ORGAN AND TISSUE DONATION AND TRANSPLANTATION

Report on the Ethics Consultation

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Canadian Blood Services
Société canadienne du sang

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This report provides an overview of the consultation and a summary of participant recommendations in response to prescribed questions on issues. Consultation participants' views represent a range of perspectives in the OTDT community.

In some cases, statements or recommendations may appear to conflict; these represent differences of opinion among respondents. In other cases, respondents may represent as factual, items that may not be entirely correct. In these cases, participants' understandings are included as they were initially provided.

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Introduction

In August 2008, Canadian Blood Services was given a mandate by the Conference of Deputy Ministers of Health to lead the development of an inter-provincial /territorial strategy for organ and tissue donation and transplantation (OTDT) in Canada. As a result, Canadian Blood Services has been working in collaboration with the OTDT community to build an integrated strategy to deliver consistency, improve performance, and, most importantly, ensure more Canadians receive the organs and tissues they urgently need.

As an initial step in the development of this strategy, a national stakeholder consultation was held in September 2008 to determine how best to establish national, integrated services that would meet the needs of patients and the OTDT community. After a comprehensive and inclusive consultation process, one of the final steps was the hosting of an OTDT Ethics Consultation on January 20-21, 2011.

The purpose of this meeting was to consult with key experts regarding ethical principles and related system design requirements to support the implementation and ongoing development of Canada's proposed OTDT system. Objectives were:

- To provide an overview of work to date on OTDT system design, ethical principles and strategy as a basis for informed discussions by consultation participants;
- To review and advise on proposed OTDT ethical principles for an integrated OTDT system for Canada;
- To discuss three key ethical issues identified in the proposed OTDT system design and make recommendations for accommodation in system design; and
- To enable the continued development of a community of experts (stakeholders) with a commitment to ongoing dialogue about ethics in OTDT.

In preparation for the meeting, the following documents were prepared by Canadian Blood Services and/or the Ethics Consultation Planning Committee and sent to participants before the meeting:

- OTDT Transplantation Overview
- OTDT Ethics Consultation – Environmental Scan
- OTDT Ethics Consultation – Literature Review
- Public Opinion on OTDT in Canada
- OTDT Ethical foundation of an Integrated OTDT System for Canada – Working Draft
- OTDT Topic 1 Background: Opportunity to Donate
- OTDT Topic 2 Background: Financial Transactions in the Tissue System
- OTDT Topic 3 Background: Potential Conflicts of Interest in Health Care Organizations and Professionals

Opening Remarks

Dr. Sam Shemie, Chair of the Consultation Planning Committee and Executive Medical Director, Donation, Canadian Blood Services, opened the meeting by thanking delegates for contributing their time and expertise at this consultation (Participants: Appendix A). He described the system development process to date as reflective, deliberative, inclusive, and painstaking: stakeholders in the system were consulted both nationally and internationally and every effort was made to address problems without negatively impacting what is currently working well.

Dr. Shemie also introduced the consultation planning committee and commented on their excellent collaboration in preparing the background documentation to support the consultation: an environmental scan, literature review, summary of public opinion, overviews on the proposed OTDT system, reviews of organ and tissue donation and transplantation and the identification and description of three priority issues. He emphasized that delegates' perspectives on these issues were essential to ensuring that ethical principles guide the final development and implementation of the system design, particularly given the need for an evidence-informed approach to the subject, and the paucity of literature on ethics in OTDT.

Dr. Shemie concluded by outlining next steps in the system design process after this consultation: submission of recommendations to the Deputy Ministers of Health and a final decision on the system design.

Purpose, Agenda and Process

Facilitator Dorothy Strachan reviewed the purpose, objectives and agenda for the consultation, making the point that participants would need to take a strategic perspective throughout the meeting, and acknowledging the challenges involved in looking at ethics from an integrated system design perspective.

After introducing themselves, participants discussed guidelines for working together and confirmed the scope of the consultation. Then Ms Strachan outlined the meeting process for analyzing and building agreement on recommendations related to each issue:

1. Read the system design recommendations, relevant system principles and related background information.
2. Review the questions for the issue.
3. Discuss the illustrative system-in-action scenarios for the issue.
4. Reflect on and discuss each question designed to address the issue.
5. Build consensus among participants on recommendations in response to each question, noting key considerations (useful points of clarity generated during plenary discussions) and discussion

highlights (further elaborations and perspectives on issues generated by individuals during plenary discussions).

Prior to discussing each issue, participants turned their attention to further understanding OTDT in Canada and the role of the OTDT community in contributing to the development of a coordinated system design.

Organ and Tissue Donation and Transplantation in Canada

Three presentations provided an overview and update on the OTDT system design process as a basis for informing participant discussions.

1. Tissue System Design

Mathias Haun, Director, Strategic Planning (Tissues) at Canadian Blood Services, outlined the proposed coordinated system design for Tissue Donation and Transplantation. He described the current tissue system as fragmented and emphasized that the proposed approach had been developed based on expressed needs in previous consultations with the tissue community. Mr. Haun made the case for change clear and emphasized that the proposed tissue system design is focused on a complete transformation involving an emphasis on quality and safety, traceability and consistent surveillance, an efficient and secure supply, with all of this embedded in an efficient, responsive and forward-looking system.

2. Organ System Design

Kimberly Young, Executive Director, Organs and Tissues at Canadian Blood Services, described the proposed coordinated system design for Organ Donation and Transplantation. She began by calling attention to the history of poor organ donation performance in Canada, and the lack of improvement in preventing deaths on organ waitlists. Based on a vision for 2017 in which Canadian patients would have a trusted, integrated transplant system that performs well among international leaders, Ms Young described the breakthrough performance potential of an integrated system based on accountability, increased organ donation and improved access to transplantation. In her presentation Ms Young also outlined what the proposed system could look like with respect to governance and information management, and concluded with next steps leading to the submission of final recommendations to the Deputy Ministers of Health.

3. System Principles

Dr. Sam Shemie described the two sets of principles outlined in the document “Ethical Foundations for an Integrated OTDT System for Canada” and described how these principles would be an important element in consultation discussions.

The first set of principles had been reaffirmed in 2004 by the First Ministers’ Meeting on the Future of Health Care:

- Universality, accessibility, portability, comprehensiveness, and public administration;
- Access to medically necessary health services based on need, not ability to pay;

- Reforms focused on the needs of patients to ensure that all Canadians have access to the health care services they need, when they need them;
- Collaboration between all governments, working together in common purpose to meet the evolving health care needs of Canadians;
- Advancement through the sharing of best practices;
- Continued accountability and provision of information to make progress transparent to citizens; and
- Jurisdictional flexibility.

The second set of principles was proposed by the OTDT committees to address unique elements associated with OTDT that deserve further consideration in system design:

- Collaboration and Integration
- Fairness
- Self-sufficiency in Organs
- Security of Tissue Supply
- A Population-Based System
- Safety
- Accountability
- Cost Effectiveness
- Privacy
- Ethical Practices in Organ and Tissue Donation and Transplantation

In addition to using these system principles as a basis for discussing the three consultation issues described earlier, at the end of the consultation participants also provided feedback on the document elaborating on these principles, “Ethical Foundations for an Integrated OTDT System for Canada”.

Three Priority Issues

Three priority issues were identified by the planning committee for the development of recommendations at this event:

A. Opportunity to Donate
B. Financial Transactions in the Tissue System, and
C. Potential Conflicts of Interest for Health Care Organizations and Professionals.

Participants' recommendations, key considerations and discussion highlights are provided below for each issue.

