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International Donation and Transplantation Legislative and Policy Forum: Methods and Purpose

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Background: Organ and tissue donation and transplantation (OTDT) legislation and policies vary around the world, and this variability contributes to discrepancies in system performance. This article describes the purpose and methodology of an international forum that was organized to create consensus recommendations related to key legal and policy attributes of an ideal OTDT system. The intent is to create guidance for legislators, regulators, and other system stakeholders who aim to create or reform OTDT legislation and policy. **Methods:** This Forum was initiated by Transplant Québec and cohosted by the Canadian Donation and Transplantation Program partnered with multiple national and international donation and transplantation organizations. Seven domains were identified by the scientific committee, and domain working groups identified specific topics for recommendations: Baseline Ethical Principles, Legal Foundations, Consent Model and Emerging Legal Issues, Donation System Architecture, Living Donation, Tissue Donation, and Research and Innovation Systems and Emerging Issues. Patient, family, and donor partners were integrated into every stage of the planning and execution of the Forum. Sixty-one participants from 13 countries contributed to recommendation generation. Topic identification and recommendation consensus was completed over a series of virtual meetings from March to September 2021. Consensus was achieved by applying the nominal group technique informed by literature reviews performed by participants. Recommendations were presented at a hybrid in-person and virtual forum in Montreal, Canada, in October 2021. **Output:** Ninety-four recommendations (9–33 per domain) and an ethical framework for evaluating new policies were developed during the Forum proceedings. The accompanying articles include the recommendations from each domain and justifications that link the consensus to existing literature and ethical or legal concepts. **Conclusions:** Although the recommendations could not account for the vast global diversity of populations, healthcare infrastructure, and resources available to OTDT systems, they were written to be as widely applicable as possible.

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Despite advances that allow hundreds of thousands of people a year worldwide to receive solid organ or tissue transplants,[1] the World Health Organization (WHO) estimates that <10% of the global transplant needs are met annually.[1] Besides limiting access to life-saving transplantation, a lack of access to donation prevents bereaved families from experiencing the sense of meaning this altruistic act can provide after the loss of a loved one.[2]

In addition to limited global access, donation and transplantation activity varies substantially between countries, even across countries with similar socioeconomic and healthcare frameworks, as shown in Figure 1. Even within the European Union, transplantation rates range from <15 to >110 transplants per million population[3] with some with the lowest rates in countries with well-funded universal healthcare systems and decades of transplantation experience.[4] This variability has led to many attempts at system reform, but some commonly proposed solutions, such as expansion of donor registries or changing of consent model, have little empiric support.[4-7]

The goal of the International Donation and Transplantation Legislative and Policy Forum (the Forum) is to provide cohesive, evidence-informed guidance for those aspiring to implement the best legislative and policy aspects for their organ and tissue donation and transplantation (OTDT) system. The primary audience for this work includes those who are responsible for defining and implementing the legislative and regulatory framework of an OTDT system in their jurisdiction. This includes organ donation organization (ODO) administrators, governmental and nongovernmental healthcare officials responsible for OTDT systems, and legislators. In doing so, we recognize that factors such as local resource constraints, cultural and religious considerations, or political realities may exclude some jurisdictions from implementing all recommendations, the goal, however, is to describe aspects of systems that stakeholders can aspire to incorporate in whole or in part. This work is informed by and builds upon past reports and commissions such as the Madrid Resolution, which resulted from the third WHO Global Consultation on Donation and Transplantation held in Madrid (Spain) in 2010[8] and the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008 by The Transplantation Society (TTS) and the International Society of Nephrology and updated in 2018.[9]

MATERIALS AND METHODS

Funding, Ethics, and Conflict of Interest Management

The majority of the Forum funding was from the Provincial Government of Québec with additional in-kind or cash funding from nonprofit research and professional organizations (CDTRP, TTS, the LEADDR program of research) and Canadian Blood Services (CBS). No funding was received from for-profit entities. The recommendation generation process did not involve any new research, and ethics approval was not required or sought out. All participants were required to complete a potential conflict of interest form, which was screened by 2 members of the planning committee. Any declaration of a past or present relationship with a for-profit entity was reviewed by the planning committee. No relevant conflicts were discovered.

