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Baseline Ethical Principles and a Framework for Evaluation of Policies: Recommendations From an International Consensus Forum

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Background. To maintain public trust and integrity in organ and tissue donation and transplantation (OTDT), policy-makers, governments, clinical leaders, and decision-makers must ensure that policies proposed to increase donation and transplant activity satisfy baseline ethical principles established by international agreement, declaration, and resolution. This article describes the output of the Baseline Ethical Domain group of an international forum designed to guide stakeholders in considering these aspects of their system. **Methods.** This Forum was initiated by Transplant Québec and co-hosted by the Canadian Donation and Transplantation Program partnered with multiple national and international donation and transplantation organizations. The domain working group members included administrative, clinical, and academic experts in deceased and living donation ethics and 2 Patient, Family, and Donor partners. Identification of internationally accepted baseline ethical principles was done after literature reviews performed by working group members, and a framework for consideration of existing or novel policies was completed over a series of virtual meetings from March to September 2021. Consensus on the framework was achieved by applying the nominal group technique. **Recommendations.** We used the 30 baseline ethical principles described in World Health Organization Guiding Principles, Declaration of Istanbul, and Barcelona Principles to generate an ethical framework—presented graphically as a spiral series of considerations—designed to assist decision makers in incorporating these ethical principles into practice and policy. We did not seek to determine what is ethical but instead described a method of evaluation for policy decisions. **Conclusions.** The proposed framework could be applied to new or existing OTDT policy decisions to facilitate the transformation of widely accepted ethical principles into practical evaluations. The framework includes adaptation for local contexts and could be applied broadly internationally. (Transplantation Direct 2023;9: e1471; doi: 10.1097/TXD.0000000000001471.)

The baseline ethical principles that should govern any country's or jurisdiction's organ and tissue donation

and transplantation (OTDT) system are well established by international agreement, declaration, and resolution.

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This includes the 30 ethical statements found in the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue, and Organ Transplantation from the Sixty-Third World Health Assembly (2010);¹ the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition);² and the Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies (2018).³ See Appendix S1 (SDC, <http://links.lww.com/TXD/A516>).

What is less well established is how governments, clinical leaders, and decision-makers should use these statements in practice to make ethical donation and transplantation policies. Decision-making organizations in the field of OTDT need to recognize and incorporate global ethical guidance in the same way that scientific advances inform worldwide donation and transplantation practice. This domain is structured to assist those responsible for making and approving ethical policy decisions whatever the context of their healthcare system.

This work was performed in the context of the International Donation and Transplantation Legislative and Policy Forum (the Forum) to create expert consensus guidance for ideal OTDT systems. In this domain, after a general description of baseline ethical principles, we propose and outline a framework to assist governments, clinical leaders, and decision-makers in incorporating ethical principles into practice and policy.

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).⁴ Dr. Gardiner 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 ethics, with emphasis on geographic and professional diversity. Appendix S2 (SDC, <http://links.lww.com/TXD/A516>) lists domain participants and their affiliations; all working group participants are listed as authors in this article, with the exception of C.C. This working group included deceased donation medical and administrative leaders in the UK (D.G.), Canada (A.G. and M.W.), South Korea (C.A.), and India (S.N.). Other members were invited based on their published academic interest in deceased donation ethics (A.M., S.N., and C.S.). Patients, families, and donor partners were incorporated into all aspects of the Forum including 2 in this domain working group (C.C. and A.K.).

All participants completed conflict of interest forms, 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 non-profit research and professional organizations and Canadian Blood Services.

The framework development process involved the application of the nominal group technique of consensus building,⁵ applied over a period of February to September 2021 in a series of virtual conferences. During early meetings, it was decided that a framework would be more useful to the international community than a re-creation of already agreed upon principles. Thus, a narrative literature search was performed to identify widely accepted international

resolutions regarding OTDT ethics. This search was aided by a common, web-based reference manager file that included references from this and related domains. The identified baseline ethical principles and background of how these principles coincide with the broader field of medical ethics were summarized in an introduction to the proposed framework. The framework itself was 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://forumtransplantationquebec.ca/en/>.

Intended Audience and Application

The goal of the Forum and this domain was to create a series of 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 that diversity, the proposed framework and accompanying background information are informed by the expertise of the panelists and the available published literature, and we believe it can be used in whole or in part to improve global OTDT services.

Recommendations

We propose that the 30 baseline ethical principles, found in the WHO Guiding Principles, Declaration of Istanbul, and Barcelona Principles, can be distilled and matched to 4 underlying themes (see Appendix S1, SDC, <http://links.lww.com/TXD/A516>):

1. Self-sufficiency—does the policy promote self-sufficiency?
2. Margin of Appreciation—does the policy fall within an acceptable margin of appreciation?
3. Efficacy—will the policy be effective?
4. Protection—what protections are required?

