OPEN

Organ and Tissue Donation Consent Model and Intent to Donate Registries: Recommendations From an International Consensus Forum

Phil Walton, BSc (Hons),[1] Alicia Pérez-Blanco, PhD, MD,[2] Stephen Beed, MD,[3] Alexandra Glazier, Esq, JD-MPH,[4] Daniela Ferreira Salomao Pontes, DFS,[5] Jennifer Kingdon, BA, Mdiv,[6] Kim Jordison, Adv Dip,[6] and Matthew J. Weiss, MD[6,7,8]

Background. Consent model and intent to donate registries are often the most public facing aspects of an organ and tissue donation and transplantation (OTDT) system. This article describes the output of an international consensus forum designed to give guidance to stakeholders considering reform of these aspects of their system. **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. This article describes the output of the consent and registries domain working group, which is 1 of 7 domains from this Forum. The domain working group members included administrative, clinical, and academic experts in deceased donation consent models in addition to 2 patient, family, and donor partners. 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 working group members. **Results.** Eleven recommendations were generated and divided into 3 topic groupings: consent model, intent to donate registry structure, and consent model change management. The recommendations emphasized the need to adapt all 3 elements to the legal, societal, and economic realities of the jurisdiction of the OTDT system. The recommendations stress the importance of consistency within the system to ensure that societal values such as autonomy and social cohesion are applied through all levels of the consent process. **Conclusions.** We did not recommend one consent model as universally superior to others, although considerations of factors that contribute to the successful deployment of consent models were discussed in detail. We also include recommendations on how to navigate changes in the consent model in a way that preserves an OTDT system's most valuable resource: public trust.

(*Transplantation Direct* 2023;9: e1416; doi: 10.1097/TXD.0000000000001416).

The consent model and intent to donate registry employed by an organ and tissue donation and transplantation (OTDT) system is often subject to scrutiny and debate from the general public and nondonation professional stakeholders.

Received 12 April 2022. Revision received 15 September 2022.

Accepted 19 September 2022.

[1] *Organ and Tissue Donation and Transplantation, NHS Blood and Transplant, London, United Kingdom.*

[2] *Organización Nacional de Trasplantes, Madrid, Spain.*

[3] *Dalhousie University, Halifax, NS, Canada.*

[4] *New England Donor Services, Waltham, MA.*

[5] *Health Department of the Distrito Federal Government, State transplant organization, Brasilia, Brazil.*

[6] *Canadian Donation and Transplantation Research Program, Edmonton, AB, Canada.*

[7] *Transplant Québec, Montréal, QC, Canada.*

[8] *Division of Critical Care, Department of Pediatrics, Centre Mère-Enfant Soleil du CHU de Québec, Québec, QC, Canada.*

The Forum is supported financially by Transplant Québec through funding from the government of Québec, the Canadian Donation and Transplantation Research Program, the LEADDR program of research, and Canadian Blood Services. The Transplantation Society has provided in-kind logistic support. Transplant Québec is the provincial organ donation organization for the province of Québec, Canada, and is a government-funded, not-for-profit organization. The Canadian Donation and Transplant Research Program is a Canadian Institute of Health Research–funded national research network in donation and transplantation. Canadian Blood Services is a national, not-for-profit, charitable organization that provides national services in the development of donation and transplantation leading practices, system performance measurement, interprovincial organ sharing registries, and public awareness and education but is not responsible for the management or funding of any Canadian organ donation organizations or transplant programs. The LEADDR research program is a Health Canada–funded research initiative investigating the impact of legislative changes in OTDT systems. The authors declare no conflicts of interest.

P.W., M.J.W., A.P.-B., S.B., A.G., and D.S. drafted, edited, and approved this manuscript. J.K. and K.J. edited and approved this manuscript.

Supplemental digital content (SDC) is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (www.transplantationdirect.com).

Correspondence: Phil Walton, BSc (Hons), NHS Blood and Transplant, 21 Mountain Rd, Craig-Cefn-Parc, Swansea, SA6 5RH, United Kingdom. (Phil.Walton@nhsbt.nhs.uk).

ISSN: 2373-8731

DOI: 10.1097/TXD.0000000000001416

Encouragement to register a decision to donate is often the most public facing aspect of an organ donation organization (ODO), and the implications of different models as how they either may impact potential availability of organs for transplant or conceivably impact personal liberties are vigorously debated in the lay press, bioethics literature, and political arena.[1-4] An understanding of the advantages and disadvantages of these models, however, must commence with an understanding of the fundamental ways in which consent for deceased organ and tissue donation is distinct from consent for other medical interventions.

Regardless of a registered decision to donate, most people will not be a deceased organ donor because of specific clinical criteria that must be met at the time of death.[5] Nonetheless, the populations in countries with developed organ donation programs are routinely solicited to express a decision regarding consent for this uncommon possibility. Antemortem first-person consent for an unlikely postmortem event is ideally sought because, in deceased donation situations, the person who is a potential donor will be incapacitated and unable to provide first-person consent when donation becomes possible. If no recorded decision regarding donation exists, the treating team and donation professionals are required to determine the likely intent of the potential donor through conversations with the family or other surrogate decision-makers (SDMs).

In this article, we will adopt the UK Donation Ethics Committee definition for family (albeit family, relatives, and SDMs are used synonymously) and shorthand for both "family members" and "family and friends" in the clinical context. However, it is important to remember that the family is not a singular unit but rather composed of various individuals whose knowledge of the deceased and opinions concerning donation may differ. Furthermore, patients' friends may also be highly relevant to the consent process in deceased organ donation.[6]

Consent models made up of various combinations of legislation, donor registries, and policies generated by ODOs and tissue authorities have been employed. There is no global consensus regarding the benefits of one model over another; however, there has been a trend toward introducing opt-out legislation in recent years, albeit with an incomplete body of evidence to guide decision-making available.[7,8] Produced in the context of the International Donation and Transplantation Legislative and Policy Forum (Weiss et al[9]), the domain described in this article is focused on recommendations on consent models and intent to donate registries. The primary audience for this work is stakeholders who are responsible for defining and implementing the deceased donation consent model for the OTDT system in their jurisdiction. Recommendations focus on both aspects of consent models—including how people register their consent—and recommendations regarding the implementation of system changes. Because the consent model applied in a jurisdiction is tightly linked to intent to donate registries, we have included recommendations for both the choice of consent model and registries within this domain.

MATERIALS AND METHODS

The details of the process used to generate these recommendations are included in the accompanying introduction and methods article (Weiss et al[9]). Mr. Walton was invited by the Forum steering committee to lead this domain group, and he subsequently invited participants based on their expertise in the field of deceased donation consent, with an emphasis on geographic and professional diversity. **Appendix I** (**SDC**, http://links.lww.com/TXD/A491) lists domain participants and their affiliations; all working group participants are listed as authors in this article. This working group included deceased donation medical and administrative leaders who led changes in consent models in the United Kingdom (P.W.), Canada (S.B.), and Brazil (D.S.). Other members were invited based on their published administrative, legal, and academic interest in deceased donation consent models (A.G., A.P.-B., M.J.W.). Patient, family, and donor partners were incorporated into all aspects of the Forum, including 2 in this domain working group (K.J. and J.K.).

Conflict of interest forms were completed by all participants, and none had conflicts with any for-profit entities. 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 and Canadian Blood Services.

