

**UCLA Division of Nephrology
Kidney Transplant Program
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**The Legal & Ethical Underpinnings
of Organ Transplantation**

**Alexander Morgan Capron
University Professor**

**Scott H. Bice Chair in Healthcare Law, Policy and Ethics
Co-Director, Pacific Center for Health Policy and Ethics**

**University of Southern California
Los Angeles, California**

Overview of Presentation

1. The Origins of Human Organ Transplantation
2. The Theme: The Confluence of Law and Ethics
 - a. The protection of the person and of the profession
 - b. Preventing exploitation
 - c. Avoiding commodification of, and trafficking in, human beings
3. The early years and development of US policies
 - a. The meaning of a “gift” (free, informed donation; no payment)
 - b. National Organ Transplant Act of 1984
4. Global ramifications
 - a. World Health Organization & governments
 - b. TTS, ISN, Declaration of Istanbul & the professions
5. Current issues: still dependent on ethics as well as law

Origins of Organ Transplantation

- Early reliance on living, related (well HLA-matched) kidney donors
 - Beginning in 1954 with identical twins
 - Expanded to other relatives
 - Understandable reluctance, given “do no harm” principle as to donor – but overcome by desire of family members to “rescue” the patient with kidney failure
- Deceased donation came in slowly, due to adverse effects on cadaveric organs while circulatory death was being diagnosed
 - 1957, Mollaret & Goulon described “**le coma dépassé**” in respirator-supported patients (necrosis & autolysis of brain)
 - Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, “**A Definition of Irreversible Coma**,” JAMA 205:337 (1968) [*NOTE: confusing terminology*]
 - Coincided with first human heart transplant, Dec. 1967

Origins of Organ Transplantation

- In short order, living donation generally – and unrelated living donation in particular – virtually disappeared
- **Uniform Anatomical Gift Act (1968)**
 - State law (NCCUSL recommends model laws for adoption)
 - NCCUSL is mostly involved in laws that aim toward standardizing business across state boundaries, but UAGA became its most quickly and uniformly adopted proposal
 - Aimed at making deceased donation easier by overcoming the barrier imposed by attitude toward control over dead bodies
 - Most of focus on facilitating the act of “donation,” **but built on assumption that bodies should be “gifts” not “commodities”**

Physicians' Concerns about Living Donors

- H. Harrison Sadler, et al, "The Living, Genetically Unrelated, Kidney Donor," Sem. in Psych. 3:86 (1971)
- Report on survey begun in 1967
 - Of the 54 world transplants that responded, half disapproved
 - Only 20% had used such donors themselves

Main objections from physicians:

1. Statistical conclusion: no better than cadaver
2. Psychological verdict: "He's crazy"
3. Ethics of medicine: Primum non nocere
4. Legal implication: someday he will harass the recipient or the hospital
5. Attitude of physicians: he offends the human conscience

Physicians' Concerns about Living Donors

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- Report on survey begun in 1967
 - Of the 54 world transplants that responded, half disapproved
 - Only 20% had used such donors themselves
 - "much evidence of distrust and suspicion towards the donors and definite repugnance concerning their use"

Main objections from physicians:

1. Statistical conclusion: no better than cadaver
2. Psychological verdict: "He's crazy"
3. Ethics of medicine: Primum non nocere
 - Harm to the personality from the donation
 - MD as "accomplice" of person wishing to risk his/her own life
4. Legal implication: someday donor will harass the recipient or the hospital
5. Attitude: Unrelated donor offends human conscience

The Confluence of Law and Ethics

Living Donors

Medical Ethics

**Primum non nocere
(vs. benefit to recipient)**

Paternalism

**Psychological discomfort
of physicians**

Legal Principles

Body is not property

**No buying/selling of
human beings**

**Rights (including
patient “autonomy”)**

**Organs (for
Transplantation)
as Gifts**

Progress in Deceased Donation

- In 1970s, growing social acceptance of determination of death in respirator-supported patients
 - Issue arises more frequently in non-donation situations
 - Esp. important before “pulling the plug” gained acceptance
- Uniform Determination of Death Act (1981)
 - Aimed at overcoming barriers posed by existence of competing “model” laws (Capron-Kass, AMA, ABA, NCCUSL)
 - Recognized that deceased donation must be easier because this had become the major source of all organs incl. kidneys (obviously essential for lungs, hearts, and at that time livers)
 - “Bifurcated” definition: permanent cessation of circulatory/respiratory functions or of all functions of the brain
 - Law is at level of “standards,” letting criteria and tests to evolve

