

## ORIGINAL ARTICLE

**Transformation of organ donation in China**Lei Zhang,<sup>1,2</sup> Li Zeng,<sup>1</sup> Xinpu Gao,<sup>3</sup> Haibo Wang<sup>4</sup> and Youhua Zhu<sup>1,5</sup>

1 Shanghai Changzheng Hospital, Shanghai, China

2 Shanghai Organ Donation Office, Shanghai, China

3 China Organ Donation Management Center, Red Cross Society of China, Beijing, China

4 The China Organ Transplant Response System Research Center, Shenzhen, China

5 The Committee of Experts of China Organ Donation, China

**Keywords**

achievements, China, constrains, organ donation, solutions.

**Correspondence**

Professor Youhua Zhu, Shanghai Changzheng Hospital, Fengyang Road 415#, Shanghai 200003, China.

Tel: (86) 21 81885753;

fax: (86) 21 63524488;

e-mail: zhuyouhua@126.com

Dr. Haibo Wang, China Organ Transplant Response System Research Center, Shenzhen China.

Tel: (86) 18688828282;

fax: (86) 755 33319061;

e-mail: haibo@hku.hk

**Conflicts of interest**

The authors declare no conflicts of interest.

Received: 2 May 2014

Revision requested: 2 June 2014

Accepted: 21 September 2014

doi:10.1111/tri.12467

**Introduction**

Organ transplantation was introduced to China from the western world in the second half of the twentieth century. With the support from overseas experts, local pioneers in organ transplantation spent strenuous efforts in the past 40 years and have transformed the technique into a standard clinical procedure, saving many lives every year. However, due to historical reasons, the development of the organ donation system in China has far lagged behind international levels, with condemned prisoners being the main source of organs [1]. The quality and safety of the

**Summary**

The organ donation system in China has far lagged behind international levels. Transformation of this situation began in July 2005. A complete organ donation system that ensures fairness, impartiality, transparency, and respect for life has now been developed. This system is composed of regulations and policies, an organizational structure, operational guidelines, organ procurement organizations, registration of donors and recipients, and an organ allocation system. Since March 2010, pilot trials on donation after circulatory death (DCD) have been carried out. In 4 years, organ donation has started in 25 of 32 provinces in the country. From 2010 to 2013, the ratio of DCD liver transplantation to total case numbers in China rose from 1.38% to 26.1%, whereas for kidney, the ratio were 0.59% and 24.6%, respectively. The total number of DCD in China has accumulated to 1564 cases, and 4243 organs were transplanted. To alleviate the further difficulties of donation, establishment of professional organ procurement organizations in transplant hospitals, legislation of brain death, and promulgation of legal guidelines on DCD will be the main targets of organ donation development in China.

organ transplantation service are not guaranteed. Furthermore, the international community has widely criticized the use of organs from executed prisoners in transplantation, hindering the advancement in this area [2]. It has become one of the most pressing problems threatening the development of organ transplantation in China.

**Methods****Establishment of a donation system**

At the World Health Organization Transplantation Senior Management Conference held in July 2005, Professor Jiefu

Huang, then Vice Minister of Health of China, for the first time admitted publicly to the international community of the source of organs for transplantation in China and stressed the Chinese Government's pledge to strengthen supervision of organ transplantation in the country [3]. Since then, transformation of organ donation in China has begun. To achieve the objective of developing an organ donation system in China and eliminating the use of organs from condemned prisoners [4], the Ministry of Health has established relevant government departments and consulted internationally renowned experts for solutions. A complete donation system has been developed. It is composed of regulations and policies, organizational structure, operational guidelines and criteria, organ procurement, registration of donors and recipients, an organ allocation system, and education programs for the public and professionals. Today, donation from condemned prisoners is no longer the main source of organs for transplantation in China.

In May 2007, *the Regulation on Human Organ Transplantation*, which aims to ensure the voluntary and gratuitous principles of organ donation and the fair and transparent principles of organ transplantation in China, was promulgated. The Ministry of Health has set down more than 30 supporting management documents to effectively implement the regulation and to strictly enforce the authentication program for approval of hospitals to perform organ transplantation, to regulate living donor transplantation, to prohibit "tourism transplant", and to establish assessments on the scientific registration of transplant data. The government has also founded the Ministry of Public Security to combat illegal organ trading (key provisions on organ donation and transplantation in China are summarized in Table 1). *The World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation* [5], which was endorsed in 2010, further enhanced the legal and scientific development of human organ donation and transplantation in China.

With the support of the State Council, the Ministry of Health and the Red Cross Society of China announced in Shanghai on August 25, 2009, the structural framework for organ donation and transplantation in China [6] and jointly set up the China National Organ Donation Committee, the top authority for the human organ donation system in China, under which the Chinese Human Organ Donation Office (officially named as the Chinese Organ Donation Management Center in 2013) is primarily responsible for handling daily work activities. Organ donation committees and offices have also been set up at the provincial level. Transplant hospitals have established their own organ procurement organizations (OPOs) and conducted donations under the guidance and supervision of the donation committees at different levels.

