American Journal of Transplantation 2016; 16: 3115–3120
Wiley Periodicals Inc.

Personal Viewpoint

doi: 10.1111/ajt.14014

Transplant Medicine in China: Need for Transparency and International Scrutiny Remains

T. Trey[1], A. Sharif[1,2], A. Schwarz[3], M. Fiatarone Singh[1,4] and J. Lavee[1,5,*]

[1]Doctors Against Forced Organ Harvesting, Washington, DC
[2]Department of Nephrology and Transplantation, Queen Elizabeth Hospital, Birmingham, United Kingdom
[3]Independent China researcher, Munich, Germany
[4]Exercise, Health and Performance, Faculty of Health Sciences and Sydney Medical School, University of Sydney, Sydney, Australia
[5]Heart Transplantation Unit, Department of Cardiac Surgery, Sheba Medical Center and the Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel
**Corresponding author: Jacob Lavee, jaylavee@netvision.net.il*

Previous publications have described unethical organ procurement procedures in the People's Republic of China. International awareness and condemnation contributed to the announcement abolishing the procurement of organs from executed prisoners starting from January 2015. Eighteen months after the announcement, and aligned with the upcoming International Congress of the Transplantation Society in Hong Kong, this paper revisits the topic and discusses whether the declared reform has indeed been implemented. China has neither addressed nor included in the reform a pledge to end the procurement of organs from prisoners of conscience, nor has the government initiated any legislative amendments. Recent reports have discussed an implausible discrepancy of officially reported steady annual transplant numbers and a steep expansion of the transplant infrastructure in China. This paper expresses the viewpoint that, in the current context, it is not possible to verify the veracity of the announced changes, and it thus remains premature to include China as an ethical partner in the international transplant community. Until we have independent and objective evidence of a complete cessation of unethical organ procurement from prisoners, the medical community has a professional responsibility to maintain the academic embargo on Chinese transplant professionals.

Abbreviations: COTRS, China Organ Transplant Response System; DICG, Declaration of Istanbul Custodian Group; DAFOH, Doctors Against Forced Organ Harvesting; DPMP, donors per million people in the population

Received 12 July 2016, revised 11 August 2016 and accepted for publication 13 August 2016

Introduction

In 2014, we published our original article in this journal on the issue of forced organ procurement from executed prisoners in China (1). In that article, we expressed our personal viewpoint regarding the evolution of modern Chinese transplantation practice, the development of forced organ procurement from prisoners (primarily prisoners of conscience) and the steps required to maintain international pressure on China to halt such unethical activity. Shortly following the publication of our paper, China announced the abolishment of the procurement of organs from executed prisoners starting from January 2015 and replacing them with voluntary organ donations of deceased citizens. The reaction within the medical community was divided (2), with some applauding the development; others reserved judgment without objective proof of cessation.

It is a moral imperative that any claims of cessation in the use of organs procured from executed prisoners in China be subject to critical appraisal. In light of significant events in the last 2 years, this paper revisits and evaluates current organ transplant practice in China. In short, we cannot conclude, based on any verifiable evidence to date, that ethical practices have replaced unethical ones. Emerging data (3) regarding the apparent actual vast magnitude of the ongoing transplant activity in China demand a new discussion, as they raise serious questions about the veracity of claims from China that the organ transplantation system is now operating under the ethical standards required by the international transplant community. As in the past, but even more urgently today, there is an unquestionable need for transparency and openness to scrutiny of what appears

to be, according to primary evidence, the world's largest transplant system.

What Has Changed Since January 2015?

Semantic language regarding cessation

In December 2014, it was announced (4) that China would end organ procurement from executed prisoners starting from January 2015. The announcement neither acknowledged nor included ending the practice of organ procurement from prisoners of conscience, primarily Falun Gong practitioners, which has been alleged since 2006 (5,6). After the announcement, there was no legislation replacing the 1984 provisional regulations (7), which permit organ procurement from executed prisoners. This has resulted in a legal ambiguity, with officials announcing an end to organ procurement from executed prisoners while the legal framework continues to permit the practice.

