Background Paper for the Organ Expert Committee

What principles should guide an improved approach to organ allocation?

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What principles should guide an improved approach to organ allocation?

1. Introduction

A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians, can be found at organsandtissues.ca, along with the other background documents in this series.

Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.
- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the Call to Action report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.

For more information on these documents or the Call to Action report, please contact:

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2. **Scope**

This paper examines the principles that should influence the allocation process for transplantation of organs in Canada. It outlines allocation principles and the context of current organ allocation in Canada, and reviews international jurisdictions with respect to principles for allocation. Organ allocation mechanisms and experience in international jurisdictions provide Canada an opportunity to build on 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.

3. **Current State**

A. Current State

Allocation is a complex activity that bridges the donation and transplantation processes. Sound principles to guide allocation decisions must 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.” These authors go on to say that “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.” According to Caulfield and Ries, utility requires that we “make optimal use of the resources, so that the greatest total benefit is obtained.”

There are five key principles (listed below) that are widely noted in the literature about organ transplantation systems such as Eurotransplant (ET), United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN), and the National Health Services Blood and Transplant (NHSBT).

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What principles should guide an improved approach to organ allocation?

Although Canada embraces these principles, they are not necessarily explicit. Generally, the principle of justice is captured under equity, and utility is reflected in the principles of safety and medically sound criteria.

- **Equity** refers to equal access to transplantation without discrimination based on race, national or ethnic origin, colour, religion, sex, age, or mental or physical disability. Geographic location 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) means allocating the right organ to the right recipient with the best possible match.

- **Transparency** means that the medical criteria and processes for allocation, including performance outcomes, are clear and readily available to health providers and the public.

- **Medically and scientifically sound criteria** that are explicit, organ specific and evidence-based are required for allocation.

- **Accountability** refers to the responsibility to be accountable for processes, actions and decisions with respect to allocation policy development, implementation, and the evaluation of policy.

### The Current Canadian System

The legislative framework for healthcare 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 healthcare. In this system, the federal and provincial governments have vastly different responsibilities. Under the Canadian constitution, healthcare is primarily under provincial jurisdiction. This sets the context for consideration of allocation principles given Canadian healthcare legislation.

One of the five pillars of the Canada Health Act is accessibility, which is 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." 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." 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 medical criteria (kidney, liver, and cardiac) have been developed and published by experts across the country. There is also common understanding within the professional community of the medical criteria for lung allocation.

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 exchanges.
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Exchange data. It is recognized that expanding the donor pool beyond provincial boundaries will assist in allocation of deceased donor organs to those patients with highest need. The national waitlist for urgent-status patients is currently a manual paper and fax process out of London Health Sciences Centre in Ontario. It lists urgent status patients waiting for hearts, heart/lungs, lungs, livers, and small bowels. 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 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.”

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 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 of public information is to enable informed choice and to support participation in 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 OTDT statistical report. The approach to national data collection is not mandated, therefore 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.

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B. Current Community Thinking

This section of the paper presents recent findings and recommendations from national and international reports to inform operating and funding model discussions.

Reports and Papers


The 2003 Accord on Health Care Renewal and the resulting 10-Year Plan to Strengthen Health Care are relevant to allocation principles discussions. Ministers agreed that access to timely care across Canada is a national priority and 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 healthcare services they need, when they need them;
- collaboration between all governments, working together in common purpose to meet the evolving healthcare 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 Transplantation

WHO sets out 11 principles including some that are specific to allocation: principles of equity, transparency, and use of clinical criteria and ethical norms. WHO indicates that there should be allocation rules defined by appropriately constituted committees; national and international transplant registries; and "public access to regularly updated comprehensive data on process", specifically with respect to allocation (Principles 9–11).

Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients, 2004

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) notes the importance of equity, fairness, and safety in the allocation process. 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."

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Forums

Kidney Allocation in Canada
(Canadian Council for Donation and Transplantation)

October 2006—Toronto, Ontario

Stakeholders responsible for kidney allocation met to develop consensus recommendations for allocation. The aim of the forum was to develop a step-by-step, allocation decision-making model that would be acceptable, useful, and adaptable within individual regions across the country. The resulting recommendations on key aspects of kidney allocation have been published\(^{16}\) 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 that:

- the kidney allocation process reflect a thoughtful and transparent balance of utility and justice, grounded in the best available evidence;

- 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 relevant information related to the consequences of accepting or declining the organ; and

- 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.\(^{17}\)

Organ Group Consultations
(Canadian Society of Transplantation)

March 2009—Banff, Alberta

Organ-specific groups (cardiac, lung, and liver) met to provide input on the optimal design of an organ sharing system 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 that 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 to 24, 2008—Gatineau, Quebec

Approximately 135 Canadian health professionals participated in the consultation. The workshop focused on the question, “Given the need for national, integrated services in OTDT, how do we establish a system that best meets the needs of Canadian patients?”\(^{18}\) The 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, patient-centered, evidence-based, and transparency.