A. Opportunity to Donate

The proposed system strategy recommends increasing organ and tissue donation by:

- Optimizing and using every possible donation;
- Maximizing identification, referral and consent by ensuring the system offers every opportunity to donate i.e. Neurological Determination of Death (NDD), Donation after Cardiocirculatory Determination of Death (DCD), Living Organ Donation; and
- Building support for and active commitment to donation through public awareness and intent to donate registries.

The system strategy recommends increasing the number of tissue donors to close the most significant tissue supply gaps – corneas, tendons and pediatric heart valves, and an emergency skin supply.

In Summary

System recommendations are to increase all forms of donation. To that end, all Canadians should have the opportunity to donate, but some hospitals and health care professionals have declined to provide opportunities for all types of donations because of logistical implications and/or ethical concerns. How can the system accommodate these conflicting perspectives ethically?

Relevant System Principles Related to this Issue

- Self sufficiency in organs: Canada has an obligation to increase the number of donor organs to meet increasing demand and to mitigate transplant tourism and organ trafficking.
- Security of tissue supply: The tissue system should ensure an adequate supply of tissues such as corneas and tendons, to meet the demand.
- Population based: Organs and tissues from deceased donors are addressed as a societal resource. An integrated OTDT system should strive to meet the needs of the population it is serving.
- Cost effectiveness: Resources for the integrated OTDT system must be used efficiently.

Illustrative System-in-Action Scenarios

a. Hospital leadership and the Intensive Care Unit (ICU) physicians have ethical concerns regarding DCD, and have chosen not to implement a DCD program, and choose not to discuss this option for organ donation with a potential donor's family. However,
   i the family has expressed a desire to have their loved one be an organ donor; or
   ii the individual has registered or indicated an intent to donate; or
   iii the patient and family wishes with respect to organ donation are unknown.
b. Living organ donation rates in province A are 5 times that of the rate in Province B. A 35 year old woman living in City X is on dialysis, has a family member who is willing to donate a kidney to her, but there is no living organ donor program in the region.
c. A young man has died in a remote northern community where there are no recovery teams capable of tissue retrieval. His family is aware of the shortage of certain tissues, and has asked that his tissues be donated for transplant.
d. A woman registered her intent to donate with the provincial Organ Procurement Organization while she was living in City Z in 2008. In January 2011, an accident occurred while she was working outside of the city, and the doctors informed her family that she appears to be brain dead. The local hospital where she has been admitted does not provide organ and/or tissue donation services. Her mother remembered that her daughter had registered her intent to donate and would like to see this carried out.

Questions and Recommendations

a. Should there be distinctions in system recommendations for tissues (where there is potential to meet demand) and organs (where there is scarcity of supply)?

b. Should the design of an integrated OTDT system accommodate geography? (e.g. urban, rural and remote centres)

Recommendations

A1. Messaging should be consistent for both organs and tissues at patient, public, and professional interfaces.

A2. Although one would want to recognize donor equity so that everyone has fair access to donation, responsible societal management of limited resources may be a determining factor.

Key Considerations

- Both organ and tissue donation should be part of end-of-life care.
- Clarity and consistency in messaging at the donor interface (for both organs and tissues) would facilitate public understanding. Clear communication to the public can alleviate confusion or concerns, and is essential in helping establish a clear understanding of the system and its limitations.

- The difference between tissues and organs is appropriate to consider (morally relevant) in that there is a greater scarcity of organs than tissues.
- The geographic location of a potential donor is appropriate to consider in that it impacts the availability of organ and tissue procurement teams and services may not be available in all communities.
- It is appropriate to share with all potential donors in Canada that donation is an important and valued practice in Canada and that any and all candidates for donation (for tissues and organs) are in principle valued and welcome and will be used wherever it is possible to do so. However, only those candidates whose tissues or organs can be utilized in a timely manner and in a broader cost effective way will be procured.

Discussion Highlights

- Donor equity and utilization should be based on both system design principles and practical realities. The importance of equity must be framed within systemic realities. The weighting of system principles is dependent on context, such as geography and there may be differing criteria for tissue and organ donors at different points in the system. If people are asked to register their decision, caution is necessary as this may be interpreted as a promise that their donation will be used – instead, invitations to register should be phrased with an appropriate caveat e.g. "we would like you to offer your organs and tissues, but we reserve the right to use them only when medically indicated and logistically feasible"? It is important to ask, but the decision to use remains a medical decision made by professionals within the framework of the system.
- Donation should be facilitated in a sustainable fashion. How can cost be framed in terms of the responsible management of limited societal resources? It may be necessary to make tradeoffs between the offer of donation and the resources required for procurement.
- Asking for donation is both a benefit and a burden i.e. asking and not using can impose an emotional burden on families. Don't ask if there is no need. Also, the refusal of "a gift" requires an explanation and the system should support such transparency.
- The system should consider both stewardship and solidarity in the Canadian public as potential system principles.
- The following values concerning opportunity to donate were referred to: effectiveness of transplantation; consistency in practice; healthcare provider buy-in; the need to increase public understanding; respect for tissue/organs (ensuring they are not wasted); minimizing harm to family; public trust; community solidarity; clear communication and consistent messaging; honesty and promise-keeping; donor equity – both in procurement of organs and in distribution (spreading) of both the benefits and burdens of donation; financial efficiency, with cost-effectiveness as part of stewardship of the system.

The next two questions were discussed together.

c. Do hospitals and health care professionals have an obligation to provide an opportunity for all types of donation (e.g. NDD, DCD, living organ donation)?

d. Is there an increased obligation to provide an opportunity to donate if a person has registered his/her intent to donate?

Recommendations

A3. Yes. The system needs to ensure proximate access consistent with public policy and broader societal values.

A4. The obligation is to inform and disclose appropriate information so that potential donors/surrogates can make an informed decision about donation. It is not mandatory to provide the service in all institutions, as long as there is proximate access to donation services, and donors or their families are informed of available options.

A5. There is an obligation to provide the opportunity to donate to everyone regardless of a previously indicated desire/intention to donate, i.e., the ethical and moral obligation is the same. Registration or advance intent to donate should not influence or enhance the existing obligation to provide the opportunity to donate, though it should help guide surrogates' decisions.

Key Considerations

- Are we calling for a broader societal responsibility for physicians?[1] The clinician and institution have a fiduciary relationship to the patient. However, responsibilities to patients should be considered further in relation to the OTDT system, the health care system, and the broader public interest.
- Consistent, cross-system public policies should not be subject to the vagaries or arbitrariness of different physicians, institutions or systems. It should be recognized that there can be a distinction between institutional values and the views of selected physicians. While DCD is qualitatively different from NDD and live donation, donation care options should be transparent. In instances where physicians or institutions do not provide services, this should not be opaque, but rather there should be a clear and publicly available explanation.
- Not everyone has the same access to making or documenting a preceding decision or registering intention.
- Registration/advance intention establishes the decision and consent, but should not influence ICU access.
- One should never be in the position of weighing critical care against opportunity to procure. The primary purpose of the ICU is not to procure organs.

Discussion Highlights

- It would be appropriate to consider whether there is access to a tissue/organ recovery program before offering the opportunity to donate, because if no resource is available, then promises for donation cannot be followed through, and broken promises could undermine trust in the system.

[1] See "Potential Conflicts of Interest for Health Care Organizations and Professionals (page 15).

