

**Organ and Tissue Donation and Transplantation
Organ Expert Committee Meeting
January 11, 2010
Sheraton Gateway Hotel, Toronto
Minutes**

Attendees:

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

Regrets:

Dr. Noel Gibney

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, Business Initiatives
Ms. Lorna Tessier, Director, Public Relations
Ms. Tracy Brand, Director, Organs and Tissues
Ms. Sherri Kashuba, Senior Program Advisor, Organs and Tissues

1. Welcome and Follow-up of Action Items

Peter welcomed the Committee members and reviewed the meeting objectives and agenda for the day. Peter also informed them that a public version of the Case for Change is being developed and will be sent to members for their comments.

2. Review of Activity to Date

Sophie reviewed the preferred options/solutions 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 topics and issues they wished to discuss. At the expert consultation in Saskatchewan, participants discussed the case for change as well as the initial solutions 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.

Brief discussion took place on how to improve attendance at the public dialogue meetings, which has been lower than expected. Canadian Blood Service is looking at decreasing the length of meetings to ½ days and to hold meetings during the week, instead of on Saturdays. It will continue to partner with community groups, like the Kidney Foundation to improve participation rates.

3. Allocation Principles – Introduction

Peter reviewed the Committee’s preliminary allocation principles developed at the previous meeting, as well as the US Organ Procurement and Transplantation Network (OPTN) final rules on organ allocation. He then introduced the two speakers for the day:

- Dr. Alan Leichtman, a transplant nephrologist at the University of Michigan, who is involved with modeling and measuring effectiveness of allocation algorithms for the Scientific Registry of Transplant Recipients (SRTR)
- Dr. Axel Rahmel, MD, a transplant cardiologist and the Medical Director for EuroTransplant (ET), who oversees development, modeling, and accountability of their allocation algorithms

4. Presentation by Dr. Alan Leichtman

Dr. Leichtman’s presentation reviewed the various simulation models that SRTR has developed to measure the effects of different allocation algorithms. He presented the current US allocation models, reviewed concepts for changes to the kidney allocation algorithm (i.e. incorporation of a measure for incremental survival (LYFT) and Quality of Life (QoL) and showed how patients groups could be affected by the changes.

Dr. Leichtman also commented on important factors to consider when determining and ranking allocation principles:

- Allocation Trade-offs need to be made: i.e. allocation to maximize a specific transplant outcome (waitlist survival, post-transplant survival, incremental survival) vs. allocation based on non-outcome-based considerations (waiting time, lottery, social worth, one chance, children first, etc.)
- Opportunity Trade-offs need to be made based on what organs will be shared and when
- “Payback” of organs (i.e. providing an organ back to a program when one is given, so that the number of organs is balanced) should be avoided
- Impact of transition from the old allocation system to the new must be considered
- Allocation elements should be measureable and clinically meaningful
- Weighting of allocation priorities such as waiting time, tissue match or sensitization should reflect the actual biological effects of these variables on survival
- Allocation algorithms should avoid arbitrary or unreliable cutoffs such as 4 points for PRA > 79, or top 20% of organs to top 20% of candidates, or organs from donors under the age of 35 years to candidates under the age of 35 years

- Allocation priorities should discriminate unlike from unlike, and assign similar scores to similar patients

5. Presentation by Dr. Axel Rahmel

Dr. Rahmel started his presentation by providing a history of ET and reviewing how this has helped shape allocation policy. He outlined the present structure of ET, current processes for determining allocation rules, and the effect these rules have had on different patient groups. The high-level allocation algorithms were provided for the different organ types.

Dr. Rahmel discussed key enablers of the ET allocation system:

- Once allocation algorithms have been agreed to, they are binding on members
- Audit of status listing is becoming a critical role that ET is playing to ensure trust amongst members

He commented on the benefits seen by countries belonging to the ET:

- Standardization and harmonization with defined quality criteria (organ procurement)
- Transparent, objective allocation rules
 - Prevention of drop in donation as result of (presumed) misuse of the allocation system
 - Increase in public trust
 - Long term positive influence on organ donation
- Better help for special patient groups
- Prevention of organ loss
- Stimulation of scientific cooperation

He also outlined several ways that he felt their system could be improved:

- Structuring the development of new allocation rules with clear responsibilities
 - Development of a medical, ethical (and political) framework for allocation involving the national authorities
 - Centralized development of allocation rules in this framework by one central organization (involving all relevant stakeholders)
- Mandatory central data collection on outcome of organ transplantation
- Using a simulation tool to predict consequences of modified allocation

A discussion panel followed Dr. Rahmel's presentation, with Dr. Leichtman and Dr. Rahmel responding to questions from the Committee.

