure clear, inclusive, and timely decision making | % of decision deadlines met | - | A better measure is needed to evaluate the effectiveness of decision making. Timeliness of decision making, including safety decisions, was considered an important aspect of this, as was the ability of the system to meet physician demand in a rapidly changing market. |
| | End user and partner satisfaction (decision making process) | - | |
| P8 - Partner with physicians to understand demand | # of allografts in Supply and Demand Plan | - | -This measure is unclear and not considered an effective way to monitor progress of the implementation plan -It should also include products that may not be on the supply plan (imported directly for all suppliers). |
| | Number of regular interactions with end-user groups | - | |
| P7 - Partner with industry and research to leverage innovations in product and practice | Number of new products and practices evaluated | Yes | This measure should be extended to evaluate the adoption of new practices and products. |
| | Number of industry and research collaborations | - | |

8. Systems Roles and Responsibilities

- Mathias presented the roles where there are existing organizations or groups already involved and where there is no anticipated change in responsibility. There was agreement in the assigned roles but it was noted that there may be an opportunity to have a better understanding of the roles/direction of the organizations involved with surveillance (ie. Health Canada and Public Health Agency of Canada).
- The committee confirmed that Canadian Blood Services could be considered as the appropriate owner for the role of quality system development.
- Some responsibilities listed in the strategy and performance role could be managed by CBS (e.g., maintain effective communication with P/Ts). However, it was identified that there is a need for independent oversight once system design and details are finalized.
- The system roles and responsibilities listed below were discussed in breakout groups. The pros and cons of each potential owner of the specific role were

discussed and a proposed owner was determined. There was consensus within the committee on the roles and proposed owners. The rationale for the selection of the owner of each role is listed below along with any enablers or accountability mechanisms that may contribute to the owner's success in carrying out the role.

Role: Donation Policy and Standard Processes

Proposed Owner: Canadian Blood Services

Responsibilities include:

- Establish standards for referral, consent, screening and family and bereavement support
- Establish a consistent approach for ID and referral of potential donors from hospitals and settings outside the hospital
- Design and manage a national professional education strategy in support of the identification and referral of potential donors

Rationale:

- Appreciation for regional and geographic differences with existing programs (e.g., OneMatch and Blood)
- Can provide a national perspective
- Has gained the public trust as an organization.

Potential Cons:

- None noted.

Enablers/Accountability Mechanisms

- None noted.

Drawbacks to other Potential Owners of the Donation Policy and Standard Processes Role:

- Existing OPO: No national scope.

Role: Referral Centre Operation

Proposed Owner: Canadian Blood Services

Responsibilities include:

- Operate a referral centre (network) available to accept referrals 24/7
- Support requesting activities (trained professional)
- Support telephone consent

Rationale:

- National scope will enable tracking and measurement
- Economies of scale
- Aligned with implementing a standardized approach
- Can promote legislative changes from a national platform e.g., required referral

Potential Cons:

-

Enablers/Accountability Mechanisms

- Business case for determination of the details of referral centre(s)
- Implementation approach is critical to success – geographical and cultural issues must be addressed

Drawbacks to other Potential Owners of the Referral Centre Operation Role:

- Existing OPO: No national scope

Role: Recovery

Proposed Owner: Canadian Blood Services

Responsibilities:

- Centralized control and operation of recovery activities (which may include contractual agreements with other organizations)
- Align multi-tissue recovery activity and ocular-only recoveries, with the volume required by the supply and demand plan
- Ensure capacity of all recovery facilities to support recovery requirements (includes facilities to recover ME/C cases)

Rationale:

- Can coordinate standardization across provinces and regions
- Can coordinate recovery activity to align with demand

Potential Cons:

- No technical expertise in tissue recovery or experience with Good Tissue Practice

Enablers/Accountability Mechanisms

- Management of supply/demand plan
- Business plan to define details

Drawbacks to other Potential Owners of the Recovery Role:

- Existing OPO: No national scope

Role: Processing

Proposed Owner: Canadian Blood Services

Responsibilities:

- Centralized control of processing either by integration of processing activities and/or by contractual agreements.
- Determine production capacity for each tissue type and based on an ongoing understanding of demand, utilization, and processing capability

Rationale:

- Experience in managing contractual agreements
- Core expertise in GMP, human biologics and testing
- Sustainability and flexibility around funding - Not as influenced by the funding streams of individual provinces

Potential Cons:

- No technical expertise in tissue processing or experience with Good Tissue Practice.

Enablers/Accountability Mechanisms

- Standard Product Specifications
- Business plan to define details

Drawbacks to other Potential Owners of the Processing Role:

- Existing OPO/tissue program: Limitations with hospital or provincial funding.