Various media interviews in the first half of 2015 (2,8) added further confusion to the legal definition of an organ donor in China. Remarkably, death row prisoners had the right to donate organs, and these should be considered similar to organ donations from citizens (2), thereby allowing their inclusion in the public organ donation system. This underlying vagueness has been described as a "semantic trick" (9) in the medical press. In the second half of 2015, the use of prisoners' organs could not be ruled out, although it was intimated that this practice was illegal and that these organs were no longer being used in the state-run system that administers organ donation and distribution (8). Even the website of the China Organ Transplantation Development Foundation, lauded as an instrument of reform, says that "prisoners can also donate organs" (10), thus making the practical strength of any changes questionable.

China Organ Transplant Response System (COTRS)

As part of the stated reform in the organ donation and transplantation system, China has set up the COTRS, a computerized organ allocation system that ostensibly promotes transparency. However, there is no transparency about the source of organs actually being entered into the COTRS computer database. In the absence of any ethical checks, COTRS simply becomes a more efficient mechanism for allocating organs, without distinguishing unethically procured from voluntary donated organs.

Data discrepancy between COTRS and independent investigators

Investigative work contradicts the data supplied by COTRS and makes clear that a great deal of secrecy still surrounds transplantation activity in China. China provides only aggregate national transplant figures, but detailed figures for all transplanted organs from deceased and living donors, on an individual transplant center basis, are necessary for true transparency and scrutiny. China's registries for kidney, liver, lung and heart transplantations do not publish detailed statistics (11), and the aggregate statistics are difficult to reconcile (3). Specifically, the transplant infrastructure in China has expanded much more than would be suggested by the steady national transplant figure of 10 000 per year (12) over the past decade. Based on a vast array of analysis and references, the report concludes that transplant departments across China increased bed counts, transplant teams, investment and gross revenues by large amounts, in contrast to the officially reported plateau. A striking example of the urgent need for transparency and scrutiny is the history of the Oriental Organ Transplant Center in Tianjin, which appears to have performed a much higher volume of transplants than it officially reports or than death row prisoners could support (13). Critical evaluation of this primary data raises serious doubts about the integrity of "official" COTRS numbers.

Voluntary organ donation in China

Instead of relying on organs obtained from executed prisoners, China claims to have implemented a new voluntary organ donation system, and organ donation numbers are reported on the website of the China Organ Donation Administrative Center (14). Yet the numbers are difficult to verify. Although the voluntary organ donation system was established only in 2013, it is quite remarkable that it has yielded a substantial number of transplant organs so soon after its inception. Within just 2 years, China claims that 2766 volunteers donated major organs after death in 2015 and that 7785 (15) transplants were performed that year—presumably fully replacing all organs previously obtained from executed prisoners with legitimately obtained organs from voluntary donors.

The recruitment of this number of donors within such a short time seems implausible for many reasons. First, there is no brain death regulation in China (16), which means that all legal donations would have to follow circulatory death in situations where vital organs were not compromised, thus limiting the potential donor pool. Second, there is a traditionally rooted reluctance to donate organs in China, based upon the cultural beliefs that a person's body must be buried intact, as evidenced in a very low organ donation rate of less than one donor per million people in the population (DPMP) a few years ago (17); this is still evident in the extremely low number of registrants for organ donation (70 217 in June 2016 [14]) relative to the size of the Chinese population compared to 26.6 DPMP in the United States, where almost 50% of the population is registered. Third, the phenomenon whereby an impressive consent rate for organ donation by families of deceased donors has been achieved so rapidly in a society that, until recently,

universally shunned such practice highlights reports that these "voluntary" donors were recruited unethically by offering the donors (often poor and rural families) cash payments for donating their deceased relative's organs (18), in amounts that are sometimes equivalent to many years' wages (19). This practice has been recently and unequivocally denounced by the Declaration of Istanbul Custodian Group (DICG) (20). Such a practice can be considered coercive, and as the DICG has stated,

. . .countries should not establish or allow others to operate public or private programs that pay money to, or for the benefit of, next of kin who consent to donate their deceased relative's organs, whether such payments are for funeral expenses, to cover charges for pre-donation hospital care, to relieve their poverty, or especially to incentivize their decision.

