

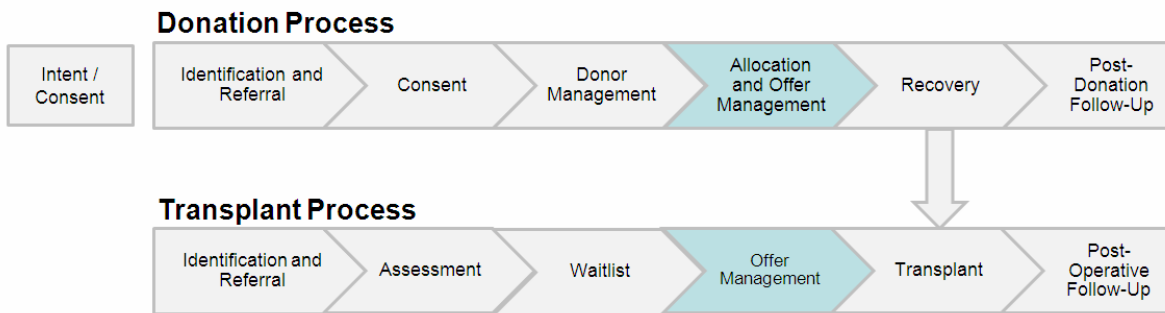
ORGAN EXPERT COMMITTEE: WHAT PRINCIPLES SHOULD GUIDE AN IMPROVED APPROACH TO ORGAN ALLOCATION? (DRAFT SOLUTION DESIGN PAPER)

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1. Scope

WHAT PRINCIPLES SHOULD GUIDE AN IMPROVED APPROACH TO ORGAN?



This question seeks to determine the principles that ought to influence the allocation process for transplantation of organs across Canada. This package outlines allocation principles, the context of current organ allocation in Canada and a review of international jurisdictions with respect to principles for allocation. The current situation for organ sharing between provinces in Canada influences discussion of allocation. Principles evidenced in structures and mechanisms for allocation of organs in international jurisdictions provide Canada an opportunity to build upon well established systems.

While the overarching principles are meant to be reflected in specific organ allocation criteria, review of the established and/or developmental criteria for specific organ allocation are not in the scope of this discussion.

2. Current State

This section seeks to provide a brief overview of how the question considered in this paper is being thought about and addressed both within Canada and in foreign systems. The “Current State” sub-section provides a synopsis of the relevant portions of the current Canadian ODT system. The “Current Community Thinking” sub-section summarizes a sampling of domestic and international viewpoints related to the topic. The “Other Models” sub-section highlights a limited selection of organizations or jurisdictions that currently address this paper’s central question in ways that may inform a broader view of possible solutions.

A. Current State

Allocation is a complex interplay of donation, waitlist dynamics and transplantation and bridges both the donation and transplantation processes. Sound principles to guide complex allocation decisions need to be explicit and embedded in all aspects of the allocation process.

Caulfield and Ries note that “in liberal democracies like Canada, most allocation policies are built on two fundamental principles: justice and utility.”¹ “Justice requires that individuals are treated equally and that unequal treatment is only justified when ‘resources are allocated in light of morally relevant differences, such as those pertaining to need or likely benefit.’”² Utility requires that we “make optimal use of the resources, so that the greatest total benefit is obtained.”³

There are five key principles that are widely reflected in the literature about organ transplantation systems, such as Eurotransplant (ET)⁴, United Network for Organ Sharing (UNOS)/Organ Procurement and Transplantation Network (OPTN)⁵, and the National Health Services Blood and Transplant (NHSBT)⁶. Although Canada embraces these principles inherently, they are not necessarily explicit. There is variability within the terminology but the following list represents these key concepts. Generally, the principle of justice is captured under equity, and utility is reflected in the principles of safety and medically sound criteria.

¹ Caulfield, T, N Ries. The Allocation of Organs: Emerging Legal Issues: A Paper prepared for the Canadian Council for Donation and Transplantation. 2006. p. 3.

