Ethical Dilemmas in Donation and Transplantation

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The Ethical Dilemma:

The Demand and thus Need

The Limit of Propriety
by what should be permitted
to address need
Global Activity in Organ Transplantation
2014 Estimates

<table>
<thead>
<tr>
<th>Kidney</th>
<th>Liver</th>
<th>Heart</th>
<th>Lung</th>
<th>Pancreas</th>
<th>Small bowel</th>
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≈ 118,127 organs reported to be transplanted in 2014
≈ 2.98 % of increase over 2013
≤ 10% of global needs
41.9% of living kidney transplants and 18.3% of

Information of 112 Member States on organ transplantation activities is included in the GODT
Organ trafficking is a global phenomenon.

The Kidney World Order

Donor countries
Recipient countries

Typical donor (ex. Philippines)
Age: 28.9
Gender: Male
Annual income: $480

Typical recipient (ex. Israel)
Age: 48.1
Gender: Male
Annual income: $53,000

Source:
Coalition for Organ Failure Solutions, Organs Watch, ESOT
Collaboration of TTS in WHO Consultations 2006-2007

- Manila, Philippines
- Port of Spain, Trinidad
- Jaipur, India
- Bamako, Mali
- Ljubljana, Slovenia
- Karachi, Pakistan
- Khartoum, Sudan
- Kuwait City, Kuwait
- Abuja, Nigeria

Luc Noel | WHO
---|---
Kathryn Wood | TTS President
Francis Delmonico | TTS Director of Medical Affairs
As a Result of the World Wide Meetings the Problems as Identified in 2008 that led to the Istanbul Summit

10% of organ transplants done illicitly around the world

Countries known where illicit organ transplants are done

Need to prohibit commercial organ donation
Need to define transplant tourism and organ trafficking

Responsibility of transplant professionals to protect the poor from harm and exploitation
The Declaration of Istanbul on Organ Trafficking and Transplant Tourism

To address the growing problems of organ sales, transplant tourism and trafficking in organ donors in the context of the global shortage of organs, a Summit Meeting was held in Istanbul of more than 150 representatives of scientific and medical bodies from 78 countries around the world, and including government officials, social scientists, and ethicists.
A multicultural steering committee planned the Summit and outlined the Declaration
Definitions: Organ Trafficking

**Act:**
- the recruitment, transport, transfer, harboring or receipt of
  - living or
  - deceased persons or
  - their organs

**By means of the threat or use of:**
- force
- coercion
- abduction
- fraud
- deception
- abuse of power or of a position of vulnerability, or
- payments to a third party to achieve control of the donor

**For purpose of:**
- exploitation by the removal of organs for transplantation
Definitions: Transplant Commercialism

Transplant commercialism is a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.

Transplant commercialism should be prohibited because it targets impoverished and otherwise vulnerable donors and leads inexorably to inequity and injustice.
The Declaration of Istanbul

on Organ Trafficking and Transplant Tourism

- Organ trafficking and transplant tourism violate respect for human dignity and the principles of equity and justice and should be prohibited.

- **Because transplant commercialism targets impoverished and otherwise vulnerable donors**, it inexorably leads to inequity and injustice and should be prohibited.
  
  (*such as minors, illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees*)

- This prohibition should include a ban on all types of advertising (including electronic and print media), soliciting, or brokering for the purpose of transplant commercialism, organ trafficking, or transplant tourism.
The DECLARATION of ISTANBUL on ORGAN TRAFFICKING and TRANSPLANT TOURISM

Screening and prevention programs
- Should be implemented by local governments

Recovery of organs from deceased and living donors
- Should be legislated by local governments according to international standards

Allocation
- Should be equitable and fair

Medical care for living donors
- Short and long-term care should be provided

Organ trafficking and transplant tourism
- Should be prohibited to protect impoverished and vulnerable donors and prevent inequity and injustice
WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

1. Consent for deceased donor's donation
2. Physicians determining death not involved in organ removal
3. Deceased donation should be maximized but also consenting live donors
4. Protection of minors and incompetent persons
5. No sale or purchase
6. Promotion of donation no advertising nor brokering
7. Responsibility on origin of transplant -- not from coerced or bought
8. Justifiable professional fees
9. Allocation rules
10. Quality safety efficacy of procedures and transplants
11. Transparency and confidentiality
WHAC Resolution 63.22, “Human organ and tissue transplantation,” adopted by the World Health Assembly on 21 May 2010, based on the principles of human dignity and solidarity which “condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations and the human trafficking that result from such practices.”