In 2010, the China Organ Donation Committee proposed three categories of death: circulatory death, brain death, and brain death followed by circulatory death. Among these categories, brain death followed by circulatory death is a creation for the transitional stage and is generally accepted by the Chinese population. The major difficulty in the definition of death for organ donation has been reconciled. On the basis of this proposal, the Organ Transplantation Division of the Chinese Medical Association has developed *the Guidelines for Organ Donation in China* [7]. The guidelines depict and illustrate various aspects of the organ donation process [8] and have become the manual for all OPOs in establishing organ donation.

Development of an OPO is a key aspect for organ donation programs. To learn the advanced management models and experiences of OPOs from other countries, a number of symposiums have been conducted. In May 2013, the 1st China Organ Procurement Organization International Forum was held in Shenzhen, China. Renowned experts, including Jose R. Nuñez, Medical Officer with the World Health Organization's transplant safety program, Francis L. Delmónico, President of the Transplantation Society, Martí Manyalich, Director of the Donation and Transplantation Institute in Spain, and Alessandro Nanni Costa, General Director of the Italian National Transplant Centre, were invited to introduce their experiences and provide Chinese OPO members with training on the workflow and major issues of professional organ donation coordinators. At the conference, the OPO of Guangzhou Military General Hospital introduced their organizational structure and operational process, sharing their local experiences with OPOs of all transplant hospitals in China.

The Ministry of Health has also been proactively developing a computer platform for organ transplantation, namely the Chinese Organ Transplant Response System, which includes a potential donor identification system, an organ donor and recipient matching system, and an organ recipient waiting list system. These subsystems have now been completely set up for operation. The Chinese Organ Transplant Response System implements equality, equity, and transparency in organ donation and transplantation and will gain the public's trust in the entire organ donation system [9].

The Red Cross Society of China is dedicated to the education programs of organ donation for both the public and professionals. Leaflets have been distributed widely at hospitals to propagate the knowledge on organ transplantation. Newspapers, TV news, and programs, and the Internet have covered many stories organ donation and transplantation cases. A new film titled "Gifts of Life", which tells a touching organ donation story, is scheduled to be shown in June around the nation. By all these means, the community has a better understanding of organ

**Table 1.** Key provisions on organ donation and transplantation in China.

	Issue date	Provisions	Issued by (Serial no)	Key points
1	2007-05-01	The Regulation on Human Organ Transplantation	State department (491)	To ensure the voluntary and gratuitous principles of all kinds of organ donation. Organ commercialization is strictly forbidden
2	2007-05-23	The Notice of Human Organ Transplant Project Registry	Ministry of Health (2007–87)	From over 600 candidates, only 164 hospitals were approved to perform organ transplantation
3	2007-06-26	The Notice of Organ Transplantation Applied by Oversea Personnel	Ministry of Health (2007–110)	“Tourism transplant” was prohibited. Applications from foreigners have to be checked by Ministry of Health
4	2009-12-28	The Regulations on Living Donate Organ Transplantation	Ministry of Health (2009–126)	Living donor and recipient have to be genetically or maritally related. Every case has to be approved by provincial health ministration
5	2010-03-01	The Notice of Pilot Program of Organ Donation	Red Cross Society (2010–13)	To demonstrate the basic organizational structure and procedure of organ donation
6	2010-12-27	The Basic Principles of Chinese Human Organ Distribution and Sharing and the Core Policy of Liver and Kidney Transplantation	Ministry of Health (2010–113)	Organ allocation must meet medical priorities and keep to the principals of fairness, impartiality, and transparency. Factors influencing the priority on the waiting list include: geography, age, medical emergency, tissue typing, waiting time, etc.
7	2010-06-24	The Notice of Registration of the Transplant Data Though Networks	Ministry of Health (2010–105)	National liver, kidney, heart, and lung scientific registries were set up. All of these kinds of transplantation data are required to be reported through networks in time
8	2011-02-25	The 8th Amendment to China’s Criminal Law	President (41)	Addressing the criminal penalties on forced organ removal and organ trading
9	2011-04-26	The Notice of Initiating Pilot Trials for Organ Donation after Circulatory Death for citizens	Ministry of Health (2011–62)	Chinese classification of deceased-organ donation was introduced as: C-I: Donation after Brain Death (DBD); C-II: Donation after Circulatory Death (DCD); C-III: Donation after Brain Death followed by Circulatory death (DBCDC)
10	2013-09-01	The Interim Provisions on Human Organ Procurement and Allocation	NHFPC (former Ministry of Health) (2013–11)	Transplant hospitals are required to set up its OPO with the permission of provincial health ministration. Each OPO encompasses the entire process of organ donation

NHFPC, National Health and Family Planning Committee.

donation. In August 2013, 633 candidates of organ donation coordinators from different parts of China gathered in Hangzhou and completed a 3-day training program organized by the Chinese Organ Donation Management Center. Among the candidates, 330 passed the examination and were authorized as the first group of certified organ donation coordinators. The same training program will be held every year.