Transparency and scrutiny are necessary for any monetary incentives given to deceased-donor families to exclude such coercive practices.

In summary, (1) the organ donation and transplantation system in China remains incompletely transparent and thus remains open to scrutiny; (2) the alleged forced organ procurement from prisoners of conscience has not yet been acknowledged, and its independent investigation and scrutiny has not been allowed; and (3) the provisional regulations from 1984 that permit the procurement of organs from executed prisoners have not yet been repealed; there is no law that would prohibit such practice, and China's own transplantation non governmental organization says that prisoners may still "donate" their organs.

Professional and academic engagement with Chinese transplantation professionals

Hosting the Transplantation Society 2016 Biennial Congress in Hong Kong has provided an opportunity to showcase clinical science abstracts from China on an international stage and gives further legitimacy to China to continue with its current practice. Although Chinese professionals have been required to promise ethically

Table 1: Potential unethical organ sources in abstracts accepted for The Transplantation Society 2016 Congress in Hong Kong

Abstract title	Abstract URL	Ethical concerns about organ sources
Conversion from mycophenolate mofetil to mizoribine and its therapeutic exposure in Chinese renal transplant recipients with leucopenia	https://confman.tts2016.org/mobis/lecture/2019	Study uses transplant cases from 2006 to 2007, when no organ donation system was used and organs were procured from prisoners (executed/of conscience)
Outcomes of kidney transplantation from DBD, DCD or DBCD donors: A single center experience from China	https://confman.tts2016.org/mobis/lecture/1902	Study uses transplant cases from 2011 to 2014 and states use of DBD, but China does not have a DBD regulation
Hemodynamics in transplant renal artery investigated by computational fluid dynamics	https://confman.tts2016.org/mobis/lecture/1636	No information on study year, so cannot rule out use of prisoners' organs
Pathological analysis of 544 cases of indicated renal allograft biopsies	https://confman.tts2016.org/mobis/lecture/1942	The study years (2010–2015) partially overlap prevoluntary donor system, so cannot rule out use of prisoners' organs
Comparison of kidney transplantation from living and deceased donation: A consecutive data analysis since implement of donation after citizen's death in China	https://confman.tts2016.org/mobis/lecture/1973	Study (2010–2015) compares 389 living-related kidney donations to 269 cases from Chinese donation after citizen's death (CDCD); how was this verified?
Effect of machine perfusion and urokinase on the kidney transplants with glomerular thrombosis	https://confman.tts2016.org/mobis/lecture/1291	No information on study year, so cannot rule out use of prisoners' organs
Kidney transplantation from donors with rhabdomyolysis and acute renal failure: A report of 16 cases	https://confman.tts2016.org/mobis/lecture/1469	The study years (2012–2015) partially overlap prevoluntary donor system, so cannot rule out use of prisoners' organs
BK polyomavirus prophylaxis with ciprofloxacin in kidney transplant recipients: A prospective study	https://confman.tts2016.org/mobis/lecture/1911	Study time (2013–2014) falls into the early phase of the organ donation program; still overlapping with organ procurement from prisoners, so cannot rule out use of prisoners' organs
Influencing factors of fatigue in liver transplant recipients	https://confman.tts2016.org/mobis/lecture/1318	No information on study year, so cannot rule out use of prisoners' organs
Health-related quality of life and its influencing factors in Chinese renal transplant recipients	https://confman.tts2016.org/mobis/lecture/1749	No information on study year, so cannot rule out use of prisoners' organs