The recommendation development process involved the application of a nominal group technique of consensus building, applied over a period of February to September 2021 in a series of virtual conferences. Once consensus around topics to be included in the domain was finalized, topics were assigned to working group members who performed narrative reviews of the literature as described in the introduction and methods article (Weiss et al[9]). This was aided by a common, web-based reference manager file that included references from this and related domains. Recommendations were iteratively developed over 5 consensus meetings and e-mail exchanges—including presentation to the broader Forum group and the scientific committee—before being presented at the hybrid in-person and virtual Forum held in Montréal, Canada, in October of 2021. Feedback from that Forum was incorporated into this, the final version of the recommendations. Recordings of the Forum sessions are available at https://forumtransplantquebec.ca/en/

INTENDED AUDIENCE AND APPLICATION

The goal of the Forum and this domain was to create aspirational recommendations that could help guide worldwide OTDT system stakeholders to improve laws and policies that govern donation and transplantation. We acknowledge the vast diversity of OTDT systems and the jurisdictions in which they exist. Multiple factors, including the resources of the OTDT system, structure of healthcare delivery, overarching legal frameworks, and cultural and religious values, will influence an individual system's capacity and desire to incorporate these recommendations. Recognizing this diversity, these expert consensus statements of principles are informed by the expertise of the panelists and the available published literature, and we believe they can be used in whole or in part to improve global OTDT services.

Consensus Scope and Topics

After the NGT process, the domain working group considered 3 topic areas to be relevant. The first was the choice of consent model in a jurisdiction. Additionally, because the

architecture of an intent to donate registry is dictated by the choice of consent model, topics related to intent to donate registries were also included. Finally, jurisdictions who alter their consent models are then faced with substantial change management challenges. These change management issues can range from bedside professionals to administrative OTDT stakeholders, to the perception of the general public. Considering the importance of these issues in implementation of any new consent model, we considered it pertinent to include consent model-specific change management issues in their recommendations.

Recommendations

Recommendation 1

We recommend that the choice of consent model for a jurisdiction be guided by a broad public consultation between donation stakeholders and the general public that includes the following:

a. Consideration of prevailing values and culture of that jurisdiction
b. Existing donation and health laws
c. OTDT infrastructure
d. The commitment to support a model with the needed resources that will maximize donation and transplantation activity

Consent is the cornerstone for ensuring the protection of people who are potential deceased donors. The World Health Organization's (WHO's) guiding principles for donation define the conditions for consent for deceased donation as follows: "Organs may be removed from the bodies of deceased persons for the purpose of transplantation if: (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal."[10] Accordingly, each country with an OTDT system has enacted and implemented a consent model for deceased donation. The most common models and the principles behind them are described in Table 1. A confiscation model is included as a theoretical comparator, although it is not currently employed openly by any country and would be in violation of fundamental ethical tenets of consent.[10-12]

TABLE 1.

Consent models[8]

Consent models	
Altruism	OPT-IN: Organs may be recovered from a deceased individual if the person or their legally recognized representative had expressly consented to it OPT-OUT: Organs may be recovered from a deceased individual, unless the person had expressed their opposition before death
Incentives	NONFINANCIAL: Prioritized in the deceased donor waiting list if the donor was a living donor or a relative was a deceased organ donor FINANCIAL: The government may fix the price of the organ donation and may consider direct or indirect payment, eg, funeral costs
Mandate	The law obliges all adults to register their donation decision in life regarding posthumous organ donation
Confiscation	Organs are considered a public resource

Transplant authorities and governments are challenged to choose between these models to maximize deceased organ donation to meet transplantation demands while preserving trust in an ethical and legal OTDT system.[10] We do acknowledge that some jurisdictions may choose a specific consent model to avoid controversy or to engender transparency and trust, particularly if that jurisdiction has been subject to donation or transplant-related scandal.[13-16] Our search of the literature thus focused on those 2 aspects, which are the published efficacy of one model compared with another and bioethical comparisons and descriptions of the models.

To address the first aspect, we searched for any published literature regarding the potential of consent models to increase donation and transplantation activity. Most reports compared opt-in and opt-out default models. Several database studies and literature reviews were discovered, which reported conflicting results. A 2014 review of 13 y of donation activity from 48 countries described more donors per million population and increased deceased liver and kidney transplantation activity in opt-out countries as opposed to opt-in.[17] This report contrasts with another that analyzed Global Observatory on Donation and Transplantation data from 35 countries published in 2019 that showed no difference between opt-in and out-out models.[18] Yet, another report analyzing 2018 data found that opt-in jurisdictions outperformed opt-out jurisdictions when the deceased donation rate was calculated as deceased donors per 10 000 deaths (versus per million living population). Of note, although database reviews conflict regarding deceased donation, living donation rates were consistently found to be lower in opt-out countries.[17,18] Literature reviews of published reports have found a more consistent trend toward an increase in donation activity with an opt-out model.[17,19] However, their authors point out that the methodological quality of included studies is often poor and almost always lacks analysis for various confounds, such as other changes in the donation and transplant system instituted at the same time as a consent model change. As would be expected, data from individual countries were more variable, with some countries reporting drastic reductions and others reporting slow and steady increases in donation and transplantation activity.[20,21] The proposed reasons for this variability are explored in detail below, but the existing data do not support a sweeping recommendation that either opt-out or opt-in should be considered as universally effective when considered strictly from the standpoint of maximizing clinical activity.

In the absence of a consent model that would offer a generalizable high likelihood of increased donation and transplantation, jurisdictions must consider the aspects that make up a consent model. Four fundamental domains must be addressed when designing a country specific opt-in or opt-out model. The first is the capacity of the system to directly solicit and respond to the deceased person's (or their SDM's) willingness to donate. Second, the default option stated by the law, applicable when the deceased's decision is unknown, must be defined. Third, the role of SDMs in consenting or denying organ recovery must be clearly stipulated, including a well-defined and socially accepted hierarchy of who qualifies as a legal SDM in these circumstances (parent, spouse, short- or long-term partner, etc). Finally, the role of healthcare professionals (HCPs) must also be clarified, including when and how donation decisions should be discussed with families.

The second domain, the default option between opt-in and opt-out, is the most widely discussed in the literature. As several authors have pointed out, both systems include a baseline assumption, but those defaults merit careful consideration.[22] In opt-in models, organs may be retrieved from a deceased person (1) if the person had expressly consented to it while alive, verbally or in a recognized intent to donate or donor registry, or (2) an SDM consents to donation after the person has lost capacity to consent for themselves. In opt-out models, organs may be retrieved from a deceased for transplantation unless (1) the person had expressed their opposition before death or (2) an SDM refuses recovery (allowed in some but not all jurisdictions).[23]

Although the differences between the systems may seem stark, the reality in most jurisdictions is that formal and informal policy and practice differences—almost all related to the SDM and HCP roles from the third and fourth domain above—create models that are functionally quite similar. For example, Spain, the United Kingdom countries, and the Canadian province of Nova Scotia employ a so-called soft opt-out system. In this system, HCPs are required to discuss with the SDM about the deceased's intent to donate. Although not always possessing the legal authority to override an expressed decision to donate, the SDM's desires will almost uniformly be respected, including overriding a previously expressed decision to donate, which happens in approximately 10% of occasions.[24] Even in "hard" opt-out models—in which SDMs are expressly forbidden from refusing donation if the patient who is a potential donor had not opted out before death—surveys have reported that many HCPs still consult with families and sometimes respect the SDM's wishes not to proceed.[2] Discrepancies between law and actual practice exist in opt-in countries as well, which are discussed in detail in the justification of Recommendation 5. The reality seems to be that, whatever default consent model is chosen, families and HCPs may make individual decisions that are more consistent with prevailing societal values, such as respect for family cohesion, the desire to respect the surviving SDM, and autonomy.[25-27]