Figure 1 diagrammatically represents these 4 themes in a spiral model, with associated questions of application. This spiral model is useful for assessing and making ethical policy decisions in OTDT. One can see in the diagram that the themes start broadly; asking overarching questions, but as one moves toward policy approval, there is a requirement for greater granularity and detail. Adopting this framework will support policy development and evaluation, as well as aid policy prioritization. A worked example is provided in Appendix S3 (SDC, <http://links.lww.com/TXD/A516>).

By encouraging these types of reflections and considerations in the development of OTDT policies, the framework can be used to help decision-makers implement policies that promote self-sufficiency and efficacy, that are protective of autonomy and the vulnerable, and which will accommodate reasonable disagreement up to a point, with due attention to the weight that should be assigned to potentially conflicting principles across cultures and between nations.

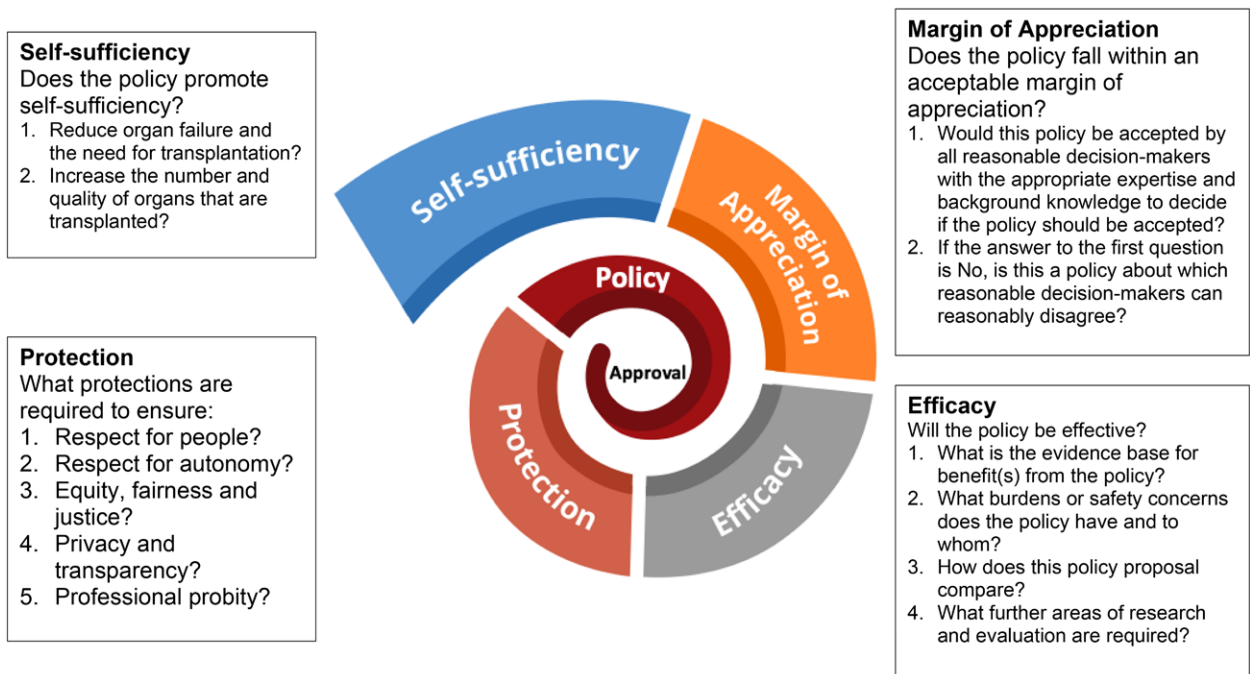


FIGURE 1. Spiral model for assessing and making ethical policy decisions in organ and tissue donation and transplantation.

The framework is useful for any OTDT decision-maker. This will include national and regional governments, organizations and regulators, hospital management, patient-centered organizations, donation and transplantation teams, and individual clinical staff. There is an associated and explicit ethical requirement for decision-makers to involve those affected by any policy decision.⁶ This should include respect for cultural sensitivity, diversity, and harder-to-engage population groups. We suggest this might be achieved by accepting there is a duty to consult, encouraging lay and patient representation on decision-making bodies, realizing that the more granular the decision the higher the need for specific lay and patient representation and involvement, and holding decision-makers accountable for acting transparently and mitigating against any perceived or real conflict of interest.

DISCUSSION

Ethics, or more precisely for this topic, normative ethics, concerns doing right and how one ought to act. In the field of medicine, normative ethics is often called bioethics. As a discipline of ethics, modern bioethics arose in the 20th Century as a response to advances in medicine but also against a backdrop of persisting ethical failings by doctors and healthcare systems.⁷⁻⁹ Furthermore, and more generally, paternalistic models are shifting toward more of a partnership between healthcare providers and patients, with an increasing emphasis on shared decision-making.

