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# Strengthening Global Efforts to Combat Organ Trafficking and Transplant Tourism: Implications of the 2018 Edition of the Declaration of Istanbul

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**Abstract:** The 2018 Edition of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (DoI) provides an updated set of principles and definitions to guide policymakers and health professionals working in organ donation and transplantation. A draft of the new edition was circulated to the public and transplant professionals through an online consultation process, which also sought feedback on a draft explanatory article that explained the principles and discussed some of their practical implications. Both drafts were revised in response to feedback from participants in the consultation. We present here the discussion article, which is intended to assist stakeholders in applying the principles of the DoI by providing more detailed information about the meaning and potential implications of implementing the DoI in various contexts.

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The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (DoI) was adopted in 2008 at an international meeting organized by The Transplantation Society and the International Society of Nephrology.<sup>1</sup> Two years later, these sponsors established the Declaration of Istanbul Custodian Group (DICG) to oversee dissemination of the document and to aid professional societies and governments in combatting organ trafficking.<sup>2</sup> In 2017, the DICG began the process of reviewing and updating the DoI to ensure that it provided clear and current guidance for policymakers and health

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Conflicts of interest: All authors are members of the DICG. At the time of preparation of the article, D.E.M. and E.M. were co-chairs of the DICG, and B.D.-G., R.G.G., and A.M.C. were also members of the DICG Executive Committee.

professionals working in organ donation and transplantation. The new edition of the Declaration, which was released on July 1, 2018, at the International Congress of The Transplantation Society in Madrid, drew on feedback from an online public consultation on a draft of the revised Declaration, prepared by an ad hoc working group established by the DICG.<sup>3</sup> The 2018 Edition<sup>4</sup> provides updated definitions of key terms (see **Box A**), and a more clearly structured and succinctly worded set of principles. A decision was made during the update process to move the set of practical "proposals" that had been part of the 2008 Declaration into a companion article that would also explain concepts, offer justifications

The original draft of this discussion article was prepared by D.E.M., K.V.A., B.D.-G., M.L.-F., and A.M.C. in consultation with members of a multidisciplinary international working group of the Declaration of Istanbul Custodian Group (DICG) that developed the 2018 Edition of the Declaration of Istanbul. That draft was circulated for feedback during a public consultation process. The second draft was prepared by D.E.M., K.V.A., B.D.-G., and M.L.-F. who drew on feedback from the public consultation process. D.M. led the development process and oversaw the revisions. K.V.A., B.D.-G., M.L.-F., R.G.G., E.M., and A.M.C. participated in the design of this article and contributed to several revisions of the draft.

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for normative positions, and provide examples of how the Declaration can be applied in practice. The final version of that document is presented here.

#### **Aim and Scope of This Article**

The aim of developing an explanatory document to support the new edition of the DoI was to provide space for explanation and discussion of the principles and their potential application in different contexts. In the decade since the publication of the original DoI, it has become evident that some health policymakers and health professionals find it challenging to apply international ethical principles relating to donation and transplantation in the context of their local health system, culture, and societal norms. Although the guidance provided by this article is not specific to any particular setting, it aims to show how the principles may be applied, acknowledging that several factors may influence application of particular principles and that the outcomes of application may vary. The DICG recognizes that diversity in policies and practices is not necessarily inconsistent with the global ethical standards reflected in the DoI and other international ethical frameworks, such as the World Health Organization's Guiding Principles on Human Cell, Tissue and Organ Transplantation.<sup>3</sup>

This article, prepared as part of the process of updating the Declaration, is intended to facilitate application of its principles and should be considered as a companion document to it.

#### **Summary of the Public Consultation on This Article**

The DICG included a draft of this article in the public consultation process that it organized in formulating the 2018 Edition of the Declaration. All participants in the public consultation were invited to review the draft and provide feedback on each section. More than 200 individuals and organizations provided comments and suggestions on the draft of the Declaration itself, of whom 27 also provided feedback on the draft of this explanatory article. The difference in response is probably due to two factors. First, the Declaration holds greater significance for members of the DICG and representatives of the professional societies that have endorsed the Declaration who comprised the majority of participants in the consultation. Second, the greater length of the explanatory article, relative to the text of the Declaration, made providing feedback on it a more onerous task, especially for respondents from non-English-speaking backgrounds.

The authors made revisions to this article in the light of the comments and suggestions received, not only on the draft explanatory article but also on the draft of the Declaration. In particular, much of the feedback on the definitions and principles in the Declaration was useful to us because in revising this article we were able to address a number of questions raised about the meaning of various parts of the text of the Declaration and about the practical implications of applying the DoI.

#### **Principles**

#### **Principle 1**

"Governments should develop and implement ethically and clinically sound programs for the prevention and treatment of organ failure, consistent with meeting the overall healthcare needs of their populations."<sup>4</sup> To achieve the objectives of organ donation and transplantation in an efficient and effective manner, these activities should arise from each nation's overall health policies and programs, especially those in primary care and public health that aim to reduce the incidence and burdens of chronic conditions that lead to end-stage organ failure and the need for transplantation.

In all countries, investment in public health programs for screening, prevention, and treatment of conditions that may lead to organ failure, such as viral hepatitis, hypertension, and diabetes, should be prioritized. Prevention is not only more cost-effective; it also reduces the burdens of ill health associated with organ failure and of donation and is particularly important in countries where treatment for end-stage organ failure may not be available.

Even with technical assistance, some countries may not currently have the means to create and sustain organ donation and transplant programs. For countries attempting to provide treatment for organ failure, transplantation is often the preferred, and sometimes the only, treatment for medically suitable patients. To minimize morbidity and mortality, transplant services, which are typically more cost-effective, should be established alongside programs that treat and maintain such patients, such as dialysis programs for those with end-stage kidney disease. Policies and procedures should be developed and implemented to maximize the number of organs available for transplantation, consistent with the principles of the Declaration.

In collaboration with healthcare institutions, health professionals, international organizations, nongovernmental organizations, professional bodies, and governments should take appropriate actions to establish and increase deceased organ donation to meet needs for transplantation. Countries that have initiated transplantation but have not established programs of deceased organ donation should adopt legislation and regulations (see **Principle 5**) and create the necessary infrastructure. In all countries in which transplantation services are offered, the therapeutic potential of deceased organ donation should be maximized to reduce the burdens on living donors and to enable transplantation of organs that cannot be obtained from living donors.

