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Gabriel Danovitch MD
Distinguished Professor of Medicine, David Geffen School of Medicine at UCLA
Medical Director, Kidney and Pancreas Transplant Program,
Ronald Reagan Medical Center at UCLA

How should the US Government and medical community respond to the continued use of executed prisoners as a source of organs for transplantation in China and the abuse of vulnerable living organ donors elsewhere?

It is my privilege to address this committee. I do so in my personal capacity as a Professor of Medicine at UCLA with a long career engaged in clinical organ transplantation, as a representative of The Transplantation Society (TTS) for which society I am Secretary, and as a representative of the Custodian Group of the Declaration of Istanbul (DICG) whose Patient Affairs Committee I co-chair. TTS (www.tts.org) is an international organization founded in 1966 of more than 5000 members with activities in more than 100 countries with organ transplantation services around the world. TTS

together with the International Society of Nephrology (ISN) cosponsored a most important international forum on transplantation ethics in 2008 leading to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism

(www.declarationofistanbul.org) which has been endorsed by over a hundred professional organizations and governmental agencies around the world.

The Declaration of Istanbul called for a prohibition of organ trafficking and organ trade and transplant tourism. It rejected the use of organs from executed prisoners.

During the late 1980's and 1990's technical expertise in organ transplantation spread across the world from the originating centers of excellence here in the United States, from Europe and from a limited number of developed Western economies such as Australia, to less developed healthcare environments across Asia, Eastern Europe, Latin America and the Indian Sub-continent. The phenomena of transplant commercialism and human organ trafficking metamorphosed during this spread of expertise from a small, hidden and limited activity such that by the turn of the century it had become a prominent and pervasive influence on organ transplantation throughout the world. The prevailing view amongst transplant physicians and surgeons in developed countries during the 1980's and 1990's was that paid organ "donation" was mostly limited to surgery undertaken by some individual "bad apples" in India, Pakistan, China and perhaps some other smaller emerging economies. It became, in the early years of the 21st Century, evident that this limited perspective was incompatible with the enormous growth in organ transplantation as a commercial "for-profit activity" especially with the rise of transplantation from executed prisoners in China for profit from wealthy foreigners from rich countries with poor transplantation healthcare infrastructure such as in the Middle East or where transplantation was curtailed for cultural reasons such as in Japan..

The governments of Colombia and Spain called attention to the problem in 2003 and asked that the World Health Organization (WHO) to enquire into the issue and determine if a revision of the 1991 Guiding Principles for organ donation and transplantation was required (1). TTS, which is a non-government organization (NGO) in official relation with the WHO was part of the consultation from the start, and built a mirror-image

professional strategy to the governmental WHO processes. TTS, in concert with the International Society of Nephrology (ISN), also examined the data and asked questions of the field to understand the truths in global organ commercialism and human organ trafficking. The answers were not reassuring and confirmed – as did the WHO – that malpractices were rampant, transplant commercialism and human organ trafficking were indeed taking place in China, Colombia, Egypt, Pakistan, The Philippines, India and in Eastern Europe amongst other places. It was clear to TTS and ISN that a professional code of practice was required irrespective of any decisions by governments. The Declaration of Istanbul was thus borne from this determination in 2008. In 2010, the World Health Assembly (WHA) endorsed a revised version of the WHO Guiding Principles on Cell, Tissue and Organ Transplantation (2). These guiding principles uphold those of the Declaration

With respect to China specifically, the practice of obtaining organs for transplantation from executed prisoners has been widely regarded as an unacceptable abrogation of human rights for decades. It was not until 2007 that expression of abhorrence of the practice and a series of practical steps to respond were published in a respected academic journal on behalf of professional transplant society- The Transplantation Society which included specific reference to these steps in its membership ethics statement (3). Prior to the Olympic Games in China in 2008 members of the Congress communicated with Chinese government to clarify the role of the Falun Gong as forced donors. Yet despite international condemnation, including recognition by highly placed government officials of the People's Republic of China that the practice is unacceptable and does not conform to international standards, it continues (4). In addition, according to Chinese law, it is illegal for foreigners to undergo transplantation in China from a deceased donor. This law is being flouted and Americans and others exploit the laxity in the fulfillment of these regulations and the culture of corruption that accompanies them that are recognized publically by Chinese authorities.