² Caulfield, T, N Ries. The Allocation of Organs: Emerging Legal Issues: A Paper prepared for the Canadian Council for Donation and Transplantation. 2006. p. 3.

³ Caulfield, T, N Ries. The Allocation of Organs: Emerging Legal Issues: A Paper prepared for the Canadian Council for Donation and Transplantation. 2006. p. 3.

⁴ Eurotransplant. <http://www.eurotransplant.nl/?id=welcome>. 2009-09-04

⁵ Organ Procurement and Transplantation Network. <http://optn.transplant.hrsa.gov/>. 2009-09-04

⁶ National Health Services Blood and Transplant. <http://www.nhsbt.nhs.uk/>. 2009-09-04

- **Equity** – reflects equal access to transplantation without discrimination based on race, national or ethnic origin, colour, religion, sex, age, or mental or physical disability (Charter of Rights and Freedoms).⁷ Geography and medical status may also influence equitable allocation of organs. Equitable access to organs is sometimes identified as a principle for fairness or accessibility which has received much attention in Canada in recent years.
- **Safety** (in the context of utility) – the right organ to the right recipient with the best possible match.⁸
- **Transparency** – the medical criteria and processes for allocation, including performance outcomes, are clear and readily available to health providers and the public.⁹
- **Medically/ scientifically sound criteria** – explicit and organ specific, evidence-based medical criteria are required for allocation.
- **Accountability** - responsibility to be accountable for processes, actions, and decisions with respect to allocation policy development, implementation, and evaluation of policy.

The Current Canadian System:

The legislative framework for health care in Canada is outlined in the *Canada Health Act* which requires that provinces and territories meet certain requirements, such as free and universal access to publicly insured health care. In this system, the federal and provincial governments have very different responsibilities. Under the Canadian Constitution, healthcare is primarily under provincial jurisdiction and provinces have responsibility for its delivery. This sets the context for consideration of allocation principles given Canadian health care legislation.

One of the five pillars of the *Canada Health Act* is accessibility; defined by Health Canada as “reasonable access by insured person to medically necessary hospital and physician services must be unimpeded by financial or other barriers.”¹⁰ The *Canadian Charter of Rights and Freedoms* (Section 15.1) states that “every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religions, sex, age, or mental or physical disability.”¹¹

⁷ Canadian Charter of Rights and Freedoms. <http://www.efc.ca/pages/law/charter/charter.text.html>. 2009-09-04

⁸ Eurotransplant. <http://www.eurotransplant.nl/?id=welcome>. 2009-09-04

⁹ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Principle 11. http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation..pdf 2009-09-04.

¹⁰ Canada Health Act. <http://www.hc-sc.gc.ca/hcs-sss/medi-assur/cha-lcs/overview-apercu-eng.php>, 2009-09-04

¹¹ Canadian Charter of Rights and Freedoms. <http://www.efc.ca/pages/law/charter/charter.text.html>. 2009-09-04

Equity in accessing transplantation services is an important principle to consider in allocation.

Currently, allocation decisions in Canada are made by local Organ Procurement Organizations (OPOs) and hospital-based transplant programs. In any allocation process, the physician has the right to accept or decline the offered organ. The patient also retains the right to refuse an organ.

There is a strong foundation for allocation policy development in Canada. Organ specific (kidney, liver, and cardiac) medical criteria have been developed by experts across the country and have been published to make them widely available. There is also common understanding of the medical criteria for lung allocation within the professional community.

Allocation is influenced by the size of the donor pool. Currently, there is limited sharing of organs across provinces for kidney, pancreas, and lung transplants as confirmed by interprovincial organ exchange data.¹² It is recognized that expanding the donor pool beyond provincial boundaries assists in allocation of deceased donor organs to those with highest need. The National List is currently a manual paper/fax process out of London Health Sciences Centre in Ontario which lists urgent status hearts, heart/lungs, lungs, livers, and small bowel transplant potential recipients. All transplant programs participate.

Principles:

Medical criteria based on scientific evidence are required to inform decisions for allocation and, when consistently applied, support safety and equity for Canadians.