The Confluence of Law and Ethics

Deceased Donors

Medical Ethics

**Relationship of brain,
heart & lungs**

**Current evidence-based
criteria and tests**

Legal Principles

**Uniformity across people
and locations**

**No buying/selling of
human beings**

**Certainty of death
determinations**

Federal Prohibition of Organ Sales

- Until early 1990s, principal reliance in US was on deceased donors
 - **Uniform Anatomical Gift Act (1968): gift = donation**
 - **No provisions directly governing living donation**
- 1983, a Virginia physician proposed overcoming shortage of kidneys for transplantation by setting up a program to bring in people from abroad (focus on Latin America), who would be paid to part with a kidney
 - **Bi-partisan response (Gore & Hatch), National Organ Transplant Act, P.L. 98-507 (1984), made it unlawful [under “commerce clause”] “for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration” (excluding costs of procurement)**
 - **Addressed shortage by establishing a network (contracted to UNOS) to coordinate the obtaining of organs from deceased donors (by OPOs) and their fair distribution**

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.

The Shameful Legacy of Organ “Donation” in Poor Countries



Rani sold her kidney to a broker named Dhanalakshmi who used to have a shop outside Devaki Hospital in Chennai.



From David Rothman New Yorker



Filipino men showing their scars from kidney operations, Manila, August 1999



The Shameful Legacy of Organ “Donation” in Poor Countries

“Organ transplantation, one of the medical miracles of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. The many great scientific and clinical advances of dedicated health professionals, as well as countless acts of generosity by organ donors and their families, have made transplantation not only a life-saving therapy but a shining symbol of human solidarity.

“Yet these accomplishments have been tarnished by numerous reports of trafficking in human beings who are used as sources of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people.”

--Opening of the Declaration of Istanbul (2008)

The Shameful Legacy of Organ “Donation” in Poor Countries



The Causes of Organ Trafficking

“Unethical practices are, in part, an undesirable consequence of the global shortage of organs for transplantation. Thus, each country should strive both to ensure that programs to prevent organ failure are implemented and to provide organs to meet the transplant needs of its residents from donors within its own population or through regional cooperation.

“The therapeutic potential of deceased organ donation should be maximized not only for kidneys but also for other organs, appropriate to the transplantation needs of each country. Efforts to initiate or enhance deceased donor transplantation are essential to minimize the burden on living donors.”

--Opening of the Declaration of Istanbul (2008)

Declaration of Istanbul: Definitions

Organ trafficking was defined as “the recruitment, transport, transfer, screening, harboring or receipt of living or deceased persons or human organs 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 another person having control over the potential donor, for the purpose of exploitation by the removal and/or transplant of organs.”

Transplant commercialism was defined as “a policy or practice in which an organ is treated as a commodity, including by being bought or sold.”

Declaration of Istanbul: Definitions

Travel for transplantation was defined as “the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation.”

Travel for transplantation becomes **transplant tourism** if:

“it involves **organ trafficking** and/or **transplant commercialism**

“or

“the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside the country **interfere with the country’s ability** to provide transplant services for its own population.”

Query: whenever there is any shortage, is the latter condition met?

Istanbul Summit



Declaration of Istanbul: Principles

1. National governments, working in collaboration with international and non-governmental organizations, should develop and implement comprehensive programs for the screening, prevention and treatment of organ failure, which include:
 - a. The advancement of clinical and basic science research;
 - b. Effective programs, based on international guidelines, to treat and maintain patients with end-stage diseases, such as dialysis programs for renal patients, to minimize morbidity and mortality, alongside transplant programs for such diseases;
 - c. Organ transplantation as the preferred treatment for organ failure for medically suitable recipients.

Declaration of Istanbul: Principles

2. Legislation should be developed and implemented by each country or jurisdiction to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards:
 - a. Policies and procedures should be developed and implemented to maximize the number of organs available for transplantation, consistent with these principles;
 - b. The practice of donation and transplantation requires oversight and accountability by health authorities in each country to ensure transparency and safety;
 - c. Oversight requires a national or regional registry to record deceased and living donor transplants;
 - d. Key components of effective programs include public education and awareness, health professional education and training, and defined responsibilities and accountabilities.

Declaration of Istanbul: Principles

3. Organs for transplantation should be equitably allocated within countries or jurisdictions to suitable recipients without regard to gender, ethnicity, religion, or social or financial status.
 - a. Financial considerations or material gain of any party must not influence the application of relevant allocation rules.
4. The primary objective of transplant policies and programs should be optimal short- and long-term medical care to promote the health of both donors and recipients.
 - a. Financial considerations or material gain of any party must not override primary consideration for the health and well-being of donors and recipients.

Declaration of Istanbul: Principles

5. Jurisdictions, countries and regions should strive to achieve **self-sufficiency in organ donation** by providing a sufficient number of organs for residents in need from within the country or through regional cooperation.
 - a. Collaboration between countries is not inconsistent with national self-sufficiency as long as the collaboration protects the vulnerable, promotes equality between donor and recipient populations, and does not violate these principles;
 - b. Treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country's ability to provide transplant services for its own population.