Countries with well-established transplantation and living and deceased donation programs are encouraged to share information, expertise, and technology with countries seeking to establish or improve their own programs. Key components of effective programs include a legal framework that supports organ recovery (including from deceased donors) and transplantation, essential hospital infrastructure including intensive care facilities and tissue-typing laboratories, transparent transplant waiting lists, deceased donor and transplant registries, public education and awareness programs, health professional education and training, and defined responsibilities and accountabilities for all stakeholders in the national organ donation and transplant system. The act of donation, both living and deceased, should be honored by society and acknowledged by representatives of the government and civil society. The advancement of clinical, basic science and social science research in donation and transplantation is also essential for continued improvement in this field.

#### **Principle 2**

"The optimal care of organ donors and transplant recipients should be a primary goal of transplant policies and programs."<sup>4</sup> Organ transplantation is an advanced medical therapy that was developed as a means of saving lives and improving health in patients with organ failure. The contributions of organ donors are essential for the success of transplantation. Present demand for organ transplantation exceeds the availability of organs obtained from deceased donors. Utilizing organs, in particular kidneys, from living donors enables more transplants to be performed; however, such efforts to promote the health of transplant recipients must be balanced by concern for the well-being and interests of potential organ donors. Thus, the best possible care must be provided not only to transplant recipients but also to donors (see **Box B**), and consent must be obtained prior to transplantation and donation procedures (see **Box C**).

Protection of prospective transplant recipients and living donors begins during the evaluation process, which, guided by established professional norms, aims to determine their medical and psychosocial suitability for donation or transplantation, their understanding of the process, and the voluntariness of their consent, and also aims to detect signs that may indicate involvement in organ trafficking, trafficking in persons for the purpose of organ removal, and/or transplant tourism.<sup>6,7</sup> Such signs may include errors or discrepancies in the documentation identifying prospective donors and recipients; lack of evidence of a relationship between the prospective donor and recipient despite claims of consanguinity or close emotional relationship; social relationships between the intended donor and recipient in which the recipient (or their relative) is in a position of power over the donor (or a relative of the donor), for example, employer or work sponsor; or refusal to permit the prospective donor to speak independently with healthcare staff.

Promoting the health and well-being of recipients and donors also requires a commitment to ensure that adequate long-term care is available to these individuals. Neither living organ donation nor transplantation is merely a surgical procedure. These procedures should not be performed in the absence of sufficient guarantee of follow-up care and access to necessary health resources such as immunosuppression. A health professional who performs an organ transplant or procures an organ from a living donor has an obligation to ensure that continuity of care is available for the recipient or donor, which means ascertaining the existence of funding or insurance coverage for such care. When donor and/or recipient have traveled to obtain the transplant, the professional's obligation includes appropriate coordination with the physicians and others who will provide medical follow-up in the country of residence of the recipient or donor, who must be given the necessary medical records to take back with them. Efforts to promote the well-being of donors should also encompass efforts to remove financial burdens of donation (see Principle 4). An appropriate framework of donor and transplant recipient care should also include collection of data relating to outcomes of donation and transplantation to enable evaluation of practice and to inform improvements to care (see Principle 6).

Care and concern for the well-being of fellow human beings should guide donation and transplantation. In contrast, the prospect of financial gain drives organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism, which results in conflicts of interest that undermine respect for the ethical norms of healthcare. The financial interests of healthcare professionals and institutions should never override the primary objective of providing optimal care for both donors and recipients (see **Principle 3**).

#### **Principle 3**

"Trafficking in human organs and trafficking in persons for the purpose of organ removal should be prohibited and criminalized."<sup>4</sup>

Trafficking in human organs and trafficking in persons for the purpose of organ removal violate the fundamental ethical values that are essential for successful and sustainable donation and transplantation programs. Trafficking practices frequently intersect with broader societal and global issues that create vulnerable populations, such as extreme poverty, armed conflict, forced migration, and corruption in healthcare and law enforcement systems. Society at large, together with governmental authorities and health professionals, must therefore collaborate in efforts to address the factors that underpin trafficking and respond to instances of trafficking. Legislation provides a framework for governance of transplant practices that makes clear the commitment of government and society to ethical practice.

No matter how financial incentives, payments, or rewards are described, presented, or delivered, their use violates respect for persons by treating the human body and its parts as commodities and hence constitutes trafficking in organs.<sup>8</sup> The financial gain or comparable advantages that are offered or provided to people in exchange for organs can take different forms. If people are offered cash, goods, or services with a monetary value in exchange for organs, this confers a financial gain or comparable advantage upon the recipient of such material benefits. Financial incentives that encourage people to consent to be a living donor or to authorize organ removal from a deceased relative constitute payment for organs. This is the case irrespective of who makes the offer or provides the payment or "reward" and how and when the payment is made, and regardless of whether a direct payment is made and how it is described. Although providing financial incentives for donation is sometimes presented as an act of "charity" or an expression of gratitude, such payments actually exploit the economic vulnerability of potential living donors and deceased donor families and expose them to physical, psychological, and social harm.<sup>9</sup> Furthermore, offering payments for organs undermines justice by reinforcing rather than reducing socioeconomic inequities; it targets the poor as a source of organs and stigmatizes donation. It also compromises the ethics of the medical profession and the public's trust in healthcare systems. Ultimately, it weakens the solidarity needed for successful organ donation programs, thereby reducing the number of organs offered altruistically.

Trafficking in persons for the purpose of organ removal, aimed at taking organs from people by means of force, deception, or abuse of power, is the most heinous form of organ trafficking. Many persons may be vulnerable to trafficking as a result of their socioeconomic circumstances, such as poverty, homelessness, indentured labor, citizenship status, civil conflict, or migration.

Over the past 3 decades, numerous international bodies have called for prohibitions on involuntary and paid removals of organs, and the majority of countries have explicitly banned and criminalized trade in organs and related activities.<sup>1,10-14</sup> Most countries have also forbidden and criminalized trafficking

in persons including for the purpose of organ removal. In recent years, several countries have sought to strengthen national legislation to address vulnerabilities that made it difficult to prosecute many of those who profit from transplant-related crimes. As a result, trafficking in human organs and trafficking in persons for the purpose of the removal of organs are recognized as criminal offenses and punishable in an increasing number of countries.

