



Canadian Blood Services  
Société canadienne du sang

# OTDT System Principles Introductory Briefing

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## Purpose of this Document

System Principles are expected to be an important element of the Strategic Plan for OTDT in Canada. **One of the goals of the October Steering Committee meeting** is to discuss this topic and agree on a preliminary set of System Principles for OTDT in Canada.

This background paper has been developed to accomplish the following:

- Introduce the topic of System Principles to the committee in advance of the meeting
- Introduce types of principles for consideration and the sensitive issues to which they relate
- Provide illustrative and stimulating examples of System Principles outside the context of OTDT in Canada

## What are System Principles?

System Principles are assertions of fundamental belief or value that can guide the behavior and decisions of an organization or system. As an organization or system seeks to fulfill an ultimate goal or mission, the principles describe the conditions under which that mission should be pursued. The following are examples of how several other organizations describe the role of their Principles:

- The World Health Organization, in its Preamble to OTDT Guiding Principles, states, “*The following Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles.*”
- The final report of the Australian National Clinical Taskforce on Organ and Tissue Donation named a set of principles, stating, “*Activity and Recommendations underpinned by the following...*”
- The Board of Assisted Human Reproduction Canada “*has adopted a set of principles to guide its activities and operations.*”
- “Building a National Diabetes Strategy” [for Canada] identifies “*potential principles for collaboration*” and “*principles for action.*”

## Why does OTDT in Canada need System Principles?

There are a number of emotionally and morally sensitive issues that arise in the context of Organ and Tissue Donation and Transplantation. These relate to end-of-life issues, definitions of “autonomy” and “consent” and the allocation of scarce resources (donated organs), among others. For the OTDT strategic plan to be successful, policy development and implementation will need to address these challenging issues. Principles can improve the system’s ability to address these issues by providing a shared understanding of core beliefs and how they can inform both mundane and contentious policy discussions and debates.

## What types of Principles can a system endorse?

Organizations and systems express their core beliefs through System Principles in different ways. Principles may vary in their source motivation, their scope for guidance or even their style of expression.

Below are some different ways to think about System Principles. It is hoped that these can provide a starting point for engaging the members for guidance on System Principles in OTDT.

### Principle Motivation

- Moral philosophy and individual rights
  - Examples: “Integrity,” “Privacy”
- The responsibilities and expectations of public organizations
  - Examples: “Accountability,” “Transparency,” “Safety is...paramount”
- How an organization or system ought to be structured or operated
  - Examples: “Knowledge-sharing,” “Integrated Approach”

### Principle Scope

In this section, a broader selection of examples is included, with some sample definitions to stimulate discussion in the upcoming committee meeting.

- Universal
  - Typically valid and meaningful even outside of the system; may be enshrined in law
  - Principles suggested for consideration include the following, with example definitions:
  - **Safety** of products and procedures
    - The importance of protection of life and quality of life and of the avoidance of adverse events
    - Consideration should be given to the relationship between safety, cost and risk
  - **Autonomy** of individuals
    - The individual right to permit or prohibit medical procedures
    - Has relevance to OTDT in many areas, including:
      - The definition of “consent” for deceased donation
      - The limits of “consent” for living donation
      - Concerns with transplant tourism and with compensated and direct donation
  - **Access**
    - The individual right to receive medically necessary care regardless of financial means
      - May have some overlap with “equity”

- **Equity / Fairness / Justice**
  - The goal of equal treatment of individuals; unequal treatment only justified “in light of morally relevant differences, such as those pertaining to need or likely benefit”<sup>1</sup>
  - Can be in tension with Utility, particularly in the realm of organ allocation
- **Utility**
  - The goal of “optimizing use of the resources so the greatest total benefit is obtained”<sup>2</sup>
  - Can be in tension with Equity/Fairness/Justice, particularly in the realm of organ allocation
- **Transparency**
  - The availability or reporting of an organization’s information, methods and/or results
  - Can be tension with Privacy, as complete transparency could imply the reporting of sensitive individual information to audit policies or procedures
- **Privacy**
  - The protection of individual information; often in accordance with the laws of a given jurisdiction
  - Can be in tension with Transparency, as complete privacy could imply a constraint on the ability to report or audit policies or procedures
- **Responsible / Accountable**
  - Results are measured and reported; organization is responsive to results and to stakeholders
  - May be interpreted with a focus on the rights of stakeholders and/or the responsibilities of the organization (e.g., reporting
- **Context-specific**
  - Typically valid only for the specific medical, political or cultural context
  - May be applications of universal principles
  - Principles suggested for consideration include the following, with example definitions:
  - **Collaboration**
    - The importance of broad input to policy development or organizational direction; may specifically reference integration of expert or public points of view, among others
    - Current project process is intended to be “consultative” and this may be similar