The dominant bioethics teaching since the 1980s has been the amalgam of the older, primarily Western ethical models, by Beauchamp and Childress, into their 4 Principles of Medical Ethics: Respect for Autonomy, Non-Maleficence, Beneficence, and Justice. Other perspectives, like feminist ethics, cultural competence, and the ethic of care have found more recent inclusion in medical school and post-graduate education. These perspectives, taken collectively, encourage reflection on relevant ethical considerations at both the clinical and healthcare system levels.

Medical advances in the 20th Century have made possible what our ancestors could only have described as miraculous. Human transplantation is an exemplar of the possibilities offered by modern medicine. As much as donation and transplantation have pushed the advance of medicine, so too have they brought with them their own ethical challenges. Blood donation represents the most common human transplantation that occurs in the world and has had its share of controversy and scandal.¹⁰⁻¹² Yet, although extremely challenging at times, many countries have established blood donation systems in which supply can usually meet demand. In contrast, in human organ donation and transplantation, demand from organ failure greatly exceeds supply.¹³ This not only represents tragic loss of life but also adds desperate need into the ethical equation.

The willingness of donors and recipients to give and receive organs relies upon widespread public trust in the OTDT system. This can only occur if the system is considered safe. This safety can be on a technical level, the science of transplantation, but safety is also strongly dependent on the ethical robustness of the system. Is the organ donation and transplantation system respectful, fair, and justifiable? Is it perceived to be these things? When it is not, the possibility of abuse, discrimination, and ultimately loss of public trust can occur. Worldwide reports of ethical failings in OTDT systems include the commercialization of transplantation,^{14,15} exploitation and coercion of donors,¹⁶ lack of consent,¹⁷ allocation scandals,¹⁸ and the execution of prisoners for donation.^{19,20}

International efforts to respond to, and ultimately, prevent such failings have been attempted by developing baseline ethical principles through consensus for OTDT systems. When these principles are incorporated into law, regulation, and practice they can help maintain and build public trust and confidence.

The WHO first endorsed Guiding Principles on Human Organ Transplantation in 1991,²¹ and these were most recently revised in 2010.¹ The Guiding Principles are justified by the WHO as a way of committing member states to the following:

1. Principles of human dignity and solidarity that condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations and the human trafficking that results from such practices,
2. Prevention of harm caused by the seeking of financial gain or comparable advantage in transactions involving human body parts, including organ trafficking and transplant tourism,
3. Voluntary, non-remunerated donation of organs, cells, and tissues from deceased and living donors to ensure a vital community resource,
4. International exchange of data to optimize the safety and efficacy of transplantation.

To address the urgent and growing problems posed by organ trafficking,²² The Transplantation Society and the International Society of Nephrology convened a Summit Meeting in Istanbul in April 2008, resulting in the publication of the Declaration of Istanbul. This subsequently led to the creation of the Declaration of Istanbul Custodian Group to disseminate the Declaration and to respond to new challenges in organ trafficking and transplant tourism.^{2,23} The 2018 edition statements from the Declaration of Istanbul are reproduced in Appendix S1 (SDC, <http://links.lww.com/TXD/A516>).

The Madrid Resolution on Organ Donation and Transplantation in 2011 acted as a way to conceptually align the WHO Guiding Principles with the Declaration of Istanbul by calling for a paradigm shift toward self-sufficiency in which “Every country, in light of its own level of economic and health system development, should progress toward the global goal of meeting patients’ needs based on the resources obtained within the country, for that country’s population, and through regulated and ethical regional or international cooperation when needed” (page S29).²⁴

Inspired by the Declaration of Istanbul and in accordance with the WHO Guiding Principles, the Global Alliance of Eye Bank Associations published The Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies in 2018 (see Appendix S1, SDC, <http://links.lww.com/TXD/A516>).³ Like the Madrid resolution, it called for the development of self-sufficient services in corneal transplantation and provided a global bioethical framework for the eye bank and ophthalmic communities.

Together, the above international agreements, declarations, and resolutions provide 30 baseline ethical principles that should govern any country’s or jurisdiction’s OTDT system. Such principles have been supported by work and similar statements from the World Medical Association.^{25,26} What follows is a discussion of our suggested thematic framework, diagrammatically displayed as a spiral (see Figure 1), on how to apply these baseline ethical principles to policy development, implementation, and decision-making.

A Framework for Ethical Policy Decision-making Self-sufficiency

—Does the Policy Promote Self-sufficiency?

The baseline ethical principle of self-sufficiency is based on there being a societal responsibility to prevent and, when necessary, provide and find treatments for organ failure.

Specifically, decision-makers should ask if the policy is intended to do the following:

1. Reduce organ failure and the need for transplantation or
2. Increase the number and quality of organs that are transplanted?