The legal default option has been paired with other aspects of consent models in various jurisdictions. For example, mandated choice models oblige all adults to make a donation decision regarding posthumous organ donation while performing other state-regulated tasks such as registering for a driving license or renewal of ID card.[28] Some countries (Chile, Israel, Singapore) have introduced reciprocity models to increase registry sign-ups by awarding citizens "priority-points" for transplant (allocation priority) and, should they ever need one, by opting-in on the register.[28-30] There is both an ethical and practical debate to this approach, not least the small real-world impact of the incentive, especially once a sizeable proportion of the population has opted-in and enough have "priority status" as to render that status effectively meaningless.[31] As such, reciprocity or incentive models may be short-term strategies and best suited for developing donation programs in earlier stages versus more mature systems. Directed donation—allowing donors or their SDMs to specify that they would donate only to specific individuals or groups of people—is another ancillary aspect of consent models. Although there have been some ethical considerations of the merits of these systems, including the possibility that allowing directed deceased donation could encourage historically underrepresented groups to donate within their communities, we discovered no data on impacts of implementation of such a system.[32,33]

Any incentive model, particularly any that includes financial incentive, must be carefully monitored to ensure that the incentive does not become a coercive influence for underrepresented members of society to pursue donation.[11] Because reciprocity and incentive approaches are embedded within the opt-in or opt-out model and there are little data to support the efficacy of any of these regimes, we did not make a recommendation on these issues, but they are topics that merit future investigation of potential benefits and harms.

All of the above models and the combination of models provide potential paths for a consent model in a particular jurisdiction. As discussed in detail below, the success of the model, in terms of both increasing donation and transplantation activity and protecting the rights of people who are potential donors, depends on a careful understanding of the laws, OTDT infrastructure, and culture of the jurisdiction.[34] Stakeholders must consider the complex interplay of these multiple factors and not assume that a single model will work in their context.

Finally, compulsory systems or confiscation models could theoretically exist in which organs are considered as a public resource and recovered without consent. These models are not discussed in detail because they would violate international and many jurisdictional laws and well-established, universally accepted principles of respect for bodily autonomy.[35,36]

Recommendation 2

We recommend that consent models provide a written regulatory framework on safeguards for vulnerable populations to assure that their donation decision satisfies the ethical and legal standards.

Jurisdictions must have a framework in place to ensure the validity of consent and protections for their population. At a minimum, this should include the legal criteria of determining competency for people who are allowed to register a donation decision. Systems should clearly define hierarchies of who has legal standing to become the formal SDM regarding consent decisions (eg, Chile, the United Kingdom, and the United States).[23,35,37] These hierarchies should include definitions of when, if ever, the state is allowed to consent for donation, in the case that no person is identified who meets the legal criteria to become an SDM.

Countries who move toward an opt-out system should clearly define, in law, exclusions to having consent presumed for donation. Typically, requirements must be met on age, mental capacity, and residency in a specific jurisdiction in order for the opt-out legislation to apply to a person. These legal protections of the most vulnerable being stipulated in law and expanded upon in regulatory guidance have been indispensable and instrumental to the successful implementation of new laws.[37-40]

Recommendation 8 addresses in detail outreach strategies to historically underrepresented communities during the implementation phase of a change in the consent model, but before implementation, formal and informal outreach should occur. For example, international and national laws often include a duty to consult indigenous or aboriginal peoples of a jurisdiction, which is a policy that is supported by the UN Declaration on the Rights of Indigenous Peoples.[41] Even

in the absence of a formal legal obligation, consultation with linguistic, cultural, or religious minorities within a jurisdiction can lead to a legal policy framework that will minimize future conflicts or misinformation around the law.

Recommendation 3

We recommend that intent to donate registry choices reflect the decision architecture as recognized in law and as aligned in practice and that these registries allow citizens to express their deceased donation intent while minimizing barriers to registering a decision.

Donation registries are common worldwide and often the most public facing aspect of an OTDT system. The goals of registries are multiple, ranging from binding legal registration of an enforceable donation decision in some jurisdictions[27] to use in OTDT awareness campaigns targeted at the general population. Data regarding the costs and benefits of registries are discussed in detail below in the justification of Recommendation 6, but multiple studies have demonstrated increased rates of organ recovery among people who have previously registered their intent to donate.[42]

Registration methods should be universally accessible to the population, and preferably, multiple pathways should exist to allow for registration and changing of registration. This will permit different populations with varying preferred modes of interface to engage. For instance, if an online registration option is available, other methods—forms that can be completed when interacting with other government or hospital services—should be available for the digitally disadvantaged. In the United States, for example, 98% of those who register as donors do so through the motor vehicles department when receiving or renewing a driver's license.[43] This large captive audience, cycling through a routinized process every 5 y (in most states), together with opportunities to register at any time through the iPhone health app, Donate Life websites, hunting licenses, and tax returns results in 169 million registered organ donors in the United States as of 2021.[43] If multiple pathways for registration exist, systems should be created to ensure that the OTDT system has access to a centralized system that is web-based, is easily searchable on a 24/7 basis at the time of a referral of a potential donor, and includes the most recent decision.

It is also important to ensure that the donation registration text aligns with the applicable legal framework. For example, if the donation registry is in an opt-in jurisdiction, the forms must clarify that registering is legal authorization for donation and should indicate if permission for tissue is also included. Similarly, the purpose of the donation should be specified (eg, transplantation and/or use of donated organs for research if not transplantable). If the donation registry is in an opt-out jurisdiction, the forms should clarify what registration means (eg, to donate, refuse to donate) and how it will be utilized. Registrants should be provided information on who will have access to their registration and how they can change their registration if they wish to change their decision in the future.

Multiple studies have analyzed the best techniques to encourage people to register donation decisions, which are recently summarized in a Cochrane review.[44] Overall, the reviewed literature was of low quality and heterogeneous in terms of outcomes, strategies, and settings. Among the 46 retained studies, few reported verified donor registrations (compared with expressed intent to register at a future time).

Ultimately, the structure of how the donation question is asked (and how often) can have a significant impact on the effectiveness of the registry.[45] For this reason, the design of a donor registry and alignment with the legal architecture will achieve the best outcomes.

Recommendation 4

We recommend that the legal and policy implications of a registered donation decision must be consistent with the social and legal norms of each jurisdiction. At a minimum,

a. Jurisdictions with opt-out consent models include the option to register a refusal to donate
b. Jurisdictions with opt-in systems include the ability to remove oneself from the registry at a future date

Donation registry architecture should consider the prevailing consent model and be developed according to existing privacy and consent laws. Multiple forms of donation registries have been employed internationally. Some are registries of decisions—allowing for registry of both a positive and negative decision (hybrid register); some are registries of donors—with only a positive decision; and some are registries of nondonors—referred to as a refusal register. As noted above, the options must be coherent with the consent model, and jurisdictions considering a consent model change must ensure that their donation registry is also updated to allow for choices that are appropriate to the new consent regime. Laws and policies should define to what extent a registration is legally binding in the event of death with clinical potential for donation and what, if any role, an SDM would have in finalizing a decision regarding donation (see below). Laws and policies must also define what organization is the responsible party for safeguarding registered decisions and who should be allowed to access the decisions, under what circumstances.