As WHO Guiding Principle 5 clearly states, “Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.”
Committed to the principles of human dignity and solidarity which condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations and the human trafficking that result from such practices;

Determined to prevent harm caused by the seeking of financial gain or comparable advantage in transactions involving human body parts, including organ trafficking and transplant tourism;

Convinced that the voluntary, non-remunerated donation of organs, cells and tissues from deceased and living donors helps to ensure a vital community resource;

Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation;

Sensitive to the need for post-transplantation surveillance of adverse events and reactions associated with the donation, including long-term follow up of the living donor, processing and transplantation of human cells, tissues and organs as such and for international exchange of such data to optimize the safety and efficacy of transplantation,

1. ENDORSES the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;
The Human Body and its Parts as Such Not the Source of Financial Gain

- Hematopoietic Stem Cells
- Advanced Therapies
- Organ
- Gametes
- Embryos
- Blood
- Plasma
- Secretions
- Excretions
- Societal Values
- Protection of the Donor
- Safety of the Recipient
- Public Health Safety

Human Derived Drugs

Stem Cells

£ $ € ¥ £ $ € £ $ € ¥ £ $ €
A call for government accountability to achieve national self-sufficiency in organ donation and transplantation

Prof Francis L Delmonico MD, Beatriz Domínguez-Gil MD, Rafael Matesanz MD, Luc Noel MD

Summary

Roughly 100 000 patients worldwide undergo organ transplantation annually, but many other patients remain on waiting lists. Transplantation rates vary substantially across countries. Affluent patients in nations with long waiting lists do not always wait for donations from within their own countries. Commercially driven transplantation, however, does not always ensure proper medical care of recipients or donors, and might lengthen waiting times for resident patients or increase the illegal and unethical purchase of organs from living donors. Governments should systematically address the needs of their countries according to a legal framework. Medical strategies to prevent end-stage organ failure must also be implemented. In view of the Madrid Resolution, the Declaration of Istanbul, and the 63rd World Health Assembly Resolution, a new paradigm of national self-sufficiency is needed. Each country or region should strive to provide a sufficient number of organs from within its own population, guided by WHO ethics principles.
Mission: Achieve Self-sufficiency

Blueprint: WHO Guiding Principles, Declaration of Istanbul
WHO Critical Pathway, Madrid Resolution

Target: Ministers of Health, Transplant Professionals, Social Media
The Doha Donation Accord Aligned With the Declaration of Istanbul: Implementations to Develop Deceased Organ Donation and Combat Commercialism

Hanan Alkuwari,¹ Riadh Fadhil,¹² Yousef Almaslamani,¹ Abdalla Alansari,¹ Hassan Almalki,¹ Hatem Khalaf,¹ and Omar Ali¹
Minister of Health
Veronica Skvortsova
Gift of Life Ceremony "Pledging for Organ Donation"
Vasile Cepoi, M.D.
Minister of Health
Republic of Romania

Dear Minister Cepoi:

The action plan of Romania to increase deceased donation entails three priority initiatives:

- the identification of a Key Donation Person in the employ of County Hospitals with intensive care unit services;
- the appointment of an in-house transplantation coordinator at centers that you would deem appropriate for such designation;
- higher level of care classification of county hospitals participating in the national transplant program.
Report of Meeting with Minister Bin Li of the National Health and Family Planning Commission of the People's Republic of China

October 29, 2013
Beijing
Office of the Minister
National Health and Family Planning Commission (NHFPC)

Participants from left to right in the enclosed picture:
Zhou Jun          Deputy Director-General, Department of Medical Administration, NHFPC
Wang Haibo        Director, China Organ Transplant Response System Research Center (COTRS)
Huang Jiefu       Head, National Organ Transplantation Committee of the NHFPC
Deminico Francis  President, The Transplantation Society,
                  Representative of the Declaration of Istanbul Custodian Group
Bin Li            Minister, NHFPC
Ren Minghui       Director-General, Department of International Cooperation, NHFPC
Liu Yong          Division Director, Department of Medical Administration, NHFPC
China