Declaration of Istanbul: Principles

6. 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**.
 - a. Prohibitions on these practices 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.
 - b. Such prohibitions should also include penalties for acts—such as medically screening donors or organs, or transplanting organs—that aid, encourage, or use the products of, organ trafficking or transplant tourism.
 - c. Practices that induce vulnerable individuals or groups (such as illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees) to become living donors are incompatible with the aim of combating organ trafficking, transplant tourism and transplant commercialism.

The DECLARATION of ISTANBUL

on ORGAN TRAFFICKING and TRANSPLANT TOURISM



WHO & Organ Transplantation



**World Health
Organization**

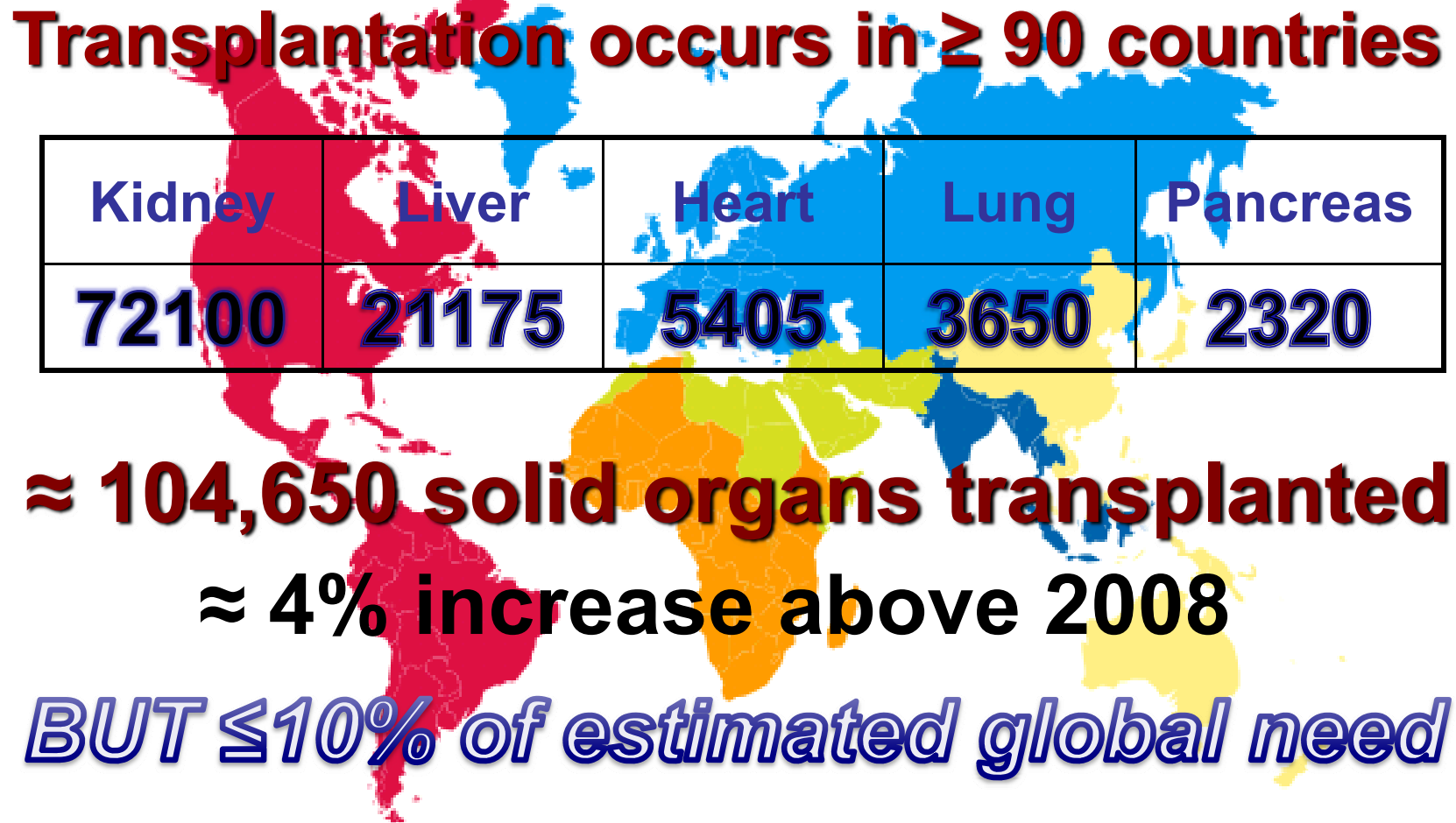
1. UN's specialized agency for health
2. Like all of UN, exists not only to provide means of peaceful cooperation among countries but to enhance human rights