DBD, donation after brain death; DCD, donation after circulatory death; DBCD, donation after circulatory and brain death.

sourced organs for their research, there has been no verification of this guarantee, and serious questions remain about the ethical nature of many clinical abstracts that made their way into the final program (Table 1) (21). In addition, the congress will feature key Chinese transplant surgeons as invited speakers, many of whom were personally involved in the use of organs from prisoners (21). The acceptance of such individuals as professional peers is decidedly not a message the international transplantation community should be conveying. Instead, the Transplantation Society should have followed the example recently set by the International Society for Heart and Lung Transplantation (ISHLT), which included the following guideline in the instructions for abstract submission for its 37th Annual Meeting 22):

Due to ongoing concerns about compliance with the Declaration of Istanbul and the ISHLT Statement on Transplant Ethics, abstracts related to transplantation and involving either organs or tissue from human donors in China will not be accepted for consideration for the 2017 Annual Meeting. This policy will be reviewed on an annual basis

Reaction of Political Bodies

The aforementioned concerns and lack of evidence for substantial objective change have led some international political bodies and institutions to take legislative steps to condemn the continued practice of illegal and unethical organ procurement in China. The most recent recognition of the issue occurred in the U.S. Congress, where the House of Representatives passed House Resolution 343 (23) unanimously on June 13, 2016, condemning the use of organs from prisoners, including prisoners of conscience. In 2015, the Taiwanese Yuan (24) adopted amendments to the transplant law that restricts traveling to China for the purpose of acquiring a transplant, and the Italian Senate (25) unanimously passed a bill to confront unethical organ recovery. In 2014, the Canadian Subcommittee on International Human Rights (26) passed a motion condemning China's practice of forced organ recovery. In 2013, the European Parliament (27) passed a resolution that condemned the practice and asked for further steps to end this abuse. In 2013, Doctors Against Forced Organ Harvesting (DAFOH) presented a petition with 1.5 million signatures addressed to the United Nations High Commissioner for Human Rights calling for an end to China's forced organ procurement practice (28). On multiple occasions, the petition was brought to the attention of the UN bodies, but no response has been received to date.

What Can the International Community Do?

Without independent verification, no assumption can be made that organ procurement from executed prisoners in China has stopped. Independent inspection is required to ensure that this practice is not continuing but with alternative labeling or classification. Discrepancy between the officially declared national number of transplants and those allegedly identified in the independent research should raise concerns about the validity of COTRS.

Transparent access to data is a basic requirement of audit and governance processes for organ donation and transplantation activity, without which verification is impossible. In regard to transplantation medicine, the World Health Organization incorporates the demand for transparency into its Guiding Principles for organ donation and transplantation (29), and compliance with transparency and openness to scrutiny should be a basic requirement that applies to all members of the transplant community. In order to verify the announced claims from China that the unethical organ procurement from executed prisoners ceased in 2015, transparent access is indispensable. Prearranged and prescheduled tours of only 6 out of the officially approved 169 transplant centers occurred in 2015 (30); these tours did not occur in any of the remaining active transplant centers. These do not constitute independent, unrestricted or objective inspections of the type urgently warranted to robustly investigate any claim of complete cessation. Requirements include: (1) open access to review organ donation processes and verify sources, (2) the ability to review all transplantation facilities (military and civilian), and (3) the ability to probe data registries to cross-check donation and transplantation activity numbers.

To achieve these aims, consistent pressure from both political and professional bodies is critical to force China to bring an end to forced organ procurement from both executed prisoners and prisoners of conscience. Maintaining and expanding the academic boycott of clinical transplantation articles provides strong motivation for China to bring itself out from international isolation; conversely, relaxing pressure from the international community provides no encouragement for change. While efforts to support China during such a transition are welcome, these must be on the basis of a complete cessation of the use of organs from executed prisoners and prisoners of conscience. Otherwise, such interventions could potentially worsen the situation by helping China add sophistication and expertise to an unethical system of organ donation and transplantation.