Initial Planning

Initiated by Transplant Québec, the first step was to organize scientific and planning committees. The planning committee (members listed in **Appendix 1, SDC**, http://links.lww.com/TXD/A495) was formed in mid-2020, responsible for recruiting members of the scientific committee, organizing logistics of the Forum, defining terms of reference for participants, identifying, and managing potential conflicts of interest, and ensuring deliverables. The planning committee also navigated agreements with partner organizations including the Canadian Donation and Transplantation Research Program (CDTRP), CBS, the Canadian Society of Transplantation, the International Society of Organ Donation and Procurement (ISODP), and TTS. All of these organizations had member representatives on the scientific committee.

The role of the scientific committee was to (1) select the domains and initial scope that would be addressed by the Forum; (2) define the overall scope of the Forum; (3) approve the methods for recommendation generation; and (4) recommend leaders of the working groups for each domain. Importantly, the scientific committee was not tasked with defining the range of topics addressed within each domain but only defining the broad domains. The scientific committee met 3 times before the work of the Forum and established the scope of the Forum to be limited to ethical and legal issues in OTDT that impact structure of the system. Issues related to a single jurisdiction or best clinical practices were considered out of scope. Domains are listed in Table 1. The scientific committee also created a glossary of terms and list of acronyms for use by the domain groups to clarify preferred language and definitions of terms (**Appendix 2, SDC**, http://links.lww.com/TXD/A496).

The 13 members of the scientific committee were selected to according to expertise and role within the OTDT system among professional contacts of the chair and initial participants. We intentionally selected members who had expertise in clinical donation and transplantation issues, ODO leadership and administration, legal issues in donation international guideline development, a patient partner, and leadership roles of international academic societies. For all committees of the Forum, including the scientific committee, equity and inclusion was explicitly sought with linguistic, gender, and visible minority representation. Although all members of the scientific committee except one were Canadian (one American), several were selected for their international roles in the global OTDT community and their potential to recruit international experts to the domain working groups. Members of the scientific committee are listed in **Appendix 1, SDC**, http://links.lww.com/TXD/A495 (available online).

Patient, Family, and Donor Partners

Fourteen patient, family, and donor (PFD) partners worked on the various committees, including representation on the planning and scientific committees and each domain working

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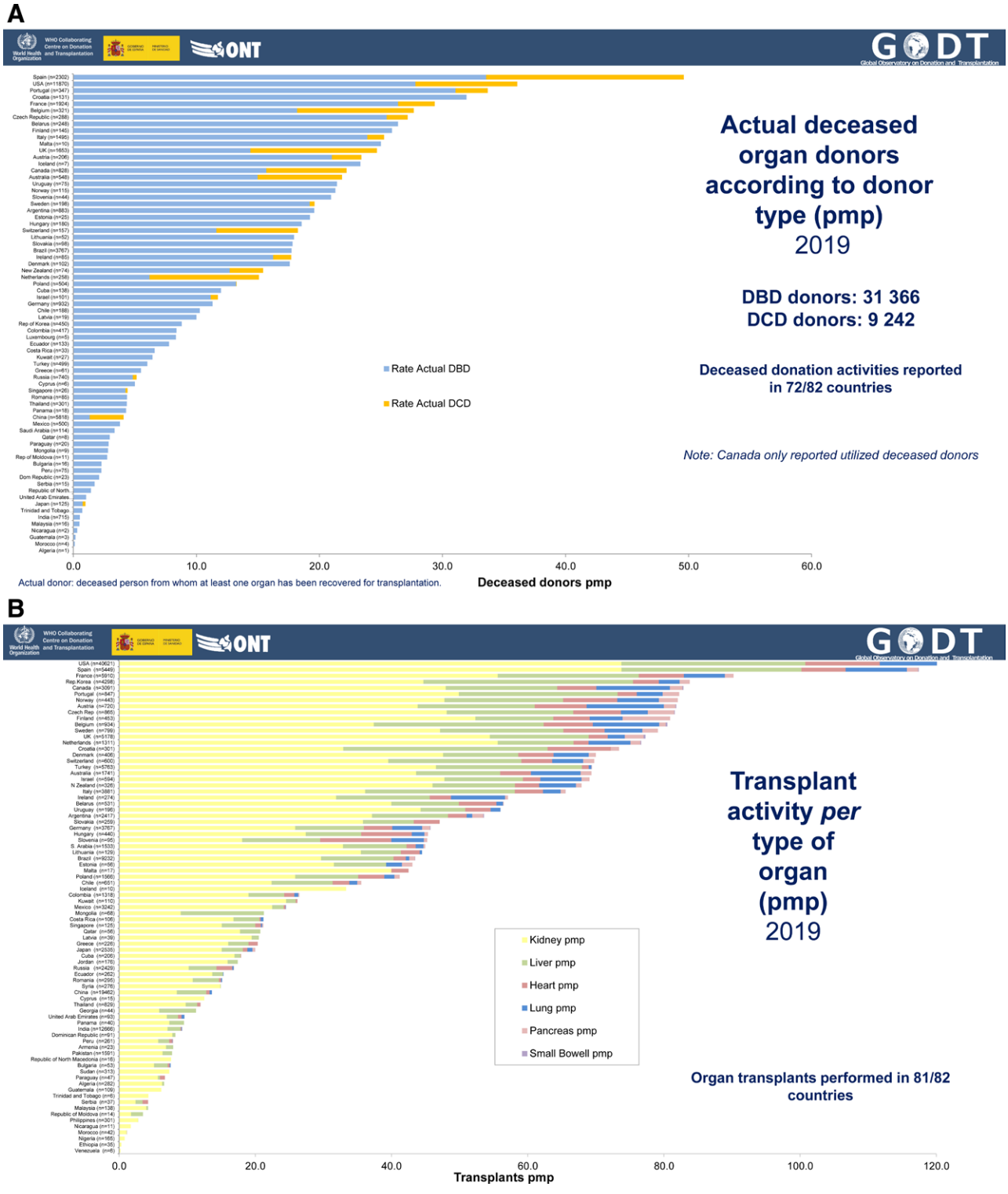