Right to health = "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition"
(WHO Constitution, 1946)

WHO & Organ Transplantation: Technical Assistance

Organs Transplanted (2009 Estimate, WHO)

Transplantation occurs in ≥ 90 countries



Kidney	Liver	Heart	Lung	Pancreas
72100	21175	5405	3650	2320

$\approx 104,650$ solid organs transplanted

$\approx 4\%$ increase above 2008

$BUT \leq 10\%$ of estimated global need

Transplantation Activity at Regional Level (WHO 2010 Report)

WHO Region	Number of Kidney Transplants (pmp)	Number of Liver Transplants (pmp)
AFR	400 (0.48)	23 (0.028)
AMR	26521 (29.5)	8606 (9.6)
EMR	5193 (9.4)	389 (0.70)
EUR	19805 (22.3)	7436 (8.4)
SEAR	6819 (3.85)	303 (0.17)
WPR	10476 (5.9)	3523 (1.97)

WHO & Organ Transplantation: Technical Assistance

Examples of WHO's engagement, based on its being the specialized UN agency on health:

1. Assistance to countries in primary and secondary prevention of organ failure

- Public health and primary care (prevention of infections, etc.)
- Management of chronic conditions (diabetes, etc.)

2. Development of medical and surgical capacity to treat end-stage organ failure

- Surgical training & guidance in equipping surgical suite
- Safety of transplantation for recipients as well as donors
- Kidney dialysis for ESRD

3. Help in developing fair & efficient national systems for obtaining and distributing organs for transplantation

- Responsible national agency
- Adequate legislation
- Specific medical guidance on death determination standards

WHO & Organ Transplantation: Human Rights

Beginning in 1987, in light of reports of organ sales in a number of developing countries, the World Health Assembly brought to WHO governing bodies first expressed concern about the commercial trade in human organs (Resolution WHA40.13).

- **Heavily supported by United States and W. Europe**

Two years later, the Health Assembly called upon Member States to take appropriate measures to prevent the purchase and sale of human organs for transplantation (Resolution WHA42.5).

In 1991, the Health Assembly endorsed the WHO *Guiding Principles on Human Organ Transplantation* (WHA44.25).

- **Influenced legislation in more than 50 Member States as well as professional codes and practices**
- **Based on “human dignity” & commitment to protect human rights**

WHO & Organ Transplantation: Human Rights

- In 2003, WHO Executive Board instructed the Director-General to examine what was occurring in organ transplantation and recommend any modifications needed in “Guiding Principles”
- In 2004, World Health Assembly received that report and urged countries to avoid “transplant tourism” and the exploitation of “the poorest and vulnerable” and to develop responsible national systems (WHA 57.18)
- In 2010, after further discussion in Executive Board, the Health Assembly approved updated “WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation” (WHA 63.22)
 - **Addressed scientific developments in cell & tissue tx**
 - **Added two principles: #10 increasing safety (requiring traceability & vigilance) & #11 organizational transparency**

WHO & Organ Transplantation: Human Rights

In WHA 63.22, the Assembly declared that it was:

“ . . . 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;