Currently, there is a divergence of opinion regarding the implications of donation registration and consent for antemortem interventions. These interventions are performed on the donor prior to death determination with the goal of increasing graft function in the setting of donation after circulatory determination of death.[46] Some of them (eg, heparin given to decrease biliary complications) carry a possible risk of hastening death, but in the context of a planned withdrawal of care and expected death, this is largely theoretical. Most authors support the notion that donation registration does not include consent to these procedures because they will be implemented before death and are almost never discussed at the time of donation registration and, therefore, require separate, informed consent.[47] Some argue that including information related to antemortem interventions during the donor registration process would increase the clarity of consent for the global donation process.[48] Others contend that the amount of information necessary to meet the criteria of truly informed consent could confuse people seeking to register and that the specific procedures evolve over time, which could make any discussion at the time of registration irrelevant when an actual donation may occur potentially decades later.[47] A recent review of the ethics of antemortem interventions did not discover any reports that described the impact of including antemortem details in a real-world donation registry.[49] However, in 2021, Scotland introduced opt-out legislation,[50] which assumes authorization to "type A" antemortem interventions (routine

investigations, eg, blood sampling, ultrasound scanning), but additional authorization is required from the SDM for "type B" procedures (eg, biopsy) that may pose a risk to the patient. It is too early to draw any conclusion on the impact of this approach on donation decisions, but answers to arguments about the clarity of consent may be found here in due course.

Recommendation 5

We recommend that law, policies, and procedures clarify resolutions to situations in which SDMs' decisions conflict with the registered decision of a patient who is a potential donor.

Alignment between law, policy, societal values, and actual practice is necessary for a maximally effective registry system. Situations in which SDMs dispute the registered intent of a person who is a potential donor represent some of the most difficult challenges to that alignment. For instance, several Canadian provinces have laws that state that a registered donation decision is binding and cannot be overruled by family or other SDMs,[51] yet some ODOs in those provinces have policies that overtly allow family override of that registered decision to donate.[52] This override was estimated to occur in up to 20% of cases of approaches of registered donors in the province of Ontario in 2015.[51] When asked, Canadian critical care physicians stated they would respect family override in the majority of circumstances, for a variety of reasons, chief among them being respect for the grieving process of the patient's family.[46] Most were unaware that this form of override ran counter to the law in their province,[46] an understandable position when ODO policy is in apparent conflict with the text of the law. The academic and public debate around these policies has been a source of confusion for professionals and the public.

Situations such as these are not static, however, and may change over time. In the United States, for example, even with binding opt-in laws, the historic practice was to permit families to decline donation even if the patient was registered. In more recent years, however, and consistent with a widely held public value of respect for autonomy in the United States, the binding nature of registered intent is operationalized in policies that do not allow for SDM override of registered decisions and a clear framework for legal and administrative enforcement if necessary.[47]

Importantly, even presumed consent models do not preclude the option to allow family override. As described above in Recommendation 1, soft opt-out models developed in Spain and emulated in the United Kingdom and parts of Canada explicitly allow for families to override even registered decisions to donate.[4,37] These systems place a strong emphasis on respecting cultural values and maintaining trust in the OTDT system.

Trust is likely enhanced through transparent policies that are consistent throughout the process from the level of legislation down to conversations with individual families. Although every system will need to deal with the situation of SDM disagreement of previously expressed decisions, OTDT stakeholders should ensure that their laws, policies, and procedures regarding potential override of a decision to donate are clearly worded, consistent with societal values, and fairly applied throughout the system.

Recommendation 6

We suggest that, for jurisdictions with developing donation systems, the time, energy, and resources required to establish and maintain a registry may outweigh potential benefits in the short-term while recognizing that strategies to increase intent to donate registrations remain a valuable outcome in more resourced OTDT systems.

The rates of recovering organs among potential donors who have previously registered have been consistently shown to be higher than among nonregistered potential donors.[53,54] There is a substantial body of literature examining the best methods to encourage donation registration involving a variety of methods and populations.[55] However, the effectiveness of increased registration to lead to increased actual donation and transplantation has been much less robustly demonstrated. For example, a 2015 report from the United States failed to demonstrate an association between efforts to increase the number of registered donors and actual transplants within those jurisdictions.[56]

There are several potential reasons cited for the lack of clearly demonstrated association between increasing registrations and increasing transplants. One is simply the rarity of a person becoming a potential donor. Because only approximately 1% to 3% of in-hospital deaths have clinical potential for organ donation, the donor registration for most people will never be applicable at the time of their death.[57] Additionally, data suggest that actual donors are less likely to have registered their intent to donate.[58] This may be because many of the injuries and illnesses associated with becoming a potential organ donor are correlated with socioeconomic barriers, which may in turn be associated with a lower likelihood of registering an intent to donate.[59,60] Finally, people who register an intent to donate are likely to come from families who generally support donation, have few socioeconomic challenges, and may have consented regardless of registration status.[25]

These factors contribute to estimates of the high costs associated with either encouraging additional registrations[58] or adding enough registrations to result in a likely increase in donation and transplantation.[61] Although a mature system with an established donation registry can justify these costs, less developed systems could and likely should focus on the development of other aspects of OTDT activity that are more likely to increase consent rates and deceased donation.[19,62]

Further research into the links between changes in the number of registrations and actual transplantations is needed. Programs or resources aimed at increasing registry numbers should include plans to evaluate impact, including correlations between the number of registrations and rates of actual donors and transplantations. Systems looking to implement or enhance a registry should consider the cost-effectiveness of such interventions and target marketing and public outreach to populations in which consent rates have the most potential to improve.

Recommendation 7

We recommend that, in the case of a consent model change, any methods used to promote the changes be sufficient to fully communicate details of the new model to the general public.

The intention of presumed consent is to increase the availability of transplantable organs, albeit without clear evidence that this will occur.[13,63] Such a change should not harm public

or professional trust in the donation-transplant continuum. Engaging our communities, particularly those most vulnerable, those less likely to donate, and those caring for them, in discussions about general issues regarding donation is paramount before a fruitful discussion on consent models can occur. Clearly, consent for donation must be informed to be valid.[10-12] This is particularly important in a society that is changing the default of consent from an opt-in to an opt-out model.[64] A shift of that magnitude requires widespread public and professional education to ensure people are making truly informed decisions and to prevent the dissemination of misinformation.[59]

Importantly, HCPs need to be engaged with both the public promotion and specific training to ensure consent is obtained within the jurisdictional legal framework. This is addressed further in Recommendation 10.

Public facing awareness and education campaigns often serve 2 major functions. The first is to ensure that people understand how to register a decision either for or against donation. Particularly in an opt-out model, if the public does not know how to register a refusal to donate, consent cannot be considered truly informed. Secondarily, ODOs and other stakeholders often desire to increase registrations to donate to increase donation and transplantation opportunities. This requires an understanding of behavior change, which starts with increased knowledge and awareness.[65] Models such as the theory of planned behavior have been effectively employed in this regard and stipulate that decisions made by individuals require accurate information.[66,67] Information can be transmitted online because the internet and social media sources are used by 72% of Americans and 83% of Europeans for health information. Online sources are less commonly used, however, by the elderly, minorities, and people with lower standards of education.[67] Importantly, as we have learned during this COVID era, mistrust in the government does influence support of government initiatives,[68] a fact relevant to the introduction of legislation regarding presumed consent. A communication method that is particularly effective at generating positive donation messaging is stories focused on the benefits to recipients and society at large.[69] Mass media campaigns—using online and traditional media—can, directly and indirectly, produce positive changes and prevent negative changes in health-related behaviors across large populations.[70] The likelihood of successful transmission of information is substantially increased by the application of multiple interventions and when the target behavior is one-off or episodic rather than habitual or ongoing.[71] Wales' marketing campaign was successful in its use of multiplatform marketing between 2013 and 2016 as their opt-out legislation was introduced at the end of 2015, with awareness of the changes peaking at 82% of the population.[72] The successful dissemination of information related to the change depended on getting that information to people using the types of media they were most comfortable with and trusted the most.

