Canadian Blood Services
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Background Paper for the OTDT Committees

Organ and Tissue Donation and Transplantation Legislative and Legal Framework

Contents

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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:

Canadian Blood Services
Organ and Tissues Donation and Transplantation
1800 Alta Vista Drive
Ottawa ON K1G 4J5

Phone: 613-739-2300
feedback@blood.ca

2. OTDT Legislative and Legal Framework

Organ and tissue donation and transplantation in Canada operates within a legislative framework shared between Federal and Provincial/Territorial governments. Generally, the Federal government has responsibility for the safety of cells, tissues and organs intended for transplantation, and the Provincial/Territorial governments are responsible for healthcare and the practice of medicine in their provinces. Pursuant to its responsibility for the safety of Canadians, the Federal government regulates the safety requirements for the importation, distribution and processing of tissues and organs for transplantation, and the manufacture, importation and distribution of medical devices. The provinces and territories, on the other hand, fulfill their responsibility for healthcare and the practice of medicine in their jurisdictions through the regulation of consent to donation and medical practice, and the funding of provincial and territorial organ procurement organizations.

OTDT is also affected by common law (or judge-made law), which amongst other things, requires reasonable care to be taken in the manufacture, procurement or collection, storage, transportation, and transplantation of biological products such as organs and tissues.

Note: Due to the many elements involved in organ and tissue donation and transplantation (OTDT) in Canada, this memo cannot provide a comprehensive summary of all laws that may impact OTDT operations. It only provides a summary of the principal avenues of regulation by the Federal government and provinces and territories, and an introduction to common law issues.

A. Federal Responsibility

Under the *Food and Drugs Act*, the Federal Government has authority to regulate biologics, including cells, tissues and organs, with the objective of assuring that biologics available to Canadians are safe, effective and of high quality. This role is fulfilled by regulations made under the Federal *Food and Drugs Act*[1], including the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*[2] (CTOs) and the *Medical Devices Regulations*[3] (MDRs). These regulations impose minimum safety standards for the use of cells, tissues and organs, and medical devices.

I. Cells, Tissues and Organs

The CTOs came into force on December 7, 2007. They regulate the importation, distribution and processing of cells, tissues and organs for transplantation. The CTOs apply to organs and minimally manipulated cells and tissues. If cells or tissues are more than minimally manipulated, they are considered medical devices, and are regulated under the MDRs.

The CTOs set out safety standards associated with donor screening; donor testing; donor suitability assessment; retrieval, except for organs and islet cells; testing and measurements performed on the cells, tissues or organs after they are retrieved; preparation for use in transplantation, except for organs; preservation; quarantine; banking; packaging and labelling; and error, accident and adverse reaction reporting. The CTOs prohibit the transplantation or importation of any cells, tissues or organs, unless they have been processed by establishments registered with Health Canada. In order to register with Health Canada, an establishment must submit an application, which includes a statement dated and signed by the medical director or scientific director of the

[1] R.S., 1985, c. F-27.
[2] SOR/2007-118.
[3] SOR/98-282.

establishment that certifies that the establishment is in compliance with the CTOs.

The CTOs incorporate by reference parts of the National Standards of Canada standards, including CAN/CSA-Z900.1 entitled *Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements*, and specific standards relating to tissues, ocular tissues, perfusable organs, and lymphohematopoietic cells. This approach is intended to ensure that the regulations stay current, in spite of rapid changes in knowledge in the field. National standards will be more easily amended than regulations, which may quickly become outdated.

II. Medical Devices

The MDRs are made under the Federal *Food and Drugs Act*. They impose safety standards on the manufacture, importation and distribution of medical devices, including more than minimally manipulated cells, tissues and organs.

Under the MDRs, all medical devices manufactured from or incorporating human or animal cells or tissues or their derivatives are classified as Class IV Medical Devices, the highest risk category. The MDRs prohibit any establishment from importing or selling any Class IV medical device unless the manufacturer of the device has a license issued by Health Canada in respect of that device. The Regulations define selling broadly, to include distribution without consideration.

The MDRs also require any establishment importing or distributing a Class IV medical device for which it does not hold the licence to have an establishment licence, subject to certain exceptions. In order to obtain an establishment license, the establishment must disclose the medical devices it is distributing or importing and their manufacturers. It must also confirm that it has procedures in place in respect of distribution records, complaint handling and recalls; mandatory problem reporting; and, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of the devices. The MDRs impose minimum standards for such procedures

B. Provincial / Territorial Responsibility

Provinces and territories are generally responsible for regulating health care and the practice of medicine within their jurisdiction. Pursuant to this responsibility, the Provinces and Territories have each passed a Human Tissue Gift Act (or equivalent), regulating the donation and transplantation human tissues in their jurisdiction. In addition, provinces and territories have jurisdiction to legislate with respect to protection of privacy, and the collection, use and disclosure of personal information.

I. Human Tissue Gift Acts

Each province and territory has a Human Tissue Gift Act (or equivalent), which regulates the donation and transplantation of human tissues and organs in that jurisdiction. There are many differences in approach to this legislation between the jurisdictions, but certain trends and similarities exist. A few commonalities and distinctions are described below:

- *Consent*: All jurisdictions address requirements for consent to post mortem donation of organs and tissues, including who may consent on behalf of an individual if he or she is incapacitated or deceased. Many jurisdictions also legislate requirements for consent to *intervivos* donation of organs and tissues. There are differences between the jurisdictions in these provisions, for example, about the minimum age for consent to donation, the circumstances under which a minor may consent, and formalities around the form of consent.