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What principles should guide an improved approach to organ allocation?

C. Other Models

International programs were reviewed with respect to principles. Three models were selected for a more detailed review.

**Eurotransplant (ET)**

Three (of five) goals of Eurotransplant 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.”\(^{19}\) 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.”\(^{20}\)

**The United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN)**\(^{21}\)

Principles are explicit in the purpose of UNOS and 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.”\(^{22}\)

UNOS Rationale for Objectives of Equitable Organ Allocation\(^{23}\) includes the following selected key points:

- The policy should be designed to treat people in similar situations as much the same as possible, in order to promote overall equity.

- The policy must promote efficient organ distribution to avoid organs becoming less

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beneficial or wasted because they were not transplanted soon enough.

- The policy should provide a degree of priority to patients who need transplants most urgently to minimize the number of waiting list deaths.

- Allocation policy should not disadvantage certain patients because of the part of the country in which they live.

- 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.

The OPTN notes that a balance must be struck amongst those principles of an allocation policy that may conflict. For example, the challenges of geography (i.e., distances over which either patients or organs must be transported for transplant) 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 is tasked “to ensure that donated organs are matched and allocated in a fair and unbiased way.”

There is public participation in the 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 state 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.

4. Analysis

A. Analysis Approach

The principles applicable to allocation were sought from a variety of sources. Various ODT systems and healthcare organizations (domestic and international) were researched in regards to their principles. Research also addressed relevant legislation in Canada, as these laws frame the context in which allocation occurs.

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

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Three ODT system comparators were chosen for their diversity in relation to governments: ET extends across a number of countries; UNOS is a private, non-profit organization supported by government; and NHSBT is part of the government health system. Australia was not included among the comparators as it is in the early stages of organizing a new structure and, like Canada, is moving in a direction not yet fully defined.

B. Findings

All reviewed documentation identified equity as the primary principle in addressing issues of allocation. The principles of transparency, safety, accountability and basis on medically and scientifically sound knowledge 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 indicate that considerations of socioeconomic status, race, gender, religion, etc., should not influence allocation processes. Collaboration, respect for roles and responsibilities, and integrity (shown through commitment to principles) were common values. The analysis of general health principles that could influence organ allocation included the Canada Health Act and the WHO. In addition, Eurotransplant (which is a formalized organization of seven countries), 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.”

To understand implementation mechanisms for the identified principles, three programs were reviewed in more detail:

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Implementation. All patients accepted on a waitlist are registered with the United Network for Organ Sharing (UNOS), where a centralized computer network links all OPOs with transplant centers. The network’s mandate includes increasing the effectiveness and efficiency of organ sharing and equity in the national system of organ allocation. All transplant hospitals, all OPOs, and all histocompatibility labs in the country are network 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 allocation.

National Health Services Blood and Transplant (NHSBT)29 is a national government organization in the UK. NHSBT combined the blood and transplantation 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 are a number of organ-specific advisory groups. The national transplant database includes details of donors and patients who are waiting for, or who have received a transplant. Matching and allocation is done centrally. A computer program identifies best-matched patients and supports safety, equity and strong data collection for ongoing program improvement.

To adopt commonly identified principles, programs have implemented a variety of practices or mechanisms:

- 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 programs.
- In each case, members of the public participate on policy committees, and can access documents (such as annual reports), policies and outcomes via websites, which improves transparency and accountability, and builds trust among the public and professionals. The OPTN Final Rule provides clear details on public engagement on committees. For example, membership on the OPTN Board of Directors must include “at least 25% transplant candidates, transplant recipients, organ donors and family members.”30 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.”31 There is a well-articulated process for including public input to proposed policy.
- A driver of all three programs is IT development—which provides data capture at national and international 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 important to cover the needs of all patients on the waiting lists. If there is no exchange of organs between

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Canadian Blood Services

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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.⁴³

5. Options and Considerations

This section presents a range of plausible solutions as well points for reflection during the discussion of solution options.

A. Options

What principles should guide an improved approach to organ donation?

Principles provide the foundation of a strong allocation system, underpinning its processes, activities, roles, committee structures and functions. A brief definition of each principle is included in the table to inform discussion.