World Health Organization

The Transplantation Society and The Declaration of Istanbul

Eradicate the use of organs from executed prisoners

Prohibit foreign patients from undergoing transplantation in China

Allocate organs transparently to patients medically suitable on a computerized waitlist
Open Letter to Xi Jinping, President of the People’s Republic of China: China’s Fight Against Corruption in Organ Transplantation

Francis Delmonico, Jeremy Chapman, John Fung, Gabriel Danovitch, Adeera Levin, Alexander Capron, Ronald Busuttil, and Phillip O’Connell

The international media have recently focused attention on the resolve of China’s new leadership to combat the rampant corruption within its society. The January 13, 2014, article in the China Daily, “For a clean and fair society,” reported your guidelines for political and legal reform. The judicial system is now charged to “carry the sword of justice and scale of equality” for all of China. “The Chinese dream” you have proposed amounts to a call for a culture of human rights linking the dignity of a great nation to the dignity of each citizen. Therefore, it is timely for the international transplant community to urge China to address the unethical practices in organ transplantation as another measure of your commitment to rid Chinese society of corruption.

The 63rd World Health Assembly in a May 2010 resolution adopted by all member states, including China. Some Chinese officials contend that prisoners give “consent” before their execution. It is obvious, however, that prison inmates condemned to death are not truly free to make an autonomous and informed consent for organ donation and that no legal due process exists to assure consent. First-hand reports from our Chinese colleagues and a number of investigations suggest that the practice of obtaining organs from prisoners in China involves notorious transactions between transplant surgeons and local judicial and penal officials.

Although the outcomes of this unethical practice can-
TPM Wuhan China 2016
Transplant Tourism

Versus

Ethical Travel for Transplantation

Guidelines from
the Declaration of Istanbul Custodian Group

Beatriz Domínguez-Gil and Elmi Muller
Purpose

• To prevent and combat the THO by providing for the criminalisation of certain acts
• To protect the rights of the victims
• To facilitate co-operation at national and international levels on action against THO
WHAT ACTIONS CONSTITUTE TRAFFICKING IN HUMAN ORGANS?

The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

- Illicit removal of organs:
  - removal without the free, informed and specific consent of the living donor, or, in the case of the deceased donor, without the removal being authorized under its domestic law;
  - where in exchange for the removal of organs, the living donor, or a third party, has been offered or has received a financial gain or comparable advantage;
  - where in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a financial gain or comparable advantage.

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In the absence of

- Organ Trafficking
- Transplant Commercialism
- Transplant Tourism

Not undermining the ability of the country of destination to provide transplant services for patients of its own community
Sent: Wednesday, April 20, 2016 11:15 PM
Subject: for your attention again its about transplant tourism in Pakistan

Dr. .......... (a respected nephrologist colleague in Vancouver, Canada --- and an ally in DICG correspondence from the past dating to 2010) has brought to the attention of the DICG the following case:

a 60 year old woman from Vancouver, blood group B with polycystic kidney disease underwent kidney transplantation from a vendor in Rawalpindi at the Al Sayed Hospital on April 2, 2016 unbeknownst to Dr. .......... until she returned home to Canada 2 weeks later--- acutely ill.

There was no documentation or medical record accompanying the patient as she returned to Vancouver.

Not surprisingly, Dr. .......... reports that the patient’s clinical course has been complicated by urosepsis and multiresistant enterococcus infection.

This case is typical in its description of Transplant Tourism that was just elaborated in Madrid:

- No notice to the physician caring for the patient that she would do so--- that is travel to Pakistan for a kidney transplant;
- No documentation from the hospital in Pakistan (if it could be referred to as such) that she underwent the transplant procedure;
- A complicated clinical course that her home country physician now bears the burden of her care and his country bears the expense.
Transplant Tourism

Prospectively

- who is your doctor
- who is your donor
- who is going to care for you upon return to the native country
- what information should be shared between the centers that provides appropriate care of the patient

Retrospectively

- There's an obligation to report to national authorities
  - In the absence of this proper clinical information
  - With the awareness of the illegal activity or clinical complications
Funding of transplant procedures

- National health authorities and/or insurance providers should not cover the costs of transplant procedures which involve organ trade or trafficking or which were otherwise inconsistent with the provisions of domestic laws governing organ removal and transplantation.