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<sup>1</sup> [The Allocation of Organs: Emerging Legal Issues; CCDT 2006](#)

<sup>2</sup> [The Allocation of Organs: Emerging Legal Issues; CCDT 2006](#)

- **Independence**
  - The importance of recognizing the responsibilities of organizational partners or jurisdictions (e.g., Provinces, Regional Health Authorities, Health Canada)
  - May be tension between an “independence” principle and the effectiveness of a national or interprovincial organization
- **Evidence-based decision making**
  - The importance of organization operating based on data and research
- **Security of Supply / Self-sufficiency**
  - The importance of Canadian supply meeting a certain percentage of Canadian demand
  - Lack of security of supply was agreed to be a problem in the Tissues Case for Change
- Situational
  - Selected for emphasis based on a combination of *context* and *time*; are there pressing issues in OTDT (or healthcare more broadly) that could *require a statement of Principle* to successfully address?
  - May be valid for a finite duration
  - Principles suggested for consideration include the following, with example definitions:
  - **Traceability**
    - A specific application of “Safety”
    - Traceability and other safety and quality concerns were cited as a specific gap in the Tissues Case for Change
  - **Efficiency**
    - Given consideration due to the the economic situation and the “inefficiency” problem in the Tissues Case for Change
  - **Measurement**
    - Though arguably a component of “Accountability,” a lack of data and measurement was cited as a problem in both the Organs and Tissues Cases for Change.
  - Examples: “Safety of all blood, components and plasma fractions should be paramount.” (Canadian Blood Services)

### Principle Style

- Headlines vs. Long form declarations
- Mandates vs. Encouragements

## Appendix - What are some examples of System Principles in other contexts?

This table includes several examples of Principles for health systems, organizations and processes in Canada and elsewhere.

### Canada Health Act

<http://www.hc-sc.gc.ca/hcs-sss/medi-assur/cha-lcs/overview-apercu-eng.php>

#### Public Administration

The public administration criterion, set out in section 8 of the CHA, applies to provincial and territorial health care insurance plans. The intent of the public administration criterion is that the provincial and territorial health care insurance plans are administered and operated on a non-profit basis by a public authority, which is accountable to the provincial or territorial government for decision making on benefit levels and services, and whose records and accounts are publicly audited.

#### Comprehensiveness

The comprehensiveness criterion of the CHA requires that the health care insurance plan of a province or territory must cover all insured health services provided by hospitals, physicians or dentists (i.e., surgical-dental services which require a hospital setting) and, where the law of the province so permits, similar or additional services rendered by other health care practitioners.

#### Universality

Under the universality criterion, all insured residents of a province or territory must be entitled to the insured health services provided by the provincial or territorial health care insurance plan on uniform terms and conditions. Provinces and territories generally require that residents register with the plans to establish entitlement. Newcomers to Canada, such as landed immigrants or Canadians returning from other countries to live in Canada, may be subject to a waiting period by a province or territory, not to exceed three months, before they are entitled to receive insured health services.

#### Portability

Residents moving from one province or territory to another must continue to be covered for insured health services by the "home" jurisdiction during any waiting period imposed by the new province or territory of residence. The waiting period for eligibility to a provincial or territorial health care insurance plan must not exceed three months. After the waiting period, the new province or territory of residence assumes responsibility for health care coverage.

Residents who are temporarily absent from their home province or territory or from Canada, must continue to be covered for insured health services during their absence. This allows individuals to travel or be absent from their home province or territory, within a prescribed duration, while retaining their health insurance coverage.

The portability criterion does not entitle a person to seek services in another province, territory or country, but is intended to permit a person to receive necessary services in relation to an urgent or emergent need when absent on a temporary basis, such as on business or vacation.

If insured persons are temporarily absent in another province or territory, the portability criterion requires that insured services be paid at the host province's rate. If insured persons are temporarily out of the country, insured services are to be paid at the home province's rate.

Prior approval by the health care insurance plan in a person's home province or territory may also be required before coverage is extended for elective (non-emergency) services to a resident while temporarily absent from their province or territory.