Transparency of medical criteria is important as a means to inform health providers as well as to provide assurances to Canadians that the system uses scientific evidence as a basis for making allocation decisions.

Safety is a principle that is adopted broadly across the health system. According to the World Health Organization (WHO), “high quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.”¹³

Local programs, provinces, organ procurement organizations, and non-governmental organizations provide written and web based information about aspects of the donation and transplantation process. The Canadian Organ Replacement Register (CORR), operated by the Canadian Institute for Health Information (CIHI), provides publicly

¹² CORR, http://www.cihi.ca/cihiweb/disPage.jsp?cw_page=services_corr_e 2009-09-04

¹³ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Guiding Principle 10. http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation..pdf 2009-09-04.

available statistical data on organ donation and transplantation. However, this data is not likely useful by the general public in terms of understanding donation and transplantation and how they may become involved. The aim for public information is to enable informed choice and to support participation for organ donation.

Accountability for organ allocation in Canada is widely distributed at program and provincial levels. Financial accountability to funders is not necessarily aligned with accountability on allocation performance activity. Programs voluntarily provide data to CORR which develops an annual statistical report on OTDT. The approach to national data collection is not mandated so data for understanding progress, identifying improvements and informing Canadians about the work of donation and transplantation is neither timely nor necessarily complete. The CORR data is limited with respect to allocation and is not robust enough to be used for accountability purposes.

B. Current Community Thinking

I. Reports and Papers

2003 Accord on Health Care Renewal – 10 Year Renewal Plan, 2003¹⁴

The 2003 Accord on Health Care Renewal and *10-Year Plan to Strengthen Health Care* is relevant for allocation principles discussions. First, Ministers agreed that access to timely care across Canada is a national priority and then laid out an action plan based on the following principles:

- 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.

World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation¹⁵

¹⁴ 10-Year Plan to Strengthen Health Care. <http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2004-fmm-rpm/index-eng.php>. 2009-09-04

¹⁵ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation..pdf 2009-09-04

The WHO *Guiding Principles on Human Cell, Tissue and Organ Transplantation* provide 11 guiding principles including some that are specific to allocation - principles of equity, transparency, and use of clinical criteria and ethical norms.¹⁶ The WHO identifies that there should be allocation rules defined by appropriately constituted committees; national and/or international transplant registries; and “public access to regularly updated comprehensive data on process”, specifically with respect to allocation (Principles 9,10,11).

Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients, 2004¹⁷

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) notes the importance of equity, fairness, and safety in the allocation process. A key mechanism whereby these principles can be manifested is through information technology. JCAHO suggests that “the use of information technology systems that support electronic sharing of information between OPOs and transplant centers should not only help to eliminate errors, but also accelerate the entire process of organ recovery and placement.”

II. Forums

**Kidney Allocation in Canada
(Canadian Council for Donation and Transplantation)
October 2006, Toronto, Ontario**

Stakeholders responsible for kidney allocation across jurisdictions met to develop consensus recommendations for allocation. The aim of the forum was to develop policy based on a step-by-step, decision-making model that would be acceptable, useful, and adaptable within unique regions across the country. The forum resulted in recommendations on key aspects of kidney allocation which have been published¹⁸ and disseminated on the Canadian Medical Association website. Clinical criteria based on consensus of experts and scientific evidence is critical to a safe allocation process, integral to allocation equity and, when published, enhances transparency. The overarching recommendations include:

- We recommend that the kidney allocation process reflect a thoughtful and transparent balance of utility and justice, grounded in the best available evidence.
- We recommend that all material information be provided to transplant recipients in a manner that is understandable and that respects existing legal requirements for both consent and donor privacy. This includes information on the potential for transmissible disease and any other

¹⁶ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation..pdf 2009-09-04.

¹⁷ Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients, p. 26. http://www.jointcommission.org/PublicPolicy/organ_donation.htm. 2009-09-04

¹⁸ Kidney Allocation in Canada: A Canadian Forum. <http://www.ccdt.ca/english/publications/final.htm>. 2009-09-04

relevant information related to the consequences of accepting or declining the organ.

