Domain Summary

LEGISLATION & POLICY

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PREPARED BY

The Canadian **Donation and Transplantation** Research Program

Programme de recherche en **don et transplantation** du Canada

TRANSPLANT QUÉBEC

Organ donation, together for life for 50 years

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INTRODUCTION

Transplant Québec and the Canadian Donation and Transplantation Research Program (CDTRP) collaborated to co-host The International Donation and Transplantation Legislative and Policy Forum (the Forum). The Forum assembled 61 national and international experts in donation and transplantation, including patient, family, and donor partners, to provide consensus guidelines on the structure of an ideal organ and tissue donation and transplantation (OTDT) system.

Legislation & Policy, one of seven domains developed through the Forum, provides expert guidance for legislative and policy reform. The 12 recommendations outlined in the chapter focus on (1) legal definitions and legislative scope; (2) consent requirements for donation; (3) allocation of organs and tissue; (4) operation of OTDT systems; and (5) travel for transplant and organ trafficking.

OTDT systems vary in how they are regulated, and local cultural, social, and economic factors impact law and policy. However, the 12 recommendations address fundamental issues in OTDT and thus, could apply wholly or in part to any jurisdiction developing or reforming its system.

The complete publication and this accompanying summary report will assist those making and implementing legislative and policy changes in an OTDT system. They also support patient, family, and donor education in understanding the legal implications of donation and transplantation. The publication can be accessed here.

LEGISLATION AND POLICY AS TOOLS TO INCREASE OTDT PERFORMANCE

The global shortage of organs and tissues for transplant has led to the implementation of laws and policies by governments and health system decision-makers to improve OTDT system performance. Building a high-functioning system means avoiding exploitation, maintaining public trust, and ensuring systems operate fairly and effectively. One method to accomplish this requires legislation and policy to remain consistent with international ethical principles outlined in the World Health Organization's Guiding Principles, Declaration of Istanbul, and the Barcelona Principles. For more information, see Baseline Ethical Principles domain.

By establishing a clear legal foundation, decision-makers and governments set the minimum standards of practice, clarify the rights, privileges, and obligations of those involved in OTDT, and safeguard the underlying ethical principles necessary for a high-functioning OTDT system.

Below is a brief summary of the recommendations and some of their justifications which are explained in detail in the full manuscript.

LEGAL DEFINITIONS & LEGISLATIVE SCOPE

RECOMMENDATION #1

Jurisdictions should have a legal definition of death that complies with expert medical consensus. In deceased donation, donated organs and tissues should not be removed before death has been determined.

Not all jurisdictions legislate what constitutes death as a matter of law. Given that deceased donation systems depend on public trust, including the expectation that organ recovery will only happen after death, [1] it is important to legally clarify the point at which death occurs and avoid future legal challenges that have questioned the clarity and application of potentially ambiguous definitions. [2,3,4]

RECOMMENDATION #2

Legislation must clearly define the scope of its application, including the substances it pertains to (i.e., organ/tissues/blood) and the activities it encompasses (i.e., donation for transplantation, anatomical instruction, or biomedical research).

Organs and tissues are recovered and processed differently, which may justify different regulations. [5,6]

CONSENT REQUIREMENTS FOR DONATION

RECOMMENDATION #3

Living organ donation must require first-person informed and voluntary consent by individuals with decision-making capacity.

As living organ donation entails serious health risks to the donor and is not for the donor's medical benefit, they must give voluntary consent, free from coercion or undue influence. They must also understand the full range of potential risks associated with living donation. [7,8]

RECOMMENDATION #4

Legislation must clarify consent or authorization requirements for deceased donation, including the role of substitute decision-makers. Legislation should also clarify consent requirements for pre-mortem interventions.