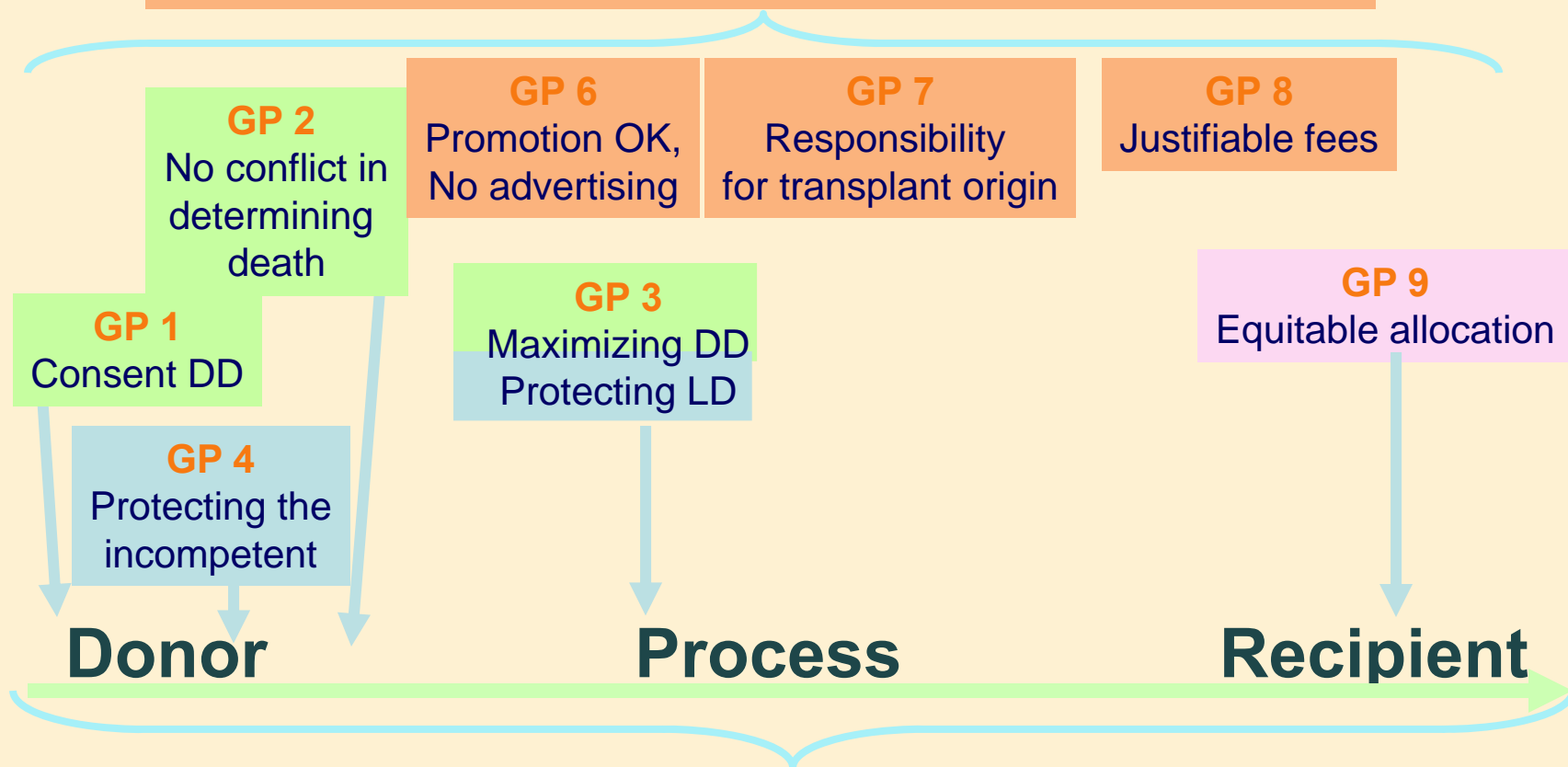
“Determined to **prevent harm caused by the seeking of financial gain or comparable advantage** in transactions involving human body parts, including organ trafficking **and transplant tourism**;

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

”
. . . .

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

GP 5 Free donation and no purchase of human transplant as such, but cost & expenditures recovery



GP 10 Monitoring long term outcomes. Quality and safety of procedures and products

GP 11 Transparency, openness to scrutiny, anonymity

Guiding Principle 5

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.

Guiding Principle 5

The prohibition on sale or purchase of cells, tissues and **organs does not preclude reimbursing reasonable and verifiable expenses** incurred by the donor, including loss of income, or **paying the costs** of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Ambiguity in What Payment is Allowed Aids Slide towards Market

Reward

Gratuities

Indemnity

Compensation

Incentives

Inducements

.....