6. Organ Allocation Principles Discussions

The Committee members then reviewed their preliminary allocation principles to determine whether they were sufficient and useful in guiding development of allocation policy, and to determine the policy implications and operation requirements generated by these principles.

- The principles of evidence-based, transparency and accountability were thought to be the most achievable, and were moved to be highest in rank order.

- Decisions made should also be scientifically sound when looked at from a societal perspective.
- Principles of equity, utility and medical need may be in conflict at times and a balance would need to be achieved between them, to take into account the consequences on various patient groups.
- The term “fairness” was preferred over the term “equity”. It was further clarified to mean similar patient groups would be treated consistently and that particular demographic/patient groups would not be disadvantaged.
- Practical limitations would also need to be considered in any allocation algorithm, i.e. the distance an organ could be transported would depend on ischemic time.
- Rules would be required for non-Canadian residents.
- A transition period would be needed to move to a new system.
- Transparency was applicable to all components of transplant: listings, outcomes and program performance (both donation and transplantation).
- Accountability could be achieved using a number of mechanisms including transparent reporting, auditing, and accreditation.

The following were noted as possible policies implications and system requirements:

- Mandatory collection of standard data into a national IT system with modelling capabilities
- Data collection includes performance measures and outcome data
- Measurement tools that are mandatory, verifiable and reliable
- Communication and public awareness
- Public involvement on allocation principles
- Formal structures for review of policies
- Standardization/SOPs for transplant programs, OPOs
- National oversight body with audit function
- Consequences for not being in compliance
- Mandatory request/referral legislation

There was extensive discussion on whether organs are a regional, provincial or national resource. It was agreed that national sharing is desirable for cases where a person may never get an organ (e.g. highly sensitized patients) or where a patient will die imminently without an organ (high urgency). While the majority of the Committee agreed that organs should be considered a national resource, there was some reluctance to fully endorse this because of the uncertainty of the impact on provinces and individual transplant programs.

The Committee requested that Canadian Blood Services investigate whether the Canadian public have expectations or strong opinions on where organs are distributed in Canada, i.e. locally, provincially or nationally?

7. Intent/Consent to Donate

In response to a request from the Committee, Kim presented further information on the cost and effectiveness of registries and other mechanisms for registering an individual’s intent / consent to donate organs after death. Kim reviewed the different mechanisms being used in

Canada and internationally, linking them to donor and registration rates. High level costing data and anecdotal evidence on reported impact was also provided.

The analysis concluded:

- there is not sufficient evidence to demonstrate that registries or other formal intent/consent mechanisms drive increased donation by themselves
- registries and other intent/consent mechanisms can positively contribute to organ donation in a number of ways, when part of a more broadly well-functioning organ donation approach
- for Canada, it will be important to have a clearer sense of the recommended system design (e.g., roles and responsibilities, identification and referral details) before making detailed recommendations about the role of intent/consent mechanisms or registries

After general discussion, the majority of the Committee agreed that a registry/registries should be included as part of the overall strategy for OTDT in Canada. The specific structure and requirements of the registry could be determined at a later date, when the system design was further developed.

8. Introduction to Costing

Sophie introduced the presentation for ODT costing. A costing project has been undertaken by Canadian Blood Services in order to understand current ODT costs and funding, to identify gaps in costing data, as well as to assist in the development of budgets for implementation of the strategic plan. Sophie introduced Alexandra Flatt, who then presented the project methodology and assumptions. While data was provided for both organ donation and transplantation, limitations of the data were reviewed. Discussion then took place on the data and potential next steps for the project.

A suggestion was made to use an activity based model, and build from there, taking into consideration differences in provincial funding arrangements. It was also suggested that work for the next phase be focused in context of questions, e.g. cost of additional donors, resources for critical care for donors, determining whether to pursue one strategy or another.

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

9. Wrap-Up and Next Steps

Peter reminded Committee members that public dialogues and expert consultation would be continuing over the next few months. He also stated that the Committee meeting set for March would be moved to April to allow time for input from these consultations and to prepare for the next meeting.

Peter provided an update on the organ registries being developed by Canadian Blood Services. The Living Donor Paired Exchange (LDPE) registry is being rolled out nationally. Privacy agreements need to be completed with each province before implementation; however, several provinces were close to final sign-off on these agreements. Work will

begin shortly on consultation with OPOs and transplant programs for registries for highly sensitized and urgent status patients.

Kim reminded the Committee of the two calls with international speakers in the next two weeks: Dr. John Kearney from NHS Blood and Transplant (UK) and Dr. Luc Noel from the World Health Organization.

Adeera informed the Committee a request will be sent to the Canadian Blood Services to endorse the Istanbul Declaration.

Peter thanked group and adjourned the meeting.