- It was noted that in many US jurisdictions where donors have registered their intent to donate, the consent rate from families is higher. Specifically, where intention to donate is documented, some OPOs will inform families of the decision, but not necessarily ask about their wishes, unless there is reason to believe that the patient's decision had changed. This is viewed as removing the "burden of choice" at a difficult time.
- Donor intention (including related beliefs) is an important part of advanced care planning. However, it was acknowledged that when family wishes conflict with donor intentions, resolving such conflicts remains problematic.
- From a system design perspective, it needs to be considered that if donation rates are increased, resulting in increasing numbers of organs, tissues, and transplants, then there are corresponding needs related to increasing the infrastructure's capacity to accommodate that increase (e.g., ICU and OR capacity).
- The quality or reliability of consent may vary based on a number of factors.
- Values concerning the opportunity to donate in questions c) and d) include: keeping our promises; fulfilling fiduciary responsibility to individual patients; obligation to the society through obligation to meeting system goals; respect for professional integrity; effectiveness of healthcare services broadly in saving life; likelihood of a positive decision to donate; respect for family wishes/values.

e. Are there special ethical considerations related to the treatment of child donors in an integrated OTDT system? If yes, why? If no, why not?

Recommendation

A6. There should be no specific exclusions to the opportunity to donate for pediatric deceased donations.

Key Considerations

- There are pediatric considerations such as:
  - For the vast majority of children, consent decisions are made exclusively by surrogates, which are based on specific ethical considerations
  - The system needs to take into account the distinct and essential nature of support available for families during the grieving process and other emotional burdens related to the loss of a child. There may be additional need for health care team support in the pediatric context.
  - Access to ICU services is generally not an issue for brain injured children.
- In many provinces, children receive priority access to adult organs.

Discussion Highlights

NA

B. Financial Transactions in the Tissue System

The proposed system strategy recommends a number of approaches to managing the supply of tissue.

- Canadian Blood Services will manage the national supply of tissues, and will contract domestic tissue banks to produce specific allografts for a national inventory. Tissue banks will be reimbursed for each allograft they produce. These allografts may be distributed to hospitals at no direct cost to the hospital, or they may be distributed to hospitals and clinics on a cost-recovery basis.
- Tissue imported from the United States is produced by both not-for-profit and for-profit companies. These tissue products will continue to be imported, and hospitals will continue to pay for these products as they need them to treat patients. The financial benefit therefore will continue to flow to those not-for-profit and for-profit companies.
- Tissue donated by Canadians may be directed to a US-based not-for-profit or for-profit company so that the tissue can be processed using advanced processing technology not available in Canada. The advanced tissue products made from the Canadian tissue would be returned to Canada for use.
- The process for obtaining consent will be standardized across the country. This consent will need to ensure potential donors/donor families are fully aware of any financial transactions associated with the donor's tissue.

In Summary

In the current tissue system, there are various types of financial transactions and various levels of disclosure related to those transactions. What are the consequences and corresponding ethical guidelines for cost-recovery and revenue generation in an integrated system?

Relevant System Principles Related to this Issue

- Security of tissue supply: The Canadian tissue system should ensure the adequate, safe and secure supply of tissues from a combination of Canadian and imported tissues.
- Accountability: Canadians have a right to be informed about the tissue system and the roles and responsibilities of each of the participants in that system.
- Transparency: Canadians have the right to know how the donor's gift is used.
- Cost effectiveness: The tissue system must optimize resources to be as efficient as possible. It is not cost-effective for Canada to process certain types of advanced tissues that can be purchased from international sources.
- Fairness: Canadians expect similar access to services of common quality, regardless of location.
- Ethical Practices in Tissue Donation and Transplantation: Tissue banking practices should be consistent with basic Canadian values and respectful of the altruistic gift made by tissue donors and their families.

- Population-based system: Tissues are considered a public resource to be shared nationally. The system serves patients and donors, and should obtain the maximum benefit for the maximum number of patients.

Illustrative System-in-Action Scenarios

a. A donor registers his/her intent to be a tissue donor on a provincial registry, but the possibility that the donated tissue may be sold to hospitals ("cost recovery") or may be sold to a processor in another country is not articulated on the registry. Upon the donor's death, the family is made aware of this potential sale of the donor's tissue, objects to the "commercial" nature of the donation and declines to consent to the donation.

b. Tissue donated by Canadians is shipped to the United States to companies that process the tissue into products that can be sent back to Canada and used to treat patients. More tissue is shipped to the processor than is returned to Canada, and the extra tissue is the "payment" to the processor for providing products back to Canada.

c. Canadian Blood Services is managing the national (inter-provincial/territorial) tissue supply, and has contracts with several Canadian tissue banks for a supply of tissue allografts that go into the national inventory. Payments to the tissue banks for the tissue allografts they produce exceed the actual costs of production, and are a source of revenue for the tissue bank. This revenue is used for other purposes, but within the Canadian health care system. The tissue revenue may pay for some of the costs of operating the hospital where the tissue bank is located, for an organ donation or transplant program, or for tissue research and development activity.

Questions and Recommendations

a. How should revenue from the sale of Canadian donor tissue be used?

Recommendations

B1. The Canadian OTDT system should not derive profit from the sale of donated human tissues.

B2. Where cost recovery is considered, the costs recovered should be those incurred in the procurement, processing, and distribution of tissue.

B3. It is essential that there be public disclosure of the system's underlying financial considerations.

B4. There is a strong ethic in Canada for the non-commodification of tissue. Commodification of tissues is not acceptable to donors and others involved in the system. However, this does not prohibit all financial transactions. More specifically, there is broad consensus that:

- Paying donors for human tissue is not permissible.
- Reasonable compensation to cover the services that support tissue procurement, processing and distribution is acceptable.
- Reasonable compensation should be on the basis of "cost recovery," pending a clear definition of the term.
- Selling and profiting ("profit" to be clearly defined) from tissue sale is not permissible.

It is therefore important to differentiate revenue streams related to cost recovery from those related to profit making.

Key Considerations

- A lexicon for financial transactions is required (cost recovery, revenue, not-for-profit, for-profit, sale). In particular, it is important to distinguish between profit and revenue and to clearly define boundaries for cost recovery.
- There is a distinction between paying for a service related to tissue, versus paying for tissue. Tissue should not be commodified (sold for profit or used as an exchange for other goods or services) because of the special nature many people attach to it. The system should attach costs to the use of tissue to the extent that this is necessary to make tissue transplantation possible and effective (procurement, processing, and distribution). Revenue should be used to benefit the OTDT system directly (organs and tissues) and not for other purposes.
- Quality assurance testing should be included as operational cost recovery.
- It is presumed that the public (both in Canada and abroad) doesn't question the financial practices of the for-profit tissue market due to a lack of awareness.

Discussion Highlights

- Commodification from the perspectives of tissue transplantation remains troublesome and difficult to reconcile:
  i. Currently, tissue transplant recipients in Canada are dependent on products from profit-generating services outside of Canada.
  ii. This poses an ethical inconsistency whereby, if it is wrong for the system to profit from donated tissue (as recommended above), then it ought to be equally wrong to purchase tissue from the US for transplantation in Canadian recipients.
    - This raises the possibility of striving for self-sufficiency. However, the likelihood of achieving a self-sufficient Canadian tissue system is low to non-existent.
    - It was noted that while we do not morally accept purchasing of organs from other countries, organ selling is illegal in the majority of the world whereas tissue sales are not, and from a moral and real perspective those who sell their organs are quantitatively much more victimized.
    - If it is not realistically achievable to rely solely on domestic tissue, then it is suggested that guidelines can support the ethical use of tissue purchases abroad and not deprive Canadians of needed tissue transplants
  iii. It was recommended that the Canadian public's views should be solicited on the question of tissues and related financial considerations.
- A key ethical problem regarding the sale of donated tissue was perceived to be related to pricing, whereby sales create economic incentives to procure increasing quantities of tissues and other related products.

