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Legislation and Policy Recommendations on Organ and Tissue Donation and Transplantation From an International Consensus Forum

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Background. There is a shared global commitment to improving baseline donation and transplantation performance metrics in a manner consistent with ethics and local cultural and social factors. The law is one tool that can help improve these metrics. Although legal systems vary across jurisdictions, our objective was to create expert, consensus guidance for law and policymakers on foundational issues underlying organ and tissue donation and transplantation (OTDT) systems around the world. **Methods.** Using the nominal group technique, a group composed of legal academics, a transplant coordinator/clinician, and a patient partner identified topic areas and recommendations on foundational legal issues. The recommendations were informed by narrative literature reviews conducted by group members based on their areas of expertise, which yielded a range of academic articles, policy documents, and sources of law. Best practices were identified from relevant sources in each subtopic, which formed the basis of the recommendations contained herein. **Results.** We reached consensus on 12 recommendations grouped into 5 subtopics: (i) legal definitions and legislative scope, (ii) consent requirements for donation, (iii) allocation of organs and tissue, (iv) operation of OTDT systems, and (v) travel for transplant and organ trafficking. We have differentiated between those foundational legal principles for which there is a firm basis of support with those requiring further consideration and resolution. Seven such areas of controversy are identified and discussed alongside relevant recommendations. **Conclusions.** Our recommendations encompass some principles staunchly enshrined in the OTDT landscape (eg, the dead donor rule), whereas others reflect more recent developments in practice (eg, mandatory referral). Although some principles are widely accepted, there is not always consensus as to how they ought to be implemented. As the OTDT landscape continues to evolve, recommendations must be reconsidered for the law to keep pace with developments in knowledge, technology, and practice.

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Donated organs and tissues save and improve lives for both patients experiencing organ failure and those in need of tissue or tissue products. Given that these substances are scarce and in demand and are sourced from human bodies, careful and clear regulation is needed to avoid exploitation, maintain public trust, and ensure that organ and tissue donation and transplantation (OTDT) systems operate fairly and effectively. A clear legal foundation sets minimum standards of practice; clarifies the rights, privileges, and obligations of those involved in OTDT; and safeguards underlying ethical principles necessary for an acceptable and defensible OTDT system.

The ways in which OTDT is regulated vary between jurisdictions because different states have different legal traditions and customs regarding the creation of new law. However, regardless of a jurisdiction's legal tradition, there are foundational legal issues and questions that all jurisdictions implementing OTDT systems must address. This article highlights these issues and makes recommendations grounded in relevant literature as to how they should be addressed in law. This project aligns with and supplements other efforts to achieve international cooperation and consensus building to improve OTDT systems around the world.[1-3]

Given the broad scope of this domain and the variations between legal systems, these recommendations provide a high-level overview of certain key issues that we recommend be addressed in law to support an ethical and effective OTDT system. These recommendations are therefore not prescriptive in terms of the precise language to be enshrined in law or method of implementation. And although there are many legal issues beyond those addressed here, we cover those most essential for OTDT systems and for ensuring the safety and wellbeing of donors and recipients.

MATERIALS AND METHODS

This article addresses 1 of 7 domains from the International Donation and Transplantation Legislative and Policy Forum. The methodology explaining how domain groups were assembled is detailed elsewhere.[4]

Participants in the Legal Foundations Chapter included 3 legal academics, 1 transplant coordinator/clinician, and 1 patient partner. Three additional members participated early in the process (1 additional legal academic, 1 additional patient partner, and 1 patient engagement manager) but were unable to continue with the project for personal reasons. They were not replaced because the patient engagement manager was only participating in an observer capacity, and the breadth of legal expertise and patient representation among the remaining members was deemed sufficient to continue with the project. M. Toews served as Chapter Lead and received training in the nominal group technique (NGT),[5] a structured consensus-building approach commonly used in the healthcare sector.[6]

Over 4 video conferences in April and May 2021, our group used NGT to reach consensus on a list of topics we viewed as foundational to the legal regulation of OTDT systems. Narrative literature reviews were then undertaken, with each topic assigned to group members according to their areas of expertise. Although formal scoping reviews were not conducted because of budgetary and time constraints, group members used a range of databases and academic search engines (including PubMed, Westlaw, and Google Scholar) to identify known literature on their respective topics. Group members also reviewed existing policy guidelines of key international organizations and medical bodies, as well as relevant international legal instruments (treaties, resolutions, etc), to identify the most authoritative and internationally relevant sources for each topic. Sources were organized into subtopics, and key points pertaining to best practices in each subtopic were identified. The group reviewed and discussed this literature over 3 subsequent video conferences and identified and reviewed further sources throughout the writing process. This broad approach was deemed appropriate because the recommendations we generated rely not only on scholarly sources but also on sources of law and policy, both international and domestic.

