

**Organ and Tissue Donation and Transplantation
Steering Committee Meeting
October 14, 2009
Sheraton Gateway Hotel, Toronto**

Minutes

Attendees:

Dr. Graham Sher (Chair)	Dr. Judith Shamian
Dr. Andrew Baker	Dr. Michael Strong
Dr. John Hamm	Dr. Simon Sutcliffe
Mr. Craig Knight (by phone)	Dr. William Wall
Dr. Maurice McGregor	

Regrets:

Commodore Hans Jung
Honourable Anne McLellan
Dr. Brian Postl

Canadian Blood Services Observers:

Dr. Peter Nickerson, Chair, Organ Expert Committee
Dr. Locksley McGann, Chair, Tissue Expert Committee
Ms. Sophie de Villers, Vice-President, Strategy Management
Dr. Sam Shemie, Medical Consultant, Organ Donation
Ms. Kimberly Young, Executive Director, Organs and Tissues
Ms. Sylvia Torrance, Director, Business Initiatives
Ms. Lorna Tessier, Director, Public Relations

1. Welcome and Administrative Items

- The Chair welcomed all Members and reviewed the meeting objectives for the day.
- Minutes from the Committee's meeting on June 29, 2009 were approved.

2. Reviewing Preparations for the TEC and OEC Meetings

- Graham began the presentation by reviewing the OTDT system design process. The Committees are currently in the second phase of the process: establishing strategic direction by analyzing issues and determining feasible solutions and options. He reminded the group that the system design would focus on system principles initially, and then move to processes and governance, and finally roles and responsibilities.

- Locksley and Peter provided updates on Tissue Expert Committee and Organ Expert Committee activities, including changes made to the Cases for Change and the solution design questions to be discussed at their upcoming meetings.
- The committee discussed whether answering the solution design questions would address the problems outlined in the case for change. For tissues, the group felt that by ensuring an adequate, safe, secure supply of tissue, 100% of the needs of patients could be met, either through domestic or imported tissue. For organs, 100% of demand is not likely to be met, regardless of efforts to increase organ donations. Therefore, the focus needs to be on maximizing organ donation in the country, and distributing organs in an equitable, transparent way.
- The group also discussed whether the organ and tissue streams should be designed as two separate, parallel streams or as one system. Similarities and differences between organs and tissues were discussed: adequacy in supply is possible for tissues, but not organs; safety, traceability and efficiency are important for both; ethical supply is a high profile issue for organs, less discussed for tissues. The organ and tissue supply chains overlap in public awareness, shared donors, common referral system and approaches to families. However, recovery, processing, allocation and distribution, and end-user communities are very different. As well, there is the potential to recover tissue only from donors who are not organ donors. A decision on this was deferred, pending information from the work of the expert committees.
- Suggestions were made to improve the Cases for Change. It was clarified that these documents were written as part of the system design process, to get agreement on what problems needed to be fixed, and to move forward to design solutions to fix them. The Committee suggested that if the document, or some derivative of the document, were to be made public, editing was needed to avoid misinterpretations and ensure accuracy. There was discussion on how to ensure that the case for change was strong enough to motivate transformational change and create a "burning platform" in a positive way.

3. OTDT in Canada: System Principles

Sophie presented information on the importance of system principles for OTDT and provided various examples. The Committee then discussed the principles applicable to OTDT in Canada.

- Principles developed need to align with broader Canadian health principles as well as international bodies like the W.H.O.
- The legal framework may not exist to support solutions that are required. There may be gaps in legislation. Options other than legislation, such as the Memorandum of Understanding (MOU) as was used for the blood system, were also discussed.

Safety

- The definition for safety needs to be broad to take into account donors, and all aspects of safety.

- Traceability is an important component of safety for both organs and tissues.
- Safety issues are different for organs and tissues, as organs are life saving while most tissues are life enhancing. The risk-benefits are different, though full disclosure and informed consent are important for both, especially in cases where high-risk organ donors are involved.
- 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.

Access

- The definition for the principle of access needs to be broad to include donors (access to opportunities to donate)

Privacy

- Privacy should be protected but should not be a barrier to collaboration and development of Canadian, inter-provincial systems, especially registries.