- Profiting from tissue banking activities (common in other countries), therefore, can create conflicts of interest.
- Working towards an integrated system within an overarching sound ethical framework involves a transition period, which itself would require ethical steering – how should this be ensured?
  - The system should continue to partner with other organizations to ensure that the immediate needs of Canadians are met, without including the sale or use of tissue as currency.
  - The system should seek to ensure that international donors are treated with respect. International guidelines need to be considered (e.g. Declaration of Istanbul on Organ Trafficking and Transplantation).
  - Tissue self-sufficiency is not a realistic goal for Canada. Where possible, we need to wean ourselves off purchasing tissues from for-profit entities.
  - Canadian leaders should advocate this ethical stance other countries in an attempt to influence their policies.
- Where does tissue best fit within current regulatory models (e.g. for drugs, biologics, devices)?

b. What degree of transparency and disclosure is required?

c. Is there a distinction between disclosure for intent-to-donate registries and consent discussions with family at time of death?

Recommendations

B5. There should be no difference between degree of information and disclosure around consent discussions for organs and tissues as long as tissue transactions are based on cost recovery. If they are based on profit, this ought to be disclosed.

B6. If, for purposes of the system, cost recovery is defined, and such information is publicly accessible, then disclosure about financial transactions is not required in the context of individual consent decisions.

Key Considerations

- Lack of transparency would likely undermine public trust in the legitimacy of the system, as well as willingness to donate.
- The public should be engaged about their values concerning the economic dimensions of OTDT. If the broader policy has been subjected to sufficient public deliberation and the policy is publicly available, transparency of the economic dimension of transplantation need not be a focus of the disclosure conversation with individual donor families. Should it be the case that any profit-related activity be part of the tissue exchange, this should be disclosed to individual donors/families as part of the consent process.
- Transparency should be considered in terms of both the benefits and risks of increased knowledge, including the potential for misinterpretation, as well as the potential erosion of support for the existing tissue system.

Discussion Highlights

NA

d. Is it acceptable to sell Canadian donor tissue to not-for-profit or for-profit companies abroad, or to exchange Canadian donor tissue abroad for other tissue products needed by Canadian patients?

Recommendations

B7. The system should not sell donated tissue for profit.

B8. It is acceptable to recover costs for direct procurement, processing, and distribution activities.

B9. Extra-territorial sale of Canadian tissue and organs should be based on recovery of cost, not for the purposes of profit.

Key Considerations

- Those who collect, process and distribute tissue in Canada are the stewards of donated tissue and this implies a responsibility for the 'chain of custody' of donated tissue.
- It is important to be clear about the boundaries related to using revenue from tissue to subsidize other programs. If it is a negotiated value, Canadian Blood Services should set the price for tissue such that it doesn't constitute a subsidy for other aspects of the OTDT system or broader health care system.

Discussion Highlights

- An integrated system would create a single point of entry for international tissue purchases and would provide leverage over suppliers to ensure they are operating as close to system principles as possible.
- There is a basic ethical obligation to ensure that the public is aware of the international "for-profit" tissue market, and what role Canadian tissues may play in it.

e. Is it acceptable to purchase tissue products from not-for-profit or for-profit companies, made from tissue donated by donors in other countries?

Recommendations

B10. On the basis that not-for-profit self-sufficiency in the Canadian tissue system is not likely to be feasible (given operational limitations regarding manufacturing capacity, scale, and cost), then Canada may continue, pro tem, to rely on advanced tissue and biopharmaceutical products purchased abroad from for-profit industry for the benefit of Canadian tissue recipients.

B11. There are divergent views on this question, and uncertainty as to whether a system can be attained that is fair, and ethically consistent internally and externally.

- While it is recognized that buying tissues from US profit-driven companies may be unethical or inconsistent, this must be reconciled with the desire to attend to the health and overall wellbeing of Canadian tissue transplant recipients.
- There will be a transition period while the system moves to operationalize a vision built on ethical principles and values.

B12. Canadian Blood Services should become the single procurement and purchasing agency for tissues; this consolidation would enable the organization to select tissue vendors of higher ethical standards of practice.

Key Considerations

- What are the justifiable gains from dealing with private sector tissue purchases? What are the justifiable harms? Halting the purchase of tissue from for-profit corporations would result in unacceptable risks of harm to Canadian patients. These competing ethical principles will need to be reconciled.
- Public consultation is an option. Would the Canadian public be comfortable with the purchase of tissues from a for-profit industry?

Discussion Highlights

- It was suggested that if Canadian Blood Services were the sole tissue agency for Canada, this would enable decision-makers in the system to be more selective regarding their suppliers. If Canada becomes one of the largest buyers in the world, this would likely enable leverage.
- There may be areas where trade-offs could be made, e.g., using a synthetic product over a human derived one. It is important to always look for the best ethical alternative.
- Values concerning financial transactions in the tissue system that arose in discussions concerning the previous questions in this section include: keeping our promises to donors; respect for the donated tissue; cost-recovery for services delivered to ensure sustainability; respect for donor autonomy for using tissue in participating in research; research for advancing healthcare delivery (social wellbeing); research for advancing OTDT; public trust (transparency); public consent for economic dimensions of policy (respect for public values and transparency); meeting the immediate tissue needs of the Canadian system; self-sufficiency of tissue to meet the needs of the system; concern for the wellbeing of the individuals outside of Canada who are the source of tissue that is imported.

C. Potential Conflicts of Interest for Health Care Organizations and Professionals

The system strategy recommends increasing organ and tissue donation by:

- Specialization of donation care within hospital systems, including the implementation of Donation Physicians

  Currently, donation care in hospitals remains a professional option rather than a standard part of end-of-life care. In leading countries such as Spain, Italy and Belgium, the presence of dedicated, funded donation physician specialists is a key element in their success. Australia and the United Kingdom have recently adopted this proven model of performance enhancements. Establishing donation physicians in major hospitals across Canada (either as a shared or dedicated resource) would increase organ and tissue donation by providing clinical leadership within hospitals, ensuring all potential donors are identified and treated appropriately, and educating other health care professionals on donation.
- Implementation of an optimized funding model to achieve a sustainable system

  Consultations with clinical and administrative leaders have identified barriers or disincentives within current funding models, e.g., lack of adequate funding of hospital costs (staff and space) associated with donation activities, failure of global funding models to reimburse operative services or critical care programs for incremental donation and transplantation activity, and lack of incentives to motivate higher performance. It is recommended that an optimized funding model be developed and implemented to ensure a sustainable system that responds to the needs of patients.
- Increased investment for enabling infrastructure and for increased organ donation and transplantation activity

  New activities and increased performance targets will require funding to frontline operations. This includes money to OPOs and hospitals to accommodate the increased number of donors and a requirement to fund the new activities, including Donation Physicians.

In Summary

Health care organizations and professionals must manage the dual obligation of caring for dying patients and their families, while providing donation care to potentially dying patients and their families. What are the ethical considerations and recommendations to guide the hospital and donation physicians in preserving their duty of care, protecting the interests of dying patients, and fulfilling best practices for donation?