Using NGT, this literature formed the basis of an initial list of recommendations. Recommendations were then presented and discussed at the International Forum in October 2021. Feedback from Forum participants (which included clinicians, ethicists, lawyers, ODO leaders, and patient and family partners from 13 countries) and the Forum's Scientific Committee was then incorporated into the final version of the recommendations contained herein. Literature reviews and primary drafting of the recommendations and article were performed by M. Toews, T. Pope, A. Sandiumenge, and J. Chandler, whereas R. Pape and M. Weiss contributed to video conference discussions and provided written comments and feedback on drafts of the article.

Recommendations

In total, we identified 158 sources, including 26 international guidelines, reports, and instruments; 13 governmental reports; 19 domestic nongovernmental reports; 76 books and journal articles; and 24 pieces of domestic law. These sources were published (or came into effect) from 1978 to 2022, with most sources (110) originating in the last 10 y. Our literature reviews and discussions yielded 12 recommendations, grouped into 5 categories: (i) legal definitions and legislative scope, (ii) consent requirements for donation, (iii) allocation of organs and tissue, (iv) operation of OTDT systems, and (v) travel for transplant and organ trafficking.

Legal Definitions and Legislative Scope

(1) We recommend that jurisdictions have a legal definition of death. Although the tests and procedures for determining if the legal definition of death has been met using neurological or circulatory criteria need not be specified in law, they should comply with expert medical consensus. In deceased donation, donated organs and tissue should not be removed before death has been determined.

Relevant Literature and Principles

Legal definitions of death have evolved over time, many of which now allow for neurological determinations of death.[7] This change was motivated, in part, to permit organ and tissue donation.[8] Not all jurisdictions, however, have explicitly legislated what death is as a matter of law. Some leave it to the common law method of judicial development of legal rules and principles.[9,10] Because deceased donation systems depend on the public trust that organ recovery will only happen after death,[11] it is important to legally clarify the point at which

this occurs. There have been recent legal challenges across common law jurisdictions as to whether an individual is truly dead,[10,12,13] highlighting the importance of a clearly written legislated definition of death. We therefore recommend that jurisdictions enact a legal definition of death but that the clinical criteria used to determine death be left to expert medical consensus.

Areas of Controversy

Definitions of death have given rise to legal and ethical concerns.[8,14-16] Until relatively recently, the absence of respiration and heartbeat were sufficient criteria to determine the death of an individual. Advances in technology, making it possible to artificially maintain circulatory and respiratory activity, forced the revision of these criteria to include the cessation of brain function as the key element that defines death, regardless of the way that this occurs (as a primary brain injury or a consequence of cardiorespiratory failure).[8]

In this regard, there has been debate on which brain functions must cease to neurologically determine death (whole brain or brainstem).[8,14,17] There have also been legal challenges as to whether definitions requiring "whole" (or "entire") brain death are satisfied in situations in which limited hormonal function persists.[14,15] Jurisdictions may want to follow recent recommendations from the World Brain Death Project, which recommend against using terms such as "whole brain death" or "brainstem death" and instead suggest using the term "brain death/death by neurologic criteria," defined as "the complete and permanent loss of brain function" as defined by specific clinical criteria.[7]

Another controversial issue relates to the term "irreversible." Legal definitions of death sometimes refer to the "irreversible" cessation of either brain function or respiratory and circulatory function.[18,19] This term is controversial in DCDD, in which there is debate over the meaning of "irreversible" and whether this requirement is satisfied at the time vital organs are recovered.[20,21] Jurisdictions may wish to follow international recommendations advocating for the use of the term "permanent" as opposed to "irreversible" in this context, in which "'permanent' refers to loss of function that cannot resume spontaneously and will not be restored through intervention."[7,17]

These issues represent some of the most contentious *legal* definitional issues. We acknowledge there are broader cultural, religious, and metaphysical conceptions and debates about the meaning of death. We further acknowledge that the legal definition of death has relevance beyond the OTDT context and therefore do not recommend that this definition be constrained to donation and transplantation. In contrast, the advantage of articulating a single, generally applicable definition is that it avoids the appearance that death is being manipulated for the purpose of OTDT.