- *Determination of Death*: Most jurisdictions place certain restrictions on the determination of death of an organ or tissue donor, including the number of physicians who must pronounce the death, and their non-involvement in the case of the transplant recipient.
- *Definition of Death*: The legislation of some jurisdictions specifies when death occurs. In most jurisdictions, legislation specifies that death must be determined in accordance with accepted medical practice. In contrast, in Manitoba, legislation specifies that death occurs "at the time at which irreversible cessation of all that person's brain function occurs"[4], while in PEI, legislation notes that death "includes brain death".[5]
- *Privacy*: The Human Tissue Gift Acts of many jurisdictions address the confidentiality of information concerning, for example, the identity of individuals who consent or refuse consent to donate and the identity of donors and transplant recipients. Some jurisdictions have provisions authorizing disclosure of personal information between hospitals and organ procurement organizations for the purposes of facilitating organ and tissue donation and transplantation. In spite of this kind of provision, a donor's consent to donation under a Human Tissue Gift Act is not considered consent to disclosure of that donor's personal information.
- *No Purchase*: Most jurisdictions have a prohibition on the purchase or sale of tissue, body or body part for remuneration. The wording of this prohibition varies from jurisdiction to jurisdiction.
- *Liability*: Most jurisdictions give protection from liability to any person acting in good faith without negligence under the authority of the relevant Tissue Gift Act.
- *Reporting Deaths*: British Columbia, Ontario and Manitoba have compulsory reporting of certain deaths to organ procurement organizations.
- *Required Inquiry*: New Brunswick and Nova Scotia require hospitals to enquire about consent to donate from the person entitled to consent, unless this would be inappropriate under the circumstances.
- *Establishment of Trillium*: In Ontario, *Trillium Gift of Life Network Act*[6], in addition to addressing many of the issues discussed above, establishes Ontario's organ procurement organization, Trillium Gift of Life Network, and gives it its OTDT mandate. Ontario is unique in this respect - no other jurisdictions create their organ procurement organizations by statute.

II. Privacy

While perhaps not directly part of the legislative framework governing organs and tissues, privacy law plays an important role in OTDT. Generally, privacy laws apply to the collection, use and disclosure of personal information, and clearly the donation and transplantation of organs and tissues requires significant collection, exchange and retention of personal information about both donors and recipients by hospitals, organ procurement organizations, product manufacturers, and Canadian Blood Services.

However, beyond this generalization, it is very difficult to summarize how the various laws apply to different participants in the OTDT process. The provinces and territories taken several distinct approaches to regulating privacy, and the various laws with privacy provisions apply to the organizations involved in OTDT differently. A number of laws contain provisions regarding the collection, use and disclosure of personal information relating to OTDT, including legislation regarding the privacy of personal health information, Freedom of Information and Protection of Privacy Acts, Hospital Acts, and Tissue Gift Acts. In addition, organizations engaging in transactions with a commercial character may be subject to the Federal *Personal Information Protection and Electronic Documents Act*[7] (PIPEDA). For example, hospitals are covered by privacy

[4] *Vital Statistics Act,* C.C.S.M. c. V60, s.2.
[5] *Human Tissue Donation Act*, R.S.P.E.I. 1988, c. H-12.1, s.1(b).
[6] R.S.O 1990. c. H.20.
[7] 2000, c. 5.

legislation as follows: Four of the provinces, Alberta, Saskatchewan, Manitoba and Ontario, have enacted privacy legislation specific to health information that hospitals and some other health organizations must comply with when collecting, using and disclosing personal health information. Several other provinces are in the process of drafting or awaiting declaration of similar legislation. In the remaining jurisdictions and until legislation is passed in those provinces that are working on health information privacy legislation, hospitals are required to comply with the privacy legislation applicable to public bodies. Provisions under some provincial and territorial Hospital Acts have also been enacted that limit a hospital's ability to disclose patient records. Other legislation has provisions dealing with the disclosure of specific personal information for specific purposes (for example, Public Health Acts).

This picture only gets more complicated when applied to organizations that are not hospitals, but participate in OTDT in some other capacity, such as organ procurement organizations, product manufacturers, and Canadian Blood Services. Due to this complexity, it will be important to examine privacy laws closely when considering any changes to the OTDT system or the establishment of national organ and tissue registries.

C. Tort Liability

Participants in the organ and tissue supply chain could also theoretically face tort liability arising out of, for example, donor selection, organ or tissue collection, transportation, importation, storage or transplantation. Tort liability is a product of common law (judge-made law), and not any specific legislation. Specific examples of tort liability relevant to OTDT include the following:

- *Product Liability:* Product liability is the area of law that holds manufacturers, wholesalers, and retailers responsible for the safety and quality of their products. It is relevant to the OTDT legal framework, because to some extent OTDT is about the procurement and distribution of the biological products of organs and tissues. These activities must be done with due care for the donor and recipient.
- *Duty to Warn:* Producers and distributors may also have a duty to warn recipients should information become known suggesting a potential risk associated with transplanted organs or tissues. If, for example, a manufacturer of tissue products becomes aware that a tissue donor may have been infected with a transplant-transmissible infection, the manufacturer has an obligation to warn all other recipients of tissues from that donor. This obligation underlines the importance of traceability of transplanted products.

3. Summary

The laws outlined above provide the broad framework in which OTDT operates in Canada. However, as described above, there are any number of additional laws which influence and apply to specific elements in the organ and tissue supply chain, such as laboratory licensing, importation and exportation, and transportation laws. In formulating any strategy for OTDT a comprehensive legal review will be required.