Remuneration

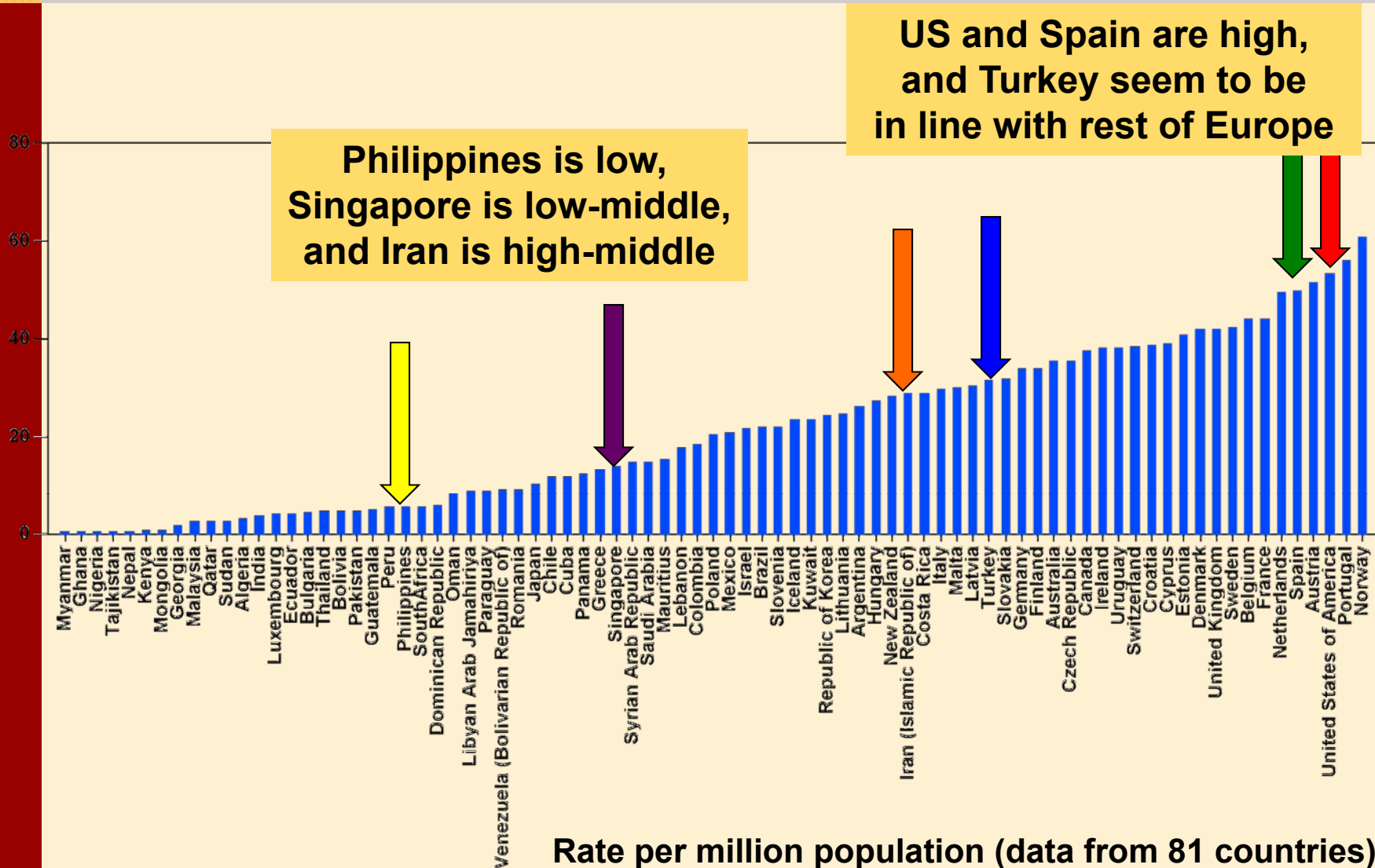
Commentary on G P 5

"National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of 'rewards' with monetary value that can be transferred to third parties are not different from monetary payments."

Much Remains to be Done

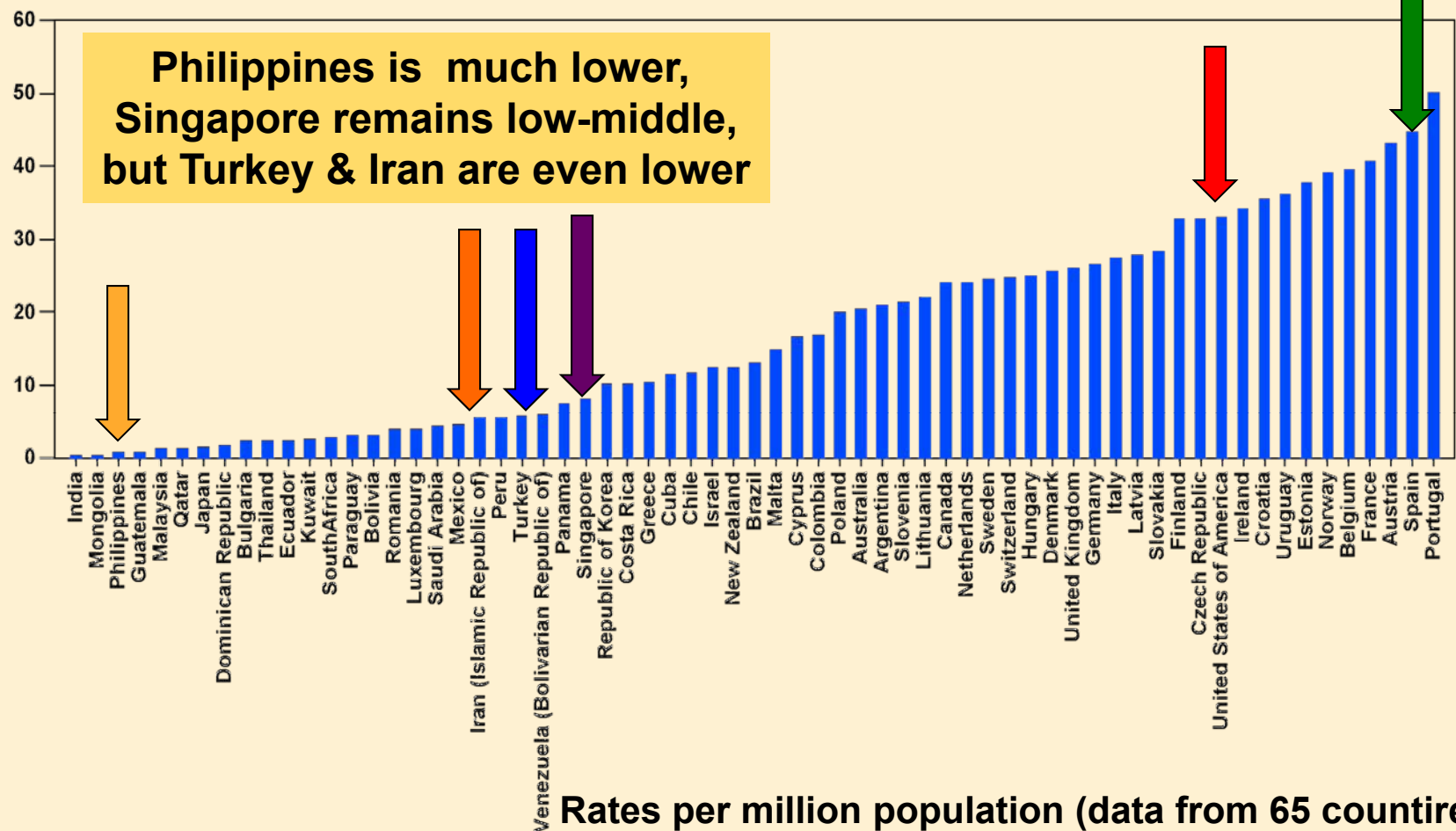
1. Increasing the completeness of data – and learning from the patterns
2. Helping countries develop legislation & regulations – and administering system fairly and effectively
 - Major area for cooperation with professional organizations, especially in relationship to medical self-regulation, journal publication, and pharmaceutical company sponsorship
3. Developing concept of “self-sufficiency” – and achieving it (especially requires deceased donation)
4. Preserving the strict prohibition on organ sales in rich countries, as an ethical example and a practical barrier to spread of commodification of human body
 - Cooperation with international “anti-trafficking” enforcement
 - Protecting NOTA against political and legal attacks

