

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

## Declaration of Istanbul Custodian Group

Sirs,

On behalf of the Executive Committee of the Declaration of Istanbul Custodian Group (DICG), we are responding to the public consultation of the Nuffield Council on Bioethics regarding the provision of bodily material for medical treatment and research. In this correspondence we relate to the unique issues concerning transplantable organs which must be clearly differentiated from those relating to other bodily material.

Our correspondence:

- I. Introduces ourselves briefly as the DICG Executive Committee;
- II. Details the development and consequences of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism;
- III. Provides solicited commentary on the Nuffield Consultation.

### **I. Introduction of the DICG Executive Committee:**

The DICG is a joint venture of The Transplantation Society (TTS) and the International Society of Nephrology (ISN)

Gabriel Danovitch is a UK born and medically trained physician and nephrologist who heads the kidney and pancreas transplant program at the David Geffen School of Medicine at UCLA and has been engaged for many years in the clinical, educational, societal, and ethical issues surrounding organ transplantation in general and kidney transplantation in specific.

Francis Delmonico is a US transplant surgeon of the Harvard Medical School at the Massachusetts General Hospital, the Director of Medical Affairs for TTS, Medical Director of New England Organ Bank, and past-president of the United Network for Organ Sharing (UNOS). He is an internationally recognized authority on the practice of deceased donation and has presided over the development of national and international standards of practice for various aspects of living donation.

Jeremy Chapman, co-chair of the DICG, is a UK born and medically trained physician and nephrologist, Director of Acute Interventional Medicine and Renal Services at Westmead Hospital, Sydney, Chairman of the Australian Bone Marrow Donor Registry, and past President of the Transplantation Society of Australia and New Zealand. He is the current President of TTS, Immediate Past President of the World Marrow Donor Association and Chair of the Global Alliance for Transplantation.

Adeera Levin, co-chair of the DICG, is a Canadian nephrologist who is the current Secretary General of the ISN and Executive director of Provincial Renal Agency of British Columbia, an organization which manages and co-ordinates the care of patients with kidney disease. She is an internationally recognized authority on the management of advanced kidney disease.

### **II. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism**

The Declaration of Istanbul was first published in *The Lancet* (1) and its text is attached. The Declaration is the principal manifestation of the professional commitment to address the serious problems caused by organ trafficking, transplant tourism, and organ commercialism while working to improve life saving organ transplantation globally and ensure that it is practiced ethically. The Declaration is jointly sponsored by TTS and ISN. The Declaration, a historical first of its kind, was adopted in May 2008 at a global meeting attended by more than 150 representatives of scientific and medical bodies from 78 countries around the world, including government officials, social scientists, and ethicists. The Declaration contains the principles by which transplantation practice should be conducted by professionals and governmental bodies alike for the care and protection of the organ donor and the effective and equitable use of donated organs. A major mission of the Declaration is also the promotion of deceased donor transplantation both to reduce the burden on living donors and permit the development of non-renal solid organ transplantation.

To date more than 90 professional organizations and government bodies in all regions of the world have endorsed the Declaration, medical and scientific journals are requiring statements of conformance with the Declaration in the publication of clinical studies, and major pharmaceutical companies are committed to conducting clinical trials only with transplant programs that conform to the principles of the Declaration.

To quote from the preamble to the Declaration “The legacy of transplantation must not be the impoverished victims of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another”.

Under the influence of the Declaration, progressive legislation has been passed in a number of countries. In Pakistan the “Transplantation of Human Organs and Tissues Ordinance” has brought the much thriving but condemned kidney bazaars almost to an end<sup>[1]</sup>; in the Philippines regulations have prevented the country from becoming a hub for organ transplant commercialism<sup>[2]</sup>; in Israel a new transplant law<sup>[3]</sup> criminalizes organ transplant brokering and provides for reimbursement of verifiable donor expenses, its provisions have virtually stopped the ‘tourism’ of citizens to other countries and have been followed by an increase in living donation in the country itself; in Singapore new regulations<sup>[4]</sup> provide for reimbursement of expenses and work-time lost while prohibiting cash payments; in Egypt a new law<sup>[5]</sup> will soon go into affect designed to permit the development of deceased donation and prevent organ transplant commercialism; in China new regulations<sup>[6]</sup> have reduced, though not stopped, transplant tourism to that country while promoting both living an deceased donor transplantation according to international standards. All these legislative changes serve not only to protect vulnerable potential organ donors but to promote both safe and effective living and deceased donor transplantation. They also serve to emphasize the global nature of the challenge to safe, ethical, and effective organ transplantation.