(2) We recommend that legislation clearly define the scope of its application, including the substances it pertains to (organ/tissues/blood) and the activities it encompasses (eg, donation for transplantation, anatomical instruction, or biomedical research).

Relevant Literature and Principles

The subject matter of donation legislation should be clearly defined. There may be specific regulations needed, depending on the purpose for which organs and tissues are donated (for therapeutic, educational, research, or investigative purposes). Similarly, organs and tissues may have different pathways for procurement and processing that justify different regulations.[22,23] The WHO's Global Glossary of Terms and Definitions differentiates between "organs," "tissues," and "cells."[24] Similarly, blood components,[25] other human substances (hair, nails, placenta, etc), and reproductive material[26] are often excluded from regulations applying to OTDT, having their own regulatory frameworks.

Consent Requirements for Donation

(3) We recommend that living organ donation require first-person informed and voluntary consent by individuals with decision-making capacity.

Relevant Literature and Principles

Because living organ donation entails serious health risks to the donor and is not done for the donor's own medical benefit, it is imperative that donors give voluntary consent themselves, free from coercion or undue influence. It is also imperative that they understand the full range of potential risks associated with living donation.[3,27]

Areas of Controversy

Whether or not minors and incapacitated adults can donate tissue and solid organs differs between jurisdictions. As there is no widespread consensus as to how best to balance the need to protect vulnerable individuals from exploitation with the need to respect individual autonomy and help those in need of a lifesaving donation, individual jurisdictions must determine whether to allow donations from these groups and, if so, what protections to put in place. Practices from other jurisdictions may be informative in this regard.

For example, for nonregenerative organs and tissues, some jurisdictions require donors to be adults.[19,28,29] Others allow donation from minors, provided that additional requirements are met, such as minimum age requirements[30] and other oversight mechanisms.[19,31] For regenerative tissue (eg, bone marrow), laws differ as to the particular requirements for donations from minors, and many include additional safeguards such as age restrictions, consent by both the minor and a parent, and oversight committees.[19,28]

It is beyond the scope of this article to resolve the ethical issues underlying this topic, but for more information as to how to best protect vulnerable individuals from exploitation in this context, see the associated article from the Forum on living organ donation.[32]

(4) We recommend that legislation clarify consent or authorization requirements for deceased donation, including the role of substitute decision-makers, as well as consent requirements for premortem interventions.

Relevant Literature and Principles

The WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation provide that tissue may be removed from the body of a deceased person provided there is no reason to believe the person would have objected and the legal requirements for consent in the particular jurisdiction have been met.[3] Consent requirements vary between jurisdictions,

with some using opt-in (or explicit consent) frameworks and others using opt-out frameworks (see the associated article from the Forum on organ and tissue donation consent model and intent to donate registries).[33] Regardless of which framework is used, the legal requirements for expressing a desire or refusal to donate must be clear. Similarly, the role of substitute decision-makers and whether they can override an individual's prior decision should be clear because practice can vary in both opt-in and opt-out jurisdictions.[34,35]

Areas of Controversy

Consent for premortem optimizing interventions also must be clear. In cases in which the donor gave prior consent to donation, the consent may encompass premortem donor management and low-risk testing necessarily incidental to donation; however, clinicians should obtain specific consent for more invasive testing and donation optimizing procedures.[36] It is, therefore, important to be clear about who has the authority to provide consent and the principles on which their decision should be based.

In terms of who should be authorized to consent, ideally, the SDM providing consent to premortem interventions would be the same person authorized to decide about donation. In some jurisdictions, however, an SDM appointed as a legal guardian or through an advance care directive may not be the same person appointed through donation legislation to make donation decisions.[37]

There are options to enhance consistency. One option is to ensure that substitute consent for donation mirrors the law governing substitute consent for medical treatment so that the same person is authorized to make decisions in both contexts.[38] Another possibility is to enable individuals to appoint their own donation decision-maker in advance, empowering that person to make decisions about both premortem interventions and donation.[37]

Decisions over premortem optimizing interventions should be based on what the patient would have chosen for themselves. In the absence of a clear indication of the patient's wishes, many jurisdictions require that decisions be made in the patient's "best interests."[39,40] Whether premortem optimizing interventions fulfill this requirement may depend on the level of risk the intervention carries and whether a broad[40] or narrow[36] interpretation of this term is applied.[41] Jurisdictions may, therefore, wish to clarify and address this issue in legislation.[36,42-46]

Allocation of Organs and Tissue

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

Relevant Literature and Principles

Organ allocation systems generally try to balance multiple potentially inconsistent factors such as utility (maximum medical benefit), fairness or justice, and public trust.[47] Sometimes a suboptimal choice in terms of utility is accepted to achieve a fairer allocation. For example, the attempt to be fair by taking into consideration wait times or HLA sensitization may lead to allocations that are suboptimal from an overall utility perspective.