Knowledge and information are important, but many other issues influence decision-making. Surveys have shown that individuals who are younger, are female, have higher education levels and socioeconomic status, hold fewer religious beliefs, have high knowledge levels, know others with positive attitudes, are more altruistic, and have fewer concerns about manipulation of the body of the deceased donor are more likely to have positive attitudes toward donation and are more willing to donate their organs.[70] Media campaigns should understand these and other factors in their target audience and adjust their message accordingly. Importantly, the way the request is made, by whom, influences consent rates.[53] Knowledgeable, trained personnel are needed to be successful. Appreciating the decision drivers provides a target as engagement strategies are developed.

Individual autonomy and the "value" of the donation gift are themes commonly emphasized when organ donation is discussed in the Western world; however, utilizing these themes in marketing campaigns may not resonate with everyone.

Recommendation 8

We recommend that, in the case of a consent model change, culturally and religiously sensitive outreach before, during, and after a consent model change be performed in collaboration with historically underrepresented populations and communities with low donation rates.

Any OTDT system considering a change in the consent model, particularly toward an opt-out system, should pay particular attention to groups that may have tendencies to distrust the healthcare system in general or the OTDT system in particular. A comprehensive review of studies,[73] conducted mostly with groups with historically low donation rates, highlighted 8 major themes regarding community attitudes; relational ties, religious beliefs, cultural beliefs, family influence, body integrity, interaction with the healthcare system, knowledge of donation, and reservations for support of donation issues influencing decision-making in an explicit consent system overlap with concerns in an opt-out model. In a recent publication from the United Kingdom,[74] people planning to opt-out discussed 3 themes of issues: self-protection (medical mistrust, concerns regarding bodily integrity, apprehension regarding recipient selection), consent versus coercion (government interference, freedom of choice, autonomy), and "riddled with pitfalls" (stigma or reproach if opting out).

There is reason to suspect that, with careful engagement, even groups with historically low donation rates could develop positive attitudes toward OTDT systems. In fact, surveys suggest that some groups with historically low donation rates nonetheless express support for donation and the opposition may represent a lack of mutual understanding more than insurmountable barriers.[42,75] For example, donation rates in countries with predominantly Muslim populations are often low, with religious dictum often cited as the reason. Although each individual experiences religious belief in their own way, formal religious teachings in any religion are rarely, if ever, against donation and transplantation.[76] A recent article[77] summarized 7 conflicting Islamic views on the issue, and the authors concluded that "all seven positions are Islamic positions and people are at liberty to adopt any one position without theological guilt or moral culpability." OTDT stakeholders should engage with faith communities with the goal of communicating these formal teachings. In England, ahead of their move to presumed consent, a fatwa was issued by a prominent Muslim scholar giving reassurance that organ donation is compatible with their faith.[78] Although this represents a single event in a particular circumstance, it illustrates that such outreach is possible, even to a population whose members may have been inclined to distrust an OTDT system. Outreach of this nature allows OTDT systems to understand that often it is rituals related to death that may impede

consent rates (bodily integrity, time to burial) rather than the willingness to donate.

Professional education, however, should also include the caveat that, whatever the formal teaching of a religion, religious belief systems are ultimately personally held. Members of faith communities have wide variation in their level of personal orthodoxy and how that orthodoxy interacts with end-of-life or donation decisions. Respect for individual decisions must prevail, even if those decisions are not necessarily in line with widely held interpretation of a particular religion.

Recommendation 9

We suggest public and professional outreach be integrated into information sources that are most trusted by the target community.

Whatever consent model is chosen, if it involves a change, the OTDT system must be ready with a clearly delineated communication plan to ensure success. Communication strategies of consent models need to reach broad sections of the population. Although access to online health information is an increasing source of healthcare information globally, it is not always the preferred source or accessible to all.[79] As demonstrated in reviews of effective strategies to seek new donor registrations, engagement methods must be credible and connected with historically marginalized groups (first nations, immigrants, religious minorities, illiterate, rural), optimally delivered by individuals trusted by the community.[80] An example is the community investment scheme[80] introduced by NHS Blood and Transplant to build support for donation among Black, Asian, mixed heritage, and minority ethnic communities by funding community and faith-based organizations. As trusted members of their respective communities, invested representatives are effective at sharing accurate information because of their specialist knowledge, understanding, and standing in the community.

Different approaches are essential for all sectors of the population. The trust and credibility afforded to web-based health information vary depending on the age of the user, education, e-literacy skills, and website usability and will influence whether the user applies that information.[81,82] The platform employed, the messenger, the messaging, and the dynamics of the target group must be factored into anticipate success. The impact of misinformation in social media is a major concern in public health and should be anticipated and addressed.[83] It can reduce the effectiveness of programs, campaigns, and initiatives aimed at citizens' health, awareness, and well-being.[70,73,74]

Knowledge gaps are not unique to the general public but are also common among professionals involved with organ donation.[84,85] As discussed in Recommendation 10, multimodal professional outreach is key to implementation and should be provided in a manner that is accessible and engaging for professionals.

Recommendation 10

We recommend the implementation of a change to a consent model be preceded by adequate time to

a. Build, test, and deliver training to clinicians who approach families and SDMs to frame the conversation in compliance with the laws and policy
b. Create and publish guidance documentation for clinicians
c. Engage and involve stakeholders across the donation system to garner support for the changes
d. Develop necessary informational technology changes

For any legislation change, systems must consider the amount of time required to safely deliver the change at an operational level. The majority of recent examples of jurisdictions changing their consent model have allowed a minimum of 12 mo[39,50,86,87] to ensure the public promotion of the law and the training and engagement of the clinical community are given sufficient time to be effective. A high-profile example in which insufficient implementation time was allowed occurred in Brazil, where approval to move from opt-in to opt-out was given in February 1997 and the changes took effect in March of the same year.[88] It was not well received by the general public or the clinical community and was subsequently abolished in October 1998.[20] Any potential mishandling of a consent model change could have a long-term negative impact on the organ donation system.

HCPs delivering clinical care must be trained sufficiently to appropriately apply consent policies and procedures. Several jurisdictions recently adopting an opt-out model have provided clinical guides to applying the new law in practice,[37-40,89,90] which serve to remove the need for clinicians to interpret the policy intent and provide reassurance regarding what practices fall within the remit of the legislation. It is recommended that the responsible body in a jurisdiction provides a similar document for clinicians and that the training of HCPs should be based on this guide. The detail of the training will vary per jurisdiction; however, there are fundamentals that will apply across any consent model change, including the need for case-based scenarios that allow clinicians to anticipate difficult situations.[91-93] Feedback loops should be instigated to ensure that training and educational interventions have developed competence in the new system. Feedback loops can include training evaluations and debriefing activities designed to enrich and reinforce learning.[94]

Outside of the OTDT teams, there is a community of HCPs that the system is reliant upon to identify and refer potential donors and those involved in organ recovery. These HCPs will be based in intensive care units, emergency departments, operating departments, and the recovery teams and transplanting centers. Specific engagement must be undertaken to ensure these groups understand their role under the consent model. Although, in most cases, the law change will have minimal impact on their practice,[95] OTDT systems can use these moments to reinforce general "best practices" in organ donation (eg, identification and referral). Organizational readiness is critical to the successful implementation of complex changes in healthcare settings.[96] A change of this magnitude will require project management that includes oversight, governance, and accountability across all workstreams to ensure that the change process is controlled and that interdependencies are aligned.

