A pilot programme of organ donation after cardiac death in China

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Lancet 2012; 379: 862–65
Published Online November 11, 2011
DOI:10.1016/S0140-6736(11)61086-6

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China's aims are to develop an ethical and sustainable organ transplantation system for the Chinese people and to be accepted as a responsible member of the international transplantation community. In 2007, China implemented the Regulation on Human Organ Transplantation, which was the first step towards the establishment of a voluntary organ donation system. Although progress has been made, several ethical and legal issues associated with transplantation in China remain, including the use of organs from executed prisoners, organ scarcity, the illegal organ trade, and transplantation tourism. In this Health Policy article we outline the standards used to define cardiac death in China and a legal and procedural framework for an organ donation system based on voluntary donation after cardiac death that adheres to both China's social and cultural principles and international transplantation standards.

Introduction

China's organ transplantation programme began in the 1960s and since then has helped thousands of patients with end-stage organ disease. About 10 000 transplantations are done every year in China. However, until 2007, no legal framework for national oversight of China's transplantation system existed. Transplantation requires regulation by relevant governmental agencies to protect the rights of donors, who gain no direct physical benefit from donation. These regulations should minimise coercion of donors for personal or financial gain, prevent wastage of donated organs by ensuring transplantation centres have good track records of organ and patient survival, and ensure that recipient selection is transparent and based on need, rather than driven by commercial forces. Importantly, access to organs should be geographically broad enough to ensure that organs go to the most suitable candidate. Finally, regular review is needed to ensure compliance with the regulations.

In 2007, the Chinese Ministry of Health published the Regulation on Human Organ Transplantation,[1] which outlined China's initial steps to regulate organ transplantation, establishing a trajectory that, if continued, will create a legal and sustainable voluntary organ donation system.[2,3] This document governs all transplantation programmes in China; institutions that do transplantations must abide by these regulations. Several challenges exist, such as the illegal organ trade and transplantation tourism, of which the reliance on prisoner organ donation, caused by a scarcity of citizen donors, is the most prominent.

Chinese medical professionals must help to provide answers to two crucial questions that will determine the future of transplantation in China. First, is the current source of organs for transplantation legal and ethical? Second, how should the government establish and enforce rules to govern transplantation?

The use of organs from executed prisoners

The use of organs from executed prisoners is common in developing organ transplantation systems previous to the establishment of voluntary deceased donor systems (which usually occurs in tandem with socioeconomic advances).[4,5] China is the only country to systematically use organs from executed prisoners in transplantation procedures. 65% of transplantation operations done in China use organs from deceased donors, over 90% of whom were executed prisoners. The other 35% of transplantations use organs from live donors.[6] Although not banned by the 2007 Regulation, the practice of using the organs of executed prisoners has long been criticised as profit-driven and unethical, with critics arguing that inmates sentenced to death might feel pressured to become donors, which could violate their personal, religious, or cultural beliefs.[7] The Chinese Ministry of Justice has mandated that the removal of a prisoner's organs can only go ahead if informed consent has been obtained from either the prisoner or their family, but the effectiveness of this mandate has yet to be determined. In a developing country as large as China, the dissemination of orders down to local authority level is a difficult task, so these legal reforms might not be uniformly enforced. Moreover, the ethical question of whether a prisoner has freedom of choice in this decision remains.[8]

The continuation of practices prohibited by the 2007 regulations (transplantation tourism in particular) has caused controversy in the international transplantation community. To curb such practices, doctors who do not comply with the 2007 regulations should be disciplined and their qualification to hold a licence for transplantation should be reassessed. Most transplantation doctors in China avoid discussion of organ procurement in international academic forums because they feel ashamed of the topic.[9] However, they feel compelled to operate within the system to help their patients.

Fewer death sentences are delivered in China with each passing year, and according to the Department of Justice the long-term goal for social and economic development in China is to abolish the death penalty. With the number of death-penalty cases decreasing, ultimately to none, without establishing a voluntary donation system, severe shortage of donor organs is inevitable.