- We recommend that members of the public be consulted when reviewing and developing kidney allocation algorithms. In addition, algorithms should be available for public scrutiny; for example, in hospital clinics, dialysis units, and on appropriate websites.¹⁹

**Organ Group Consultations
(Canadian Society of Transplantation)
March 2009, Banff, Alberta**

Organ specific groups (cardiac, lung, and liver) met in Banff in March 2009. The purpose of the consultation was to solicit input on the optimal design of a system of organ sharing that would facilitate the needs of transplant programs linked to national registries. The meetings provided valuable input to support the development of transparent, equitable, and accountable organ allocation policy. Key findings support:

- public involvement in policy development;
- mandated data reporting;
- a single national information management system;
- mandating program participation in Canadian registries; and
- a structure which includes a national multi-organ oversight committee and national organ-specific committees.

**National Consultation: Organ and Tissue Donation and Transplantation
(Canadian Blood Services)
September 22-24, 2008, Gatineau, Quebec**

Approximately 135 Canadian health professionals participated in the consultation. The workshop focused on the central question, “Given the need for national, integrated services in OTDT, how do we establish a system that best meets the needs of Canadian patients?”²⁰ This community of participants suggested that the governance structure for OTDT must respond to the public demand for a safe, transparent, accessible, and accountable system. Principles suggested for a national approach to allocation included: fairness, equity based on geography, is of the greatest benefit, innovative, ethical, engages stakeholders, patient-centered, based on evidence, and transparent.

C. Other Models

International programs were reviewed at a high level, with respect to principles. Three models were selected for a more detailed review:

Eurotransplant (ET)

¹⁹ Kidney Allocation in Canada: A Canadian Forum. <http://www.ccdt.ca/english/publications/final.htm>. 2009-09-04, p. 21.

²⁰ Canadian Blood Services. Organ Donation and Transplantation Syntegration Consolidated Output. Canadian Blood Services. 2009.

Three (of five) goals of Eurotransplant, which are evidence of incorporating principles, are: “to achieve an optimal use of available donor organs and tissues; to secure a transparent and objective selection system, based upon medical and ethical criteria; and to assess the importance of factors which have the greatest influence on waiting list mortality and transplant results.”²¹ In a Joint Declaration on cooperation within the framework of Eurotransplant International Foundation, all member countries agreed to the following key statements (which reflect principles for allocation).

“We emphasize:

- that the importance of international cooperation on organ transplantation within the Eurotransplant International Foundation framework has been demonstrated and should be continued;
- the necessity and added value of a fruitful cooperation between the professionals and the national authorities within the framework of ET as opposed to separate agreements;
- it is of crucial importance for the acceptance of transplantation medicine in the participating countries and in the interest of the patients that distribution of the allocated donor organs is performed as fairly as possible within a transparent and objective allocation system according to medical criteria;
- the necessity of having systems operational for quality and safety in the area of organ donation is noted. The state of a donor organ eligible to be allocated by Eurotransplant International Foundation must comply with those safety and quality requirements that are or might be imposed in accordance with the most recent advancements in medical science; and
- our involvement as Ministers of Health with Eurotransplant International Foundation, its transparent and unambiguous allocation system, and the responsibility of Eurotransplant International Foundation towards the participating member states.”²²

The United Network for Organ Sharing (UNOS)/ Organ Procurement and Transplantation Network (OPTN)²³

Again, principles are addressed in the explicit purpose of UNOS/ OPTN. “The primary purposes of the OPTN are to operate and monitor an equitable system for allocating organs donated for transplantation; maintain a waiting list of potential recipients; match potential recipients with organ donors according to established medical criteria for allocation of organs and, to the extent feasible, for listing and de-listing transplant patients; facilitate the efficient, effective placements of organs for transplantation; and increase organ donation.”²⁴ UNOS Rationale for Objectives of Equitable Organ Allocation²⁵ includes the following selected key points:

²¹ Eurotransplant. 2008 Annual Report. http://www.eurotransplant.nl/?id=annual_report p.2

²² Eurotransplant. 2008 Annual Report. http://www.eurotransplant.nl/?id=annual_report p. 18.