Sometimes, a utility-based allocation policy advantages one demographic group and disadvantages another group.[48] For example, allocation to those with the closest antigen match may best promote global utility but could disadvantage members of a minority ethnic group in terms of access.[48,49]

Many jurisdictions have enacted human rights laws that protect against discrimination based upon factors such as age, sex, race, religion, and disability. Some of these, like age, are used directly in allocation decisions, whereas others are indirectly relevant (eg, race or ethnicity, or disability). For example, recent litigation in Canada involved an alcohol abstinence period before waitlisting people with alcohol-induced liver failure, in which alcohol use disorder was raised as a basis for the claim that the policy discriminates on the grounds of disability.[50-52]

OTDT systems must consider how waitlist and transplant policies are affected by antidiscrimination laws. Because these policies seek to balance inconsistent principles of utility and equity, it is possible that allocation policies will often directly or indirectly disadvantage groups protected by these laws to some degree. Antidiscrimination laws may accept that some discriminatory impact may sometimes be unavoidable but tend to require that the possibility of reasonable accommodations be considered and ruled out.

Furthermore, sometimes inequities in listing are because of complex and compounding effects of a variety of factors that are hard to untangle. One possible response is to legally mandate data collection to identify and address the inequities.

Areas of Controversy

In recent years, the use of intellectual or mental health disabilities as a contraindication to waitlisting has come under scrutiny. The rationale reflects a concern about patients' abilities to adhere to postoperative care regimens.[53] However, accommodations in the form of adequate supports may address this risk.[54] At a minimum, jurisdictions should require through laws and regulations that any proposal that may disadvantage a class of people be supported by a robust scientific justification and subject to oversight by groups that include input from potentially impacted stakeholder groups.

Operation of OTDT Systems

(6) We recommend that legislation 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 that have the legal authority to operationalize and enforce these standards.

Relevant Literature and Principles

Transplantation is not without risks for both the living donor and the recipient, including transmitting infections or neoplasms, as well as other incidents occurring during the

process that may impact recipients. Only organs and tissues procured under strict quality and safety parameters are likely to function properly and provide the best clinical outcomes for recipients.[46,55-57]

Part of implementing a quality and safety system includes ensuring traceability of organs and tissues from donation to transplantation. It is therefore important that these systems enable the detection and investigation of serious adverse events and reactions and that they be applied at all levels of action, starting with the detection process, evaluation of the donor and the individual organ, retrieval, preservation, transport, traceability, and registration, including processing, and concluding with implantation and follow-up of the recipient.[55,58,59]

It is also important to maintain a mechanism for ensuring that OTDT clinicians and facilities are properly qualified and trained. Legislation can help ensure that healthcare personnel directly involved, at all stages of the chain from donation to transplantation or disposal, are suitably qualified and competent.[2,3,46,55,60-64] Government oversight and regulation can require minimum qualifications for transplant surgeons and physicians and minimum ancillary and support services, together with minimum standards for organ donor evaluation, screening, and documentation. To assess compliance, we recommend government authorities be given access to data and the authority to audit and inspect OTDT organizations.

(7) We recommend that legislation includes "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, and that ODOs and tissue authorities have the legal authority to confirm mandatory referral compliance through the auditing of records of deaths within institutions. If necessary, existing privacy laws may need to be amended to ensure necessary patient information can be communicated to OTDT authorities for the purpose of meeting these obligations.

Relevant Literature and Principles

We acknowledge that there are cost implications for creating and implementing a mandatory referral program and that this recommendation may not be embraced in communities less supportive of donation. However, the success of OTDT relies upon the timely identification, referral, and assessment of potential donors. Failure to identify possible donors is the largest factor explaining differences in deceased donation rates across jurisdictions.[65,66] To maximize donation opportunities and ensure uniformity in how potential donors are evaluated, we recommend that, to the extent it is feasible to do so, dedicated protocols in end-of-life care be established to ensure that donation is considered for all individuals at the end-of-life.