- However, patients should always be provided with necessary healthcare upon their return.
Living and deceased organ donation should be financially neutral acts.

Delmonico FL, Martin D, Domínguez-Gil B, Muller E, Jha V, Levin A, Danovitch GM, Capron AM.

Abstract
The supply of organs—particularly kidneys—donated by living and deceased donors falls short of the number of patients added annually to transplant waiting lists in the United States. To remedy this problem, a number of prominent physicians, ethicists, economists and others have mounted a campaign to suspend the prohibitions in the National Organ Transplant Act of 1984 (NOTA) on the buying and selling of organs. The argument that providing financial benefits would incentivize enough people to part with a kidney (or a portion of a liver) to clear the waiting lists is flawed. This commentary marshals arguments against the claim that the shortage of donor organs would best be overcome by providing financial incentives for donation. We can increase the number of organs available for transplantation by removing all financial disincentives that deter unpaid living or deceased kidney donation. These disincentives include a range of burdens, such as the costs of travel and lodging for medical evaluation and surgery, lost wages, and the expense of dependent care during the period of organ removal and recuperation. Organ donation should remain an act that is financially neutral for donors, neither imposing financial burdens nor enriching them monetarily.
**Universal Legal Framework: Trafficking in Human Beings for the Purpose of Organ Removal**

**Actions**
- The recruitment, transportation, transfer, harboring or receipt of persons,

**Means**
- 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

**Purpose**
- for the purpose of exploitation...including the removal of organs


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TRAFFICKING IN HUMAN BEINGS FOR THE REMOVAL OF ORGANS VS TRAFFICKING IN HUMAN ORGANS

The need to distinguish clearly between “Trafficking in Human Organs” (THO) and “Trafficking in human beings for the purpose of the removal of organs” (HTOR)

HTOR: effectiveness of existing international standards and no need for further international legal instruments

THO: need for an internationally agreed definition

Recommendation to elaborate an international legal instrument setting out a definition of THO, the measures to prevent it and protect victims, and criminal law measures to punish the crime


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A needed Convention against trafficking in human organs.

López-Fraga M1, Domínguez-Gil B2, Capron AM3, Van Assche K4, Martin D5, Cozzi E6, Delmonico FL7.

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5Centre for Health and Society, School of Population and Global Health, University of Melbourne, Melbourne, VA, Australia.
6Centro Nazionale Trapianti, Istituto Superiore di Sanità, Rome, Italy; Transplant Immunology Unit, Padua University Hospital, Padua, Italy.
7The Transplantation Society, Montreal, QC, Canada; Advisory for Human Transplantation, World Health Organization, Geneva, Switzerland; Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA; New England Organ Bank, Waltham, MA, USA.

The transplantation of solid organs is an increasingly global therapeutic modality, with more than 114,000 transplants performed annually in over 100 countries. Although legislation and regulations forbidding organ sales now exist in most countries, progress in ending this trafficking has been impeded by weak enforcement in some countries and the absence of a complete set of legally binding international instruments that would harmonize national regulations and facilitate cross-national co-operation.
Yet the legal instruments aimed at combatting human trafficking leave gaps because sometimes one or more of the three components for HTOR are difficult to prove. Establishing an illegal “means” can be especially problematic, given that force or fraud is not always used and “abuse of a position of vulnerability” is a rather indefinite act. Likewise, when the seller takes the initiative, through contacting a potential organ recipient or an intermediary, prosecutors are hard pressed to demonstrate that the person has been trafficked, even if the seller had been led to act by poverty or some other desperate need. Moreover, HTOR does not reach commercial transactions involving organs from deceased persons nor the diversion of properly obtained organs for illicit use by physicians providing transplant services to patients who do not qualify to receive them within the national program or at facilities that serve foreign “transplant tourists”.
**COMPLEMENTARITY TO THE EXISTING LEGAL FRAMEWORK**