FIGURE 1. Actual donors and transplants per million population by country, reproduced with permission of the Global Observatory on Donation and Transplantation.[1] DBD, donation after brain death; DCD, donation after circulatory death; pmp, per million population.

group. PFD partners were recruited through existing relationships with PFD research partners primarily in Canada and the United Kingdom. They were encouraged to express their experiences across the OTDT continuum to ensure that the language and content of the recommendations reflected issues that were important to them. PFD participants were reimbursed according to established practices.[10]

Domain Working Groups Role and Composition

Once the domains were selected, participants were invited to the domain working groups. These groups were responsible for (1) generating the list of topics that merit recommendations, (2) gathering and summarizing relevant evidence, and (3) creating recommendations using the methodology described next. Potential leads and participants were selected from the

TABLE 1.

List of domain titles

Domain	No. recommendations	Sample recommendation
Baseline ethical principles	None	Framework created to evaluate novel policies
Legal foundations	12	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
Consent model and emerging legal issues	11	Law, policies, and procedures should clarify resolutions to situations where surrogate decision-makers' decisions conflict with the registered decision of a patient who is a potential donor
Donation system architecture	33	Privacy laws and regulations should allow for the exchange of patient information within the critical care and organ donation teams and administrators before consent for donation is obtained to enable potential donor evaluation
Living donation	9	All living-donor stakeholder groups, from governments to individual transplant programs, should develop policies to ensure equitable access to all populations and communities within their jurisdictions
Tissue donation	13	The principle of voluntary unpaid donation should have a central role in the donation process of any type of tissue or cell. Compensation to donors should cover only justifiable expenses and loss of income and should not act as a direct or indirect inducement
Research and innovation systems and emerging issues	16	We strongly recommend patients, families, donors, and public engagement/involvement in research based on the principles of inclusiveness, support, mutual respect, and co-building

OTDT, organ and tissue donation and transplantation.

professional contacts of the scientific committee, followed by individuals recommended by the domain leads or other participants. Group leads were required to be recognized experts in the specific domain of that group with active clinical, administrative, or academic roles in OTDT systems. Sixty-one participants (including domain leads) were recruited from 13 countries (see **Appendix 1, SDC**, http://links.lww.com/TXD/A495 for details). In selecting both leads and participants, an emphasis was placed on professional, geographic, and personal diversity with an attempt to include members from systems with varying levels of capacity and resources. The range of expertise included donation-focused physicians (9), medical or surgical transplanters (12), donation ethics focused academics (10), academic lawyers (7), tissue transplant experts (6), academic society leaders (11), researchers (26), and ODO leaders (25) (several participants have multiple professional roles). Thirty-three participants (including all administrative support staff) came from North America, 14 from Europe and the United Kingdom, 5 from Asia, 3 from Australia, and 1 each from South America and Africa. Participants were not asked their gender identity, but apparent gender equity was achieved both for participants and group leadership. Professional participants received no financial reimbursement for their participation beyond travel allowances for the few participants who attended the Forum in person.