These protocols should specify clinical triggers for clinicians to notify the OTDT authority when they have patients either with catastrophic brain injury or for whom there is a plan to withdraw life-sustaining treatment expected to result in circulatory death. DBD and DCDD donors proceed from very different clinical scenarios that require separate and distinct clinical triggers for identification and referral. These clinical triggers should be simple, clearly defined, and easy to audit. They should focus on prognostic factors and should lead to referral regardless of a patient's age or comorbidity even though few will ultimately be declared brain dead or eligible for DCD without contraindicated medical conditions.[65]

Early and timely notification should be required, especially before interventions (like removal of mechanical ventilation) that might result in the inability to use the organs. It is important, however, to ensure that donation is only raised with families after a decision is reached to withdraw ventilation. Although ODO representatives have training and expertise to raise and discuss donation with families, they should interface with the treatment team with respect to the proper time to initiate these discussions.

Early referral has many advantages. Donors' medical suitability can be assessed earlier, which may reduce delays for both the ICU and the donor's family. If needed, expert assistance for NDD testing or physiological optimization of the donor can be provided. The family approach can be planned sooner, and any coroner/judicial issues can be identified early and resolved.[40,41,44,58,59,62,64,66-76] Unsuitable candidates can also be ruled out at an earlier stage to help avoid disappointment for families wanting to donate.

Areas of Controversy

Whether patients accessing medical assistance in dying (MAID) ought to be considered for donation or encompassed by mandatory referral obligations raises ethical concerns.[77] It is important that decisions about MAID are separate and made before decisions about donation.[78] Full consideration of this issue is beyond the scope of this chapter, but jurisdictions that allow MAID must determine whether MAID patients are eligible donors and, if so, how mandatory referral and consent requirements apply in that context.[79]

(8) We recommend that legislation require OTDT systems to operate with transparency (eg, public reporting of system performance metrics) while maintaining the privacy of donors and recipients.

Relevant Literature and Principles

OTDT systems are dependent on public trust. To maintain that trust, donation and transplantation activities must operate fairly and openly. The WHO Guiding Principles provide that "the organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, whereas ensuring that the personal anonymity and privacy of donors and recipients are always protected."[3]

To monitor and improve OTDT systems and to maintain transparency, it is useful to collect certain data, such as the number of donated organs (living and deceased), organ donation pathways (DBD versus DCDD), the number of people waiting for transplants of different types, the number of transplants performed, and outcomes of transplantation.[80] In addition, collecting more granular data may be beneficial in monitoring equity and fairness in allocation. To protect donor and recipient privacy, nonidentifying information should be collected and maintained when possible.[80]

Areas of Controversy

There is controversy over judging the performance of OTDT programs and organizations based on outcome data. The need to balance utility and equity concerns must be considered when interpreting and using data to justify donation

and allocation policy. In addition, ODO performance may be affected by factors such as low donation rates among some demographic groups within the population served. The suggestion that this be taken into consideration in evaluating ODO performance has, however, been criticized in the United States as removing the incentive for ODOs to improve outreach to communities less likely to donate.[81]

(9) We recommend that jurisdictions clarify through legislation or policy whether and when recipients and donor/donor families can meet posttransplant. If contact is permitted, it should occur posttransplant, with bilateral consent, and subject to oversight and regulation.

Relevant Literature and Principles

Some international instruments[3,56] and national laws[82] reflect the view that anonymity ought to be maintained between recipients and donors/donor families. However, internet search engines and social media are making it difficult to enforce prohibitions against such contact, and as a result, some in the OTDT community are considering how to facilitate this process.[82-84] Some jurisdictions and international bodies support contact, provided that both the recipient and donor/donor family consent and anonymity is maintained before transplant.[85]

If contact is permitted, individuals should be informed of the benefits and risks of revoking anonymity at the beginning of the transplant process and provided with adequate counseling and support.[46,49] In addition, a third party should manage and oversee the process for revoking anonymity, which should not be done until after the transplantation has occurred.[86,87] These requirements help prevent commercialism and coercion and help ensure fairness in the allocation system.[88]

Travel for Transplant and Organ Trafficking

(10) We recommend that legislation explicitly prohibit both trafficking in human organs, tissues, and cells and trafficking in persons for the purpose of organ removal.