These questions may not necessarily have a binary answer. What is important is the intention behind and the general plausibility of the proposal. For some jurisdictions, particularly those with limited healthcare resources, efforts at the prevention of organ failure may be of a higher priority than establishing transplant programs. Yet, even in these nations, the needs of those with established organ failure should not be ignored and may require the best available medical technology, which at the current time means human organ and tissue transplantation. Mechanical, gene, and xenotransplantation technologies may offer alternative, perhaps superior, treatments for organ failure in the future.

Any system that relies on the importation of organs or tissues for transplant (or a nation’s residents going elsewhere for transplantation) risks exacerbating health inequities and exploitation of residents from resource-poor areas by those with more resources. Until jurisdictions with OTDT systems are self-sufficient, trafficking in human organs and trafficking in persons for the purpose of organ removal will continue. Carefully constructed ethical systems for regional cooperation can support and improve self-sufficiency and should be explored wherever possible.

Other benefits of self-sufficient systems are that they can more accurately monitor the health and safety of both donors and recipients, emphasizing that it is not just the quantity of organs but also the quality of organs that must be improved (this is discussed further as part of the efficacy section). Finally, making self-sufficiency an explicit goal could promote a culture of donation that increases rates of transplantation.^{27,28}

Margin of Appreciation

—Does the Policy Fall Within an Acceptable Margin of Appreciation?

With 30 baseline ethical principles, differences in opinion as to their interpretation or how best to implement them will occur. These differences will naturally lead to different policy decisions between jurisdictions. It is important for individual jurisdictions to be respectful of policies that are different from their own, while at the same time being able to judge, along with the international community, what policies and practices are unacceptable. This concept of respect and judgment requires one to first identify the “margin of appreciation” around any policy or practice, a term we borrow from European case law.²⁹ In European law, the margin of appreciation holds that states are allowed to have a measure of diversity in their interpretation and application of human rights treaties and responsibilities, to reflect the reasonable ethical disagreements that underlie them. In the case of states, these disagreements typically center on the weight that should be accorded to conflicting principles, in which each principle reflects important values in a jurisdiction.

We can take this concept of the margin of appreciation and apply it to the ethically controversial questions arising out of the development and implementation of OTDT policy in different jurisdictions. We adopt the concept from its legal home as applied to sovereign states and extend it to the type of reasonable disagreement that can occur within and between

different jurisdictions about particular measures that may improve OTDT outcomes.

The central function of the margin of appreciation in our framework is to provide a way to acknowledge that different weights to conflicting principles may reasonably be allocated by reasonable decision-makers; also, it is a way of acknowledging that the balance between conflicting principles may reasonably differ across different jurisdictions or even within them. Our use of the term “margin of appreciation” is intended to reflect the reality of reasonable disagreement about some measures and, in particular, to emphasize that this disagreement is indeed reasonable.

To decide that a policy is acceptable within a margin of appreciation, we suggest asking 2 questions:

1. Would this policy be accepted by all reasonable decision-makers with the appropriate expertise and background knowledge to decide if the policy should be accepted?
2. If the answer to the first question is No, we then ask, “Is this a policy about which reasonable decision-makers can reasonably disagree?”

The first of the 2 questions identifies proposals that reasonable people would agree to. The second question identifies proposals about which there can be reasonable disagreement. The concept of the “reasonable” decision-maker is similarly used in law as the “Reasonable Person Standard,” which asks what an imaginary character—the reasonable person—would do in similar circumstances.³⁰

For the purpose of our margin of appreciation theme and the 2 associated questions of application, it is usually clear when policies are universally acceptable and reasonable people will have little debate (eg, transplant surgeons should be competent to perform the surgery). Similarly, some practices and policies are ones that reasonable people find universally unacceptable (eg, taking organs against the wishes of the donor) and therefore fall outside a margin of appreciation. Whereas for many policies, reasonable people can and will debate.

An illustration of reasonable disagreement is opt-out consent for deceased organ donation, which some countries have introduced. The WHO Guiding Principle 1 says that 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. Internationally, there is no agreed, single correct way of implementing this baseline ethical principle, and there is disagreement about the optimal way of implementing it. The first of our 2 framework application questions asks whether the policy of opt-out would be accepted by all reasonable decision-makers with the appropriate expertise and background knowledge. The answer is clearly No, we know reasonable decision-makers disagree about the merits of introducing opt-out.³¹ The second question then asks whether the disagreement is reasonable or whether one side of the argument is simply wrong. Most reasonable decision-makers would conclude that on the topic of opt-out, reasonable people can reasonably disagree. Having accepted the reasonableness of disagreement, this should lead those who disagree to be respectful of each other’s position or implementation of any policy.

Another way of understanding the margin of appreciation is as a gray zone extending around any baseline ethical

principle. Within the gray zone, the size of which will vary depending on the principle, the policy should be regarded as ethically acceptable (in which reasonable people will reasonably disagree), whereas outside the gray zone and the baseline ethical principle, it would be concluded to be unethical. This is diagrammatically illustrated in Figure 2A, and an example of the baseline ethical principle that “organ donation should be a financially neutral act” (Statement 3—Declaration of Istanbul, Appendix S1, SDC, <http://links.lww.com/TXD/A516>) is provided in Figure 2B. By invoking the concept of a margin of appreciation, we better identify the limits of ethical acceptability around a given baseline ethical principle; we promote cultural humility; and we encourage jurisdictions to try, research, and evaluate differing policies.