Consent requirements vary between jurisdictions, some with opt-in (or explicit consent) frameworks and others with opt-out frameworks (presumed consent). Regardless of the framework, legal requirements for expressing intent or refusal to donate must be clear. The role of substitute decision-makers and if they can override a prior decision should be clear. [9,10]

ALLOCATION OF ORGANS AND TISSUE

RECOMMENDATION #5

Access to the organ transplant waitlist and organ allocation algorithms must be consistent with the non-discrimination provisions of applicable human rights laws. This will usually mean ensuring that allocation policies do not discriminate directly or indirectly based on certain characteristics set out in law (i.e., age, race, sex, religion, sexual orientation, disability, etc.). When there is differential access to transplantation based on one of these characteristics, this must be legally justifiable under relevant human rights laws.

Organ allocation systems balance multiple and potentially inconsistent factors, such as utility (maximum medical benefit), fairness, justice, and public trust. [11] In developing legislation and policy, decision-makers must consider how waitlist and transplant policies are affected by anti-discrimination laws.

In seeking to balance utility and equity, allocation policies often directly or indirectly disadvantage protected groups (e.g. not allocating an organ to an elderly recipient with multiple co-morbidities). Anti-discrimination laws may accept some discriminatory impacts as suitable if the benefits are clear (e.g. number of life years gained by allocating to a younger recipient) but require transparent, well-reasoned rationales for such decisions.

RECOMMENDATION #6

Legislation should include quality and safety standards that govern the entire process, from identification of patients who are potential donors to transplantation or disposal of recovered organs and tissues, including auditing when necessary. Legislation should clearly identify agencies with the legal authority to operationalize and enforce these standards.

Organs and tissues recovered under strict quality and safety parameters are likely to provide the best clinical outcomes for recipients. [12–15] This pathway includes the referral process, evaluation of the donor and the individual organ, retrieval, preservation, transport, tracing and registration, processing, and conclude with transplantation and follow-up of the recipient. [13,16,17]

This can be accomplished by having legislation and regulations ensuring that healthcare personnel directly involved at all stages of donation and transplantation are suitably qualified and competent. [7,12,13,18-23]

To assess compliance, government authorities must have access to OTDT data and metrics.

RECOMMENDATION #7

Legislation should include "mandatory referral," namely the legal requirement that clinicians and administrators notify OTDT authorities of every death and imminent death according to clinical triggers and in a timely manner. ODOs and tissue authorities should have the legal authority to confirm mandatory referral compliance by auditing records of deaths within institutions. If necessary, existing privacy laws should be amended to ensure necessary patient information can be communicated to OTDT authorities to meet these obligations.

Timely identification, referral, and assessment of potential donors are the building blocks of an effective and functioning OTDT system. Globally, the failure to identify possible donors is the most significant factor explaining differences in deceased donation rates across jurisdictions. The OTDT authority should determine whether a patient could be a potential donor. This task should not be done by individual treating clinicians, who may not always be familiar with the acceptance criteria.

Dedicated protocols for individuals in end-of-life care should be established to ensure donation is considered. Protocols that correspond with this legal requirement should specify clinical triggers for clinicians to notify the OTDT authority when they have patients with catastrophic brain injury or when there is a plan to withdraw life-sustaining treatment expected to result in circulatory death. These clinical triggers should be simple, clearly defined, and easy to audit. They should also focus on prognostic factors and should lead to referral regardless of a patient's age or co-morbidities.

Access the Forum's fact sheet on Mandatory Referral here.

RECOMMENDATION #8

Legislation should require OTDT systems to operate with transparency (e.g., public reporting of system performance metrics) while maintaining the privacy of donors and recipients.

Collecting specific data to monitor and improve OTDT systems and maintain transparency is necessary. This can include, but is not limited to, the number of donated organs (living and deceased), organ donation pathways (donation after brainstem death or donation after circulatory determination of death), the number of people waiting for transplants of different types, the number of transplants performed, and the outcomes of transplantations. [24] Collecting more detailed data can be used to monitor equity and fairness in allocation, though respecting the privacy of both the donors and recipients is paramount.

Access the Forum's fact sheet on Data Collection and Public Reporting here.