Relevant System Principles Related to this Issue

- Collaboration and Integration: Organ and tissue donation should be integrated into routine end-of-life care. Donation physician specialists will collaborate with multiple OTDT parties to ensure that every potential donor is identified.
- Self-sufficiency in Organs: The Canadian organ donation system should pursue self-sufficiency by professionalizing donation services and increasing the supply of organs. In doing this, the system meets the expectations of the population, as well as meeting the ethical and legal obligations to mitigate transplant tourism and organ trafficking.
- Security of Tissue Supply: The tissue system should ensure an adequate supply of tissues such as corneas and tendons, to meet the demand.
- Accountability: OTDT needs to be driven by clear authorities with clear objectives, where each participant understands their roles and responsibilities and is held accountable for results.
- Ethical Practices in OTDT:
    - Human Rights: Canadians have a moral and legal obligation to ensure that activities associated with organ and tissue donation and transplantation are carried out in an ethical manner, and are consistent with basic human rights and values, in order to prevent exploitation of vulnerable people both within and outside of Canada.
    - Accountability: the demand for organs is expected to increase, and there needs to be accountability at the hospital level for the identification of potential donors.
    - Ethical practices in organ and tissue donation and transplantation: OTDT services need to be carried out in an ethical manner that respects patient rights.

Illustrative System-in-Action Scenarios

a. Health Care region X, which has low deceased donor rates, is not willing to implement a donation physician program because of philosophical and ethical concerns. Health care region Y has implemented donation physicians and has improved donation performance. Transplant centre Y is no longer willing to share organs with transplant centre X because of differing donation rates related to this organizational policy.
b. Hospital A is a donation and transplantation hospital and has recently implemented ICU donation physicians to support all aspects of OTD. Patient H is admitted to the ICU on Thursday with a massive brain hemorrhage and a high likelihood of death. Dr. P is responsible for the ICU until Friday, after which she begins her shift as donation physician for the weekend. The attending neurosurgeon, who was previously unaware of the program, accuses the ICU physician and institution of being paid to care more for the organs than the patient.
c. Dr. W is the ICU attending physician and donation physician on call. There is a patient in the ICU with risk of imminent death awaiting a liver transplant. The ICU is at full capacity and planned high risk surgeries are being cancelled. There is a request for transfer of a brain dead patient from a referral hospital for consideration of donation.
d. The agency responsible for system performance measurement and accountability identifies a consistently low donation rate in health region B despite the costly implementation of a donation

physician program. There is consideration to withdraw funding, causing an uproar in the hospital and ICU community, both of which accuse the agency of predicating funding on organs rather than efficiency of donation care.

Consultation Questions and Recommendations

a. Is organ/tissue donation truly part of end-of-life care for deceased donation?

Recommendations

C1. Yes. The option of participating in organ and tissue donation should be a standard part of end-of-life care. The opportunity to participate is an important dimension of respecting patient values and beliefs.

Key Considerations

- Duty to the patient extends after death. Respecting a patient's wishes after death is a benefit to their legacy. To honour patients' wishes also furthers public trust in the system.
- There is some evidence that some families have felt wronged by not having the opportunity to donate.

Discussion Highlights

- End-of-life care is a series of decisions and it makes sense to have donation as part of the continuum of care.
- Explicit institutional declarations of mission and organ donation policies are important.
- Are we asking physicians to take on a broader societal obligation with respect to organ and tissue donation?
- Depending on time pressures, workload, job description and personal values, individual physicians may or may not offer the opportunity to donate. Physicians who lack the time or role should be supported by more time, appropriate remuneration, and clearly defined and supported roles.
- Answering 'yes' to this question entails additional education and training of medical professionals.

b. Does upholding the patient's benefit and best interest standard include the option of organ/tissue donation?

Recommendations

C2. Yes. Knowing a patient's preferences helps provide care that will be of benefit to them. In this regard, respecting the stated wishes, or values and beliefs of the patient are considered to be in the patient's best interest. Supporting those interests after death applies in this context through

the benefit of full sharing of information with the potential donor/surrogate decision-maker and knowledge that the donor's values and beliefs will be followed.

Key Considerations

- To the system, donation is a benefit. From the viewpoint of individual patients, the concept of benefit varies, such that donation may or may not constitute a benefit.
- Advanced registration or documented intent to donate is a form of evidence of the patient's values and beliefs but not the only form.
- Consent to treatment legislation is different than post-mortem tissue legislation. There is a need for clarity on "best interest" of a dead person.

Discussion Highlights

- The following values concerning conflicts of interest in the two previous questions arose in discussion: community solidarity; quality end-of-life care for the patient; quality end-of-life care and the good death of a loved one for family members; benefit for the patient by providing an opportunity to donate and legacy; respect for patient wishes; respect for family wishes; bereavement support for families; public consent on social policy; support for OTDT care providers; protection of the vulnerable (e.g. children); care provider integrity; support for care providers.

c. Does OTD jeopardize the duty of care to the patient and family, and if so, what ethical guidelines should protect against this?

Recommendations

C3. Yes, there is the potential for OTD to jeopardize the duty of care.

Key Considerations

- While conflict of interest has been discussed relative to the service provider level, the financing of these procedures touches both individual and organizational levels.
- There is a need to address both real and perceived conflicts of interest. Where a physician has a dual role, there has to be a clear disclosure of both roles to family members or surrogate decision makers.
- Even with licensing and regulatory frameworks, it may be difficult for individual care providers to manage this conflict (or perception of conflict) by themselves. There should be a clear separation of donation, transplantation, and care giving roles.

Discussion Highlights

- If care providers remain in a position of conflict of interest (which consultation participants believe is inappropriate if they cannot be adequately mitigated), they should have access to

resources to assist in dealing with these circumstances (such as ethical decision-frameworks to guide decision-making, access to clinical ethics consultation, guidelines for communication with patients and family, etc.).

- Survey data indicate that 19% of respondents question physicians' motives with regards to treatment decisions at the end of life.
- Currently there is no defined or funded role for physicians providing this service. Manitoba has a pilot program in place. In hospitals, where authority and power primarily resides with physicians, donation programs need to be led by physicians if they are to be sustainable.
- The following values concerning conflicts of interest in this question arose in the discussion: patient trust of the system; fiduciary responsibility/duty of care of health care professionals to patients; quality end-of-life care and the good death of a loved one for families; care provider integrity; support for care providers to live with integrity through structural conflict of interest; transparency of care provider conflict of interest to patients and families; supporting the relationship between primary physicians and patients and families.

d. Does defining the responsibilities and accountabilities attached to this role have ethical implications beyond current practice where the role is largely unstructured?

Recommendations

There were several perspectives in response to this question.

C4. Yes: there are ethical implications and they are all positive with significant benefits to the public, and donors and recipients.

C5. No: the system should already have responsibilities and accountabilities defined. Formalizing these should make no difference.

C6. Yes: if an integrated OTDT system is achieved, defining roles enhances system accountability and benefits patients.

Key Considerations

- Accountability to performance standards has the potential for conflicts related to patients' best interest (e.g. quotas, process efficiencies).
- While there will be performance metrics in the donation system, it has not been decided which metrics will be linked to the donation physician role. If institutional performance standards are linked to funding, this must be transparent. It is advisable to have metrics linked to relative efficiency, defined in terms of the proportion of donations relative to the number of willing donors, rather than absolute numbers of organs or donors (which might lead to coercion where willing donors are not prevalent).

Discussion Highlights

NA

e. Does explicit funding for the donation physician role have ethical implications beyond current practice where the role is largely unfunded?

Recommendations

While participants could envision some concerns, they also recognized that these would depend on operational considerations that were not available in the context of this consultation.

