

**Organ and Tissue Donation and Transplantation
Organ Expert Committee Meeting
April 27, 2010
Sheraton Gateway Hotel, Toronto
Minutes**

Attendees:

Dr. Peter Nickerson (Chair)	Dr. Debra Isaac	Ms. Raylene Matlock
Dr. Ian Alwayn	Dr. Anthony Jevnikar	Mr. Scott McIntaggart
Dr. Stephen Beed	Dr. Greg Knoll	Dr. Joe Pagliarello
Dr. Michel Carrier	Dr. Adeera Levin (by phone)	Ms. Deanna Paulson
Dr. David Grant	Dr. Robert Levy	Dr. Sam Shemie
Dr. Greg Grant	Dr. Frank Markel	Ms. Kimberly Young
Dr. Tom Blydt-Hansen		

Regrets:

Dr. Noel Gibney
Dr. Shaf Keshavjee
Dr. Norman Kneteman
Dr. John Tallon

Canadian Blood Services Representatives:

Dr. Graham Sher, Chair, Steering Committee
Dr. Locksley McGann, Chair, Tissue Expert Committee
Ms. Sophie de Villers, Vice-President, Strategy Management
Ms. Sylvia Torrance, Director, Strategic Planning
Ms. Lorna Tessier, Director, Public Relations
Ms. PJ Vankoughnett-Olsen, Senior Project Manager, Organs and Tissues

1. Welcome and Follow-Up of Action Items:

Peter welcomed the committee members to the meeting and outlined the agenda for the day. The follow-up action items were then reviewed:

- The OEC meeting minutes from January 11, 2010 were approved by the committee.
- Peter informed the group of a letter received from the Co-Chairs of the Professional Organizations Task Force for the Declaration of Istanbul, seeking support from Canadian Blood Services for the Istanbul Declaration on Organ Trafficking and Transplant Tourism. Canadian Blood Services is reviewing the letter and will be drafting a response of support.
- The group was also informed that Canadian Blood Services has commissioned a public opinion poll on OTDT. A report with the results will be sent to the committee once complete.
- Conflict of interest disclosure was discussed by the committee. The group agreed to complete forms to disclose relations with either provincial agencies or commercial interests.
- The committee was informed that a photographer would be taking pictures in the afternoon and those who did not want to be in the photos should inform the chair.

2. Living Donor Paired Exchange (LDPE), Highly Sensitized Patient (HSP) and Urgent Status Registries Update:

Peter began the presentation by giving an overview of the three registries that Canadian Blood Services had been mandated to develop by the provincial and territorial governments. Dr. Ed Cole then presented an update on the LDPE and provided data from the first year of the LDPE's

implementation. He also discussed the importance of non-directed donations, HLA standardization and the benefits of having a large number of pairs in the registry. The issues related to privacy impact assessments, shipping of kidneys, and the points allocation system were also discussed. Dr. Cole then answered questions from the committee. The committee suggested that efforts should be made to honour non-directed living donors and to encourage non-directed donation. A suggestion was made to expand the program for liver donation, both directed and non-directed. Dr. Cole thanked the Canadian Blood Services for their collaboration and partnership.

Peter then reviewed the conceptual design and framework for the HSP and urgent status (national organ waitlist) registries. The issue of privacy assessments was discussed again. Graham will bring this issue to the attention of the Deputy Ministers. It was clarified that all capabilities discussed in the presentation could be built into the system, including regional variances. There was no technological limitation to achieve the total scope of the framework but it should be defined and driven by the needs of the ODT community.

3. Activity to Date

The strategic planning process was reviewed with the committee, and an update was given on the public, expert and government engagement activities.

The committee discussed the Case for Change which outlines the critical issues that need to be fixed in the ODT system. Sophie noted that this is the third version of the document sent to committee members and highlighted the major changes from the previous version:

- The introduction was updated to clarify the scope and purpose of the document
- The numbers in the table on page 10 were updated
- There will be clarification of an apparent data discrepancy in section 2.2 pg 12
- The following wording change is proposed to the second problem statement: “The Canadian organ donation and transplantation is not *sufficiently* equitable nor *sufficiently* transparent”.

There were several concerns raised in releasing the document to the public:

- Concern was raised that public release for the Case for Change would unnecessarily alarm the public and governments, and could decrease trust and donation rates in the country. It was noted that the Case for Change problem statements had been presented at the public and expert dialogues and feedback from these consultations indicated broad support and agreement with the statements. There was debate by the group on whether softening the language of the document would make the case less compelling for Deputy Ministers who would need to approve the recommendations.
- The concern was raised that regional and provincial areas of excellence and efforts to make improvements were not acknowledged and the document was overly negative. Peter had suggested addition of the following paragraph into the document, and requested committee members to provide him feedback on the potential change:

“Furthermore, while the case for change highlights those areas that are most important to address to improve patient outcomes, it is important to recognize that many changes have been undertaken in OTDT programs within provincial provinces or regions and there have been, and continue to be, variable performance improvements in areas across the country. These are positive achievements. However, the evidence is compelling that Canada as a whole and all of its provinces individually can perform better in many areas of OTDT, and the work building on this case for change will identify options and priorities for closing some of these performance gaps.”