Laws governing trafficking in human organs and trafficking in persons for the purpose of organ removal should aim to hold those who profit from transplant-related crimes criminally accountable and to protect those who may be victims.<sup>6</sup> The involvement of 'donors' or recipients in the sale or purchase of an organ should be prohibited. However, it is for national governments to decide whether to also criminalize these persons for their involvement in these acts. Many people who have been the victims of trafficking are financially vulnerable and may face barriers to obtaining legal support. The legal protections and social and medical support provided to victims of human trafficking should also be guaranteed for victims of organ trafficking. Such protections are required under international human rights instruments<sup>13</sup> and have the practical benefit of making it more likely that these victims will come forward and report what has occurred. Health professionals or others who provide information to support investigation of suspected transplant-related crimes should also be legally protected as whistle-blowers.

To be effective, legal prohibitions need to include a ban on all types of advertising (including electronic and print media) or brokering for the purpose of facilitating organ trafficking or trafficking in persons for the purpose of organ removal. Health professionals who intentionally facilitate trafficking, including by failing to adequately evaluate prospective living donors and transplant recipients or by knowingly removing or transplanting trafficked organs, should be held criminally accountable and not merely risk disciplinary sanctions for professional misconduct.

Law enforcement agencies (inclusive of international agencies) should receive specific training and guidance considering the diverse and subtle manifestations of these crimes and should work on effective ways of ensuring cooperation with health authorities in addressing these crimes.<sup>7</sup>

#### **Principle 4**

"Organ donation should be a financially neutral act."<sup>4</sup>

Just as donation should not enrich donors (or the next of kin of deceased donors) financially, it should not burden them financially. Achieving financial neutrality or, at the very least, reducing the financial burdens of donation enables more people to donate and improves equity in donation and transplantation.

This principle emphasizes that the prohibition of trade in organs and financial incentives for donation does not preclude efforts to prevent financial injury to donors. As the World Health Organization and other national and regional bodies recognize, comprehensive reimbursement of verifiable expenses related to donating an organ does not constitute paying for the organ but is part of the total cost of treating the recipient.<sup>5,9,12</sup> However, although most health systems that provide organ transplantation treat the medical expenses of removing, preparing, and transporting a donated organ for implantation as part of the cost of performing a transplant, not all systems cover the costs related to donation, even when their laws permit such reimbursements. This may be due to the unavailability of resources to cover all costs of donation. It may also be due to the belief on the part of health policymakers, healthcare institutions, or health professionals that providing a payment to cover the costs of donation would violate the prohibitions against trade in organs.

When kidney-paired donation programs were first being developed, the question arose whether an exchange of kidneys amounted to the giving of "valuable consideration" to obtain a kidney.<sup>15</sup> Kidney-paired donations and organ chains triggered by "Good Samaritan" (nondirected altruistic) donors allow patients who are biologically incompatible with a living related donor to exchange that donor's kidney for one that would be compatible. So long as the donors or their beneficiaries receive no financial gain or comparable advantage in exchange for their donation or participation in a paired exchange, the principle of financial neutrality has not been violated.<sup>16</sup>

For potential living donors, out-of-pocket expenses and losses can include the costs of travel, lost income, the medical costs of screening and evaluation to become a donor, and the expenses of postdonation care<sup>17,18</sup> (see **Box D**). Many of these costs may be incurred even if donation does not take place, for example if screening reveals that a potential donor is not suitable. Donation-related expenses that the families of deceased donors may face include charges for additional days of care in an intensive care unit while the potential donor is maintained pending a determination of death or additional tests to determine eligibility to donate.

The prospect of having to pay such expenses and bear such losses can be a major deterrent for many people who are considering donating an organ. Indeed, in some cases, these costs may prevent donation. It is therefore important that the authorities charged with overseeing the transplant system endeavor to reduce, and ideally eliminate, donation-associated financial burdens.

The scope of reimbursement for the expenses incurred by living donors or families of deceased donors, including outof-pocket costs and lost earnings, should be clearly defined by law, transparently administered, and carefully communicated to people making a decision about donation.<sup>19</sup> Specifying items for reimbursement may not be appropriate within legislation since these may change over time. However, it is important to establish a legal framework that upholds the principle of financial neutrality and that will support the implementation of transparent and efficient systems to assist donors in avoiding or recovering costs. In implementing these systems, due care must be taken to avoid reimbursements becoming inducements. For example, providing a fixed sum for lost income may attract persons with no or low wages as donors; a policy covering only actual, documented losses and expenses is therefore required to avoid creating a financial incentive. To fulfill the obligation to provide care for donors (see Principle 2), donors may be provided additional health insurance to cover donation-related events, or free access to long-term follow-up care where these protections are not assured as part of universal health coverage. However, offering special benefits not related to donation in exchange for donation, such as general health insurance coverage in a country where such insurance is not universal, the payment of funeral costs of a deceased donor, an income tax credit, or a tuition

voucher, is inconsistent with the principle of financial neutrality. By saving donors or donor families the expenses that they would have faced regardless of having donated an organ, these financial benefits violate the ban on providing a financial gain or comparable advantage to organ donors.<sup>9</sup>

Coverage of upfront costs associated with living donation is currently limited in most countries, in particular with regard to payment of lost wages. Where limited resources are available to reduce costs, a system to allocate these resources should be implemented that promotes equitable access. Where it is not possible to completely cover all costs, thus leaving some living donors financially worse off after donation, this does not necessarily mean that living donation is ethically unacceptable. Just as living donors may incur some risks of physical and psychological harm to fulfill their desire to donate, they may incur some risk of financial injury when these are risks that are unavoidable, judged proportionate to the expected benefits, and voluntarily incurred.

Efforts to achieve financial neutrality for the living donor should also address less direct financial burdens potentially associated with donation, for example, discrimination against donors in the context of employment and health insurance opportunities.<sup>20</sup>

#### **Principle 5**

"Each country or jurisdiction should develop and implement legislation and regulations to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards."<sup>4</sup>

Clear, consistent, and properly enforced laws are needed to provide a framework for governance of donation and transplantation practices, to communicate society's expectations with regard to organ donation and transplantation, to establish accountability for those who transgress the principles and rules adopted, and to allow scrutiny and evaluation of laws in the light of international standards and ethical principles. The process of developing laws on organ donation and transplantation requires governmental bodies to examine existing structures and rules to address technical as well as ethical shortcomings.

Some of the components of the laws on living and deceased organ donation and on the distribution and transplantation of those organs will be universal and some particular to each country, with its individual history, culture, and medical and political systems. The particular features result from differences in the way healthcare is provided and financed (eg, whether facilities that perform transplants must be specially licensed or whether deceased donor organs are obtained and distributed locally, regionally, or nationally in the first instance). The universal features will be both technical (eg, the legal standard for the determination of death) and ethical (eg, the "dead donor rule"; the separation of the physicians who care for a patient and declare death from the physicians who participate in removing and transplanting organs after death).