Process for Recommendation Generation

The first virtual meeting of all domain leads and participants in February 2021, where the goals of the Forum and the methodology were introduced to all members. The scientific committee chose to apply the nominal group technique (NGT) for consensus generation in consultation with a firm with experience in healthcare guideline development production (STA HealthCare Communications). NGT is a structured approach to facilitate problem identification, solution generation, and decisions-making.[11] NGT has been used extensively in healthcare to identify priorities, to support the development of guidelines,[12] and explore opinions of different health professionals,[13] lay people, and carers.[14,15] The 4 key phases of NGT are summarized in Figure 2. To ensure proper uptake of NGT methods, we engaged to design and develop a Group Process Agenda for each domain. All domain leads received an individual coaching session from STA on how to implement NGT to enhance balanced group discussion, promote efficient identification of challenges, and produce a prioritized list of topics.

Domain leads then organized and chaired several 3–4 topic prioritization meetings with their groups—all held virtually—between March and May 2021. These meetings were attended by 5–8 members at a time with a duration of 1–1.5 h. The purpose of these meetings was to generate and prioritize the list of topics that merited recommendations. PFD partners were involved in nearly all domain discussions, and their input was solicited throughout the process. Groups were encouraged to identify 8–12 priority topics for each group. Group leads and members of the planning committee emphasized that topics should be generalizable to jurisdictions with different levels of economic development and healthcare infrastructure. Topic selection was completed during progressive rounds of the 4 steps of the NGT process (Figure 2). All meetings were recorded, and absent members were encouraged to review recordings and provide written feedback to the domain lead.

To ensure a lack of overlap between domain groups and key topics, each domain group presented their list of proposed topics to the other groups in a series of virtual meetings in June 2021. During these meetings, feedback was given to either modify or refine domain scope and written feedback was solicited from all members following the virtual presentations. At that point, the scope and topic list of each domain was considered final, and working groups began to review the literature and then draft recommendations.

Domain group members performed narrative literature reviews on each topic. Reference searches were performed by working group members informed by their experience and expertise in the field. Due to time and resource constraints, formal scoping reviews were not undertaken. Because the literature base for the different domains was often shared, a web-based reference manager file was created with common references that was accessible to all participants. Reference lists from retained references were also searched, and the groups actively exchanged discovered references that could