Although the above comments could imply that the margin of appreciation is applicable only between jurisdictions, this is not the case. It also serves an important function within a jurisdiction by highlighting, and asking decision-makers to directly consider and respect, reasonable disagreement by those patients, communities, and groups most impacted by a proposal. This should prompt careful reflection and accommodation within the theme of protection (outlined below). By way of example, because of the concerns of some community groups when England introduced opt-out, a change to the National Health Service Organ Donor Register was made to allow individuals to make a faith and beliefs declaration if this is important to them.³²

Efficacy

—Will the Policy be Effective?

It is incumbent on decision-makers to choose and support effective donation and transplantation practices and policies. To ask if a policy will be effective is to examine policy proposals in detail and decide if the suggested benefit warrants further exploration, including which policies may work best within their own context. This theme encourages decision-makers to consider the benefits and burdens of any given policy proposal, allowing competing proposals or differing formulations to be compared and prioritized.

WHO Guiding Principle 10 calls for “high-quality, safe and efficacious procedures... for donors and recipients alike” (see Appendix S1, SDC, <http://links.lww.com/TXD/A516>). “Efficacious” in this context refers to the likelihood of achieving the desired result. Some policies, even though they are intended to promote self-sufficiency and fall within an acceptable margin of appreciation, will fail on more detailed examination, and should accordingly not be implemented. This failure may be due to insufficient evidence of benefit (scientific), burdens and safety concerns (risks too high), pragmatism (financial and training), or, when compared to other policy proposals, may be of lower priority.

We suggest that, when assessing efficacy, decision-makers should ask the following questions:

1. What is the evidence base for benefit(s) from the policy?
2. What burdens or safety concerns does the policy have, and to whom?
3. How does this policy proposal compare?
4. What further areas of research and evaluation are required?

The evidence base for benefit(s) from specific donation and transplantation policies and interventions is essential