Laws need to remove obstacles and disincentives to living as well as deceased organ donation, assure the public of adequate protections for donors and equity in allocation of organs, and support transparency of donation and transplantation practices to enable public trust and accountability of service providers. Laws also enable health professionals to be confident in the performance of their duties, for example by providing clarity concerning the determination of death and organ recovery after death. National legislation and regulations must have at their core the principle of financial neutrality and, in particular, the prohibitions on organ trafficking and trafficking in persons for the purpose of organ removal, as set forth in this Declaration (see **Principle 3**) and many other international conventions and guidelines.

#### **Principle 6**

"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."<sup>4</sup>

Transplantation, which depends upon individuals to assist in meeting the health needs of others through organ donation, is a societal as well as a medical activity. Organ donation and transplantation activities should be regulated and supervised by identified agencies responsible for increasing the system's ability to successfully meet the organ-replacement needs of the population and for ensuring the system's fairness, safety, and quality. The establishment of such authorities will also foster public trust, encourage participation in donation, and promote continued improvement in these activities.

As societal activities, transplantation and donation should be governed by the principle of solidarity, which describes individuals working together to meet common challenges and needs, and by human rights principles, which articulate the basic protections that states must provide for individuals' liberty, physical integrity, and welfare. Mechanisms are thus required to ensure that these principles and values are upheld in practices and policies relating to donation and transplantation.

Meeting the goals of quality, safety, efficacy, and equity in organ donation and transplantation requires the establishment of a national transplantation system, governed by health authorities or bodies designated by the government that is responsible for the supervision of all donation and transplant activities carried out in the country. Such designated authorities should be easily identifiable and readily accessible. They should be given responsibility to authorize and monitor the practice of organ donation and transplantation and to implement an effective framework for quality and safety through standardization, traceability, vigilance, and transparency. Such a framework should ensure that donation and transplantation are carried out by suitably qualified healthcare personnel and in accredited and properly equipped facilities; that organs are traceable throughout the entire chain from donation to transplantation, allowing the identification of donors, recipients, and donation and transplantation centers; that adverse events and reactions are accurately and rapidly reported and managed; and that the organization, practice, and results of donation and transplant activities are transparent and open to scrutiny, with due regard for individual privacy and confidentiality.

Essential mechanisms include national or regional registries to record and report all deceased and living donor transplants, including those obtained by residents abroad, and all living and deceased organ donations, including living donations made by nonresidents. Financial investment should be made by governments to establish or develop such registries and to ensure their quality and sustainability. Accreditation and auditing processes are also needed to ensure that practices and outcomes in all centers are consistent with national standards.

Care for living donors and recipients (see Principle 2) should be informed by short- and long-term data collected during follow-up care and recorded in registries. Such data facilitate evaluation of the consequences of donating or receiving an organ. International collaboration to standardize data collection, to facilitate cross-border sharing of data, and to collate global data on practices and outcomes should be optimized. Where possible, compiling harmonized data from the various countries with living donor programs (such as the data sets proposed in Council of Europe Resolution CM/Res(2015)11 on establishing harmonized national living donor registries with a view to facilitating international data sharing<sup>21</sup>) would allow designated authorities and healthcare professionals to obtain sufficient information to define and secure proper follow-up of living donors, document living donor prognoses (safety/morbidity), and investigate causal relationships between predonation risk factors (body mass index, estimated kidney or liver function, mild hypertension, etc.) and future prospects, including cardiovascular events, kidney or liver failure, and death.

Globalization has led to increasing movement of persons between countries, and many people who have undergone living donation or transplantation in their country of origin or a transit country will require follow-up care or monitoring of long-term outcomes in new countries. International systems of traceability and/or proactive communication between designated authorities in the countries concerned would facilitate the establishment of effective transnational biovigilance systems for the reporting and investigation of any serious adverse events or reactions in donors or recipients and the identification and investigation of suspected cases of organ trafficking and trafficking in persons for the purpose of organ removal.<sup>7</sup>

#### **Principle 7**

"All residents of a country should have equitable access to donation and transplant services and to organs procured from deceased donors."<sup>4</sup>

Equitable access to transplant services includes access to organs procured from deceased donors. The equitable allocation of organs for transplantation is only meaningful if it occurs in the context of a system of equitable access to transplant services.

Inequities of access may be particularly notable in the context of migrant populations, countries providing access to transplantation for foreign patients, and countries lacking universal coverage for health. International migration is growing, with increasing waves of migrants seeking permanent or temporary residence in new countries. Migrants may take up residence in a country (and are sometimes recruited to do so) to participate in the workforce with the intention of remaining for a finite or indefinite period, or in the hope of obtaining permanent residency. Others may be forced to flee their homes as a result of armed conflict or other humanitarian crises. In some cases, migrant communities may reside for several generations in countries without obtaining citizenship or legal residency. The presence of migrants, refugees, asylum seekers, or other groups with a particular legal status among the residents of a country may require review and revision of policies or legislation governing donation and transplantation, if those governance tools have been designed for specific categories of residents that may exclude migrants such as those lacking citizenship or legal residency status.

Globalization of healthcare has also encouraged travel for healthcare services, including travel for transplantation. If nonresidents-regardless of their legal status-are traveling to a country specifically for the purpose of transplantation, this may undermine efforts to achieve self-sufficiency in donation and transplantation within a country (see **Principle 11**) or impact on the allocation of organs for transplantation (see **Principle 8**) and should also prompt review of policies that govern access to transplant services and organs from deceased donors.

Policies governing donation and transplantation should aim to maximize opportunities for donation, by allowing all residents within a country to donate their organs after death or to become living donors if they are clinically suitable. Efforts are often made to reduce legal and financial barriers to deceased donation for populations who are legally or financially disadvantaged in accessing transplantation services. Migrants and even short-term temporary residents of countries such as visiting tourists are widely accepted as deceased donors, regardless of their legal status. However, raising awareness of and educating migrants about donation opportunities is important to address barriers such as lack of familiarity with donation and transplantation, distrust of healthcare systems or social marginalization or discrimination among migrant groups, and language barriers.