### **Accessibility**

The intent of the accessibility criterion is to ensure insured persons in a province or territory have reasonable access to insured hospital, medical and surgical-dental services on uniform terms and conditions, unprecluded or unimpeded, either directly or indirectly, by charges (user charges or extra-billing) or other means (e.g., discrimination on the basis of age, health status or financial circumstances). In addition, the health care insurance plans of the province or territory must provide:

- a. reasonable compensation to physicians and dentists for all the insured health services they provide; and
- b. payment to hospitals to cover the cost of insured health services.

Reasonable access in terms of physical availability of medically necessary services has been interpreted under the Act using the "where and as available" rule. Thus, residents of a province or territory are entitled to have access on uniform terms and conditions to insured health services at the setting "where" the services are provided and "as" the services are available in that setting.

### **Board of Directors of Assisted Human Reproduction Canada**

<http://www.ahrc-pac.gc.ca/doc.php?did=9&lang=eng>

1. Independence
2. Transparency
3. Evidence-informed decision-making
4. Inclusiveness
5. Knowledge-sharing
6. Accountability

### **OPTN / UNOS Organ Allocation Principles (US)**

1. Shall be based on sound medical judgment;
2. Shall seek to achieve the best use of donated organs;
3. Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
4. Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
5. Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
6. Shall be reviewed periodically and revised as appropriate;
7. Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
8. Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

### **Canadian Blood Services**

1. The safety of the blood supply is paramount
2. A fully integrated approach is essential
3. Accountabilities must be clear
4. The renewed blood supply system must be transparent
5. Voluntary donations should be maintained and protected
6. National self-sufficiency in blood and plasma collections should be encouraged
7. Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged
8. Safety of all blood, components and plasma fractions should be paramount
9. Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained
10. A cost-effective and cost-efficient blood supply for Canadians should be encouraged
11. A national blood supply program should be maintained

### **Citizens for Mental Health “Framework for Action”**

[http://www.cmha.ca/data/1/rec\\_docs/119\\_citizens\\_report04\\_eng.pdf](http://www.cmha.ca/data/1/rec_docs/119_citizens_report04_eng.pdf)

1. Value mental health as much as physical health
2. Develop the political will to break down barriers within government – among departments at the federal level; jurisdictionally between federal and provincial governments and municipal levels as required and appropriate
3. Work collaboratively with all partners: various levels of government, voluntary sector organizations, private interests
4. Support community capacity and individual empowerment and promote the development of caring communities by providing appropriate resources and tools for knowledge and skill development; acknowledge the value of experience and expertise at the community level
5. Acknowledge and support the key role of basic necessities of life such as housing and sufficient income in supporting the (mental) health needs of the population and the prevention of (mental) health problems
6. Ensure equitable access to appropriate housing, training and education, employment opportunity, and health services as a basic right
7. Maximize consumer engagement in policy and planning process, and development and delivery of programs and services
8. Respect diversity in the development and provision of appropriate programs and services; consideration to include consumer status, gender, life stage, race, ethnocultural uniqueness, resident status, urban/rural and regional needs
9. Work against stigma through all policy and program areas
10. Ensure non-discriminatory policy and practices; ensure that all government policies and practices comply with international standards of human rights
11. Provide adequate and sustained funding to make it all work.

### **Australia National Taskforce on Organ and Tissue Donation**

<http://www.health.gov.au/internet/main/publishing.nsf/Content/organ-donation-nctf-final-report.htm>

1. That all governments have overarching policy and funding responsibilities to implement policy and program reforms.
2. That there is a shared responsibility for the implementation of specific policy and program reforms between governments and the clinical sector.
3. That leadership is required from individual government ministers and clinical leaders.

4. That given the nature of Australia's decentralised health system, improvements will require those involved to think nationally but act locally.
5. That it is essential to engage the sector widely in order to develop practical and supported initiatives.
6. That the treatment and care of patients and their families will always be the priority of clinical staff.
7. That the needs of all those involved in the donation process must be acknowledged and respected.
8. That organ, eye and tissue donation should be regarded as a natural and routine aspect of end-of-life considerations and that state and territory governments are responsible for ensuring appropriate end-of-life care services.
9. That ongoing social and clinical research, using robust research methodologies, must be utilised to properly define the solutions, especially in the development social marketing and community awareness activities. and implementation of
10. That international comparators must be understood in depth.
11. That we must learn from the lessons of history.

#### **World Health Organization (Guiding Principles for Transplantation)**

1. Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if: (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal.
2. Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.
3. Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients. Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.
4. No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law.

Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

5. Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned. The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.
6. Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation. Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.
7. Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.
8. All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.
9. The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.
10. 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. The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.
11. The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.