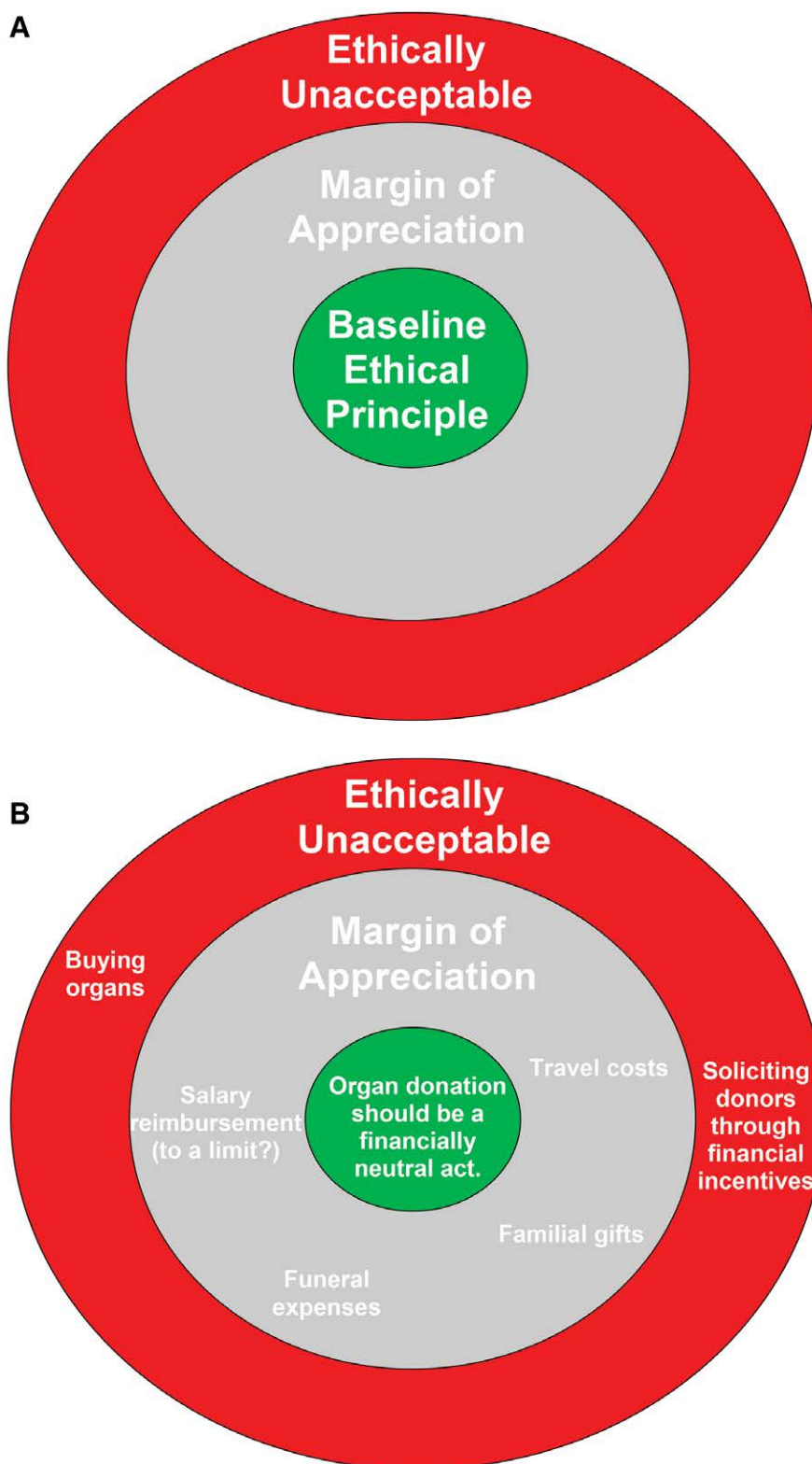


FIGURE 2. (A) Margin of Appreciation – a theoretical model. A gray zone can be pictured extending around any baseline ethical principle (green zone). Within the gray zone, the size of which will vary depending on the principle, the policy should be regarded as ethically acceptable. Whereas in the red zone, it would be concluded to be unethical. (B) For illustrative purposes only, an example of how the Margin of Appreciation model might be used when considering the baseline ethical principle, “Organ donation should be a financially neutral act.”

in judging efficacy. The greater the evidence for benefit, the greater the imperative to implement. For example, post-transplant the evidence for benefit from immunosuppression is overwhelming and patients who have received an organ

transplant require it. However, there are many types of immunosuppressive agents, each with a different evidence base for benefit and safety profile. Some of the burdens may not accrue to the patient but to the health system—for example, financial

burdens. A comparable agent, although perhaps not as beneficial or with some increased burdens, but costs much less, may become the agent of choice for immunosuppression in a jurisdiction.

The example above explored a scientific and, to some extent, financial question—which immunosuppressive agent is best (recognizing that “best” can be interpreted in different ways) after an organ transplant? Many policy decisions also raise cultural questions. For example, should opt-out be introduced into a jurisdiction? The intention of opt-out is to promote self-sufficiency; many nations already have opt-out and it falls within an acceptable margin of appreciation test. Is opt-out effective? Here, one finds that the literature base is divided as to the benefit of opt-out.^{33–35} So, what burdens or safety concerns could there be in introducing opt-out, and how does this relate to the cultural context within which this policy may be introduced? Is this something that will be seen as acceptable or appropriate? A cultural perspective is an essential part of determining what consent models might work best in a country. For further details regarding considerations when implementing a consent model, refer to domain 4 of the Forum, *Consent Model and Emerging Legal Issues*.

On this basis, what is effective in one jurisdiction may be ineffective, or even detrimental, in another.³⁶ Similarly, a judgment may be made that other ways of increasing consent for organ and tissue donation (eg, marketing and promotion, stronger first-person consent, and reciprocity) may be more effective in a given jurisdiction and be prioritized over an opt-out policy.^{37,38}

As can be seen, the starting point for judging efficacy is the evidence base for benefit. In many areas of donation and transplantation, the evidence base is poor, not because the proposal is poor but because the evidence has not been gathered. Research and evaluation of any new policy is the only way the donation and transplantation community can learn and assess the efficacy of these policies. For this reason, research must be given priority within any OTDT system, and programs should participate in national and international transplant registries, making their data freely available. For further details on the role of research and data management in OTDT systems, refer to the Research & Innovation domain (Escoto et al).³⁹

Protection

—What Protections are Required?

Any ethical donation and transplantation policy must ensure that relevant protections have been identified and implemented. This is important in and of itself as part of demonstrating and instantiating the baseline ethical principles, but it also helps to foster and maintain public trust.

In an OTDT system, which relies upon the willingness of donors and recipients to give and receive organs, the anonymous quote that “Trust takes years to build, seconds to break, and forever to repair,” should be, even if metaphorically, written upon the door of every decision-maker’s office. Trust is a function of how safe people feel, exposing that being safe is not enough. Individuals must feel safe, free from harm, manipulation, abuse, and discrimination. OTDT activity includes multiple risk factors for potential abuse. It involves high-risk, and technical medical procedures, patients who are often desperately sick and dying, a need for lifesaving organs when demand far outstrips supply, and conflicting ethical argument and discourse (eg, precisely determining the moment of death).

In these circumstances, maintaining and building trust and avoiding abuse of power is a constant challenge.