All categories of residents who make their lives within a country and who therefore may contribute to the potential donor pool should be entitled to a fair share of the benefits of transplantation, including by being given access to the waiting list for organs from deceased donors and to financial support to access transplantation services. This is consistent with the principles of solidarity and reciprocity that should underpin participation in deceased donation. To realize this entitlement, residents require access to transplantation services. If residents cannot access transplant services—for example, if they are not covered by public health insurance as a result of lack of citizenship—then it is not sufficient to have nondiscrimination in the allocation of organs from deceased donors (see Principle 8).

Policies should be developed and transparently communicated that define and justify criteria governing access to transplant services for all residents, irrespective of their category of residency or legal status. In granting residents access to transplant services, consideration may be given to the duration of an individual's residency within a country, the primary reason for their travel to the country, intended length of stay, and ability to secure the care needed to maintain an organ transplant in the longer term. Care should be taken to distinguish between those individuals whose need for transplantation is either an unexpected event occurring after traveling to the country or secondary to their rationale for migration, and those who appear to have traveled for the purpose of obtaining an organ transplant. While the latter group may not be routinely excluded from transplant opportunities, their needs must be evaluated in the context of efforts to achieve self-sufficiency in donation and transplantation (see Principle 11). Residents, on the other hand, comprise the population of a country or jurisdiction seeking to meet transplant needs together. As members of the potential donor population they should also be recognized as members of the potential recipient population.

Each country should establish and transparently communicate policies that govern access to transplant services and eligibility to access organs from deceased donors. Equity of access does not necessarily mean that all residents will have equal access privileges, but rather that any inequalities of access are underpinned by clear and specific criteria that are consistently applied. Criteria must justify discrimination and respect the fundamental principle that those who may be asked to donate should also be entitled to receive.

#### **Principle 8**

"Organs for transplantation should be equitably allocated within countries or jurisdictions, in conformity with objective, nondiscriminatory, externally justified and transparent rules, guided by clinical criteria and ethical norms."<sup>4</sup>

Fairness in the distribution of organs donated for transplantation, which are exceptional health resources with limited availability, is an expectation of potential donors and a right of potential recipients.

Allocation of organs from deceased donors and of organs from living donors in countries where nondirected living donation is allowed may be ethically, clinically, and logistically complex. In many cases, several individuals might benefit from transplantation of a specific organ, yet the degree of potential benefit predicted for each individual may differ. Several factors will influence the probability of an individual recipient benefiting from transplantation of a specific organ at a given time. These include the severity and urgency of the recipient's need for transplantation; the presence of comorbidities in the recipient; individual and societal socioeconomic factors that may influence long-term outcomes posttransplant; the clinical qualities of the organ, including immunologic compatibility; and risk factors for disease transmission, size, and function. Moreover, probable benefits and risks of using the organ in question need to be assessed against the benefits of waiting, which depend on such considerations as the probability that the allocation system will be able to provide another suitably matched organ in time to benefit this patient, or the availability of an alternative treatment for the recipient's organ failure such as a transplant from a living donor. Many of these factors will be influenced by the broader context of social welfare and healthcare systems in a particular country.

The recovery and allocation of organs from deceased donors should be organized and governed so as to avoid financial conflicts of interest for healthcare institutions involved in recovery, allocation, or transplantation of these organs. Where organs are procured, allocated, and transplanted across public and private healthcare systems, cost recovery mechanisms and financing of transplant services must be independently overseen to prevent the emergence of perverse incentives or financial barriers to both donation and transplant that may undermine equity in allocation of organs.

As is the case with the distribution of other scarce health resources, allocation policies that focus solely on maximizing aggregated therapeutic benefits, for example by providing transplants to those most likely to live longest and to enjoy the greatest overall health, would tend to disadvantage or exclude entirely some of the people most in need of treatment. Fairness therefore dictates that organ allocation policies should strive both to efficiently maximize the benefits gained from transplantation of each organ and to maximize equity in opportunities for transplantation among potential recipients.

In some jurisdictions, allocation policies may give weight to particular values or goals agreed upon by elected representatives of the population. For example, a degree of priority in the allocation of organs may be accorded to individuals who have previously donated an organ or registered their willingness to become a donor after death.<sup>22</sup> Some jurisdictions also permit "directed donation," in which an organ may be allocated to the relative of a deceased donor when clinically appropriate.<sup>23</sup> Such directed donations should not be confused with conditional donation, in which consent is provided for donation only on the condition that donated organs (or tissues) are allocated to—or withheld from—recipients of a specific race, gender, age, religion, or the like. The latter is usually considered ethically unacceptable.

The specific criteria considered and the weighting of these criteria in particular allocation policies may differ between healthcare systems to promote fairness in access to the benefits of deceased organ donation among members of a population in a particular country or jurisdiction. Nevertheless, certain core values and principles should govern the allocation process. These include the requirement for transparency of policy and procedure, such that allocation activities and outcomes are open to public scrutiny; the exclusion of financial considerations or material gain of any party in allocation decision-making; the emphasis on objective clinical criteria; and the principle of nondiscrimination.

#### **Principle 9**

"Health professionals and healthcare institutions should assist in preventing and addressing organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism."<sup>4</sup>

Ethical transplantation cannot be achieved unless all health professionals refrain from engaging in or facilitating transplant-related crimes and provide information that will assist the relevant authorities in preventing and prosecuting such crimes. Given the central role that health professionals play in organ donation and transplantation, fulfilling their collective responsibility to uphold the ethical and professional values by supporting efforts to combat transplant-related crimes will foster trust in legitimate donation and transplantation programs and in the medical profession and healthcare systems more generally.

Health professionals may contribute in several positive ways to efforts to prevent and address trafficking, depending on their role and area of  $\operatorname{practice}^{24,25}$  (see **Box E**). Health professionals who may be involved in donation and transplantation practices require dedicated training to ensure that they have the ethical, legal, and clinical knowledge and skills required to fulfill their responsibilities. In some jurisdictions, professionals may have legal duties to assist in the efforts to combat trafficking.

Health professionals do not violate their professional duties by obeying laws requiring cooperation with national authorities in the enforcement of transplant-related laws. For example, health professionals may be legally required to collaborate in data collection and submission to dedicated national or international registries established to guarantee quality and safety in organ donation and transplantation. This responsibility pertains irrespective of the jurisdiction in which patients have donated or received an organ transplant. Health authorities should ensure that legislative frameworks and policies provide clear guidance on data collection systems and any reporting duties to ensure that issues relating to confidentiality and privacy have been addressed, consistent with similar practices concerning reporting duties of health professionals in other contexts. Such initiatives should be in accordance with reporting duties and medical confidentiality requirements provided for by law and should to the maximum extent possible respect patients' privacy.