A patient education pamphlet, developed by the Patient Affairs task force of the DICG is attached. The following recent developments are also of relevance:

- In March, 2010 the Madrid Conference and the 3<sup>rd</sup> WHO Global Consultation on Donation and Transplantation organized by the Spanish Presidency of the European Union, took place under the auspices of TTS, and the Organización Nacional de Trasplantes (ONT). This conference emphasized the critical importance of national and regional responsibility and self-sufficiency in the provision of transplanted organs for those in need consistent with the principles of the Declaration.
- In May, 2010 The European Directive<sup>[7]</sup> was adopted by the European Parliament with a clear stipulation regarding voluntary and unpaid donation consistent with the Declaration.
- In May, 2010 the World Health Assembly (WHA) adopted the WHO Revised Guiding Principles on Transplantation (attached) in full accord with the Istanbul Declaration. Article 6 of the WHA Resolution calls for the prohibition of the giving or receiving of money or anything of value in exchange for cells, tissues or organs for transplantation. However, the Principles do sanction the reimbursement of both expenses (such as those for medical care arising from donation) and losses (such as wages foregone).

[1] [www.declarationofistanbul.org](http://www.declarationofistanbul.org)

[2] Philippines health department issues 2008-004-A to amend section 7 of 2008-004

[3] Israel Transplant Law 2008

[4] Singapore Human Organ Transplants Act (HOTA)

[5] Egypt: <http://bikyamasr.com/wordpress/?p=9227>

[6] China Organ Transplant Law 2007 [7] European directive: <http://www.eubusiness.com/topics/health/organ-donations.10>

### III. DICG response to the Nuffield Consultation:

The letter of introduction to the Nuffield Consultation asks the question: "How far should we as a society go in encouraging or even incentivizing people to provide material?" The Declaration of Istanbul clearly differentiates between "encouraging or even incentivizing people" through cash payments or financial equivalents on the one hand and through education of the community and societal recognition of the donation event on the other. As noted above, a critical distinction is made by the Declaration of Istanbul and the WHA Resolution between the removal of financial (and other) disincentives to donation, which is sanctioned, and the offering of financial incentives to donation, which is prohibited. This distinction is at the core of the US National Organ Transplant Act (NOTA) of 1984 [8] and article 13.24 of the April 1995 Nuffield Council of Bioethics report. This prohibition is based not only on bioethical concerns which have been debated at length, but on concerns about patient safety which have been repeatedly documented (2,3). Experience in several countries has also shown an *inverse* relationship between financially incentivized donation and voluntary, unpaid, or 'altruistic' donation (4,5). It is thus facile to presume that financially incentivized donation offers any kind of 'solution' to the organ donor shortage.

In the UK there has been an encouraging increase in altruistic donation in recent years [9], including an increase in donation from living donors who are not biologically related to their recipients, a trend also noted in the USA. In the UK there is also much that can be done to improve rates of deceased donation including, for example, the recognition and referral of eligible deaths in the intensive care units.

The DICG last met in Cairo in March 2010. The mission of the DICG [10] is to promote and implement the Declaration of Istanbul so as to combat organ trafficking, transplant tourism and transplant commercialism ([www.declarationofistanbul.org](http://www.declarationofistanbul.org)). We respectfully ask that the Nuffield Council on Bioethics note the international accord centred around the Declaration of Istanbul and consider the impact of its conclusions on transplant practice worldwide and not only in the UK. We invite the Nuffield council to consider joining the many professional organizations that have endorsed the Declaration of Istanbul in a concerted effort to sustain and promote ethical organ donation and transplantation throughout the world. Declaration of Istanbul so as to combat organ trafficking, transplant tourism and transplant commercialism

Sincerely,

Gabriel M. Danovitch  
Co-Chair, Patient Affairs

Francis L. Delmonico  
Executive Secretary

Adeera Levin Co-Chair

Jeremy R. Chapman  
Co-Chair

#### ENCLS. Declaration of Istanbul Patient Brochure (English) WHO Revised Guiding Principles

- 1) [Steering Committee of the Istanbul Summit](#) Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul. *Lancet* 2008;372:5-6
- 2) Gill J, Bhaskara R, Madhira, Gjertson D, Lipshutz G, Cecka M, Pham T, Wilkinson A, Bunnapradist S, and Danovitch GM. Transplant Tourism in the United States: A Single-Center Experience. *Clin J Am Soc Nephrol* 2008;3:1820-1828
- 3) Naqvi S, Rizvi A, Zafar M, et al. Health status and renal function evaluation of kidney vendors: a report from Pakistan. *Am J Transplant* 2008;8:1444-1450
- 4) Danovitch GM, Leichtman A. Kidney vending: The Trojan Horse of kidney transplantation. *Clin J Am Soc Nephrol* 2006;2:1133-1135.
- 5) Danovitch G. Cash, rewards, and benefits in organ transplantation: an open letter to Senator Arlen Specter. *Curr Opin Organ Transplant*. 14:129-133;2009

[8] NOTA: The National Organ Transplant Act (1984 Pub.L 98-507), approved October 19, 1984 and amended in 1988 and 1990, outlawed the sale of human organs.

[9] <http://www.uktransplant.org>.

[10] [www.declarationofistanbul.org](http://www.declarationofistanbul.org)