The theme of protection comes as the final step in the framework, and it involves the most detailed and granular questions. The overarching question in the theme is, “What protections are required?”

This is entirely predicated on the expectation that protections will be required. The role of decision-makers is to identify, communicate and implement necessary protections before approving any policy or practice.

Finding a balance between exigencies within the protective theme may be helped by breaking the question down into a series of sub-questions. Each sub-question requires an explicit response from decision-makers, even if, for a given policy or practice, the answer may be none.

Decision-makers must address what protections they are required to ensure:

1. Respect for people? (eg, the patient is the first concern and vulnerable populations)
2. Respect for autonomy? (eg, donor and recipient choice)
3. Fairness, equity, and justice? (eg, allocation and prioritization)
4. Privacy and transparency? (eg, confidentiality, data, and policies)
5. Professional probity? (eg, behavior and institutional trustworthiness)

Respect for People?

Respect for people is an intentionally broad concept in ethics. It is based on recognizing the inherent worth and value of human beings. As such, people should be treated in ways that reflect this value. Although there is a great demand for organs and tissues to be donated to meet patient needs, this does not mean that donation and transplantation systems can or should do whatever is conceivable to meet these needs.

An example of protection is the dead donor rule, a foundational ethical statement in deceased donation practice.⁴⁰ One of the earliest historical formulations that helped lead to the dead donor rule was given in 1968 by the Judicial Council of the American Medical Association. They included the statement, “In making this determination, the ethical physician will use all available, currently accepted scientific tests.”⁴¹ This endures in the Uniform Determination of Death Act as, “A determination of death must be made in accordance with accepted medical standards.”⁴² The Judicial Council recognized that dying patients are a vulnerable group, and as such, they need the protection given by the requirement that the standard of medical care they receive, in this case, a determination of death, must not be compromised, even if donation of their organs may save another life. Decision-makers today must continue to identify vulnerable groups who might be affected by a policy or practice and implement actions to protect them.

A second aspect of respect for people was highlighted in the margin of appreciation theme. This theme asks decision-makers to directly consider and respect the reasonable views of others, as embodied by the concept of reasonable disagreement among those patients, communities, and groups impacted by policy and practice decisions. When possible, ways to accommodate differing societal views should be implemented. Even when accommodation is not possible, respect for people

encourages decision-makers and the donation and transplantation system to respect alternative opinions.

Based on respect for people, any donation and transplantation legislation, policy, or proposed change to processes, needs to assess carefully whether respect for people is assured.

Respect for Autonomy?

One of the ways in which respect for people is frequently demonstrated in practice is through respect for autonomy. Autonomy means self-governance, ie, the ability to think about and make one's own decisions. Respecting these decisions entails showing due deference to what a person has decided as well as ensuring decisions are freely made and with the provision of appropriate and relevant information. In the healthcare context, this is often referred to as respect for informed choice or consent.

Respect for autonomy will be applicable in different ways depending on the policy or practice concerned. Decision-makers must answer the question: what steps are required in any policy and practice to maximize respect for autonomy? There are also situations that highlight an ethical tension between respect for people and respect for autonomy. An example would be a desire to donate one's heart while alive, resulting in the death of the donor. Even if such a donation could satisfy respect for autonomy, it will not satisfy respect for people as outlined above. It can be helpful to recognize that although donation law, consent, and desire to donate permit donation, it should never mandate that it go ahead.

Equity, Fairness, and Justice?

Although noble in ambition, fairness and justice are often aspirational, whereas their achievement is debatable, non-universal, and transient. The principles of fairness and justice come into focus when it is not possible to benefit all patients equally, and difficult choices must be made. We believe John Rawls's "difference principle" can be helpful in this setting.⁴³ Rawls's principle, which was created to form part of the political basis for a fair society, holds that any inequalities resulting from the distribution of resources must be "reasonably expected to be to everyone's advantage." In making allocation decisions, this requires us to "try to maximize the interests of the worst off."

In practical terms, decision-makers should focus on making pragmatic steps toward equity. This can be achieved by first identifying who is the worst-off in the donation and transplantation system and then taking the necessary actions to improve their situation and opportunity.

An example policy would be the change to the UK Kidney Offering Scheme that made it easier for those who find it hard to get a match, such as patients from a minority ethnic background or those who have been waiting for several years. Under the new allocation rules, these patients are given a higher priority level. Of all deceased donor kidney transplants performed between September 2019 and February 2020, 40% were in minority patients compared with 33% in the same period the previous year.⁴⁴ However, policies that explicitly include race may have undesirable and unexpected effects. Equations to estimate kidney function that use race as a variable have been shown to systematically under-recognize kidney disease in some racial groups, thus decreasing their chances of receiving preventative therapy or transplantation.^{45,46} As we move to more complex algorithms and artificial intelligence to guide clinical processes, decision-makers must remain alert to the risk of unknowingly furthering inequity.