Health professionals should always ensure a proper evaluation of prospective donors and their intended recipients, as outlined in the context of **Principle 2**. Those who procure or transplant an organ they know or suspect to be of illicit origin should be sanctioned by the relevant governmental authority and professional organizations.

In some contexts, health professionals who strive to address organ trafficking by reporting concerns about practices in their own countries may face stigmatization by colleagues, discrimination in opportunities for employments, or even threats to their life from those who profit from organ trafficking crimes. International collaboration is therefore needed to support advocacy by those working in hostile environments that lack effective protections for whistleblowers.

#### **Principle 10**

"Governments and health professionals should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism."<sup>4</sup>

Countries that adopt and enforce strict prohibitions against organ trafficking within their borders but fail to hold their residents accountable for engaging in such activities in another country not only undermine their own laws but unfairly impose burdens on other countries, to the detriment of those countries' residents and their law enforcement systems. As the definition of transplant tourism in the DoI indicates, countries may also be negatively affected by unethical forms of travel for transplantation, even in the absence of criminal activity, such as when nonresidents travel there for transplantation and obtain access to transplant services and organs from deceased donors at the expense of residents in need of transplantation. Thus, some countries also impose unfair burdens on other countries by failing to deter their residents from becoming transplant tourists, or by supporting or even encouraging their residents to engage in this practice, rather than working to meet their own transplant needs through development of deceased donation and transplant services.

Organ trafficking, trafficking in persons for the purpose of organ removal, and other forms of transplant tourism are increasingly globalized activities, often involving individuals from several countries in one transplant case. Strategies to prevent and address trafficking cases therefore often depend on cross-border collaboration and cooperation to obtain information about activities and implement multilateral solutions and are aided by the application of extraterritorial jurisdiction to national statutes criminalizing organ trafficking and trafficking in persons for the purpose of organ removal.<sup>26</sup> The threat that their home country will prosecute them for engaging in such transplant-related crimes in another country can be a substantial deterrent for patients, brokers, and health professionals contemplating travel for these purposes. Patients considering transplantation abroad may also be deterred from involvement in organ trafficking if their governments or insurance companies refuse to cover the costs of transplants performed abroad unless the transplant is proven to be ethically and legally appropriate.<sup>27,28</sup> Health professionals also play an important role in deterring transplant tourism, as discussed in the context of Principle 9 and Box E.

Two forms of collaboration are needed to combat trafficking in human organs and trafficking in persons for the purpose of organ removal in the context of transplant tourism. If the countries where transplant tourists originate adopt laws that allow them to prosecute transplant tourists for acts that are illegal either where they occurred or in their home countries, this will benefit destination countries.<sup>26</sup> Having adopted such laws, the tourists' home countries also need the help of the countries where the illicit activities occur to investigate suspected cases and supply the evidence that will permit a successful prosecution. National legislation should facilitate engagement by law enforcement and health professionals in national and cross-border efforts to prevent, investigate, and prosecute such crimes.<sup>26,29</sup>

Second, collecting and sharing information about transnational activities, including transplant-related crimes, requires international collaboration on a large scale. International organizations can facilitate such collaboration through the operation of databanks and the development of legal agreements to enable countries to supply information to them with confidence about how it will be used to trace and apprehend traffickers rather than embarrass countries.<sup>30,31</sup> Conversely, organizations and corporations (including banks) should be legally obligated to take responsibility when their platforms are being used to facilitate unethical or illegal practices.

It is important that countries that have limited resources, and whose residents have to rely on accessing transplant services in a foreign country, work toward establishing transplant infrastructure or increasing resources to service the needs of their population. Patients who legally seek medical care elsewhere because they have no clinical service available in their own country should not be criminalized. For example, transplant candidates and their prospective living related donor may be screened in their own country and may receive government funding to travel to another country for surgery. However, countries with limited availability of transplant services should make arrangements with other ministries of health on a governmental level to ensure that travel for transplantation is ethically appropriate, that mechanisms are in place to ensure monitoring of transplant activities, and that longer term solutions are developed to promote self-sufficiency in each country independently or in collaboration (see Principle 11).

#### **Principle 11**

"Countries should strive to achieve self-sufficiency in organ donation and transplantation."<sup>4</sup>

Efforts to meet transplant needs using organs donated and transplant services provided within a country or through regional cooperation have practical and ethical benefits. Practically, this enables better oversight of practices to ensure quality and safety as well as compliance with ethical and legal norms, and it stimulates efforts to meet the needs of patients domestically or regionally. Ethically, providing for transplant needs domestically or regionally discourages or prevents reliance on transplant tourism, thereby avoiding causing harm to other countries (see **Principle 10**).

Countries should aim to achieve self-sufficiency, independently or in collaboration with others, with regard to the resources that are essential for delivering the full range of organ recovery and transplant services, including organs from deceased donors.<sup>32</sup> Self-sufficiency may be pursued at the level of a state, province, or other jurisdiction, or in collaboration with other countries where necessary to most effectively and efficiently meet the transplant needs of the relevant population.

Collaboration between or within countries is consistent with the pursuit of national self-sufficiency when there is equitable sharing of transplant resources between partners. Collaboration may be needed where populations are insufficiently large to provide a supply of donor organs sufficient to meet the transplant needs of the community, or where occasional organ sharing is required to assist each population in efforts to meet urgent needs for transplants in a timely manner or to address matching difficulties. Collaboration may also occur to help address gaps in technical resources or expertise. For example, patients may be transferred abroad for heart or lung transplantation with the appropriately matched organs recovered from donors in their own country if heart or lung transplantation services are available in their own health system. Mutually agreed and equitable organ exchanges among countries to meet special clinical needs or to optimize efficiency and efficacy in meeting transplant needs are ethically acceptable provided that all participating countries adhere to international standards in obtaining organs. In any case, this cooperation should be established through formal collaboration agreements between governments (and never within the discretion of individual health professionals or centers) and should be overseen by the national designated authorities (see Principle 6).

The provision of transplant services to nonresident patients undermines progress toward national self-sufficiency if it impairs a country's ability to provide adequate transplant services for its own population. Providing nonresident patients access to the deceased donor organ waiting list may reduce access to transplantation for members of the domestic population. This problem may be exacerbated when transplant services are preferentially provided in the private sector to nonresident patients who are able to pay higher fees.