Americans who travel to China and elsewhere to purchase organs also do so at great risk. It has been well-documented that the medical outcomes of such transplants are poor;

mortality and morbidity rates are unacceptably high, and on their return to the US many such transplant recipients require long and complex hospital admissions and medical care as a result of life-threatening surgical and infectious complications. My own personal experience in this regard has been published (5)

The last decade has seen a welcomed sea-change in the nature of interaction between China and the rest of the world on many levels, such that it is hard to recall the near isolation of that great country a mere generation ago. Medical research from China commonly reaches the English-speaking world, medical exchange and training is common, and pharmaceutical companies do business on a massive level and conduct drug-development and clinical research. These normative and welcome interactions are now accompanied for the first time by submission of reports of organ transplant-related clinical experience and clinical research where the “donor” source has been executed prisoners. Overtly benign statements of the source of transplanted organs obscure the fact that deceased donor organ recovery in China involves death by execution and that those euphemistically described as ‘donating’ their organs were prisoners, whose ‘severe brain injury’ was most likely a result of execution by a gun-shot to the head. It is difficult to know for sure how many such “donation by execution” take place in China but it is safe to say that the numbers provided by the official China Liver Transplant Registry (www.cltr.org.cn), which reported over 21,000 cases in the period between January 1993 and August 2012, are likely to represent a low estimate: there may be many more.

What can the US medical community do?

The *American Journal of Transplantation* (AJT) is the official journal of the American Society of Transplantation (AST) and The American Society of Transplant Surgeons (ASTS). In an editorial commentary (6) in AJT on the publication of data obtained from transplants where executed prisoners were the donor source a series of options for action by the professional transplant community was proposed: these included

- International and national professional medical societies and journals should not accept abstracts, publications or presentations from Chinese transplant centers

unless the authors clearly indicate that the data presented is in concordance with the most recent Chinese government regulations regarding transplant tourism and that executed prisoners were not the source of organs.

- Membership of international professional societies by Chinese transplant professionals must be conditioned by acceptance of ethics policies that specifically express the unacceptability of executed prisoners as a source of organs.
- Pharmaceutical companies must ensure that no executed prisoners are the source of organs used in their studies and that Chinese government regulations regarding transplant tourism are adhered to rigorously.
- Training of Chinese transplant professionals by the international community must be conditioned on commitments that trainees will not engage, directly or indirectly, in the use of organs from executed prisoners.

Since May 2011, the *American Journal of Transplantation* routinely includes in the instructions to authors submitting manuscripts for publication the following statement:

“The *American Journal of Transplantation* (AJT) will not accept manuscripts whose data derives from transplants involving organs obtained from executed prisoners. Manuscripts writing about this practice (e.g. an editorial or a report recounting the secondary consequences of this practice) may be considered at the discretion of the Editorial Board, but require a written appeal to the Board prior to submission of the manuscript.”

The prestigious US Biomedical Research publication the *Journal of Clinical Investigation* published a specific editorial position statement regarding publication of articles on human organ transplantation opening with the following statement (7):

“The practice of transplanting organs from executed prisoners in China appears to be widespread. We vigorously condemn this practice and, effective immediately, will not consider manuscripts on human organ transplantation for publication unless appropriate non-coerced consent of the donor is provided and substantiated”.

Other steps have been taken. The website of the Declaration of Istanbul on organ Trafficking and Transplant Tourism (www.declarationofistanbul.org) includes a document on Policy for Meeting Content which includes the following statement

“All abstract submission forms should include a statement to the effect that ‘The authors attest that (a) all data (clinical finding, description of clinical material, etc) were derived from research and clinical activities carried out in accordance with the Principles of the Declaration of Istanbul and (b) executed prisoners were not the source or organs and tissues in any of the activities reported’.”

This policy was included in the instructions for abstract submission at the International Society for Organ Donation and Procurement (ISODP) meeting in Buenos Aires in November 2011 and at the World Transplant Congress in Berlin in July 2012.

What can the US Government do?