A consent model change will likely come with at least 2 technological changes required to deliver the new law. As per Recommendation 4, the donor registry will systematically require updating to reflect the purpose of the new law. Second, where a donation system has an electronic donor audit, this will need to be amended to reflect the new consent model, which will have cost and resource implications for programming and testing before deployment into the live system.

All these preparatory and postimplementation changes require adequate staffing in funding for the legislative and policies to achieve their intended outcomes.

Recommendation 11

We recommend that measuring the impact of a consent model change is a high priority for an OTDT system.

Considering the enormity of such a change, systems must be prepared and have a plan to measure the impact of a consent model change over time. These measures will hold interest for the media, public, policymakers, and healthcare teams over time. However, measures must be plausibly related to the actual influence a change in consent rate can exert over an OTDT system. For example, a consent model change will not increase the number of potential donors or alter the rate of medical refusals for organ recovery. Thus, outcomes must be carefully defined and the tools to measure them implemented. In general, changes in consent models would be expected to impact consent rates, donor identification and referral rates, and public attitudes toward donation. Many of these outcomes are best measured through potential donor audits, which should be equipped to capture quantitative data and compare outcomes before and after change. In Wales, a series of studies incorporating both qualitative and quantitative data has provided insight into the impact of the move to deemed consent.[21,97-100] Notably, one article[101] describes a statistically significant increase in the consent rate from donors after brain death in Wales in the period after the legislation change. Further studies are ongoing in England,[102] Scotland, and Nova Scotia,[103] which will add to the body of literature available and aid in decision-making in jurisdictions contemplating a consent model change. While looking at the impact on quantifiable donation and transplantation outcomes, these programs are also evaluating public and professional opinions and exploring the lived experiences of people who are impacted by the donation and transplantation process. Similar methods should be applied to the many other questions around optimal consent models, such as if directed donation, reciprocity, or incentive models result in the outcomes desired by stakeholders, either for specific groups or for the OTDT system as a whole.

CONCLUSION

This article identifies the important areas for consideration by a government and an OPO when contemplating a consent model change. The choice of consent model, donor registry, public messaging, and healthcare engagement is discussed in the context of the prevailing culture and norms in any given jurisdiction and recommendations provided based on the available literature and expertise of the authors.

ACKNOWLEDGMENTS

We would like to acknowledge Manuel Escoto for coordinating our group's conferences and providing invaluable administrative support. We would also like to acknowledge the Scientific Committee and the Planning Committee for their coordination of the project and feedback on our group's draft manuscript and all the other participants in the Forum for engaging with our ideas throughout the process.

REFERENCES

1. Parsons JA. Deemed consent for organ donation: a comparison of the English and Scottish approaches. *J Law Biosci.* 2021;8:lsab003.
2. Molina-Pérez A, Rodríguez-Arias D, Delgado J. Differential impact of opt-in, opt-out policies on deceased organ donation rates: a mixed conceptual and empirical study. *BMJ Open*. 2022;12:e057107.
3. Weiss MJ, Dirk J. Deemed consent for deceased organ donation. *CMAJ.* 2021;193:E1008–E1009.
4. Matesanz R, Domínguez-Gil B. Opt-out legislations: the mysterious viability of the false. *Kidney Int.* 2019;95:1301–1303.
5. NHS Blood and Transplant. The journey through intensive care and the gift of organ donation. Available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17328/the-journey-through-the-gift-of-organ-donation-2019-mv4.pdf. Accessed November 11, 2021.
6. Academy of Medical Royal Colleges: UK Donation Ethics Committee. Involving the family in deceased organ donation. 2016. Available at https://www.aomrc.org.uk/wp-content/uploads/2016/07/Involving_family_deceased_organ_donation_0416-2.pdf. Accessed July 5, 2022.
7. Welsh Government. Opt-out systems of organ donation: international evidence review. Number 44/2012. Available at https://gov.wales/sites/default/files/statistics-and-research/2018-12/121203optoutorgandonationen.pdf. Accessed November 11, 2021.
8. Scottish Government. Opt out organ donation: a rapid evidence review. 2018. Available at http://www.gov.scot/publications/opt-out-organ-donation-rapid-evidence-review/. Accessed November 11, 2022.
9. Weiss MJ, Cantarovich M, Chaudhury P, et al. International Donation and Transplantation Legislative and Policy Forum: methods and purpose. *Transplant Direct*. 2023;9:e1351.
10. World Health Organization. *WHO guiding principles on human cell, tissue and organ transplantation*. World Health Organization. 2010. Available at https://apps.who.int/iris/handle/10665/341814. Accessed August 30, 2022.
11. International Society of Nephrology, The Transplantation Society. Declaration of Istanbul. 2018. Available at https://doi.tts.org/images/documents/doi_2018_English.pdf. Accessed January 2, 2022.
12. Global Alliance of Eye Bank Associations. Barcelona principles. An agreement on the use of human donated tissue for ocular transplantation, research, and future technologies. 2018. Available at https://www.gaeba.org/wp-content/uploads/2018/05/GAEBA-2018-The-Barcelona-Principles-FINAL.pdf. Accessed December 11, 2021.
13. Etheredge HR. Assessing global organ donation policies: opt-in vs opt-out. *Risk Manag Healthc Policy.* 2021;14:1985–1998.
14. Etheredge HR, Penn C, Watermeyer J. A qualitative analysis of South African health professionals' discussion on distrust and unwillingness to refer organ donors. *Prog Transplant.* 2018;28:163–169.
15. Sidley P. South African doctors charged with involvement in organ trade. *BMJ.* 2004;329:190.2190.
16. Shaw D, Neuberger J, Murphy P. Lessons from the German organ donation scandal. *J Intensive Care Soc*. 2013;14:200–201.
17. Shepherd L, O'Carroll RE, Ferguson E. An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study. *BMC Med.* 2014;12:131.
18. Arshad A, Anderson B, Sharif A. Comparison of organ donation and transplantation rates between opt-out and opt-in systems. *Kidney Int.* 2019;95:1453–1460.
19. Ahmad MU, Hanna A, Mohamed AZ, et al. A systematic review of opt-out versus opt-in consent on deceased organ donation and transplantation (2006-2016). *World J Surg.* 2019;43:3161–3171.
20. Csillag C. Brazil abolishes "presumed consent" in organ donation. *Lancet.* 1998;352:1367.
21. Noyes J, McLaughlin L, Morgan K, et al. Short-term impact of introducing a soft opt-out organ donation system in Wales: before and after study. *BMJ Open.* 2019;9:e025159.
22. Johnson EJ, Goldstein D. Medicine. Do defaults save lives? *Science.* 2003;302:1338–1339.
23. Delgado J, Molina-Pérez A, Shaw D, et al. The role of the family in deceased organ procurement: a guide for clinicians and policymakers. *Transplantation.* 2019;103:e112–e118.
24. NHS Blood and Transplant. Organ and tissue donation and transplantation activity report 2020/21. Available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/24053/activity-report-2020-2021.pdf. Accessed January 12, 2022.
25. Coppen R, Friele RD, Gevers SKM, et al. Imagining the impact of different consent systems on organ donation: the decisions of next of kin. *Death Stud.* 2010;34:835–847.