Countries that choose to provide nonresident patients with "compassionate access" to the waiting list for deceased donor organs must take steps to ensure that such patients are not limited to those who are sufficiently wealthy to travel abroad for transplantation, for example, by also including in such "compassionate" programs refugees or patients with unusual conditions that cannot be treated in their home country. Unfortunately, compassionate access programs in wealthy countries may not only fail to provide equitable opportunities for all patients from countries with inadequate transplant programs but also fail to assist such countries in developing or improving their transplant services and donation programs.

Countries that lack transplant programs may send, through appropriate referral systems and with proper documentation, prospective living donor and recipient pairs abroad for transplantation. Where it is possible to offer transplant services to such pairs, additional efforts may be required to ensure that there is adequate evaluation of the donor and recipient. This should include a psychosocial assessment that is informed by an understanding of the healthcare system and social context of the country or countries where these individuals reside as well as an assessment of the preoperative and postoperative risks that takes account of the availability of follow-up care and long-term monitoring of patients once they return home. The health professionals involved in the transplant should liaise closely with referring clinicians in a patient's country of origin to ensure continuity of care.

Countries that offer transplant services to nonresident recipient-donor pairs should aim to do so only in conjunction with efforts to develop transplant programs in these patients' countries of origin whenever that is feasible, and only when arrangements for ongoing care of nonresident patients are made. Receiving countries should also ensure that delivery of transplant services to nonresident patients traveling for transplantation does not undermine the availability of services for resident patients, especially when financial conflicts of interest favoring nonresident patients may be present.

Integrity in the pursuit of self-sufficiency begins with transparent public communication of detailed information regarding transplantation and donation activities in both the public and private health sector. Information shared with the public should include data on the provision of services to nonresident transplant recipients and on residents who have traveled to another country for transplantation, as well as information relating to the exchange of organs or other resources in collaborative arrangements.

## Box A. Definition of key terms from the Declaration of Istanbul (2018 Edition)<sup>4</sup>

The following terms have specified meanings in the context of this document.

**Organ trafficking** consists of any of the following activities:

- (a) removing organs from living or deceased donors without valid consent or authorization or in exchange for financial gain or comparable advantage to the donor and/or a third person;
- (b) any transportation, manipulation, transplantation, or other use of such organs;
- (c) offering any undue advantage to, or requesting the same by, a healthcare professional, public official, or employee of a private sector entity to facilitate or perform such removal or use;
- (d) soliciting or recruiting donors or recipients, where carried out for financial gain or comparable advantage; or
- (e) attempting to commit, or aiding or abetting the commission of, any of these acts.<sup>a</sup>

Trafficking in persons for the purpose of organ removal is the recruitment, transportation, transfer, harboring, or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power, or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of the removal of organs.<sup>b</sup> In the context of this Declaration, the term **resident** denotes a person who makes their life within a country, whether or not as a citizen; the term **nonresident** denotes all persons who are not residents, including those who travel to, and

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then reside temporarily within, a country for the purpose of obtaining a transplant.

Travel for transplantation is the movement of persons across jurisdictional<sup>c</sup> borders for transplantation purposes. Travel for transplantation becomes **transplant tourism**, and thus unethical, if it involves trafficking in persons for the purpose of organ removal or trafficking in human organs, or if the resources (organs, professionals, and transplant centers) devoted to providing transplants to nonresident patients undermine the country's ability to provide transplant services for its own population.

Self-sufficiency in organ donation and transplantation means meeting the transplant needs of a country by use of donation and transplant services provided within the country and organs donated by its residents, or by equitably sharing resources with other countries or jurisdictions. Financial neutrality in organ donation means that donors and their families neither lose nor gain financially as a result of donation.

- <sup>a</sup> This definition is derived from the Council of Europe Convention against Trafficking in Human Organs (2015).<sup>10</sup>
- <sup>b</sup> This definition is derived from the *Protocol to Prevent*, *Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organized Crime* (2000).<sup>11</sup> The Protocol provides that 'consent' of a victim of trafficking in persons shall be irrelevant where any of the means set forth in the definition have been used.
- <sup>c</sup> In the context of this Declaration, the term jurisdiction encompasses not only nations but also states, provinces, other formally defined areas within countries, and regional or other supra-national legal entities with the authority to regulate organ donation and transplantation.

### Box B. Care of the living organ donor

The care of living organ donors is an important responsibility of countries. Provision of care for the living donor includes medical and psychosocial care by suitably qualified health professionals throughout the process of organ donation and for any short- and long-term consequences related to donation. Care should also be provided to those who are victims of trafficking.

The foundation for optimal care of the living donor has two components: a comprehensive evaluation of the donor and a robust process for obtaining informed consent from all prospective donors, including those who are closely related to the intended transplant recipient (see **Box C**). The evaluation should routinely include rigorous, standardized psychosocial assessment of all prospective donors by competent professionals, including screening mechanisms aimed at prevention of organ trafficking and human trafficking for organ removal. The determination of the medical and psychosocial suitability of the living donor should be guided by current best-practice and evidence-based standards.

The selection, evaluation, and assurance of care for nonresident living donors may be particularly challenging. For these donors, who travel from another country to donate, additional measures, such as those outlined in Council of Europe *Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the nonresident living organ donors*,<sup>33</sup> may be needed to ensure their protection and care.

Efforts to safeguard the long-term well-being of living donors should be a priority when developing transplant programs. In the event of organ failure in the donor, they should receive supportive medical care, including dialysis for those with renal failure, and priority for access to transplantation, integrated into existing allocation rules for organs from both living and deceased donors. Living donors' existing health and life insurance coverage and employment opportunities should not be compromised as a result of donation, and any gaps in their disability, life, and health insurance should be covered for short- and long-term consequences related to the donation. Where such protections are not assured, the resulting risks should be carefully considered in evaluating the suitability of prospective donors and in informing their decisions (see Box C).

In the case of nonresident living donors, arrangements for long-term follow-up once the living donor has returned home should be discussed before accepting any potential donor. If adequate long-term lifelong follow-up cannot be guaranteed, the donor should not be accepted.

In sum, efforts to safeguard the short- and long-term wellbeing of organ donors should be a priority when developing living donation programs.

#### Box C. Consent for donation and transplantation

Protection of potential donors and transplant recipients requires a comprehensive process of consent. The law should require that consent for donation or transplantation be informed, free, specific, and explicit, and be provided either in writing or before an official body.