²³ Organ Procurement and Transplantation Network. <http://optn.transplant.hrsa.gov/>. 2009-09-04

²⁴ Organ Procurement and Transplantation Network Charter (Article II). <http://optn.transplant.hrsa.gov/>

²⁵ UNOS Rationale for Objectives of Equitable Organ Allocation (1996).

<http://unos.org/resources/bioethics.asp?index+10>

- The policy should be designed to treat people in similar situations as much the same as possible, in order to promote overall equity. (equity)
- The policy must promote efficient organ distribution to avoid organs becoming less beneficial or wasted because they were not transplanted soon enough. (efficiency)
- The policy should provide a degree of priority to patients who need transplants most urgently to minimize the number of Waiting List deaths. (reflected in medical criteria/guidelines)
- Allocation policy should not disadvantage certain patients because of the part of the country in which they live. (equity)
- The operation of organ allocation policy must be accomplished in a way that provides for accountability by all participants so as to engender trust among patients, transplant professionals, and the public. (transparency and accountability)

The OPTN notes that principles of an allocation policy may be in conflict – but that a balance must be struck amongst those competing and/or conflicting. For example, the challenges of geography (with respect to cold ischemic time) must factor in to the principles of equity, medically sound criteria, and safety.

National Health Services Blood and Transplant (NHSBT)

The NHSBT mandate includes responsibility for matching and allocating organs. The transplant arm has a “remit to ensure that donated organs are matched and allocated in a fair and unbiased way.”²⁶ There is public participation in development of policy to support transparency. The United Kingdom Transplant Advisory Group (UKTAG), which is a main source of advice to NHSBT, is responsible for ensuring equity of access to transplantation and existence of appropriate national clinical standards. The NHSBT guidelines for allocation of organs outline that the organ and tissue matching and allocation service needs to ensure: maximum and most effective use of organs and tissues; safety of persons and their survival rates; and equity and integrity of the organ sharing system.²⁷

²⁶ National Health Services Blood and Transplant. <http://www.nhsbt.nhs.uk/>. 2009-09-04

²⁷ CCDT, International Allocation and Governance Practices. March. 2008. (prepared by Deloitte).

3. Analysis

This section briefly describes the data collected and reviewed, the assumptions made, the analysis conducted, and the findings discovered during the process of identifying a slate of recommendations. For the sake of conciseness, most, if not all, of the background research and analysis details are not included. The findings listed in this section are those that seem most applicable to the evaluation of possible solutions to the central question of this paper.

A. Analysis Approach

For this paper, the principles applicable to the topic of allocation were sought from a variety of sources. Various organizations were researched in regards to their principles, both ODT systems as well as other healthcare organizations (domestic and international). Additionally, research into legislation in Canada factored into the paper as these laws are part of the context in which allocation occurs.

The primary analysis approach involved model comparisons with respect to principles for allocation and the key program mechanisms for applying those principles. For the most part, data was qualitative and included program descriptions, annual reports, policies, and/or details about allocation processes from web sites. Quantitative data was minimal, and reviewed where available as it pertained to the questions of organ allocation.

Rationale for selection of the three ODT system comparators was the diversity with respect to relationship to government(s): ET extends across countries, UNOS is a private, non-profit organization supported by government and NHSBT is part of the government health system. Australia was not included in the list of three comparators as they are in early stages of organizing around a new structure and, like Canada, are moving in a direction not yet fully developed.