26. Bea S. Opt-out policy and the organ shortage problem: critical insights and practical considerations. *Transplant Rev (Orlando).* 2021;35:100589.
27. Glazier AK. Organ donation and the principles of gift law. *CJASN*. 2018;13:1283–1284.
28. Ghahramani N. Paid living donation and growth of deceased donor programs. *Transplantation.* 2016;100:1165–1169.
29. Ashkenazi T, Lavee J, Mor E. Organ donation in Israel--achievements and challenges. *Transplantation.* 2015;99:265–266.
30. Zúñiga-Fajuri A. Increasing organ donation by presumed consent and allocation priority: Chile. *Bull World Health Organ.* 2015;93:199–202.
31. Levy M. State incentives to promote organ donation: honoring the principles of reciprocity and solidarity inherent in the gift relationship. *J Law Biosci.* 2018;5:398–435.
32. Moorlock G, Ives J, Bramhall S, et al. Should we reject donated organs on moral grounds or permit allocation using non-medical criteria?: a qualitative study. *Bioethics.* 2016;30:282–292.
33. Cronin AJ, Price D. Directed organ donation: is the donor the owner? *Clin Ethics.* 2008;3:127–131.
34. Glazier A, Mone T. Success of opt-in organ donation policy in the United States. *JAMA.* 2019;322:719–720.
35. Molina Pérez A, Delgado J, Rodríguez-Arias D, et al. Defining consent: autonomy and the role of family. In: Hansen SL, Schicktanz S, eds. *Ethical Challenges of Organ Transplantation: Current Debates and International Perspectives*. Transcript Verlag; 2021:43–64.
36. Morla-González M, Moya-Guillem C, Rodríguez-Arias D, et al. Addressing organ shortage: an automatic organ procurement model as a proposal. *Clin Ethics.* 2021;16:278–290.
37. Human Tissue Authority. Code of Practice on the Human Transplantation (Wales) Act 2013. 2020. Available at https://content.hta.gov.uk/sites/default/files/2020-11/Code%20of%20Practice%20on%20the%20Human%20Transplantation%20%28Wales%29%20Act%202013.pdf. Accessed October 14, 2021.
38. Human Tissue Authority. Donation of solid organs and tissue for transplantation. Part two: deceased organ and tissue donation. Code of practice. 2020. Available at https://content.hta.gov.uk/sites/default/files/2020-11/Code%20F%20part%202.pdf. Accessed October 14, 2021.
39. Nova Scotia Department of Health and Wellness. Human Organ and Tissue Donation Act Information Guide. 2020. Available at https://beta.novascotia.ca/sites/default/files/documents/1-2403/human-organ-and-tissue-donation-act-information-guide-en.pdf. Accessed October 14, 2021.
40. Scottish Government. *Guidance on Deceased Organ and Tissue Donation in Scotland: Authorisation Requirements for Donation and Pre-death Procedures*. 1st ed. 2021. Available at https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2021/03/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures-1st-edition-published-march-2021-1st-ed/documents/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures/govscot%3Adocument/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures.pdf. Accessed October 14, 2021.
41. United Nations High Commissioner. United Nations Declaration on the Rights of Indigenous Peoples: resolution/adopted by the General Assembly. Refworld. 2007. Available at https://www.refworld.org/docid/471355a82.html. Accessed January 25, 2022.
42. Siminoff LA, Bolt S, Gardiner HM, et al. Family first: Asian Americans' attitudes and behaviors toward deceased organ donation. *J Racial Ethn Health Disparities.* 2020;7:72–83.
43. Donate Life America. Annual update. 2021. Available at https://www.donatelife.net/wp-content/uploads/2022/02/2021DonateLifeAmericaAnnualUpdate.pdf. Accessed January 16, 2022.
44. Li AH, Lo M, Crawshaw JE, et al. Interventions for increasing solid organ donor registration. *Cochrane Database Syst Rev.* 2021;4:CD10829.
45. Vese D. *Nudge: The Final Edition*. Thaler RH, Sunstein CR, eds. Allen Lane, Penguin; 2021.
46. Weiss MJ, English SW, D'Aragon F, et al. Survey of Canadian intensivists on physician non-referral and family override of deceased organ donation. *Can J Anaesth.* 2020;67:313–323.
47. Glazier AK. The principles of gift law and the regulation of organ donation. *Transpl Int.* 2011;24:368–372.
48. Brown SJR. Organ donor registration in the UK: the need for informed consent for ante-mortem interventions to facilitate organ donation. *Med Law Int*. 2019;19:113–135.
49. Weiss MJ, van Beinum A, Chandler J. Ethical considerations in the use of pre-mortem interventions to support deceased organ donation: a scoping review. *Transplant Rev (Orlando)*. 2021;35:100635.
50. Scottish Government. Human Tissue (Authorisation) (Scotland) Act 2019. Available at https://www.legislation.gov.uk/asp/2019/11/contents. Accessed November 17, 2021.
51. Toews M, Caulfield T. Evaluating the "family veto" of consent for organ donation. *CMAJ*. 2016;188:E436–E437.
52. Anthony SJ, Toews M, Caulfield T, et al. Family veto in organ donation in Canada: framing within English-language newspaper articles. *CMAJ Open.* 2017;5:E768–E772.
53. Hulme W, Allen J, Manara AR, et al. Factors influencing the family consent rate for organ donation in the UK. *Anaesthesia.* 2016;71:1053–1063.
54. Curtis RMK, Manara AR, Madden S, et al. Validation of the factors influencing family consent for organ donation in the UK. *Anaesthesia.* 2021;76:1625–1634.
55. Li X, Miao J, Gao R, et al. The general public new views on deceased organ donation in China. *Medicine (Baltim).* 2020;99:e23438.
56. Chatterjee P, Venkataramani AS, Vijayan A, et al. The effect of state policies on organ donation and transplantation in the United States. *JAMA Intern Med.* 2015;175:1323–1329.
57. Goldberg D, Kallan MJ, Fu L, et al. Changing metrics of organ procurement organization performance in order to increase organ donation rates in the United States. *Am J Transplant.* 2017;17:3183–3192.
58. Howard DH, Byrne MM. Should we promote organ donor registries when so few registrants will end up being donors? *Med Decis Making.* 2007;27:243–249.
59. Shacham E, Loux T, Barnidge EK, et al. Determinants of organ donation registration. *Am J Transplant.* 2018;18:2798–2803.
60. Reibel M, Olmo C, Andrada S, et al. Deep demographics: understanding local variation in donor registration. *Prog Transplant.* 2016;26:191–198.
61. Razdan M, Smith KJ, Bryce CL, et al. Promoting organ donor registries through public education: what is the cost of securing organ donors? *Transplantation.* 2016;100:1332–1338.
62. Vania DK, Randall GE. Can evidence-based health policy from high-income countries be applied to lower-income countries: considering barriers and facilitators to an organ donor registry in Mumbai, India. *Health Res Policy Syst.* 2016;14:3.
63. Vanholder R, Domínguez-Gil B, Busic M, et al. Organ donation and transplantation: a multi-stakeholder call to action. *Nat Rev Nephrol.* 2021;17:554–568.
64. Shaw D. Presumed evidence in deemed consent to organ donation. *J Intensive Care Soc.* 2018;19:2–3.
65. Ghaffari M, Latifi M, Rocheleau CA, et al. Using the theory of planned behavior framework for designing interventions related to organ donation. *Ir J Med Sci.* 2018;187:609–613.
66. DuBay DA, Ivankova N, Herby I, et al. African American organ donor registration: a mixed methods design using the theory of planned behavior. *Prog Transplant.* 2014;24:273–283.
67. Massey PM. Where do U.S. adults who do not use the internet get health information? Examining digital health information disparities from 2008 to 2013. *J Health Commun.* 2016;21:118–124.
68. Jennings W, Stoker G, Bunting H, et al. Lack of trust, conspiracy beliefs, and social media use predict COVID-19 vaccine hesitancy. *Vaccines (Basel).* 2021;9:593.
69. Jiang X, Jiang W, Cai J, et al. Characterizing media content and effects of organ donation on a social media platform: content analysis. *J Med Internet Res.* 2019;21:e13058.
70. Wakefield MA, Loken B, Hornik RC. Use of mass media campaigns to change health behaviour. *Lancet.* 2010;376:1261–1271.
71. Kotler P, Armstrong G. *Principles of Marketing*. 14th ed. Pearson Prentice Hall; 2022.
72. Welsh Government. Public attitudes to organ donation: waves 10, 11 and 12. 2016. Available at https://gov.wales/public-attitudes-organ-donation-waves-10-11-and-12. Accessed January 8, 2022.
73. Irving MJ, Tong A, Jan S, et al. Factors that influence the decision to be an organ donor: a systematic review of the qualitative literature. *Nephrol Dial Transplant.* 2012;27:2526–2533.