RECOMMENDATION #9

Jurisdictions should clarify through legislation or policy whether and when recipients and donor/donor families can meet post-transplant. If contact is permitted, it should occur post-transplant, with bilateral consent, and subject to oversight and regulation.

If a jurisdiction determines contact is permitted, all individuals must be informed of the benefits and risks of revoking anonymity at the beginning of the transplant process and be provided with adequate counselling and support. [25,26] It is recommended that a third-party facilitator manages the process of revoking anonymity, which should not be done until after transplantation. [27,28]

TRAVEL FOR TRANSPLANT AND ORGAN TRAFFICKING

RECOMMENDATION #10

Legislation must explicitly prohibit both trafficking in human organs, tissues, and cells, and trafficking in persons for the purpose of organ removal.

Organ trafficking and trafficking in persons for organ removal are universally condemned practices.[18,29–31] Experts have argued that these prohibitions should be enforced through criminal law to facilitate the international prosecutions of organ trafficking practices. [35,36]

There are different definitions of organtrafficking. While earlier international legal guidelines focused more on trafficking in persons, recent guidelines (such as the updated Declaration of Istanbul and the Council of Europe Convention) are more specifically targeted at organ trafficking and cover a broader range of activities inherent in this practice.

It is recommended that prohibitions on organ trafficking and trafficking in persons for the purpose of organ removal use these more recent definitions. States should also consider ratifying international treaties prohibiting these practices, such as the Council of Europe Convention Against Trafficking in Human Organs. [30]

RECOMMENDATION #11

Legislation should prohibit commercial transactions for organs that go beyond cost recovery by institutions.

Entering or facilitating commercial transactions for organs should be prohibited. [7,30,31] Although there are costs associated with organ donation and transplantation that may legitimately be charged, these costs should be regulated and limited to those directly related to recovery, storage, allocation, and transplantation. They should not include compensation for the organ itself. [32]

Similarly, although living donors may be reimbursed for out-of-pocket expenses incurred from their donation (i.e., travel, accommodation, etc.), they should not receive compensation for the donated organ.

RECOMMENDATION #12

Jurisdictions should establish bilateral or multilateral organ and data sharing programs.

While organ trafficking is prohibited and jurisdictions should aim for OTDT self-sufficiency, international travel for transplantation is permitted under officially regulated bilateral or multilateral organ sharing programs. [7,18,33-35] Exchanging organs across jurisdictional boundaries within a country (i.e., from one state or province to another), should be regulated through national data-sharing agreements.

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REFERENCES

[1] Robertson JA. The Dead Donor Rule. The Hastings Center Report. 1999;29(6):6-14. doi:10.2307/3527865

[2] McKitty v Hayani. ONCA 2019, 805 (Ontario Court of Appeal).

[3] Re A (A Child). EWHC [2015], 443 (High Court of Justice (Family Division) 2015)

[4] In Re Guardianship of Hailu, 361 P.3d 542.(Supreme Court of Nevada 2015).

[5] Sandiumenge A, Domínguez-Gil B, Pont T, et al. Critical pathway for deceased tissue donation: a novel adaptative European systematic approach. Transpl Int. 2021;34(5):865-871. doi:10.1111/tri.13841

[6] Domínguez-Gil B, Delmonico FL, Shaheen FAM, et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transplant International. 2011;24(4):373-378. doi:10.1111/j.1432-2277.2011.01243.x

[7] World Health Organization. WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Published online 2010. https://apps.who.int/iris/handle/10665/341814

[8] World Medical Association. WMA Statement on Organ and Tissue Donation. WMA; 2017.