C7. Yes. It was suggested that it is necessary but not sufficient to rely on legal statutes, licensing standards, training requirements, clinical guidelines and physician integrity. Rather, structural design considerations and transparent institutional policies would likely be required to mitigate conflicts of interest arising from professional care providers' dual roles, or dual commitments.

C8. Yes. It is unreasonable to ask physicians to perform additional services without payment.

Key Considerations

- This question needs to focus on ethical implications at both provider and system levels.
- It is reasonable to expect that donation physicians would be recognized for their specialization in donation care.
- An approach that isn't fee for service is less likely to raise ethical concerns, (e.g., funding based on a distinct set of responsibilities, rather than being paid per organ donated).

Discussion Highlights

- Transparency and clear messaging were considered essential. It would be necessary to cultivate public trust in the system. It was noted that Manitoba has had success with the public launch of its donation physician program.

f. In summary, what safeguards are suggested to protect the integrity of the donation physician role?

An Ethical Framework including the following could provide initial safeguards:

- Separation of roles
- Transparency and disclosure
- Funding is required and should be consistent with providing the opportunity to donate, not as an incentive system to increase organ yield
- Structural design considerations and transparent institutional policies.

System Principles

After discussing priority issues, participants turned their attention to the document "Ethical Foundations of an Integrated OTDT System for Canada – Working Draft" and discussed the systems principles involved, who would use this document, and how it could be operationalized. The Krever report specified principles that a revamped blood supply must achieve. The proposed OTDT system design seeks to do the same. In addition to the system principles outlined in the ethical foundations document, participants identified the following principles as being important to an integrated OTDT system design:

- Cost (defined as responsible use of resources)
- Democratic legitimacy (the values held by the group are the values that inform decisions made on behalf of that group)
- Equity (donor, recipient)
- Global citizenship (recognizing international obligations of OTDT in a global context/marketplace)
- Humility (we will do our best, recognizing we are fallible)
- Pluralism (as a response to diversity e.g., respect for the diversities of views within the public, and recognition of the limitations of the perspectives of experts)
- Professional ethics
- Responsiveness (ability to respond to changing realities e.g., new evidence)
- Solidarity (a collectivist ethic)
- Stewardship
- Sustainability
- System integrity (honouring promises and commitments, (e.g., to make intentional and deliberate, values-based decisions)

Discussion Highlights

- The document on system principles needs to be a practical and accessible tool to help people make decisions about ethical challenges. It is meant to expose what work remains to be done.
- The language in the document should be straightforward, clear, and accessible to everyone with definitions for words such as 'principles', 'values', and 'rules'.
- The organization of the document should be true to what is deemed to be important, rather than categorizing ideas under the umbrella of principles or values, or words that can be misinterpreted (e.g., justice, utility, fairness).
- It is important to recognize the multitude of perspectives on OTDT, e.g., there are some communities in which the idea of organ transplantation is abhorrent, and others where there is great opportunity for further development of perspectives on OTDT.

- The System Design Steering Committee felt strongly that recommendations to governments should be made within the context of principles to which these governments already aspire. Not only are these recommendations tactical changes that need to be implemented, they fall under current realities such as the Canada Health Act, and the Romanow report.
- It was suggested that there are values we understand to be so important that we never name them.
- It was argued that there were risks involved in having an overarching framework with a single principle (e.g., human dignity, public good) or the four traditional “bioethics” principles at the top.
- A comprehensive list of principles potentially enables greater engagement by more people with the system design.
- Some questioned how we can promote a societal undertaking that isn't in the immediate good of individual participants but is in the ultimate good for society. For this reason, it was noted that it is important to be clear about what we think is good, and what we think is just.

Embedding Ethics in a Coordinated System for OTDT

Dr. Sam Shemie introduced a discussion on the need for an obvious and transparent system component that would alert staff to ethical challenges on an ongoing basis.

Criteria for an Effective Mechanism

Participants responded to the following question in plenary discussion:

"Given your experience, our discussions in this consultation, and in particular the scenarios-in-action we have explored, what criteria for an effective mechanism make sense for an integrated OTDT system?"

The following suggestions were offered.

- This mechanism should be responsive, nimble, sustainable and ongoing – something more than an ad hoc committee.
- A substantive, flexible and transparent reporting mechanism is essential. It should accommodate diversity of many types and perspectives, e.g., health professionals, informed lay public, pan-Canadian, regional and local, different bodies of knowledge, legal minds, anthropology, various countries, cultural similarities and differences, both organs and tissues.
- Include an educational component in the mechanism so that those involved have an opportunity for ongoing learning.
- Include a way for issues to be identified and addressed so that those engaged can see how their work is translated in action. How will issues be identified at various levels such as pan-Canadian and regional, and then acted upon?
- Make clear the mandate, level of independence and oversight for the mechanism, e.g., referral process, advisory nature, input to action.
- It is essential to engage transplant ethics specialists, relying on gender-based analysis among other perspectives, to assist with deliberations on emergent issues.
- Consider engaging and training a tissue expert to provide an ethicist's perspective.
- To address the paucity of published literature in this area, commission scholarship and research to support and inform the mechanism, e.g., in areas such as commodification of tissues.
- Publish (internationally) the results emerging from this mechanism as a way to share leading practice with other countries.

Optional Mechanisms

Participants developed four options for action with respect to a mechanism for monitoring, identifying and addressing ongoing ethical issues.

Option 1: A committee embedded in the integrated OTDT system with:

- Multiple points of entry where information can flow to the committee
- Access to those within and outside the system so they can send issues forward
- Inter-provincial/territorial and international connectivity
- A clear and trustworthy strategy for taking cases forward
- Appropriate funding to ensure input on public opinions (not just those of committee members) through focus groups, interviews, etc.
- Co-chairing by Canadian Blood Services and an OTDT system person.

Option 2 – A Canadian Organ and Tissue Transplant Committee

- This committee must meet an unfulfilled need through a clearly stated value proposition.
- Clarify accountabilities for this committee, e.g., is it accountable to all players, the public, Ministries of Health?
- Determine a mandate with reasonable boundaries: is it only about ethics or about ethics and law? Where do ethical issues start and stop?
- Clarify the committee's level of independence and oversight.
- Ensure the committee is technology enabled.
- Situate the committee so that its independence and integrity can't be questioned.
- Consider including an ombudsperson role in the committee structure.

Option 3 – Strategies for how to do this work

- Explore the possibility of working offline through a template that fast-tracks input to committee members and enables people to articulate their perspectives on an issue.
- Focus on drawing people into the debate and engaging them in meaningful ways.
- Consider small groups focused on specific topics in a workshop format.
- Develop ways to work iteratively on issues as they evolve in response to emerging system realities.
- Create an ombudsperson who can provide an "ethical ear" and responds to issues as they emerge.
- To accommodate diversity, consider forming citizen panels that might be able to make it more comfortable for people to bring forward their concerns.
- Create deliberate strategies to build trust in panels and committees so that the public feels confident with the process and outcomes.

Option 4 – Information Management

- Engage physician specialists in providing a conduit for gathering issues and information from other physicians and related health professionals.
- Create multiple channels for gathering information (e.g., other processes and nodes such as a website for patients, families and the public.

- Engage patient advocacy groups in providing input on concerns, (e.g., the Kidney Foundation of Canada).
- Create a way to determine the levels of complaints and how to link with provincial/ territorial colleges.
- Create a timely feedback loop for responding to concerns.
- Learn from the tools already in place in Canada's blood system, e.g., whistle blower programs, anonymous processes, a variety of escalation methods all the way up to the Canadian Blood Services Board of Directors, public feedback through a phone line, board meetings that are open to the public, contact through the provincial/territorial Ministers of Health.
- Consider processes such as a national advisory committee and an independent scientific advisory panel.
- Gather information on what works for other national systems such as cancer.