- There was a request to refer to the sharing of best practices within the country in the document.
- Many felt there was a need to finalize the document and move on with the process.

Peter encouraged members to provide further feedback to him. He noted that the document will be rescinded and the final version will be distributed to the committee.

4. System Strategy

Sophie presented the process and tools used to develop the strategy map. The draft strategic destination statement and the draft strategy map were reviewed and discussed.

- The term “self-sufficiency” was confusing and subject to different interpretation. Some would interpret self-sufficiency as meaning the elimination of the wait list, which was not a feasible goal. Self-sufficiency was discussed in terms of optimizing the system so that as many transplantation opportunities as possible were provided to patients. Optimizing the system so that Canadian patients would not feel the need to go outside the country (transplant tourism) to obtain transplants was also considered an important concept.
- In the objective “allocate to optimize outcomes for patients”, the term “outcomes” was considered too narrow. It conflicts with equity and needs to be modified to take into consideration other allocation principles.
- It is not enough to increase the number of transplants (“..the best opportunity to receive a transplant.”). The outcome of the transplant in terms of quality of life, health and added life span are also important and should be reflected in the map. Patient outcomes should also be used as a metric for measurement.

Sophie indicated that changes would be made to the map and that measures would be developed for the committee’s review at the next meeting.

Later in the meeting it was noted that there was no reference to research and development in the map and that it should be added, possibly as an infrastructure and capability item. Safety was also mentioned as being missing, but it could be captured in the objective addressing “appropriate outcomes”.

5. System Design

The committee reviewed their preferred solutions from previous meetings, as well as public and expert feedback received from the public dialogues and the expert consultations. They then discussed the system requirements and elements that were presented to them. During discussions it was noted that while the information reflected their thinking, the messaging and communication strategy would need to be developed in a sensitive manner, as many recommendations would be a big shift for the ODT community. Transition strategies would also be important and more effort would be needed to work out the details. These would need to be developed through a formalized consensus process with broad representation from all across the country.

The committee then discussed the following questions in break-out groups and came to several recommendations.

a. What approach to donor registries should we recommend?

The majority of the committee agreed that there should be web-based donor registries available to health care practitioners at the point of care. There were varying opinions on the following points:

- Some felt there should be one central registry for the country; others felt that inter-provincial registries linked together would also work. One opinion was that registries should have common standards but be independent.
- Many felt that these registries should be legally binding and donor wishes should be carried out, regardless of family opinion. Further work is needed on the legal implications of registry consent and DCD.
- Most felt that the registry should be promoted as a donation registry and register only “yes” or intent/consent to donate. If the registry was an opt-out registry with presumed consent then it would need to capture all options (yes/no/unsure).
- Further discussion needs to be take place on presumed consent and reciprocity (i.e. obtaining some advantage from registering to be a donor)
- The return on investment should also be evaluated to determine whether donor registries should be a priority over other initiatives.

b. Should allocation rules be consistent across provinces and programs?

The committee agreed that there should be a single framework and common allocation rules across provinces and programs. The development of the framework and rules should take the following factors into consideration:

- Strict evidence-based criteria and use of a points system
- A system and criteria that will foster innovation and public trust
- Organ-specific criteria by consensus with broad-based input from the public, medical experts, intensivists, legal experts and ethicists.

The committee listed the following enablers:

- Agreement on listing and eligibility criteria
- Data to develop, validate and improve allocation models over time
- IT system
- Accountability mechanisms to ensure compliance to rules
- Allow variances for specific experimental procedures

Note that the committee restricted the discussion to allocation within provinces, and did not discuss allocation rules for organ sharing. The committee also noted that while the medical decision to refuse an organ for a patient remains the right of the treating physician, justification of the decision should be required.

c. How should a central system support allocation (beyond urgent, HSP and LDPE)?

The committee recommended that a central IT system also provide allocation and offer management functionality. The committee provided the following advantages of this system:

- Improved central data collection
- Enhanced standardization
- Decreased donor loss
- Potential for process improvements
- Increased system efficiencies
- Improved sharing
- Consistent with the current move by governments to an electronic health record (EHR) model

The committee listed the following enablers and capabilities:

- Ability for migration of data from other systems and alignment with other systems

- Resources
- Ability to capture data from multiple sources (imaging)
- Best design for users needs (user requirements)
- Determination of organ sharing rules

d. What additional mechanisms will ensure that ODT service delivery organizations will be accountable for agree-to standards, policies and performance?

Final recommendations were not reached on this topic, as it was felt that this should be discussed in the context of roles and responsibilities at the next meeting. However, initial discussions indicated that the following mechanisms would improve accountability:

- National common data set for ODT metrics and performance targets
- Mandatory reporting
- Open professional and public access to program and OPO data
- Consequences and remedies for non-compliance
- Consistent feed from OPOs and transplant program to provincial funder

The group noted the need for effective accountability for inter-provincial organ sharing

Peter then reviewed the next steps in the process. He thanked the committee members for their participation and adjourned the meeting.