Relevant Literature and Principles

Organ trafficking and trafficking in persons for the purpose of organ removal are universally condemned practices, prohibited by international instruments and legislation in many countries.[2,89-91] We recommend that these prohibitions be enforced through criminal law to facilitate international prosecutions of organ trafficking rings and to provide a clear commitment to international ethical norms.[92,93] States should also consider ratifying international treaties prohibiting these practices, such as the Council of Europe *Convention Against Trafficking in Human Organs*.[90]

There are different definitions of "organ trafficking." Although earlier international legal instruments focused more on trafficking in persons, recent instruments (such as the updated Declaration of Istanbul and the Council of Europe *Convention*) are more specifically targeted at organ trafficking and therefore cover a broader range of activities inherent in this practice. It is therefore recommended that legal prohibitions on organ trafficking and trafficking in persons for the purpose of organ removal use these more recent definitions.

Areas of Controversy

There is no consensus as to whether recipients of illegal organ transplants should face legal consequences. As a result, individual states should determine whether to prosecute recipients of trafficked organs.[92,93] If this is desired, states will need to consider giving extraterritorial effect to their criminal law because it is ordinarily not possible to prosecute an individual under domestic criminal law for an illegal act committed abroad.[94,95]

(11) We recommend that legislation prohibit commercial transactions for organs that go beyond cost recovery by institutions.

Relevant Literature and Principles

As part of the prohibition on organ trafficking, entering or facilitating commercial transactions for organs should be prohibited. Such prohibitions are consistent with a wide array of international instruments[3,90,91] and the laws of almost every country around the world, with the exception of Iran.[96]

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 and should not include compensation for the organ itself.[27] Similarly, although living donors may be reimbursed for out-of-pocket expenses incurred from their donation (eg, travel and accommodation), they should not receive compensation for the donated organ itself. The Declaration of Istanbul recommends that donation be a "financially neutral" act.[2,92]

Prohibitions on the commercial exchange of organs and tissues should not prohibit or impede the operation of kidney paired exchanges. For example, some jurisdictions prohibit the exchange of "valuable consideration" for an organ, which could be interpreted to encompass kidney paired donation.[97]

(12) We recommend that jurisdictions consider establishing bilateral or multilateral organ and data sharing programs.

Relevant Literature and Principles

Although organ trafficking is prohibited and jurisdictions should aim for OTDT self-sufficiency, international travel for transplantation is permitted pursuant to officially regulated bilateral or multilateral organ sharing programs. Consequently, jurisdictions should consider formally establishing agreements that specify the necessary collaboration of clinical teams in all involved countries to ensure proper assessment and follow-up care of the recipient and, if appropriate, the donor.[2,44,98-100] Exchanging organs across jurisdictional boundaries within a country (eg, from one state or province to another) should be regulated through national data sharing agreements that allow for the exchange of confidential patient information for the use of clinical and quality improvement purposes.

STRENGTHS AND LIMITATIONS

Our group was strengthened by having members with both legal and clinical expertise, as well as a patient partner. Although we had geographic representation from North America, Europe, and Australia, wider geographic

representation would have been beneficial, including legal expertise from civil law jurisdictions. This limitation was mitigated, to an extent, by subjecting our recommendations to review and comment by the wider Forum group, which included participants from all continents, with wide-ranging expertise in law, ethics, and medical sciences.

CONCLUSIONS

The legal foundations of OTDT systems are broad and encompass wide-ranging issues, actors, and aspects of the OTDT process. These foundational topics touch on questions of how one can donate, to whom organs and tissues should be allocated, and how donation and transplant systems should function. The 12 recommendations in this article reflect some principles that have been firmly embedded in OTDT systems for a long time (eg, the "dead donor rule" and requiring first-person informed consent for living donation), whereas others are reflective of more recent practices and debates (eg, mandatory referral and evolving definitions of death).

This article has differentiated those foundational legal principles for which there is a firm basis of support from those requiring further consideration and resolution. There is wide support, for example, to prohibit organ trafficking, yet there is no clear consensus as to the consequences that recipients of trafficked organs should face. Similarly, technology is posing challenges to some foundational principles. For example, internet searches and social media are challenging traditional notions of privacy and the need to maintain donor and recipient anonymity. As practices and technology evolve, this list of recommendations will need to be revisited because the law must keep pace with ethically sound developments in the OTDT field.

Although this brief article cannot be comprehensive in addressing all legal and regulatory issues arising in OTDT, it provides a baseline of legal recommendations supported by international literature and sets the foundation for subsequent Forum domains focusing on issues of donation systems and structure, consent models, living donation, tissue donation, and research and innovation.

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