The health professional who obtains consent for donation (someone not involved in the care of the potential transplant recipient) should ensure that the person responsible for making a decision about donation (eg, living donor or family of a potential deceased donor) is free from deception, coercion, or undue influence. Assessing the validity of consent in nonresident donors may be particularly challenging due to language barriers, differences in documentation, for example, of identity, between countries, and differences in cultural norms, thus necessitating additional efforts during evaluation.

To promote voluntariness, regulations may prescribe that donors and recipients have access to independent advice by experienced health professionals with knowledge of donation and transplantation who are not involved in their donation or transplantation.<sup>6</sup> Care should be taken to ensure that the independence of such "donor advocates" is not undermined by conflicts of interest, for example the potential financial interests of a healthcare institution in performing transplants. In the case of potential nonresident living donors or recipients, information about the donation or transplantation procedure should be provided in a manner able to be fully understood by the potential donor or recipient, relying on interpreters and culturally competent advocates where required, to ensure that any outstanding issue or concern is thoroughly addressed. Should an interpreter be required, the services should not be provided or arranged by the donor, the recipient, or anyone in their entourage.

Living donors should be assured that at any time prior to the commencement of the recipient's surgery they may withdraw consent, in absolute confidentiality and without indication of reasons.<sup>33</sup> Children and adults who lack the capacity to consent, or who are otherwise especially vulnerable, should not be considered as living donors, except in exceptional circumstances allowed under law and subject to comprehensive additional safeguards.<sup>5</sup>

Mechanisms for obtaining informed consent from prospective recipients and living donors should incorporate provisions for evaluating their medical and psychosocial suitability. Likewise, their understanding of the nature and purpose of all interventions, from screening to surgery and follow-up, and the potential consequences and risks of such interventions should be assessed. They should always

be informed of the availability of alternatives to donation or transplantation. Finally, candidates for transplantation or donation should be made aware of the clinical and legal risks, and the ethical concerns associated with trafficking activities. Legislation governing the recovery of organs for transplantation (see Principle 5) should specify that organs may be removed from the body of a deceased person only if either the person before death freely agreed to be a donor or, where the law presumes consent, there is no reason to believe that the deceased person objected to it. In the absence of registration of consent or objection, the deceased person's wishes should be ascertained in the way provided for by law (such as consultation of the next of kin). From a deceased person who has not had the capacity to consent, organs may be removed only if authorization required by law has been obtained. Appropriate measures should be taken to inform the general public on the applicable consent regime and on how to register consent or objection to organ donation after death.<sup>12</sup>

Under no circumstances should executed prisoners be used as donors, as their situation precludes voluntary informed consent.

# Box D. Covering costs to achieve financial neutrality in donation

The financial costs associated with organ donation vary according to the characteristics of healthcare systems in which donation occurs and attributes of potential donors or the families. For example, if a prospective living kidney donor has comprehensive health insurance and sick leave entitlements that may be used for donation, she may face few substantial costs insofar as healthcare and absence from work are concerned. Each country or jurisdiction should develop clear guidance for healthcare providers, donation and transplantation programs, and the public concerning reimbursement or coverage of donation-related costs, and policies or guidelines should be regularly reviewed. Legitimate items may include

- the cost of any medical and psychological evaluations of potential living donors including those who are excluded from donation (eg, because of medical or immunologic issues discovered during the evaluation process);
- hospital and medical charges for preserving the opportunity for donation of potential deceased donors (eg, by providing elective ventilation), including those who are subsequently excluded from donation;
- costs incurred in arranging and effecting the preoperative, perioperative, and postoperative phases of the donation process (eg, long-distance telephone calls, travel, accommodation, and subsistence expenses of potential donors or donor families);

- medical expenses incurred for postdischarge care of the living donor;
- the cost of hiring someone to provide personal assistance during recuperation of living donors, including caring for dependent family members; and
- income lost as a result of donating the organ.

Providing living donors with compensation in case of undue damage resulting from the removal of an organ is compatible with the principle of financial neutrality. The donor who has suffered such damage is entitled to fair compensation in accordance with the conditions and procedures provided for by law. When full coverage for such losses is guaranteed for all members of society, such as by a national health insurance program, special coverage for donation-related injuries is not needed. Where such coverage is incomplete, the provision to living donors of disability, life, and health insurance coverage for donation-related events is a necessary requirement to extend the principle of financial neutrality into the postdonation future. Such coverage should provide access to appropriate long-term medical and psychosocial monitoring and care required to minimize the risks of organ donation.<sup>20</sup>

Where such protections for living donors cannot be assured for a prospective donor, the increased risks of donation should be considered carefully in evaluating that person's suitability as a donor and these risks should be conveyed to the prospective donor during their decisionmaking process.

# Box E. Health professionals' duties to address organ trafficking and transplant tourism

The following procedures derive from health professionals' obligations not only to avoid facilitating transplant-related crimes and to prevent harm to others but also to provide care for their own patients whose involvement in such activities could result in criminal liability and severe health risks.

First, when providing care to patients with end-stage organ failure who are candidates for transplantation, health professionals should

- provide information about the clinical and legal risks and the ethical concerns associated with involvement in these illegal activities and
- discourage patients who are considering traveling abroad to receive an organ obtained through transplant-related criminal activities.<sup>24</sup>

Second, health professionals and agents of healthcare facilities or insurers should not

- refer patients to transplant facilities that they know, or suspect, use organs obtained through transplant-related criminal activities and
- perform diagnostic tests, release medical records, or prescribe medications if they believe that this information or medications will be used for the transplantation of an organ obtained through any form of trafficking.<sup>25</sup>

Third, health professionals involved in the recovery or transplantation of organs should

- exercise the utmost diligence in evaluating prospective living donors and recipients, with particular attention to verifying claims of family relationships and altruistic donor motivation and
- only proceed if the evaluation and consent processes have confirmed the appropriateness of the procedure.

Fourth, health professionals confronted with a patient who may have obtained an organ through unlawful means and is in urgent need for medical care should provide appropriate care.<sup>7</sup> When the need is not emergent, and the patient has access to alternative care providers, in some jurisdictions health professionals may be permitted to refer the patient to another provider for their follow-up care.<sup>34</sup> Routine care for all transplant patients, including those who obtain a transplant abroad, should include collection and submission of clinical data to appropriate registries.<sup>7</sup>

Fifth, health professionals, including those who may not be directly involved in transplantation or donation practices, should be encouraged to report suspected transplant-related criminal activities to law enforcement agencies. Reporting duties should be legally defined and clearly communicated to health professionals as part of national frameworks.<sup>7</sup>

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