Role: Supply and Demand Planning

Proposed Owner: Canadian Blood Services

Responsibilities include:

- Manage domestic supply chain from processing to distribution
- Manage volume of tissue imported
- Ensure strong relationships with end users
- Produce a single supply and demand plan that balances domestically and imported product and aligns supply with Canadian end-user demand
- Revise and manage against the supply and demand plan to ensure security of supply and mitigate risks
- Evaluate the feasibility of processing advanced tissues in Canadian facilities
- Collect and analyze data to support evidence-based planning

Rationale:

- Core expertise and infrastructure for developing and managing a supply plan for domestic and imported products
- Single organization with existing hospital relationships and inter-provincial reach
- National scope with representation in every province

Potential Cons:

- Potential conflict with blood priorities
- Lack of tissue expertise
- May not be quick to respond to local issues

Enablers/Accountability Mechanisms

- IT Systems

Drawbacks to other Potential Owners of the Supply Demand Planning Role:

- Existing OPO/tissue program: Too small, no national scope or coordinated network, political issues with having one existing OPO or tissue program performing this role.
- New supply planning agency: Does not leverage current infrastructure; there would be considerable cost and time to get it up and running

Role: Inventory and Distribution

Proposed Owner: Canadian Blood Services

Responsibilities:

- Operate a single inventory of all domestically produced and imported tissues and tissue products
- Import product for which domestic production is not sufficient
- Manages contracts and bulk purchasing for imported product
- Keep sufficient inventory on hand at all times to have a secure supply and the ability to respond to emergencies
- Operate an ordering and shipping process which provides the required product to the customer on time
- Manages costing and pricing activities

Rationale:

- Core expertise in developing and managing a national inventory of domestic and imported products
- Core expertise in risk management approach to supply planning
- Core expertise in ordering and distribution logistics nationally
- Ability to capitalize on existing infrastructure

Potential Cons:

- Potential conflict with blood priorities
- Lack of tissue expertise
- May not be quick to respond to local issues

Enablers/Accountability Mechanisms

- IT Systems

Drawbacks to other Potential Owners of the Inventory and Distribution Role:

- Existing OPO/tissue program: Too small, no national scope or coordinated network, political issues with having one existing OPO or tissue program performing this role.
- Medical supply distributor: Potential financial conflict of interest (profit considerations)
- New supply planning agency: Does not leverage current infrastructure; there would be considerable cost and time to get it up and running

Role: Hospital Tissue Management

Proposed Owner: Canadian Blood Services in collaboration with professional organizations (e.g., AATB, EBAA, Accreditation Canada)

Responsibilities:

- Develop and disseminate leading practices for hospital tissue management (e.g. informed consent, traceability processes)
- Ensure collection of outcome and utilization data

Rationale:

- Canadian Blood Services has existing relationships with hospitals and already obtains data from hospitals to inform planning activities
- Professional organizations can provide the subject matter expertise. Members may also be more inclined to comply with practices that have been developed through their professional organizations.
- Professional organizations are familiar with developing standards.

Potential Cons:

- None noted.

Enablers/Accountability Mechanisms

- Leading practices should be developed at the policy level, leaving hospitals to individually develop their processes and SOPs

Drawbacks to other Potential Owners of the Hospital Tissue Management Role:

- Professional Organizations: No coordination between practices, standards are often voluntary.

Role: Recruitment and Training

Proposed Owner:

The responsibilities in this category were assigned to multiple groups:

Professional Conduct Standards and Practices: This should be done by professional organizations, such as the AATB, CAETB and the EBAA.

Human resource strategy and planning:

This should be done by the system operator/service delivery organization.

Standardized education and training:

It was determined that it was too early to define the recommended owner of education and training. This should be re-evaluated at a later date, when there is a better idea of the number of staff in the system and the level of training needed. Depending on numbers, one option could be partnering with an educational institution to provide training.

Enablers/Accountability Mechanisms

- Partnerships with professional organizations

9. Implementation Prioritization

Mathias presented an overview of the process of implementation planning. The Committee's discussion on prioritization included the following points:

- A matrix may need to be created to evaluate the different options by tissue type and to consider the different implementation contexts for each initiative
- Initiatives that improve the effectiveness of the system and provide cost savings should be prioritized
- Ocular should be considered as a high priority as there is the potential for a significant impact

Other suggestions for initiatives that should be prioritized included inventory and distribution, bulk purchasing of imported tissues and TD testing centralization.

10. Wrap-Up and Next Steps

Locksley thanked the committee members for their contributions to the work over the past year. He noted that the work will continue through the summer and that individuals on the committee may be contacted for further input. Locksley thanked the members for their attendance and adjourned the meeting.