Living organ donation in China

The reduction in organ supply from the prison system has resulted in a rapid increase in the number of organ transplantations from living donors, which generates a new set of challenges. In an adult living liver transplantation, more than half of the donor's liver is resected, and over 30% of donors have complications of varying severity, including death.[10–12] Ministry of Health data show that complications after living liver transplantation have caused the deaths of at least five healthy donors in China between 2001 and 2006. Living kidney transplantation is associated with less risk than liver transplantation, but could still adversely affect the physical health of the donor.

Because of these risks to the donor, living organ transplantation is considered a last resort;[13] China's health-care capabilities and health financial policy discourage the promotion of these surgeries. The health-care reform plan introduced in 2009 to develop universal insurance coverage for essential health services, does not cover complications from living donor operations. Even in developed countries, the high cost of organ transplantation is a source of continued controversy and, in countries without universal health care, the living donor not having health insurance is often a contraindication for donation.

The Regulation on Human Organ Transplantation strictly stipulates that living organ donation is limited to relatives. Unfortunately, due to extreme demand, limited supply, and huge profits, an illegal trade in human organs from living donors has emerged in China. This practice violates the principle of equity adopted in China's health reform. To effectively regulate living donor organ transplantation, the Ministry of Health has introduced new policies, such as a requirement for approval from a provincial-level health department for every living donor organ transplantation. However, we cannot depend on containment strategies to solve the problem; rather, we need to improve access to donor organs by deepening the voluntary organ donor pool.

Donation after brain death

Over 90 countries use brain death as the criterion to declare death, but since organ transplantation's inception in China in the 1960s, cardiac death has been used. Many medical professionals in China advise that we should adopt brain death as our standard criterion, and in 2003, the Chinese Ministry of Health investigated this possibility and published technical diagnostic criteria and operational specifications for brain death.[14,15] However, the public and even some medical workers had poor understanding of the concept, and legislation on the adoption of brain death as the standard was subsequently not endorsed.[16–19] With the improved dissemination of science and education in China, the Ministry of Health will promote brain death criterion when society is more ready to discuss and accept such a concept. In the absence of such legislation, the current recommendation is to use cardiac death as the standard criteria, but in some circumstances (described later), the patient's next of kin or legal representative in consultation with the patient's physicians will be allowed to choose which criterion to use to determine death.Irrespective of the criterion used, standardised definitions for each are necessary.

Donation after cardiac death

Cultural resistance to organ donation in China is often based in the traditional Confucianist view that the bodies of dead people should be kept intact, but these beliefs are becoming less common as economic and social development progresses.[17] A survey of 606 undergraduate students in the cities of Wuhan and Guangzhou showed that 34% were willing to be organ donors, 17·3–23·0% were against donation, and 41·7–48·5% were undecided.[20] In a survey of families whose loved ones donated organs after death, 85–90% felt the act had a positive effect during their grieving period.[21] In 2006, there were 8·9 million deaths in China; 17·1% of these people died from cardiovascular diseases, 17·7% from cerebrovascular diseases, and 6·1% from stroke or trauma, which includes over 60 000 from traffic accidents.[22,23] Thus, China has a large pool of potentially suitable donor organs.

Organ donation should proceed only if at least one of the following conditions is met: the deceased has expressed a willingness to be an organ donor in either a living will or another written form; their closest relative provides written consent for organ donation, provided that the potential donor had not expressed opposition to donation previous to his or her death; or the potential organ donor orally expressed a will to donate while in a conscious state in the presence of two doctors who are not part of the organ procurement and transplantation team, and the donor's close relatives do not object to organ donation.