[9] Rosenblum AM, Horvat LD, Siminoff LA, Prakash V, Beitel J, Garg AX. The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. Nephrol Dial Transplant. 2012;27(6):2533-2546. doi:10.1093/ndt/gfr619

[10] Chon WJ, Josephson MA, Gordon EJ, et al. When the Living and the Deceased Cannot Agree on Organ Donation: A Survey of US Organ Procurement Organizations (OPOs). American Journal of Transplantation. 2014;14(1):172-177. doi:10.1111/ajt.12519

[11] Tong A, Jan S, Wong G, et al. Rationing scarce organs for transplantation: healthcare provider perspectives on waitlisting and organ allocation. Clin Transplant. 2013;27(1):60-71. doi:10.1111/ctr.12004

[12] Council of Europe. Guide to the Quality and Safety of Organs for Transplantation. 7th ed. Council of Europe; 2018.

[13] World Health Assembly. Human Organ and Tissue Transplantation WHA63.22. World Health Assembly; 2010.

[14] Council of Europe, Committee of Ministers. Recommendation Rec(2004)19 of the Committee of Ministers to Member States on Criteria for the Authorisation of Organ Transplantation Facilities.; 2004.

[15] Council of Europe, Committee of Ministers. Recommendation CM/Rec(2020)4 of the Committee of Ministers to Member States on the Quality and Safety of Organs for Transplantation.; 2020.

[16] European Parliament. Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

[17] Editrice Compositori. Notify: Exploring Vigilance Notification for Organs, Tissues and Cells.; 2011.

[18] The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition). Transplantation. 2019;103(2):218-219. doi:10.1097/TP.0000000000002540

[19] Advisory Committee on Organ Transplantation. Consensus Recommendations. U.S. Health Resources and Services Administration; 2002.

[20] U.S. Centers for Medicare and Medicaid Services. Conditions of participation for hospitals, Code of Federal Regulations 2021;42:482.45.

[21] American Medical Association. Code of Medical Ethics: Opinions on Organ Procurement and Transplantation. AMA; 2016.

[22] Nuffield Council on Bioethics. Human Bodies: Donation for Medicine and Research. Nuffield Council on Bioethics; 2019.

[23] Institutes of Medicine. Organ Donation: Opportunities for Action. (Childress JF, Liverman CT, eds.). The National Academies Press; 2006. doi:10.17226/11643

[24] National Health and Medical Research Council. Ethical Guidelines for Organ Transplantation from Deceased Donors. NHMRC; 2016

[25] UBCIC Obo Indigenous Persons v. BC Ministry of Health and Others. BCHRT 2020, 144 (British Columbia Human Rights Tribunal 2020).

[26] National Council on Disability. Organ Transplant Discrimination Against People with Disabilities.; 2019.

[27] Petrini C, Green R. Organ donor families should be free to meet their recipients under controlled conditions if both sides wish, Italian National Committee for Bioethics says. Commentary. Ann Ist Super Sanita. 2019;55(1):6-9. doi:10.4415/ANN_19_01_03

[28] Dicks SG, Northam H, van Haren FM, Boer DP. An exploration of the relationship between families of deceased organ donors and transplant recipients: A systematic review and qualitative synthesis. Health Psychology Open. 2018;5(1):2055102918782172. doi:10.1177/2055102918782172

[29] UN Protocol to Prevent, Suppress and Punish Trafficking in Persons Especially Women and Children. United Nations; 2000.

[30] Convention against Trafficking in Human Organs, CETS 216. Couoncil of Europe; 2015.

[31] Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin. Council of Europe; 2002.

[32] World Medical Association. WMA Statement on Organ and Tissue Donation. WMA; 2017.

[33] Rudge C, Matesanz R, Delmonico FL, Chapman J. International practices of organ donation. BJA: British Journal of Anaesthesia. 2012;108(suppl_1):i48-i55. doi:10.1093/bja/aer399

[34] Delmonico FL. The development of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Nephrology Dialysis Transplantation. 2008;23(11):3381-3382. doi:10.1093/ndt/gfn552

[35] Consultation Meeting on Transplantation with National Health Authorities in the Western Pacific Region: Meeting Report. WHO; 2005.

[36] Directorate-General for External Policies of the Union (European Parliament), Bos M. Trafficking in Human Organs. Publications Office of the European Union; 2015.