1. Gathering & Understanding Data: Kidney Transplant Activity in 2009

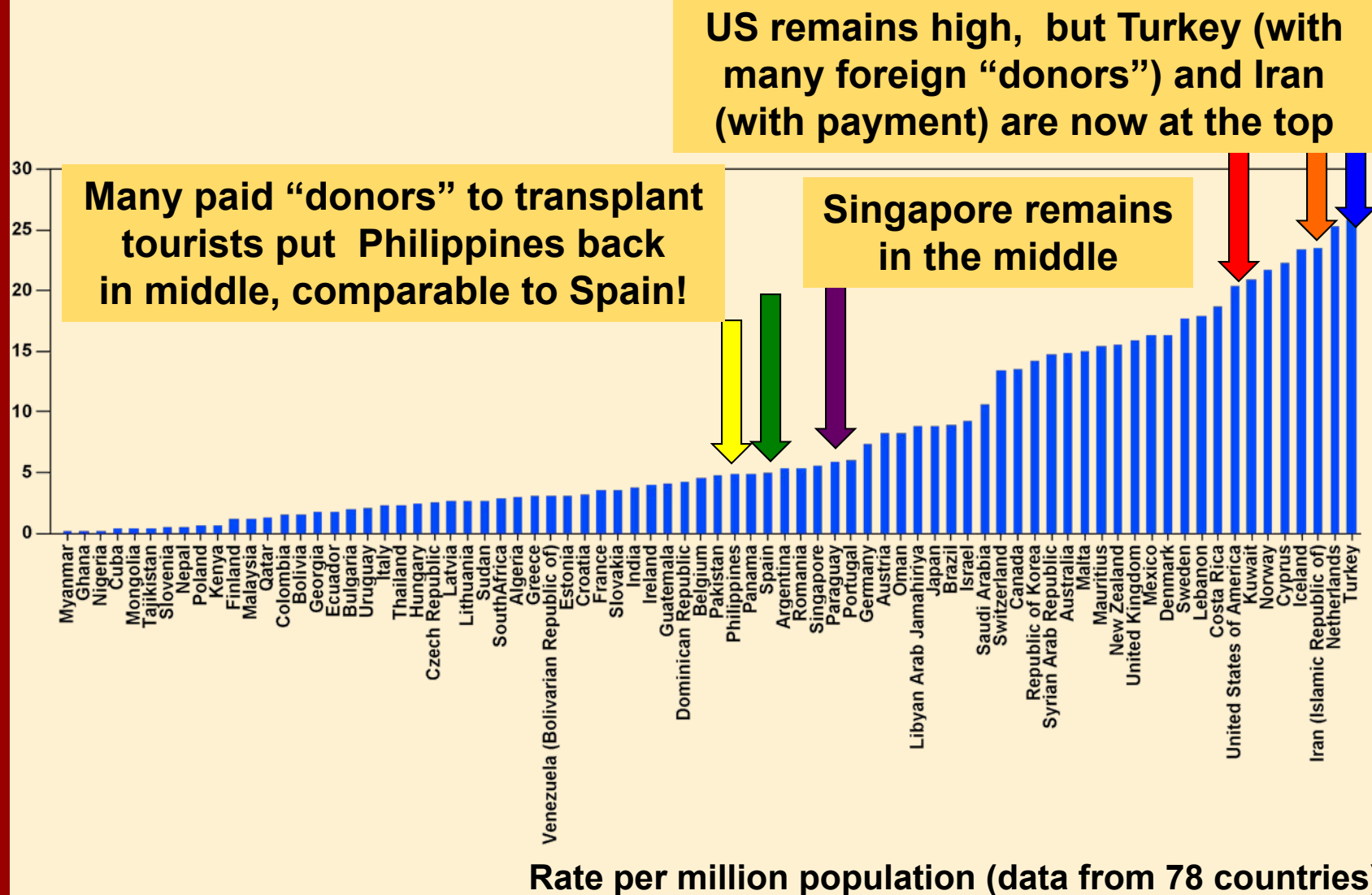


Kidney Transplant Activity from Deceased Donors in 2009

US and Spain remain high, but positions have switched



Kidney Transplant Activity from Living Donors in 2009



2. Helping Countries with Laws: Gathering Momentum

China:

- Adoption by the State Council of the Transplantation Law (6 April 2007)
- Awaited: law on death determination with neurological criteria

Pakistan:

- Promulgation of Ordinance on Human Cell and Tissue Transplantation by President Musharraf (4 September 2007), now the Transplantation Bill
- HOTMA, Human Organ Transplantation Monitoring Authority is actively enforcing the law

Philippines

Ban on Foreigners Transplantation (28 April 2008)

Egypt

November 2008 : President Mubarak put transplantation as one of 9 major issues that need to be legislated, during this round of Parliament.

Active Enforcement of Legislation in China, but . . .

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China punishes hospitals for illegal organ trade

01 Nov 2008 10:45:03 GMT

Source: Reuters

SHANGHAI, Nov 1 (Reuters) - China's health ministry has penalised three hospitals for illegally selling human organs to foreigners, a local media report said on Saturday, citing a deputy health minister.

Huang Jiefu did not identify the hospitals or doctors involved in the illegal organ transplant cases or the penalties handed out, Caijing Magazine, an influential financial magazine, said.

But at the same time, use of executed prisoners as “voluntary donors” continues, principally to provide kidneys and livers for “transplant tourists”

3. “National or Regional Self-Sufficiency” in Organ Donation

Equitably meeting the transplantation needs of a given population using resources from within that population.

- Aims at emphasizing countries’ obligations not to rely on other countries (esp. with organ commercialism).
- “Population” may be defined on state, country, sub-regional or regional basis.
- Self-sufficiency can also be used for on global (for example, with hematopoietic stem cells using registries internationally), where there is no “self” vs. “other.”
- Issue also arises because of apparent departure from usual obligations (solidarity) to assist other countries.

The Madrid Resolution on Organ Donation and Transplantation – National Responsibility in Meeting the Needs of Patients Guided by the WHO Principles (2010)



4. Preserving Strict Prohibition on Buying and Selling Organs

Last October, the UN Office on Drugs and Crime reported to the Conference of the Parties on the United Nations Convention against Transnational Organized Crime:

“Trafficking in persons for the removal of organs’, a term that refers to the trafficking in people specifically for the purpose of removing organs, has been identified as an offence under the Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children.”

Current Ethical and Legal Issues

1. Pressure from some MDs & libertarians to allow a market in organs
 - a. NOTA is under attack: politically (based on “ethical” claims regarding the desirability of allowing payment for organs) and in the courts (in a challenge to the inclusion of bone marrow on the list of prohibited items)
2. Global resistance to Declaration of Istanbul & GPs
 - a. “Transplant tourism is not medical tourism”
 - b. China: progress but continued use of executed prisoners
 - c. Getting “enforcement” by professional bodies, journals, and pharmaceutical company support for research
3. Determination of death: “brain death” and DCDD protocols
 - a. Cellular & chemical activity in brain after death
 - b. Continued confusion over term “brain death” (sep. category)
 - c. DCDD – confusion over “cardiac” death & “irreversibility”

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Director, Kidney and Pancreas Transplant Program

Questions?

Thank you!

Alex Capron

acapron@law.usc.edu