B. Findings

All of the documentation reviewed identified equity as the primary principle in addressing issues of allocation. The principles of transparency, safety, basis on medically and scientifically sound knowledge, and accountability were also identified widely in the literature. While terminology was somewhat variable, the general concepts were similar. Equity, fairness, and accessibility were used interchangeably to address the idea that considerations of socioeconomic status, race, gender, religion, etc., should not be part of an allocation process. Values of collaboration, respect for roles and responsibilities, and integrity shown through commitment to the principles were common

themes. Analysis of general principles in health that could influence organ allocation included the *Canada Health Act* and the WHO. In addition, Eurotransplant (which is a formalized organization of seven countries including Austria, Belgium, Germany, Luxembourg, the Netherlands, Slovenia and Croatia), the United Kingdom, and the United States were included in the broad review of principles.

The allocation principles identified through the analysis are broad in scope and may well be applied to other phases of the processes of donation and transplantation. For example, “the concept of transparency is not exclusive to the allocation process but is central to all aspects of transplantation.”²⁸

In order to understand implementation mechanisms for the identified principles, three programs were reviewed in more detail.

Eurotransplant²⁹ is a formalized organization which represents service delivery across seven countries that have individual responsibility for health services (not unlike the provinces in Canada who have jurisdictional responsibility for health services). The mandate includes distribution of donor organs fairly within a transparent and objective allocation system according to medical criteria. The mandate takes into consideration the national regulatory frameworks of each country. There is a Board of Management which approves all policy and nine Advisory Committees, four of which are organ specific committees to develop policy. Allocation is supported by an IT system. All countries except 1 submit electronic donor data and an automated matching process takes into account country-specific laws. A culture of safety and on going quality assurance reinforces the importance of data collection, audits, monitoring and reporting for evaluation of policy and accountability.

The Organ Procurement and Transplantation Network (OPTN)³⁰ is the unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984. The act set out a network to be operated by a private, non-profit organization under federal contract. The OPTN is a unique public-private partnership that links all professionals involved in the donation and transplantation system. A compelling strength of this model is the legislation of NOTA, which requires data sharing and subsequently permits reporting and auditing as accountability processes and input to ongoing policy planning and implementation. All patients accepted on a wait list are registered with the United Network for Organ Sharing (UNOS) where a centralized computer network links all OPOs with transplant centers. All transplant hospitals, all OPOs, and all histocompatibility labs in the country are members. Membership means that programs are certified by UNOS and that they play an active role in forming the policies that govern the transplant community, including

²⁸ WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation..pdf. 2009-09-04

²⁹ Eurotransplant. 2008 Annual Report. http://www.eurotransplant.nl/?id=annual_report

³⁰ Organ Procurement and Transplantation Network. <http://optn.transplant.hrsa.gov/>. 2009-09-04

allocation. The mandate includes increasing the effectiveness and efficiency of organ sharing and equity in the national system of organ allocation.

National Health Services Blood and Transplant (NHSBT)³¹ is a government organization at the national level in the United Kingdom (which includes Wales and Ireland). NHSBT combined the blood and transplant organizations previously operating in the UK and was created under an Establishment and Constitution order. NHSBT's mandate includes responsibility for matching and allocating organs. There is an overarching organ advisory group and organ specific groups. The National Transplant Database includes details of donors and patients who are waiting for, or who have received a transplant and matching/ allocation is done centrally. A computer program is used to identify the best matched patient which supports safety, equity, and strong data collection for ongoing program improvement.

In order to realize commonly identified principles, programs have implemented a variety of practices or mechanisms.

- All three programs analyzed have a strong, centralized coordination role for allocation across jurisdictions either internationally (for ET) or nationally (UNOS and NHSBT). This is expressed in their mandate and goal statements.
- Policy development, knowledge sharing of allocation criteria and processes, data collection and analysis, monitoring and audit functions, and engagement of clinical experts are key components of all three comparators.
- Public engagement includes participation by members of the public on policy committees, access to program policies and outcomes on publicly available websites and access to documents (such as annual reports), which improves both transparency and accountability. Organ allocation policy that is transparent and supports accountability establishes trust among the public and professionals. The OPTN Final Rule provides clear details on public engagement on committees. For example, the OPTN Board of Directors must include “at least 25% transplant candidates, transplant recipients, organ donors and family members.”³² The Final Rule also outlines that “the OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.”³³ There is a well articulated process for including public input to proposed policy.
- A driver of all three programs is IT development which provides for data capture at (inter)national levels, use of computer algorithms for allocation purposes, and use of data to inform policy, monitor progress, and report on the system.
- Finally, each program explicitly acknowledges the importance of collaboration for the purpose of expanding the donor pool across the population. The larger the donor population aggregate available to the allocation process, the better the matching opportunities will be. According to the Commission of the European Communities “the cross border exchange of organs has clear benefits. Given the need of matching between donor and recipient, a large donor pool is