Closing Remarks

The consultation concluded with Dr. Shemie thanking everyone involved – participants, planning committee members, Canadian Blood Services staff, speakers and consultants – for all the time and effort they put into ensuring a constructive and productive process. In response to the fourth objective for the consultation – "To enable the continued development of a community of experts (stakeholders) with a commitment to ongoing dialogue about ethics in OTDT" – participants confirmed that they had achieved the purpose and objectives of the consultation and were keen to stay involved in next steps.

Dr. Graham Sher, Chief Executive Officer, Canadian Blood Services, commented that "It was an initial honour for our organization to take on the design of a new system. And representing Canadian Blood Services in working with the OTDT community has also been an honour. This consultation is an important part of our collaborative journey in making this the best OTDT system that we can."

Regarding next steps, Dr. Sher confirmed that there is still a lot of work to do and the report on this consultation will be an important piece for the Canadian Blood Services leadership team to consider when creating the final report that goes to government later in the year. He closed the consultation by again thanking participants for their valuable contribution to the OTDT system design process.

Appendix A: Consultation Participants

MARK P. AULISIO, PHD

Dr. Aulisio is Associate Professor of Biomedical Ethics at MetroHealth Medical Center, Case Western Reserve University, Cleveland Ohio, where he chairs the medical ethics committee, does ethics consultation, offers regular ethics education for health professionals and students, and is a member of both the Institutional Review and Privacy boards. Having served as executive director of the national task force that issued the American Society of Bioethics and Humanities (ASBH) report *Core Competencies for Health Care Ethics Consultation (ASBH, 1998)* and as co-chair of the ASBH Clinical Ethics Task Force (funded by the Greenwall Foundation) that developed *Improving Competence in Ethics Consultation: An Education Guide (ASBH, 2009*), Dr. Aulisio was given the ASBH Distinguished Service Award in October of 2009. He also has international experience in clinical ethics and ethics consultation, most notably through serving as project director and principal investigator on two projects funded by The Center for Global Partnership of the Japan Foundation aimed at promoting intercultural dialogue on clinical ethics between Japan and the U.S. (2003-2006), and as one of two U.S. participants in an 11 nation project "Bioethical Education on Medical Progress and Human Rights in a Multicultural, Multidisciplinary and Multireligious Environment", funded by the European Union (2006-2008). In addition, he has authored numerous articles on clinical ethics, ethics consultation, double effect, organ donation and transplant, and related areas; served as Associate Editor and contributor to the *Encyclopedia of Bioethics* (Macmillan Reference U.S.A. 2004), lead editor and contributor to the volume *Ethics Consultation: From Theory to Practice* (The Johns Hopkins University Press, 2003), and editorial board member or reviewer for over twenty peer-reviewed journals.

FRANCO A. CARNEVALE, RN, PHD

Franco Carnevale is a nurse, psychologist and clinical ethicist. He completed his undergraduate nursing degree, master's degrees in nursing, education, and bioethics, and a doctorate in counseling psychology at McGill University, as well a master’s degree in philosophy at Université de Sherbrooke. He has also completed graduate studies in health law, anthropology, and cultural psychiatry. Dr Carnevale's primary research interests include a wide range of concerns in pediatric ethics. His current academic appointments include (all at McGill University): Associate Professor (Masters Program Director), School of Nursing; Associate Member, Faculty of Medicine (Pediatrics); Adjunct Professor, Counselling Psychology; Affiliate Member, Biomedical Ethics Unit. His clinical appointments include: Clinical Ethics Consultant, Chair of the Pediatric Ethics Committee, Nursing Consultant, and Associate Member of Pediatric Critical Care, all at the Montreal Children's Hospital – McGill University Health Centre; as well as Clinical Ethics Consultant at Le Phare, Enfants et Familles (pediatric hospice and respite care).

PROF. JOHN B. DOSSETOR

Professor Dossetor is Emeritus Professor, University of Alberta, Bioethics. He has had an impressive career that included being the coordinating physician for the first kidney transplant in Canada between identical twins (1958); being appointed Director, Renal and Urologic Research, Royal Victoria Hospital, Montreal (1961); and being appointed Professor of Medicine, University of Alberta, Edmonton and director of the Division of Nephrology and Immunology, and Co-Director (with Dr. Erwin Diener) of the Research Group in Transplantation at the University of Alberta. From 1961 to 1969, immunological aspects of renal transplantation became a principal research field and Professor Dossetor was appointed as Career Investigator of the Medical Research Council of Canada from 1969 to 1989. Professor Dossetor was co-founder of the Kidney Foundation of Canada, and the founding member of the Canadian Society of Nephrology, and the Canadian Society of Transplantation. In 1985, interest in medical ethics led Professor Dossetor to a career change. After a sabbatical year in ethics at University of California, San Francisco, the Bio-ethics Centre in Montreal, the Hastings Centre, New York and an ethics course at the Kennedy Institute of Ethics, Georgetown, Professor Dossetor was appointed 1986 as Director, and later, first Professor of Bio-ethics at the University of Alberta. He was part of the founding group of the Provincial Health Ethics Network in Alberta (1996) and was Vice-Chair and Executive Director of the Network until 1998. In August, 2001, Professor Dossetor was appointed to the board of the Canadian Council for Donation and Transplantation. From 2002-2006 he was appointed Ombudsman/Ethicist to the Canadian Medical Association Journal (CMAJ) and in 2006 was co-Chair of the Governance Panel for the CMAJ. In addition to this illustrious career, Professor Dossetor has received numerous awards including: 1992: Awarded the 125th Canadian Confederation commemorative medal for work with the Kidney Foundation of Canada; Named Officer of the Order of Canada in recognition of work in medicince and bio-ethics; Awarded the Queen's Jubilee Gold Medal; Named among 'the 100 Physicians of the Century' by the Alberta Medical Association; Received the William Marsden Medal in Medical Ethics of the Canadian Medical Association. In 1995, 2003, 2006, 2007 he was awarded Lifetime Achievement awards from the Canadian Society of Transplantation and the Canadian Society of Nephrology.

MITA GIACOMINI

Mita Giacomini is a Professor in Clinical Epidemiology and Biostatistics at McMaster University, and a member of the Centre for Health Economics and Policy Analysis. Her broad research areas include social values and ethics in health technology assessment, health policy ethics, and rhetoric and reasoning in health care coverage decision making. Dr. Giacomini has provided consultation and service to local, provincial, national and international health agencies on related topics, and currently serves a member of the Ontario Health Technology Assessment Committee and Chairs its Subcommittee on Social Values and Ethics Evaluation Subcommittee. She teaches in the areas of philosophy of science, qualitative and conceptual research methods, and health policy.

AVIVA GOLDBERG

Aviva Goldberg is a pediatric nephrologist at the University of Manitoba and the ethics medical advisor to the Winnipeg Regional Health Authority. She founded and chairs the Canadian Society of Transplantation Ethics Committee and is a founding board member of the Chicago Transplant Ethics Consortium. She received a Master's degree in Bioethics and Health Policy from Loyola University of Chicago in 2006 and completed a clinical fellowship in Medical Humanities and Bioethics at Northwestern University in 2005.