Our proposed donation after cardiac death pilot programme will register people who are willing to donate their organs after death in a national database (to be called the National Organ Deceased Donor Database). To encourage people to register, we will appeal to altruism and community spirit. A fund will also be set up to ensure that organ donation does not negatively affect the donor family's financial situation, but will not issue payments. Instead, non-financial compensation such as thank-you letters to the donor family, honorary titles, and commemoratory parks will be offered to boost the voluntary spirit.[24]

Legal framework for donation after cardiac death

To establish a deceased donor system that is consistent with China's social and economic development a legal framework must be put in place in accordance with WHO guidelines on organ transplantation. Such a framework must include a third party non-profit organisation to implement donation policy with the authority of the law. The Red Cross will fulfil this role in our system. Once potential donors have been identified by their care team, the Red Cross or the organ procurement organisation will

Panel: **Maastricht criteria of donation after cardiac death**

Type 1: patient is dead on arrival
Type 2: unsuccessful emergency resuscitation
Type 3: imminent cardiac arrest in intensive-care unit after withdrawal of life support
Type 4: cardiac arrest during or after brain death diagnostic procedure
Type 5: unexpected cardiac arrest in intensive care

discuss the possibility of organ donation with the family. The role also involves charging organ recipients for the costs associated with development of the donor system and for the costs associated with the placement of organs, such as care for the donor and transportation of the organ. The charge to the recipient will be the same regardless of the financial status of the recipient (ie, the organ will not be placed to the highest bidder). Health-care professionals responsible for making decisions regarding discontinuation of cardiopulmonary resuscitation to the potential donor must be completely distinct from the organ donation coordinators who are responsible for the assessment of patients as donors and for approaching their families.

In 1995, the Maastricht criteria of donation after cardiac death were proposed,[25] with a fifth criterion subsequently added in 2000 (panel).[26] The five Maastricht types can be categorised into two groups: controlled (types 3 and 4) and uncontrolled (types 1, 2, and 5). Controlled donors will probably make up most potential donors in China. Controlled donation allows for extensive discussion with the family and prospective allocation of organs, removal of life support timed with arrival of the procurement team, and minimises warm and cold ischaemia time. Uncontrolled DCD donors require a much greater allocation of hospital resources and provide significantly inferior organs in terms of graft function and survival. Uncontrolled DCD donors will not be considered suitable organ donors in the pilot scheme.

The Maastricht criteria allow for patient progression to brain death, but because brain death regulations have not been established, the Chinese cardiac death criteria will be different. We propose that donation after cardiac death according to the Maastricht categorisation is limited to Maastricht types 3 and 4 because types 1, 2, and 5 provide organs with increased risk of transplantation failure. There will be a transitional period when all donors will be regarded as donation after cardiac death even if they would meet brain death criteria in more developed countries, because of the current lack of brain death regulation (similar to category 4 in Maastricht criteria).

International standards for donation after brain death could be used in cases where brain death has been declared after medical evaluation, the donor's family has given informed consent, and an ethics committee has given its approval.[27] Donors after brain death who do not meet these criteria, but whose family members agree to donation after cardiac death will be treated as donors after cardiac death—hence, almost all donors will be managed as such donors.

Led by a national organ donor and transplantation committee and coordinated by the Chinese Ministry of Health and Red Cross, we will establish the Chinese Organ Transplant Response System. This organisation will consist of four modules: recipient administration; waiting list administration; donor administration; and organ distribution and matching, and will strictly follow the Ministry of Health protocol titled "The basic principle of Chinese human organ distribution and sharing and core policy of liver and kidney transplant". The committees established to develop these four components will count transplantation professionals, government authorities, donor families, and recipients among their members, and the proceedings of their meetings will be open to the public. Foreign experts will be included as necessary. The Chinese Organ Transplant Response System will make the transplantation process transparent to the public, which will make it more credible. We believe that the success of this pilot programme for organ donation after cardiac death will lead to a sustainable and ethical organ transplantation system in China.

Contributors
All authors contributed to the drafting and critical revision of the manuscript and provided administrative and material support.

Conflicts of Interest
The Peking Union Medical College receives grant support from the China Medical Board for the time, meetings, and travel associated with the work described in this manuscript JMM and MAM have received funding from the China Medical Board for travel associated with the work described in this manuscript.

Acknowledgments
This work was supported by a China Medical Board grant (CMB 06-837). We thank ST Fan, Youmin Wu, Haibo Wang, Zhonghua Chen, Yongfeng Liu, Zhongyang Shen, Xiaoshun He, Jiahong Dong, and Jiye Zhu for their kindly contributions to this work.

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