Equity

- There was agreement that equity across provinces should be a principle for tissues. A tissue recovered and processed in Nova Scotia should be available to someone in British Columbia if needed.
- There was extensive debate on what equity means across provincial boundaries with respect to organ allocation. Does equity mean similar outcomes across province, or is equity in outcomes and waitlist restricted to within the province? There was a strong argument that those regions and programs that put much effort and money into improving donation rates and obtaining organs should not have to subsidize poor performing regions, or regions that do not invest in this area. As well, equity in access to organs between provinces would be difficult because of the authorities of provinces in health care. However, it was also argued that Canadian patients waiting for organs should not be penalized because they happen to live in a region where programs are not performing well. In the end, the Committee agreed that the system should strive for equitable access for all Canadians, recognizing that geography and location 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 Committee discussed what adequacy meant in terms of meeting the legitimate needs of Canadian patients. While they agreed that a tissue system could meet all needs for tissue, it was recognized that demand for organs could not be met 100%,

Collaborative Approach/ Interdependence and Accountability

- Because of the number of different service providers in OTDT and the jurisdictional authority of provinces with respect to health care that must be respected, collaboration is critical in developing, implementing and operating an OTDT system in Canada. As such, there will need to be a moral obligation to commit to and deliver on responsibilities. A mutual accountability framework needs to be developed to

ensure that all take responsibility for the system. It was also noted that if this principal was adopted, it would have wide ranging impact on how the system is designed and eventually managed. It was determined that potential impacts need to be further discussed.

Transparency

- The impression of the Committee was that the public would donate organs and tissues if they have confidence that the system would optimize use of organs and distribute them fairly.

System Efficiency and Effectiveness

- The whole system should be greater than the sum of the parts, in terms of effectiveness, efficiencies and benefits, i.e. provinces should obtain more benefits from being part of the system, than they would have on their own.
- For organs these benefits include having a larger donor pool to improve matching opportunities for smaller provinces, highly sensitized and urgent status patients, and patient with mismatched living donors (living donor paired exchange).
- For tissues, added value would result from critical mass, and shared infrastructure and technology.
- For both organ and tissue, added value comes from establishment of best practises, benchmarking, performance; mechanisms for collaboration; performance measures and reporting.

Autonomy of Individuals

- The system should respect not only the rights of recipients but also the rights of donors, in terms of informed consent, and donor wishes being overridden by family.
- While there may be the right to express your intent to donate, an individual may not necessarily have the right to donate based on medical or other factors.
- Because of the number of issues related to this area, further discussion is needed on this topic to clarify the intent.

In terms of next steps, Sophie noted that a summary of these discussions would be presented to the Expert Committees to help in their deliberations, and any feedback from the two groups on the principles would be brought back to the Steering Committee.

4. OTDT Public Affairs Plan

Sophie provided an overview of the Canadian Blood Services OTDT public affairs plan. The goal is to create a favourable environment for Deputy Ministers to receive the OTDT strategic plan. Because broad outreach is key to the success of this process, the plan is divided into three areas of focus: stakeholder relations, government relations, and media relations. The plan also takes into account the special situation in Quebec. While the Quebec government and Hema-Quebec have clearly indicated that their strategy for tissue lies in developing the provincial system, the situation for organs is less clear. Because of the advantages in accessing a larger pool of donors, especially for highly sensitized and urgent status patients and for a Living Donor Paired Exchange registry,

Quebec patients will benefit from a national system. Therefore, the OTDT system design should be designed to allow for Quebec participation.

The Committee Members then provided several suggestions on how to strengthen the plan including:

- OTDT needs to become a priority for Ministers of Health, as it is in competition with other good initiatives.
- Develop clear, concise messaging for the public, using social marketing expertise. Increased public awareness will increase political awareness.
- Get buy-in from partners and stakeholders before the plan is presented.
- Because of the economic recession, funding for new programs will be limited. The cost of the plan needs to be reasonable and benefits must be articulated and mapped.
- Identify champions for the public and for governments to help sell the plan (e.g. intergovernmental deputies)

5. Making the OTDT Strategic Plan a Success

Sophie reviewed a listing of public reports with recommendations related to organ and tissue donation and transplantation. She noted that in spite of all these efforts, there has been little improvement in national donation rates. Discussion then took place on which elements help in making a strategic plan successful.

- Costing will be a very important element of the plan. What will the cost be and what added performance will this deliver? Will there be cost savings at any point in the system, e.g. getting patients off dialysis? Will it increase costs in other programs or areas? Is it sustainable? Are there any other less quantifiable benefits/costs, e.g. effect of end-stage organ disease on patient's wages and productivity? Sophie informed the Committee that a costing study was in progress to examine these areas.
- The way the case for change is presented is critical. The message needs to go beyond deaths on the wait list, i.e. many diseases result in deaths that we can't do anything about, but most deaths from end-stage organ failure are preventable, if enough organs were available. Yet every day viable organs that can save lives are buried.
- Committee members also suggested that the approach for the plan be tested with governments prior to submission.
- It was stated that the largest barrier and challenge were the provincial, territorial, and federal jurisdictional issues around health care.

6. Upcoming Activities and Next Steps

Graham gave a brief update on the planned conference calls with international experts, the tissue end user forums, and the public dialogues. He noted that the principles discussions of the Steering Committee would be shared with the two expert committees

at their meetings. He also proposed consultations with bioethicists to review and advise the group on the preliminary principles when drafted.

9. Meeting Adjournment

Graham thanked the Committee Members for their participation at the meeting and reminded them that the next meeting was scheduled for January 20, 2010 at the same location.