The new DS-160 US visa application form: "Security And Background : Part 3" includes the following new questions for all visa types: “Have you ever been directly involved in the coercive transplantation of human organs or bodily tissue?” Inclusion of this question represent official US Government recognition of the abrogation Human Rights that is intrinsic to commercial organ donation form both the living and the dead and that the use of organs and tissues from executed prisoners is intrinsically coercive. US law through the National Organ Transplant Act (NOTA (1984 Pub.L. 98-507) criminalizes commercial organ donation and the first prosecution under this Act has recently been successfully completed (8). Regulations of the United Network for Organ Donation (UNOS, available at www.unos.org) relating to the transplantation of non-US residents have been updated as of September 2012 and serve to increase the public transparency and accountability of this practice. Yet much remains to be done.

- NOTA criminalizes the buying and selling of organs in the US but says nothing of such practice outside of the US. Chinese Ministry of Health regulations officially prohibit the selling of both living and deceased donor organs to foreigners, yet

the practice continues. The US should prohibit US citizens from contravening the organ transplant laws of other countries and should work to achieve international consensus and agreement to that effect. NOTA should be given extraterritorial jurisdiction.

- All US residents returning to this country after receiving an organ transplant, performed, legally or illegally, in another country, should be required to declare this fact on their return. Such a policy would permit transparency and protect public health

- Through its good offices in China and elsewhere the US Government should make it clear that the use of organs from executed prisoners and the buying and selling of organs from the living and the dead, is an unacceptable abrogation of Human Rights.

- The US should be prepared to offer the Chinese authorities assistance in the developments of alternative, ethically acceptable, organ retrieval practice.

- The US Organ Procurement and Transplant Network (OPTN a branch of the Department of Health and Human Services) has accepted the Definitions of the Declaration of Istanbul and UNOS has accepted the Principles of the Declaration. Several governments now include reference to the Declaration in their transplant regulations. The US government should promote the Principles of the Declaration of Istanbul and the World Health Assembly both at home and abroad.

- Human trafficking for organ removal (HTOR) should be added to the Trafficking Victims Protection Act (TVPA)

- US companies should be prohibited from undertaking organ transplant-related clinical research activity or benefitting from the sale of equipment or pharmaceuticals if the source of the organs is from executed prisoners or commercial organ donation.

Concluding comments

Since the promulgation of the Declaration of Istanbul and under its influence positive changes have taken place in the organ transplant endeavors of several countries that were previously designated as “hotspots” of transplant tourism by the WHO; including India, Pakistan, Columbia, and the Philippines. Positive changes have also taken place in countries that had historically “exported” its citizens to receive organ transplant overseas; these include Israel, Gulf countries, and Japan (9). With respect to China, it should be emphasized that it is the intent of the suggestions listed in this document to provide succor to those in China and elsewhere who wish to see positive change. In this respect, to their credit, some Chinese Ministry of Health officials have indicated their intention to end the practice and pilot projects with the use of brain dead donors and are underway (10). TTS and DICG maintain active contact with colleagues in China who are working to develop ethically acceptable alternatives to the use of executed prisoner organs and commercial living donation. Yet the use of executed prisoner organs continues.

Expressions of good intentions are not enough. For the professional transplant community and government authorities it is not adequate to merely give lip service to our repugnance. We cannot control events in China, but:

- Professional organizations that control the content of their meetings and journals must continue to categorically insist that Chinese professionals apply internationally accepted ethical standards and work towards the day when Chinese organ transplantation will take its place as an honored and respected member of the international organ transplant community.
- Congress and can legislatively influence the behavior of US citizens.
- The State Department can call for a transparency of practice as it pertains to the products of human origin to make certain that the rights of individuals are not exploited through organ trade.

The US Congress leads the world in effecting acceptable organ transplant practice. The US needs to provide an example in its own practice and demonstrate lack of acceptance of anyone within US jurisdiction profiteering from the desperation of patients in need of transplantation, or the poor and vulnerable of the world for money, or from prisoners whose body parts are worth large sums of money when they are executed. The Transplantation Society and the Declaration of Istanbul Custodian Group seek the help of Congress and the State Department to set the example for the rest of the world so that individuals not be victimized for their organs.

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