³¹ National Health Services Blood and Transplant. <http://www.nhsbt.nhs.uk/>. 2009-09-04

³² OPTN Final Rule. www.unow.org/SharedContentDocuments/final_rule_1.pdf. p. 14.

³³ OPTN Final Rule. www.unow.org/SharedContentDocuments/final_rule_1.pdf. p. 16.

important to cover the needs of all patients on the waiting lists. If there is no exchange of organs between Member States, then recipients that need an infrequent match will have very low chances of receiving an organ, while at the same time donors are not considered because there is not a compatible recipient in the waiting lists. This is particularly true for difficult-to-treat patients (pediatric, urgent or hyper-sensitized patients that require very specific matching) and small Member States.”³⁴

³⁴ Commission of the European Communities. 2008. Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. p. 3.

4. Options and Considerations

The purpose of this section is to provide options as a starting point for discussing the central question of this paper. The options provided are intended to illustrate a range of plausible solutions; it is likely that the Committee will ultimately recommend solution(s) to this question that incorporate elements of multiple options in addition to any elements or mechanisms that may not be represented in this paper.

In addition to the options, this section suggests "considerations" that may be helpful to reflect on during the discussion of solution options.

A. Options

I. What principles should guide an improved approach to organ allocation?

Principles provide the foundation of a strong allocation system. Processes, activities, roles, committee structures and functions ought to be based upon the agreed upon principles. Very brief definitions of the principles are identified in the table to promote discussion.

Equity	
→ equal access to transplantation without discrimination	
Mechanisms to support equity	<ul style="list-style-type: none"> ▪ Equitable allocation decisions are critically dependent upon organ specific clinical criteria applied consistently. ▪ Computerized clinical algorithms to match donors and recipients diminish the potential for inequitable allocation decisions by individuals. Consideration of national registry development for the purpose of allocation. ▪ A centralized, national allocation approach expands the donor pool for each individual recipient so all potential recipients have equal access to the same donor pool (this also relates to safety - a better and/or earlier match). The intent is not to dismiss the impact of geography (because of the time critical nature of donation to transplantation) but to create equity with considerations of geography. ▪ Increased donation by ethnically diverse populations would expand the donor pool and support equity in allocation. ▪ Oversight and committee structures to incorporate representation from all jurisdictions for all organs and to include health providers as well as members of the public (for example, persons from NGOs, ethicists, lawyers, general members of the public). ▪ A centralized allocation model would create equity for Canadians who are mobile across the country supporting portability across provinces for

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	waitlist/allocation decisions.
Mechanisms that are barriers to equity	<ul style="list-style-type: none"> ▪ When allocation is done by local programs, the donor pool is much smaller thus equity is compromised for patients across Canada. Geographic differences are highly variable. ▪ Medically sound criteria that are optional or inconsistently applied will not support the principles of safety or equity. ▪ Provinces where wait lists are shorter and donor rates are high may feel that their patients are disadvantaged by a centralized allocation model for equity of all Canadians.