<table>
<thead>
<tr>
<th>Equity: Equal access to transplantation without discrimination</th>
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<tbody>
<tr>
<td><strong>Ways to support equity</strong></td>
</tr>
<tr>
<td>• Equitable allocation decisions are critically dependent on consistently applied, organ-specific clinical criteria.</td>
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<tr>
<td>• Computerized clinical algorithms to match donors and recipients diminish the potential for inequitable allocation decisions by individuals.</td>
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<tr>
<td>• A centralized, national-registry allocation approach would help ensure that all potential recipients have equal access to the same expanded donor pool (this also relates to safety by ensuring a better or faster match). The intent is not to dismiss the impact of geography (because of the time critical nature of donation to transplantation) but to uphold equity by taking into geography considerations.</td>
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<tr>
<td>• A centralized allocation model would improve equity by ensuring portability (waitlist and allocation decisions would apply even if patients move between provinces).</td>
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<td>• Increased donation by ethnically diverse populations would expand the donor pool and improve allocation equity.</td>
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<tr>
<td>• Establish committee and other oversight structures (incorporating representation from all jurisdictions, for all organs and including health providers as well as members of the public (for example, NGO representatives, ethicists, lawyers and citizens).</td>
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</tbody>
</table>

What principles should guide an improved approach to organ allocation?

Barriers to equity
- When allocation is carried out by local programs, the donor pool is much smaller, thus equity is compromised for patients across Canada.
- Medically sound criteria that are optional or inconsistently applied will not support the principles of safety or equity.
- Provinces where waitlists are shorter and donor rates are high may feel that their patients are disadvantaged by a centralized allocation model that improves equity for all Canadians.

<table>
<thead>
<tr>
<th>Safety: The right organ allocated to the right recipient with the best possible match</th>
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<tbody>
<tr>
<td>Ways to support safety</td>
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<tr>
<td>- Identify best matches using a clinically driven, computerized algorithm. All offers would honour a physician’s judgment (medical decision making), as well as the physician-patient relationship. Waitlist patients can accept or reject the opportunity for transplantation. Similarly, the physician may exercise judgment in determining whether a specific organ, once available for transplant, is suitable for the patient.</td>
</tr>
<tr>
<td>- Policies and guidelines that are based on scientific evidence and medical criteria which are consistently applied.</td>
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<td>- A larger donor pool creates opportunities for an earlier or better match.</td>
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<td>- Standardization of laboratory processes and reporting for testing.</td>
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<td>- Access to data, which includes the availability of data for policy evaluation and scholarly study to identify risks and facilitate their correction to minimize harm to donors and recipients.</td>
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<thead>
<tr>
<th>Barriers to safety</th>
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<tr>
<td>- Safety may be compromised with a smaller donor pool because patients may wait longer for a match (resulting in decreased quality of life and the potential for poor clinical outcomes as sicker patients undergo transplant).</td>
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<tr>
<td>- Inconsistent application of listing criteria could erode trust in the system.</td>
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<table>
<thead>
<tr>
<th>Transparency: Criteria and processes for allocation are clear and readily available to health providers and the public</th>
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<tbody>
<tr>
<td>Ways to support transparency</td>
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<tr>
<td>- Maintain public access to comprehensive and regularly updated data on allocation processes. Such transparency is not inconsistent with shielding 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.</td>
</tr>
<tr>
<td>- Participation by the public on allocation committees. WHO suggests that allocation committees include medical experts and members of the public to ensure not only a medical focus but also one that reflects community values and ethics.</td>
</tr>
</tbody>
</table>
What principles should guide an improved approach to organ allocation?

| Barriers to transparency | • Lack of public knowledge of, or access to, organ allocation criteria and processes.  
| | • No public representation for allocation policy development. |

| Medically and scientifically sound criteria:  
Organ-specific medical criteria are required for allocation |
|---|
| Ways to support medical criteria | • Consistent application of medical criteria promotes objective, safe and justifiable allocation decisions. Consistency requires widespread knowledge of the criteria by health providers, and general awareness of the criteria by the public.  
| | • Data about the allocation process is required to inform policy revision and ongoing system improvements. |

| Barriers to medical criteria | • Lack of publication of medical criteria, or lack of knowledge of published medical criteria that applies to the allocation process.  
| | • Application of medical criteria being optional or inconsistently applied can erode trust in the system |

<table>
<thead>
<tr>
<th>Accountability: Organ-specific medical criteria are required for allocation</th>
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</table>
| Ways to support accountability | • Required reporting of allocation processes and activities for local, provincial and national accountability.  
| | • Data shared to a central repository that enables reports and evaluation of policy.  
| | • Monitoring and audits support accountability.  
| | • Computerized listings, matching, allocation and offer management can identify all activities related to transplant events. |

| Barriers to accountability | • Lack of centralized, comprehensive data on allocation in Canada limits understanding of any variances or potential improvements.  
| | • Current data limitations restrict Canada’s ability to report on either allocation at the international level or accountability to funders. |
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- 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.
- Provinces where donor rates are low face no repercussions.

B. Considerations

A statement of national principles will guide future decisions, policy, and 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 and safety. Additionally, because data collection is inherent in the use of such an IT system, accountability can be more readily demonstrated through data and data analysis.