BASHIR JIWANI, PHD

Dr. Jiwani is Ethicist and Director for Fraser Health Ethics Services whose mandate includes clinical and organizational ethics and diversity services. His academic background is in philosophy and public health including a Doctorate from the University of Alberta's Public Health Sciences department and a Master's degree in Applied Ethics, specializing in Bioethics, from UBC. He has been with Fraser Health since the inception of the department in 2005 and has been working in the field for 15 years. At Fraser Health Ethics Services Dr. Jiwani's role involves clinical ethics consultation, ethics-based organizational policy analysis, ethics infrastructure development and support, and ongoing ethics-based education and programming. Previously, Dr. Jiwani has served as Ethicist and Leader of the Ethics Network for Providence Health Care and Northern Alberta Coordinator for the Provincial Health Ethics Network. He has worked with a number of committees and special task forces including the Joint Oncology Drug Review Ethics Group and the College of Physicians and Surgeons of BC's Ethical Standards and Conduct Review Committee. Dr. Jiwani has just completed two terms with the Canadian Bioethics Society. His research interests include ethics and public health policy, health care resource allocation, the work of ethics resources in both clinical and organizational ethics, ethical decision-making, ethics in Islam, bioethics in a multicultural context, and issues in ethics and identity.

LOCKSLEY MCGANN, PHD

Dr. McGann is Professor, Department of Laboratory Medicine and Pathology, University of Alberta and Adjunct Scientist, Canadian Blood Services Dr. McGann's research explores methods for cryopreservation of viability and function in cell and tissue systems. This research in cryobiology aims to understand the responses of living cells and tissues to low temperatures, and to apply this information to the cryopreservation of cells and tissues. His research and experience has contributed to the development of the Edmonton Hematopoietic Stem Cell Transplant Program, the Alberta Cord Blood Bank (Canada's first public umbilical cord blood bank), and the Comprehensive Tissue Centre (a major Canadian tissue bank). In addition to his academic and research responsibilities, Dr. McGann served as Director of the Comprehensive Tissue Centre (1993-1999), Research Director of the Alberta Cord Blood Bank (1996-2000), and Laboratory Director of the Canadian Blood Services Hematopoietic Stem Cell Laboratory in Edmonton (since 2001). In 2010, he chaired the Tissue Expert Committee that developed a proposal for a national tissue bank in Canada as a part of the Canadian Blood Services OTDT Transplantation program.

KARINE MORIN, LLM

As Genome Canada's Director, National GE3LS Program, Karine Morin oversees activities related to the ethical, economic, environmental, legal and social (GE3LS) aspects of genomics research. Prior to joining Genome Canada, Karine was a Senior Ethics Policy Advisor at the Canadian Institutes of Health Research (CIHR). She also conducted research on ethical, legal and social issues related to genomics at the University of Ottawa's Institute of Science, Society and Policy. Karine worked in the US for several years as the Director of Ethics Policy at the American Medical Association, and previously as an Ethics and Health Policy Associate at the American College of Physicians. Before leaving Canada, she worked for the Commission of Inquiry on the Blood System in Canada (Krever Commission). Karine holds a Masters in Law (LLM) from the University of Pennsylvania and is a graduate of McGill University School of Law, where she obtained a joint degree in civil (B.C.L.) and common law (LL.B). Over the years, she has published widely in bioethics and law, and has taught as an adjunct at several universities in the US and Canada.

ERIN NELSON

Erin Nelson is an Associate Professor in the Faculty of Law at the University of Alberta. She holds an LLB from the University of Alberta and LLM and JSD degrees from Columbia University. Professor Nelson clerked at the Supreme Court of Canada and completed her articles, then spent two years as Project Manager at the Health Law Institute at the University of Alberta. She joined the Faculty of Law in 2000, and teaches Tort Law, Health Care Ethics and the Law and Health Law and Policy. Her research interests span the health law spectrum, and include the interface of health care law and ethics, women's health, issues in reproductive health and issues in organ and tissue donation. She has published articles and book chapters on a number of health law related topics.

DR. SAM D. SHEMIE MD

Dr. Shemie is pediatric critical care physician and director of Extracorporeal Life Support program at the Montreal Children's Hospital, McGill University; Professor of Pediatrics at McGill University Health Centre; and Medical Director (Donation), Organs and Tissues, Canadian Blood Services. Dr. Shemie's area of specialty is organ replacement in critical illness. His recent research interests have included the clinical and policy impact of organ failure support technologies and the development and implementation of national ICU based organ donation strategies, including Neurological Determination of Death, Donor Management and DCD. In December 2006, he was appointed as the Bertram Loeb Chair in Organ and Tissue Donation in the Faculty of Arts at the University of Ottawa. The mandate of the Loeb chair is to provide research leadership in current and emerging issues related to technology, death, organ donation and transplantation with an emphasis on collaborative interdisciplinary research (ethical, philosophical, religious, cultural, legal, technological and biomedical).

DR. GRAHAM D. SHER

Graham Sher, a haematologist by training, is the Chief Executive Officer of Canadian Blood Services, the agency charged with managing Canada's national blood, plasma and stem cell programs in all provinces and territories across Canada, excluding Quebec (FY 2010 revenues approx. $980 million; 4,700 employees). He has been with Canadian Blood Services since it began operations in September 1998, when he joined as its first Vice President for medical and scientific affairs. He was appointed to the position of CEO in June 2001. Under Graham's leadership Canadian Blood Services has been asked by the Federal, Provincial and Territorial governments to assume responsibility for leading the development of a national strategy for organ and tissue donation and transplantation. Graham is a recognized expert in transfusion medicine and science, and is widely sought after as a speaker nationally and internationally. He sits on a number of blood system and health care related advisory bodies, and has provided consulting support to other countries in the transformation of their health care systems. Graham is a founding member and the current Chair of the Alliance of Blood Operators and was one of the first international directors on the Board of AABB (formerly the American Association of Blood Banks).

CHRISTY SIMPSON

Christy Simpson is an associate professor in the Department of Bioethics at Dalhousie University. She is the Coordinator for the ethics-based collaborations between the Department, Capital Health and the IWK Health Centre, as well as the recently formed Nova Scotia Health Ethics Network. Her primary responsibilities include ethics education and capacity-building, policy development and review, and support for clinical and organizational ethics consultations. Christy completed her doctorate in philosophy, specializing in bioethics, at the Department of Philosophy, Dalhousie University in 2001. During her doctoral studies, Christy also undertook two clinical practicum's at local health care facilities. Christy was also a participant in the Organ Allocation in Canada Forum. Phase 1 held by the Kidney Canadian Council for Donation and Transplantation (2006).

LINDA WRIGHT

Linda Wright is Director of Bioethics and Palliative Care for the University Health Network (UHN), Toronto, Assistant Professor in the Department of Surgery, Faculty of Medicine, and a member of the Joint Centre for Bioethics at the University of Toronto. Linda provides clinical and organizational ethics consultation and teaching and has research expertise in organ transplantation ethics. She is a member of the UHN Research Ethics Board and ethics section editor of the journal Progress in Transplantation.

KIMBERLY YOUNG

Kimberly Young is Executive Director, Organs and Tissues, Canadian Blood Services. Ms. Young has a history of accomplishments in the OTDT field, including contributions at the program, provincial and national levels. As Chief Executive Officer of the former Canadian Council for Donation and

Transplantation, Ms. Young led the development of several pivotal leading practice and policy reports which resulted in improvements in patient care and system organization. Her commitment to collaborative leadership is key in building relationships with governments, programs and stakeholders leading to the development and implementation of innovative improvements in OTDT across Canada.