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Papers based on data concerning organs from executed prisoners should not be published: Response to Zheng and Yan

To The Editors,

Thank you for the opportunity to respond to the unpublished letter by Zheng and Yan regarding the provenance of the transplant organs reported in Yu et al.[1]

Shusen Zheng and Sheng Yan offer no proof whatsoever concerning the source of the organs reported in their research, therefore, we respectfully urge you to proceed with retraction of the paper. Instead of proof, Zheng and Yan merely repeat unverifiable assertions. Here, we analyse in detail the alleged evidence they have provided to show how it undermines, rather than proves, their claims.

First, they "declare that all organs were recovered from donors after cardiac death and no grafts obtained from executed prisoners were used." This is merely a repetition of the original assertion in the paper.

Second, they report "All transplants were registered at China Liver Transplant Registry (CLTR, www.cltr.org)." As this registry is not open to independent or public scrutiny, it is not possible to know what information is collected in the registry and whether this could provide reliable evidence about the source of transplanted livers. The CLTR was established in 2005, when nearly all organs in China were sourced from prisoners – thus, unethically obtained organs have been recorded in this registry for over a decade. Even if the transplants were registered, this would not constitute proof that the organs were retrieved from volunteer donors.

Third, Zheng and Yan claim that "The pilot program pertaining [to] donation after cardiac death (DCD) was initiated on March 2, 2010 by Chinese Ministry of Health and Red Cross in order to eventually abandon the donor organs from executed prisoners." This point is important because it is an open admission that the aim of the pilot programme is to commence the *eventual* move away from the use of organs from executed prisoners. Any reasonable reading of this remark implies that organs from prisoners continued to be used alongside the pilot. Using prisoner organs was still official *spoken* policy until 1 January 2015. After that date, it became official policy to deny that prisoner organs were used – yet there are currently no laws or regulations against this, no monitoring mechanisms to prevent it, and no rescinsion of the 1984 regulation allowing use of prisoner organs. The leadership of TTS made clear in Hong Kong, August 2016, that it does not believe that China has ceased use of prisoner organs.[2]

Importantly, the pilot project for DCD volunteer donors, while announced in 2010, did not begin in Zhejiang (the site of the reported research) until 2011:

> 我国 *DCD* 管理体系的正式建设始于 *2010* 年,*2011* 年在浙江、广东、天津等部分地区开展试点工作。.[3]
>
> *China's DCD management system was formally established in 2010; in 2011 pilot work was launched in Zhejiang, Guangdong, and Tianjin, among other places.*

In fact, an official circular from the Zhejiang Province Department of Health to hospitals in Zhejiang about the pilot programme, which lists the hospitals and the transplants they are authorised to do by DCD, is dated October 18, 2011.[4] This makes clear that the programme did not start in Zhejiang until at least late 2011. Moreover, the institution of the authors is the First Affiliated Hospital, School of Medicine, Zhejiang University. According to the Zhejiang provincial circular cited above, this hospital was enrolled in the pilot only to do heart transplants, not liver transplants. According to the Ministry of Health, the pilot was to run until May 2012.[5] In sum, even if some liver transplants were performed as part of the pilot (despite the lack of authorisation), and even if some of the organs reported in the Yu et al. paper came from the pilot DCD programme, the programme did not start in their hospital until late 2011. This means that for at least the first 18 months of their research, the *only* source of organs was from executed prisoners. Furthermore, the pilot programme operated for several years alongside the use of prisoner organs, so the fact that the Zhejiang was one of the pilot sites does not constitute proof that volunteer organs only were used in the research.

Rather than support their assertion, Zheng and Yan have provided evidence to show that there was *no* voluntary donation programme during the first 18 months of their research.

Fourth, Zheng and Yan claim that Chinese methods lead to a success rate of 90% for retrieval of livers from DCD donors. The paper cited in their letter contains no such clinical evidence.[6] Instead, there is reporting of factors that may increase organ retrieval success:

> 使用严格的供者标准,包括 *BMI<29kg/m2* 和功能性热缺血时间 *<20min(*收缩压 *<50mmHg=*, 从供者停搏至开始灌注的时间 *<10min,DCD*可达 到与 *DBD*供肝相同的移植成功率 *[10-11, 14-22]*
>
> *By using strict donor criteria, including BMI of less than 29 kg/m^2 and functional WIT of less than 20 minutes (systolic blood pressure of <50 mmHg), with perfusion beginning 10 minutes within cessation of heart beat, DCD can achieve similar organ transplantation success as DBD.[10-11,14-22]*

The references in this extract (10-11, 14-22) are all to English-language papers reporting on DCD liver retrieval and transplantation in Western countries. There is no data from Chinese sources, thus no evidence that retrieval success rates are 90% in China. Instead, this reference is a consensus paper about diagnostic criteria for DCD, the procurement of organs, evaluation of organs and perioperative management of recipients (details from English-language abstract). It is not proof about the effectiveness of DCD retrievals in China. Absent such proof, it is reasonable to presume that DCD retrieval rates in China are similar to those in the rest of the world, suggesting that it would not have been possible to source all of the livers reported in Yu et al.'s research from the pilot programme.

Zheng himself has affirmed this supposition. At the second Chinese Transplant Doctor's Congress in 2015, he stated: "Due to the challenges facing DCD organ donation in quality of donor organs, in the last few years Chinese scholars have been working hard to transition from DCD donation to DBD donation. Everyone knows that brain death donor organs are far superior in quality to DCD donor organs."[7] This statement contradicts the claim in Zheng and Yan's letter, that China's DCD system yields a retrieval rate of over 90%.

The continued extensive use of prisoner organs past 2010 is also made clear by a presentation given by Zheng, again at the 2nd Chinese Transplant Doctor's Congress in 2015, titled "China's Liver Transplant Situation and Challenges." In it he provides a slide comparing the total number of liver transplants in China vs. those obtained via DCD, showing very small total figures until around 2013. The graph he provides indicates that in 2010 and 2011, DCD livers only constituted 1.38% and 4.94% of liver transplants in China.[8]

In summary, your demand for proof about the ethical sourcing of organs has not been met. Instead, the authors have repeated unverifiable claims and provided misleading references that undermine, rather than support their assertions.

We urge you not to accept the misleading information in the Zheng and Yan letter as proof of ethical sourcing of organs in China. To do so is an implicit acceptance of using organs procured from executed prisoners, and paves the way for further submissions containing false claims about organ procurement. In addition, there will be little impetus for true reform of China's organ donation system unless Chinese authors are strictly held to international ethical standards.

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CONFLICTS OF INTEREST

The authors have no financial or other conflicts of interest to declare.

Wendy A. Rogers[1]
Maria A. Fiatarone Singh[2]
Jacob Lavee[3]

[1]*Department of Philosophy and Department of Clinical Medicine, Macquarie University, Sydney, NSW, Australia*
[2]*Health and Performance Research Group, Faculty of Health Sciences, University of Sydney, Sydney, NSW, Australia*
[3]*Department of Cardiac Surgery, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel*

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