74. Miller J, Currie S, McGregor LM, et al. "It's like being conscripted, one volunteer is better than 10 pressed men": a qualitative study into the views of people who plan to opt-out of organ donation. *Br J Health Psychol.* 2020;25:257–274.
75. Setta SM, Shemie SD. An explanation and analysis of how world religions formulate their ethical decisions on withdrawing treatment and determining death. *Philos Ethics Humanit Med.* 2015;10:6.
76. Metwally AM, Abdel-Latif GA, Eletreby L, et al. Egyptians' social acceptance and consenting options for posthumous organ donation; a cross sectional study. *BMC Med Ethics.* 2020;21:49.
77. Ali M, Maravia U. Seven faces of a Fatwa: organ transplantation and Islam. *Religions.* 2020;11:99.
78. BBC News. Fatwa approves organ donation principle after Bristol man's efforts. 2019. Available at https://www.bbc.com/news/uk-england-bristol-48660208. Accessed January 7, 2022.
79. Clarke MA, Moore JL, Steege LM, et al. Health information needs, sources, and barriers of primary care patients to achieve patient-centered care: a literature review. *Health Informatics J.* 2016;22:992–1016.
80. Deedat S, Kenten C, Morgan M. What are effective approaches to increasing rates of organ donor registration among ethnic minority populations: a systematic review. *BMJ Open.* 2013;3:e003453.
81. Sbaffi L, Rowley J. Trust and credibility in web-based health information: a review and agenda for future research. *J Med Internet Res.* 2017;19:e218.
82. Fisher J, Burstein F, Lynch K, et al. "Usability + usefulness = trust": an exploratory study of Australian health web sites. *Internet Res.* 2008;18:477–498.
83. Suarez-Lledo V, Alvarez-Galvez J. Prevalence of health misinformation on social media: systematic review. *J Med Internet Res.* 2021;23:e17187.
84. Oo WL, Ong JS, Foong JW, et al. Knowledge and attitudes of healthcare professionals and the impact on willingness to donate organs: a tertiary hospital survey. *Singapore Med J.* 2020;61:154–161.
85. Kocaay AF, Celik SU, Eker T, et al. Brain death and organ donation: knowledge, awareness, and attitudes of medical, law, divinity, nursing, and communication students. *Transplant Proc.* 2015;47:1244–1248.
86. National Assembly for Wales. Human Transplantation (Wales) Act 2013. Available at https://www.legislation.gov.uk/anaw/2013/5/contents. Accessed January 12, 2022.
87. UK Government. Organ Donation (Deemed Consent) Act 2019. Available at https://www.legislation.gov.uk/ukpga/2019/7/contents. Accessed January 12, 2022.
88. Csillag C. Brazil's law on organ donation passed. *Lancet.* 1997;349:482.
89. Nederlandse Transplantie Stichting. Kwaliteits- standaard Donatie versie. 2020. Available at https://www.transplantatiestichting.nl/files/2020-12/nts-kwaliteitsstandaard-donatie-versie1.1-april-2020.pdf?c5f7988255. Accessed January 12, 2022.
90. Ministerio de Sanidad, Consumo Y Bienestar Social and Organización Nacional de Trasplantes. Programa Marco de Calidad y Seguridad Proceso de Consentimiento a la donación de fallecido. 2018. Available at http://www.ont.es/infesp/Programa%20Marco%20de%20calidad%20y%20Seguridad/1.%201.%20Proceso%20de%20consentimiento%20a%20la%20donaci%C3%B3n%20de%20fallecido.pdf. Accessed January 13, 2022.
91. Miller C, Hubner L, Griffiths A. Legislation change in organ and tissue donation: educating specialist staff. *Br J Nurs.* 2020;29:318–320.
92. Miller C, Hubner L, Roberts C, et al. Evaluation of staff training on legislation change in organ and tissue donation. *Br J Nurs.* 2020;29:974–977.
93. Miller C, Hubner L, Cotter B. Consolidating education on organ and tissue donation legislation changes. *Br J Nurs.* 2020;29:1282–1285.
94. Miller C, Hubner L, Paterson S, et al. Embedding changes in legislation for organ and tissue donation across England and Jersey. *Br J Nurs.* 2021;30:310–312.
95. Walton P, Miller C, Maycock S, et al. Deemed consent to organ donation: what critical care nurses need to know. *Br J Nurs.* 2020;29:910–912.
96. Weiner BJ. A theory of organizational readiness for change. *Implement Sci.* 2009;4:67.
97. Noyes J, Morgan K, Walton P, et al. Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: mixed-method study protocol. *BMJ Open.* 2017;7:e017287.
98. Noyes J, Mclaughlin L, Morgan K, et al. Designing a co-productive study to overcome known methodological challenges in organ donation research with bereaved family members. *Health Expect.* 2019;22:824–835.
99. Noyes J, Mclaughlin L, Morgan K, et al. Process evaluation of specialist nurse implementation of a soft opt-out organ donation system in Wales. *BMC Health Serv Res.* 2019;19:414.
100. Dallimore DJ, McLaughlin L, Williams C, et al. Media content analysis of the introduction of a "soft opt-out" system of organ donation in Wales 2015-17. *Health Expect.* 2019;22:485–495.
101. Madden S, Collett D, Walton P, et al. The effect on consent rates for deceased organ donation in Wales after the introduction of an opt-out system. *Anaesthesia.* 2020;75:1146–1152.
102. Policy Innovation and Evaluation Research Unit. Evaluation of changes to organ donation legislation in England—Policy Innovation Research Unit. 2021. Available at https://piru.ac.uk/projects/current-projects/evaluation-of-changes-to-organ-donation-legislation-in-england.html. Accessed December 11, 2021.
103. Weiss MJ, Krmpotic K, Cyr T, et al. A program of research to evaluate the impact of deceased organ donation legislative reform in Nova Scotia: the LEADDR Program. *Transplant Direct.* 2021;7:e641.