**Actions**
- Recruitment, transportation, transfer, harboring or receipt of persons

**Means**
- 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

**Purpose**
- Removal of organs

**Human Trafficking**
- Sexual exploitation
- Forced labour
- Slavery

**OTC Trafficking**
- Cells
- Organs
- Tissues

**Complementarity to HTOR framework**, for instance:
- when it is difficult to prove that the person whose organ was illicitly removed had been subjected to human trafficking (e.g. when sellers take the initiative, by contacting potential recipients or intermediaries)
- when it is difficult to prove that the person concerned has engaged in actions within the scope of the definition of HTOR or has used any of the illegal means set forth in the definition of HTOR
- commercial transactions involving organs from deceased persons
- diversion of properly obtained organs for illicit use by physicians providing transplant services to patients who do not qualify to receive them within national programs or at facilities that serve “transplant tourists”
The pivotal role of health professionals in the fight against transplant-related crimes

This identifies the obligation of health professionals to discourage and prevent any harm to individuals by not providing patients with any information or services that could enable them to purchase illicitly obtained organs and by appropriately screening all potential donors to avoid any transplant related crimes.

Health professionals are further obliged to report illicit conducts by peers or patients to law enforcement authorities when they suspect or know of the illicit origin of the transplanted organ.
The pivotal role of health professionals in the fight against transplant-related crimes

• Establish and promulgate a prospective program that emphasizes care and professional responsibility.

• That care entails an awareness of the circumstances of the transplant and the responsibility entails an obligation of reporting when the patient does not fulfil the established plan of referral.

• The consequence for the patient and physician is a reporting to appropriate authorities.
Ways to Reduce the Kidney Shortage

The United States and many other nations are confronting a heart-rending problem: The number of kidneys available for transplants falls far short of the need.

While some argue that the way to reduce the growing shortage is to pay living donors for kidneys, either in cash or government benefits, there are many ways to increase the supply without paying for human organs, which is prohibited by the 1984 National Organ Transplant Act and generally opposed by the World Health Organization.

In the United States, the number of kidney transplants fell to 14,000 last year, while the waiting list for kidneys currently exceeds 100,000 patients. The average wait time for a transplant has risen to almost five years; more than 4,000 people die each year while waiting and a great many more, possibly thousands, become too sick to undergo transplantation and are dropped from the wait lists.

The first step in easing the shortage is to end the current shameful waste of organs.

plantation or research. Many people already do that through driver’s license check-offs, but a stronger national campaign to get more people to allow donation could help increase the kidney supply.

To encourage more living donors, some disincentives could be corrected. Some experts propose that government agencies or health insurers pay all costs a living donor faces, like travel and lodging for trips to the transplant center for evaluation and then for surgery, dependent care while recovering from the surgery and wages lost while recuperating.

Others want to make sure that donors can jump to the top of the transplant list if they develop disease in their remaining kidney, and also allow their loved ones to jump to the top of the list if they unexpectedly need a transplant. Some say donors should be given government-paid life insurance to cover a death during surgery or later complications from the surgery.
Hundreds of kidneys taken from deceased donors that are suitable for transplant are discarded every year, probably more than 1,000 some experts say. Surgeons typically hope to transplant a kidney within 24 hours to 36 hours of the time it is recovered and placed on ice for evaluation. Sometimes the clock runs out before a suitable recipient can be found. The United Network for Organ Sharing, which runs the allocation system, will revise its formulas in December in ways that it believes will increase the utilization of donated kidneys and thus reduce wastage.

Meanwhile, many patients, possibly in the hundreds, who do receive transplants become ill again because they can’t afford to pay for antirejection drugs that can cost more than $1,000 a month; Medicare stops paying for the drugs after three years unless the patient is old or disabled. Congress ought to extend coverage for as long as necessary.

Equally important is increasing the number of people who agree in advance to donate their organs for transplant. The American Society of Transplant Surgeons and American Society of Transplantation have proposed pilot projects to test the effect of many of these ideas. Most of these proposals seem consistent with the Declaration of Istanbul, a consensus statement adopted in 2008 by an international meeting of experts that aimed to increase the kidney supply while protecting poor people from illegal organ traffickers. But some may skirt close to infringing the federal law.

A few advocates would go further by having state or federal agencies offer benefits to donors, perhaps a tax credit, college tuition, early access to Medicare or a contribution to a retirement fund. But such benefits, though not cash, clearly have monetary value, and raises the troubling issue of inducing people — most likely the poor — to sell their kidneys, which violates federal law.

There are lots of reforms that could be made without resorting to paying for kidneys. Congress ought to hold hearings on the best ways to reduce the shortage and save more lives on the waiting list.