For many places in the world, equity simply means access to a transplant opportunity or the availability of affordable immunosuppression. Although the politics of fair and just distribution of the world's resources are beyond the scope of this domain, there is at the very least a responsibility among those who lead donation and transplantation systems to share knowledge and expertise, with the goal of improving and promoting equitable donation and transplantation practice worldwide.

There is also an inherent tension between the desire to achieve equity, fairness, and justice, and the theme of efficacy and its emphasis on safety, quality, and cost-benefit. The role of the decision-maker, is therefore, to explicitly acknowledge these competing goals and to implement reasonable protections.

Privacy and Transparency?

There are several tensions decision-makers need to navigate when ensuring privacy and transparency. Increasingly there is recognition that individuals have privacy rights to data protection.⁴⁷ Yet, there is another responsibility to be transparent and open to public scrutiny.

Specifically, within the 30 baseline ethical principles there are the following:

WHO Guiding Principle 12.¹

"The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected."

Declaration of Istanbul Statement 6.²

"Designated authorities in each jurisdiction should oversee and be accountable for organ donation, allocation and transplantation practices to ensure standardization, traceability, transparency, quality, safety, fairness, and public trust."

There is tension at a patient level in donation and transplantation owing to the complexity and the nature of organs being gifted. For example, given the practice of anonymity (donor and recipient to remain anonymous to each other), the tension is to decide what information can or should be shared about a donor with a recipient (and vice-versa). This can become even more complicated when one considers respect for autonomy (eg, what if donor and recipient want to meet?) and margin of appreciation—in which some have advocated that the balance should move toward less privacy (secrecy) and more transparency (sharing of more information).⁴⁸ An even further complexity is that a single doctor-patient relationship does not exist, with clinical decision-making being instead part of a Multi-Disciplinary Team often operating across the boundaries of health jurisdictions.

From the above discussion, we would encourage decision-makers to consider how they can accomplish the following:

1. Foster lay and patient representation in decision-making bodies.
2. Ensure allocation policies are visible and the information accessible.
3. Meet the desires of both donors and recipients for data sharing, which simultaneously has due regard to the confidentiality and autonomy of both parties.
4. Commit to making personal health-related data accessible to the individual it concerns (because this supports both informed decision-making and trust).

Professional Probity?

Donors, their families, and transplant recipients can be considered vulnerable populations. Structures and processes must therefore ensure institutional and professional trustworthiness and integrity. These characteristics define professional and institutional probity.

Given past and current abuses, scandals, and unethical transplants in the world,¹⁴⁻²⁰ it is no wonder that within the 30 baseline ethical principles, there are multiple warnings against the risk of improbity. The temptation for healthcare professionals to engage in unethical practice can arise from several motivations. Some are blatant malfeasance—such as a desire for financial gain—but others, perhaps more insidiously, could include a misguided focus on one patient at the expense of another. Whatever the motivation, individuals and, more importantly, institutions must constantly monitor clinical activity to assess for possible improper practices whatever the motivation.

Professional probity cannot and should not be simplified to concerns around conflicts of interest and their mitigation via transparent disclosure.^{49,50} A 2015 Canadian publication drew an important distinction between disclosure and institutional trustworthiness in managing conflicts of interest.⁵¹ Automatic and insensitively timed disclosure of roles or interests may be potentially harmful to a family or patient, especially when the motivation to disclose is professional protection rather than information sharing of relevance to a healthcare decision.⁵² Putting the onus on the receiver to weigh the relevance of any disclosure of a potential conflict of interest can be unfair, uninterpretable, and irresponsible. What was highlighted in the Canadian Guidance was that institutional trustworthiness, created by appropriate and clear role boundaries and policies of behaviour, was the essential patient protection for inevitable conflicts of interest, not disclosure.⁵¹ This does not mean that disclosure is unimportant. It is, but transparency in such circumstances is a means to trustworthiness; it does not, in and of itself, mean integrity. For this protection, we encourage policy-makers to assess proposals and their implications for practice from the perspective of what will contribute to building, maintaining, or enhancing professional probity and, thereby, trust in the OTDT system.

CONCLUSION

The aim of this domain was to propose a framework of how to make an ethical policy decision that would be practical and useful for policymakers, governments, clinical leaders, and decision-makers. We did not seek to determine what is ethical but instead align the framework—and policy decisions that could be made under it—with the 30 baseline ethical principles established by international standards for OTDT found in the WHO Guiding Principles, Declaration of Istanbul, and Barcelona Principles.

By encouraging these reflections and considerations in the development of OTDT, the framework can be used to implement policies and practice that promote self-sufficiency and efficacy, are protective of autonomy and the vulnerable, and accommodate reasonable disagreement, with due attention to the weight assigned to potentially conflicting principles across cultures and between nations.

It is our enduring hope that decision-makers will prove to be wise, humble, and respectful, that the care of patients and

their families is always the priority, and that donation and transplantation remain worthy of public trust.

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