Conclusion

Given the allegations of crimes against humanity in China in the form of the killing of executed prisoners and prisoners of conscience—mainly of Falun Gong practitioners—in a state-led, systematic process, demands for transparency are indispensable. The inclusion of China in the international transplant community

must be strictly dependent upon the independent verification of a complete cessation in the use of organs procured from executed prisoners, acknowledgment from China of the previous use of prisoners of conscience for their organs and the repeal of legislation that still permits the practice. As the global transplant community converges on Hong Kong for the congress of the Transplantation Society, it is both timely and imperative to remind the transplantation community of the plight of victims of forced organ procurement that, on the basis of current evidence, continues to this day in China.

Disclosure

The authors of this manuscript have conflicts of interest to disclose as described by the *American Journal of Transplantation*. Doctors Against Forced Organ Harvesting (DAFOH) is a charitable organization founded by medical doctors and is independent of Falun Gong. T.T. is the Executive Director of DAFOH, A.S. is the Secretary of DAFOH, and both M.F.S. and J.L. are members of the DAFOH Advisory Board.

References

1. Sharif A, Fiatarone Singh M, Trey T, Lavee J. Organ procurement from executed prisoners in China. Am J Transplant 2014: 14: 2246–2252.
2. Allison KC, Caplan A, Shapiro ME, et al. Historical development and current status of organ procurement from death-row prisoners in China. BMC Medical Ethics 2015; 16: 1–7. doi: 10.1186/s12910-015- 0074-0.
3. Kilgour D, Gutmann E, Matas D. Bloody Harvest/The Slaughter—An update. 2016 [cited 2016 Jul 8]. Available from: http://endorganpillaging.org/wp-content/uploads/2016/06/Bloody_Harvest-The_Slaughter-June-23-V2.pdf.
4. Hayden S. China makes a New Year's resolution: To stop harvesting the organs of executed prisoners. News Vice 2014 [cited 2016 Jul 8]. Available from: https://news.vice.com/article/china-makes-a-new-years-resolution-to-stop-harvesting-the-organs-of-executed-prisoners.
5. Kilgour D, Matas D. Bloody Harvest. 2007 [cited 2016 Jul 8]. Available from: http://organharvestinvestigation.net.
6. Gutmann E. The Slaughter. New York: Prometheus Books; 2014.
7. Provisional Regulations on the Use of Dead Bodies or Organs from Condemned Criminals. In: Organs for Sale: China's growing trade and ultimate violation of prisoners' rights. Hearing before the Subcommittee on International Operations and Human Rights of the Committee on International Relations, US House of Representatives, 2001 [cited 2016 Jul 8]. 50–51. Available from: https://catalog.hathitrust.org/Record/008519262.
8. Tatlow DK. Transplant chief in China denies breaking vow to ban prisoners' organs. New York Times 2015 [cited 2016 Jul 8]. Available from: http://www.nytimes.com/2015/11/26/world/asia/china-organ-transplants-prisoner-donations-huang-jiefu.html.
9. Allison KC, Paul NW, Shapiro ME, Els C, Li H. China's semantic trick with prisoner organs. BMJ Blog 2015 [cited 2016 Jul 8]. Available from: http://blogs.bmj.com/bmj/2015/10/08/chinas-semantic-trick-with-prisoner-organs/.
10. China Organ Transplantation Development Foundation, Frequently Asked Questions. [cited 2016 Aug 9]. Available from: http://www.yzjjh.org/index.php?m=content&c=index&a=show&catid=26&id=238.
11. Matas D. Transparency of organ donations in China. 2015 [cited 2016 Jul 8]. Available from: http://endorganpillaging.org/transparency-of-organ-donations-the-case-of-china/.
12. Juan S. Registry to open for organ donors. China Daily 2013 [cited 2016 Jul 8]. Available from: http://usa.chinadaily.com.cn/china/2013-06/13/content_16612435_2.htm.