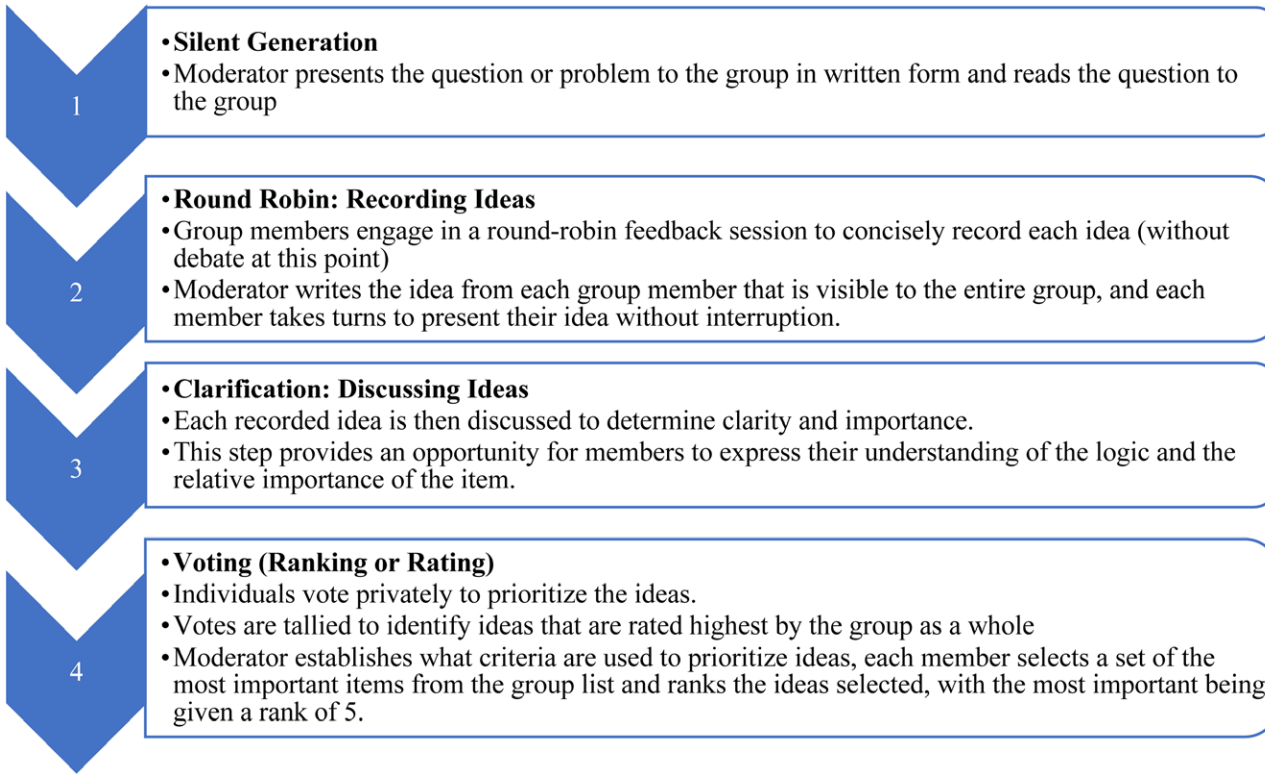

FIGURE 2. The four-step process of the nominal group technique.[11,12]

be of use to the other groups. Supporting literature was used to inform consensus building meetings to determine the actual recommendations. Each group had 4–6 consensus meetings of 1–1.5 h with 4–8 group members at each meeting that were managed with the same NGT processes applied during topic selection. Again, recordings of these meetings were available for absent members. Group leaders were instructed to encourage diversity of opinions, consider factors that may influence international acceptance of recommendations, and limit attempts to dominate conversations by single voices. Draft recommendations were completed by late September 2021 and submitted to the scientific committee for review before presentation at the Forum. No substantive changes were made during review by the scientific committee.

The Forum was held as a hybrid in-person/virtual event based in Montreal in October of 2021. Domain leads presented all recommendations in sessions that included time for discussion and feedback from all stakeholder participants and attendees. This feedback was summarized and available for during the drafting of the final reports of their recommendations that accompany this article.

RESULTS

The Forum generated 94 recommendations across 6 of the 7 domains. As shown in Table 1, 5 of the domain groups made 9–16 recommendations with ODO Systems, creating 33 recommendations across 10 subdomains. Instead of new recommendations, the Baseline Ethical Principles Group chose to create a framework to evaluate newly proposed policies. The recommendations and justifications are available in the accompanying manuscripts (ref to other articles). Recordings of the Forum in English and French are available to view at https://forumtransplantquebec.ca/en/.

DISSEMINATION

The dissemination and knowledge translation (KT) strategy for this work is being led by a joint KT committee with membership from CBS, Transplant Québec, and CDTRP. The proximal goals revolve around the creation and dissemination of reports. These will include housing the full reports on partner websites and open access publications. Other forms include summary reports targeted to various lay and professional stakeholder groups. The KT team includes PFD partners to verify that the message is communicated appropriately to lay audiences. An example of a lay summary on mandatory referral is included as **Appendix 3, SDC**, http://links.lww.com/TXD/A497 (available online). Within Canada, Transplant Québec is collaborating with legislators to inform an update of their OTDT legal structure. The KT committee is also liaising with other provincial ODOs and governmental authorities to encourage uptake of recommendations. Success of the Forum within Canada will be determined by the number of provinces who incorporate recommendations into their law and policy.

Further dissemination of these reports will include presentations at scientific meetings, social media channels of partner and stakeholder organizations, and the distribution of the Forum website. Additionally, many domain participants hold active leadership roles at ODOs or academic organizations throughout the world, which will facilitate further dissemination. Internationally, the KT committee will monitor dissemination efforts and uptake of recommendations outside of Canada.

DISCUSSION

The Forum has resulted in an extensive list of expert consensus legal and policy recommendations for both developed and developing OTDT systems. These recommendations were created through a structured consensus building process with world experts informed by their extensive experience and the published literature in the field. The resulting recommendations are not specific to any one program or jurisdiction but instead represent guidance that is adaptable in whole or in part to a variety of contexts. Taken as whole, we believe the Forum recommendations provide a template that can be clearly communicated to stakeholders who are in position to reform an OTDT system.