Safety	
→ the right organ to the right recipient with the best possible match	
Mechanisms to support safety	<ul style="list-style-type: none"> ▪ Use of a clinically driven, computerized algorithm to identify best matches. All offers would honour a physician's judgment (medical decision making) and the physician – patient relationship. Waiting list patients have the ability to accept or reject the opportunity for transplantation whenever it arises. Similarly, the physician may exercise judgment in determining whether a specific organ, once available for transplant, is suitable for the patient. ▪ Policy/guidelines that are based on scientific evidence and medical criteria which are consistently applied. ▪ A larger donor pool creates opportunities for an earlier/better match. ▪ Standardization of laboratory processes and reporting for testing. ▪ Access to data – this includes the availability of data for policy evaluation and scholarly study to identify risks and facilitate their correction in order to minimize harm to donors or recipients. ▪ The Health Canada standards for Safety of Human Cells, Tissues and Organs for Transplantation Regulations.
Mechanisms that are barriers to safety	<ul style="list-style-type: none"> ▪ Safety may be compromised with a smaller donor pool because patients may wait longer for a match (resulting in decreased quality of life and sicker patients going for transplant with the potential for poor clinical outcomes). ▪ Inconsistent application of listing criteria could erode trust in the system.

Transparency	
→ criteria and processes for allocation are clear and readily available to health providers and the public	
Mechanisms to support transparency	<ul style="list-style-type: none"> ▪ Maintaining public access to regularly updated comprehensive data on allocation processes. Such transparency is not inconsistent with shielding from public access information that could identify individual donors or recipients while still respecting the necessity of traceability (WHO, Principle 10). UNOS, ET and NHSBT all have websites with widely accessible information for the public. ▪ Participation by public members on allocation committees. WHO suggests that allocation committees include medical experts and members of the public to ensure not only a medical focus but one that reflects community values and ethics. ▪ Public hearings could be built in to new allocation policy development (as done by UNOS).

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	<ul style="list-style-type: none"> ▪ Public declaration of commitment to the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation that relate to allocation (Principles 9, 10, 11) which support equity, safety, medically sound criteria, and accountability. ▪ Full transparency of matching and allocation results as well as offers and related accept/decline (with rationale).
Mechanisms that are barriers to transparency	<ul style="list-style-type: none"> ▪ Lack of public knowledge of or access to the criteria/processes for allocation of organs. ▪ No public representation for allocation policy development.

Medically / scientifically sound criteria

→ organ specific medical criteria are required for allocation.

Mechanisms to support medical criteria	<ul style="list-style-type: none"> ▪ Consistent application of medical criteria promotes objective, safe and justifiable allocation decisions. Consistency requires widespread knowledge of the criteria by health providers and is supported by public awareness of the criteria. ▪ Data about the allocation process is required to support expert opinion and inform policy revision and ongoing improvements to allocation.
Mechanisms that are barriers to medical criteria	<ul style="list-style-type: none"> ▪ Lack of publication of medical criteria, or lack of knowledge of published medical criteria for application to the allocation process. ▪ Application of medical criteria being optional or inconsistently applied can erode trust in the system.

Accountability

→ responsibility to be accountable for processes, actions and decisions with respect to allocation policy development, implementation and evaluation of policy.

Mechanisms to support accountability	<ul style="list-style-type: none"> ▪ Required reporting of allocation processes and activities for local/provincial and national accountability. ▪ Data shared to a central repository which enables reports and evaluation of policy. ▪ Monitoring and audits support accountability. ▪ Computerized listings, matching, allocation and offer management can identify all activities related to a transplant event.
Mechanisms that are barriers to accountability	<ul style="list-style-type: none"> ▪ Lack of centralized, comprehensive data on allocation in Canada limits understanding on any variances or possible improvements. ▪ Canada has limited ability to report on allocation at the international level or for accountability to the funders due to limitations in data. ▪ Organizations that may 'own' data may be reluctant to share it for fear that it could be used out of context, especially if benchmarks suggest their organization's performance is lagging behind. ▪ Provinces where donor rates are low have no repercussions.

B. Considerations:

A statement of national principles will guide future decisions, policy, and/or mechanisms for the complex work of allocation. For example, an IT structure that aligns donors with potential recipients using a clinically relevant algorithm will more fully realize equity and potentially improve matching (safety). Additionally, data collection is inherent in the use of such an IT system and therefore accountability can be more readily demonstrated through data and data analysis.