13. Robertson M, Fang S. Investigative report: A hospital built for murder. Epoch Times 2016 [cited 2016 Jul 8]. Available from: http://www.theepochtimes.com/n3/1958171-china-hospital-builtformurder/4/.
14. China Organ Donation Administrative Center. [cited 2016 Jul 8]. Available from: http://www.china-organdonation.org/ (Chinese).
15. Chinese organ donation on the rise. Xinhua 2016 [cited 2016 Jul 8]. Available from: http://news.xinhuanet.com/english/2016-04/01/c_135243312.htm.
16. Huang J, Millis JM, Mao Y, Millis MA, Sang X, Zhong S. Voluntary organ donation system adapted to Chinese cultural values and social reality. Liver Transplant 2015; 21: 419–422.
17. China to stop harvesting executed prisoners' organs. BBC 2014 [cited 2016 Jul 8]. Available from: http://www.bbc.com/news/world-asia-china-30324440.
18. Wu X, Fang Q. Financial compensation for deceased organ donation in China. J Med Ethics 2013; 39: 378–379.
19. Robertson M. China tries paying for organs. Epoch Times 2013 [cited 2016 Jul 8]. Available from: http://www.theepochtimes.com/n3/46985-china-tries-paying-for-organs/.
20. Statement of the Declaration of Istanbul Custodian Group Regarding Payments to Families of Deceased Organ Donors. Transplantation Online 2016 [cited 2016 Jul 8]. Available from: http://www.declarationofistanbul.org/resources/policy-documents/675-dicg-statement-regarding-payments-to-families-of-deceased-organ-donors.
21. Robertson M. A transplant conference plays host to China, and its surgeons accused of killing. Epoch Times 2016 [cited 2016 Aug 9]. Available from: http://www.theepochtimes.com/n3/2130297-a-transplant-conference-plays-host-to-china-and-its-surgeons-accused-of-killing/.
22. International Society for Heart and Lung Transplantation. Abstract submission instructions. [cited 2016 Aug 16]. Available from: http://www.ishlt.org/ContentDocuments/ISHLT_Call4Abstracts_2017.pdf.
23. US House Resolution 343. Expressing concern regarding persistent and credible reports of systematic, state-sanctioned organ harvesting from non-consenting prisoners of conscience in the People's Republic of China, including from large numbers of Falun Gong practitioners and members of other religious and ethnic minority groups. 2016 [cited 2016 Jul 8]. Available from: https://www.congress.gov/bill/114th-congress/house-resolution/343.
24. Taiwan to ban trade in human organs after new rules are given the nod. The China Post 2015 [cited 2016 Jul 8]. Available from: http://m.chinapost.com.tw/taiwan/2015/06/15/438466/Taiwan-to.htm.
25. Cassano V. Italy censures China organ harvest with Senate Bill. Epoch Times 2015 [cited 2016 Jul 8]. Available from: http://www.theepochtimes.com/n3/1276265-italy-censures-china-organ-harvest-with-senate-bill/print/.

26. Statement of the Subcommittee on International Human Rights of the Standing Committee on Foreign Affairs and International Development of the Parliament of Canada. 2014 [cited 2016 Jul 8]. Available from: http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6769309&Language=E&Mode=1.
27. European Parliament resolution on organ harvesting in China. 2013 [cited 2016 Jul 8]. Available from: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2013-0603&language=EN&ring=P7-RC-2013-0562.
28. Doctors Against Forced Organ Harvesting. 2013 [cited 2016 Jul 8]. Available from: http://www.dafoh.org/1-5-million-people-worldwide-sign-petition-to-un-high-commissioner-for-human-rights/.
29. WHO Guiding Principles on human cell, tissue and organ transplantation. [cited 2016 Jul 8]. Available from: http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf.
30. The First Affiliated Hospital of Xi and Jiaotong University. [cited 2016 Jul 8]. Available from: http://www.dyyy.xjtu.edu.cn/info/1779/13602.htm (Chinese).