The Forum work builds on a long tradition of national and international recommendations for OTDT systems. Some—the WHO guiding principles, the declaration of Istanbul, and the Barcelona Principles—focused on ethical principles[9,16,17] and others—the Madrid resolution, and the Institute of Medicine Opportunities for Action—on more practical aspects of an OTDT system.[8,18] All provided an important base to build this new set of recommendations. Our work updates these documents with an analysis of evidence published in the interim as well as applying the aspects discussed next.

Besides using updated literature, our work added to these existing documents in 3 distinct ways. First, we strove to describe aspects of an ideal system while respecting the realities of variable international practice. Groups were encouraged to create recommendations that could be generalizable outside of their own practice and based on the best available evidence in the field. Thus, although a practice such as presumed consent may be effective in a setting such as the United Kingdom, we recognized that it could be harmful if improperly deployed in other settings. Likewise, strongly enforced first person consent as currently deployed in the United States may be less effective in a country that does not value personal autonomy as strongly. Generally, this led to recommendations that explored the principles and concepts behind a topic while encouraging an individual jurisdiction to create a system that respected their socioeconomic, political, and cultural realities and traditions. Second, we employed a structured consensus building methodology among relatively small groups of highly experienced individuals. Doing so allowed maximum participation from group members while still valuing diversity of opinion. Finally, as described here, PFD partners were more actively involved in all aspects of the process than in previous iterations of international recommendations. By including PFD partners in this way, we have maintained focus on the people most impacted by OTDT law and policy: patients awaiting transplantation, living donors, caregivers, and the families of deceased donors.

These recommendations have several limitations. Although geographic diversity was sought, not all countries or all regions are represented. We do not assume that the vast diversity of the world's systems and peoples are captured in this work. Instead, we strove to recruit leaders from as many regions as possible while acknowledging the need to restrict groups to sizes that allowed for efficient consensus building. The method to recruit participants was further limited by the fact that they were primarily recruited by members of the planning and steering committees. Ideally, future iterations of the Forum would involve nomination of representatives by international OTDT organizations to ensure diversity of opinion and authority to speak for their respective organizations. Related to that issue, PFD partners were recruited exclusively from Canada and the United Kingdom. This was both a factor of ease of recruitment by committee members and the reality that many countries do not have patient partner networks that allow for easy identification of potential partners. Future work in this field should strive to further understand the diverse lived experience by global PFDs impacted by the OTDT system. Finally, the available literature was reviewed by the domain working groups but without the support of a medical librarian with a formal search strategy. It is possible that some studies that could have influenced recommendations was not discovered due to the lack of a more structured review of the literature.

We also recognize that in many ways donation and transplantation, particularly deceased donation, is currently only feasible in relatively well-funded healthcare systems or to very few wealthy individuals in developing countries. Although it is unassailable that decreasing the need for transplantation through better preventative care is a laudable goal, the reality is that millions of people around the world suffer from end-stage organ failure for which transplantation is the only viable long-term strategy. A recent workshop commissioned by the WHO and the Pontifical Academy of Sciences explored these issues extensively and concluded that even in developing nations, prioritization of ethical, well-regulated living and deceased donation should be pursued both for improvement of patient health and to decrease the long-term costs of organ support therapies such as hemodialysis.[19]

As mentioned here, the intent of the Forum was to provide a template for OTDT law and policy reform. However, the success of this process depends not on the uptake of such laws and policies, but the study of the impact postimplementation. Throughout the Forum process, our PFD partners reminded us of a simple truth: no one's life was ever improved through law alone. Only law that is transformed into policy and practice results in improved quality of life for patients and donor families. Several of the recommendations point to the importance of transparent and publicly reported performance measures. These measures should be prioritized by all stakeholders and reported in a way that allows global systems to learn from each other.

We also hope that this work is not seen as a single set of recommendations. Our long-term strategy is to capitalize on our partnership with organizations such as the TTS and the ISODP to disseminate the current work and spark interest in further iterations of this Forum. Doing so will require sustained interest and investment from our partner organizations but would create a platform where more truly global participation would be possible. This participation would allow for more nuanced content that could be incorporated into workshops or other services for jurisdictions hoping to improve their systems.

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