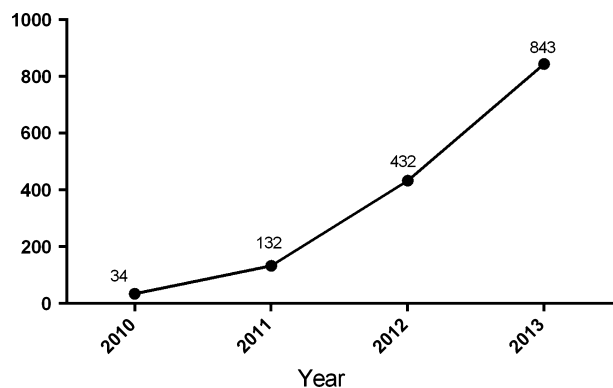
## Results

### Rapid progress of organ donation

While the organ donation system was initially constructed, in March 2010, the Red Cross Society of China and the

Ministry of Health started pilot trials for organ donation after circulatory death for citizens in 11 provinces. These trials have achieved remarkable results. Among the 32 provinces and autonomous regions in the country, 25 provinces have started organ donation.

From 2010 to 2013, there was rapid development in organ donation with an annual growth rate at about 100% (Fig. 1). Official announcement was made on August 15, 2013 that the total number of organ donation after death has accumulated over 1000 cases [10], and until February 27, 2014, this number has reached 1564 cases and 4243 organs have been transplanted. Among these cases, 9% were donation after brain death, 47.5% were donation after circulatory death, and 43.5%



**Figure 1** Numbers of organ donation each year in China from 2010 to 2013. Data from the Chinese Organ Donation Management Center.

were donation after brain death followed by circulatory death.

The procedures of organ donation are summarized as follows: Potential donors are identified by their nurses or physicians in hospital and examined by respective medical professionals. If the “irreversible state” is diagnosed and accepted by the family, an organ transplant coordinator would come and formally ask for consent for organ donation from the immediate family. The ethic committee of the hospital would review the case and give approval of donation. After the life-supporting system is withdrawn, the cessation of circulation is monitored by invasive blood pressure and affirmed by 2–5 min “no touching period”. The organ procurement procedure starts as soon as two unrelated physicians have declared the death. If the brain death is diagnosed by national certified experts, accepted by the family, and approved by the local health ministry, the international standard donation after brain death could be carried out.

From 2010 to 2013, the donation after circulatory death liver transplantation and donation after circulatory death kidney transplantation ratio in China rose from 1.38% and

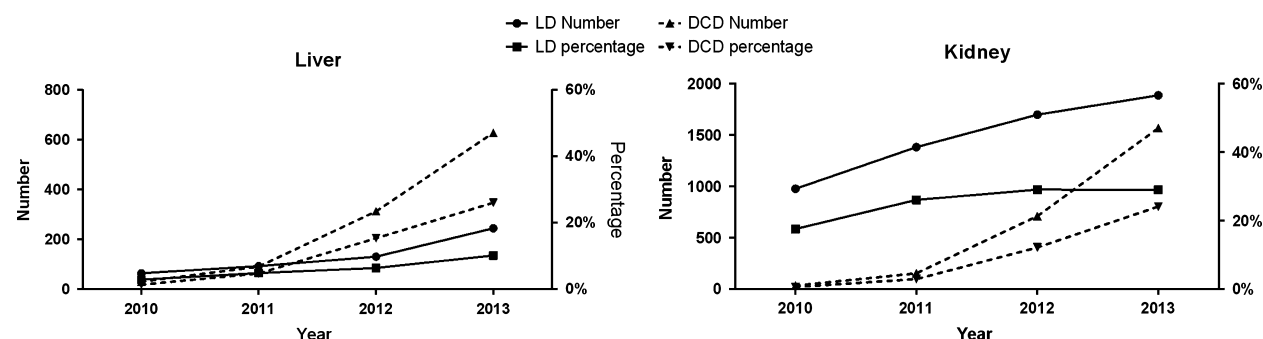
0.59% to 26.1% and 24.6%, respectively. Meanwhile, the number of living donor transplants has also increased (Fig. 2). The First Affiliated Hospital of Zhongshan Medical University in Guangzhou is the first hospital in China that has performed more donation after circulatory death kidney or liver transplants than transplants from traditional sources. In 2013 alone, the number of living donor donation and donation after circulatory death is accounted for half of all organ transplants in China [11]. This has marked a new era of organ donation in China, symbolizing that executed prisoners are no longer the major sources of human organs for transplantation in China. It is estimated that the number of transplants using organs from executed prisoners has dramatically decreased from about 12 000 [4] in 2004 to below 4324 in 2013 [11].

### Discussion

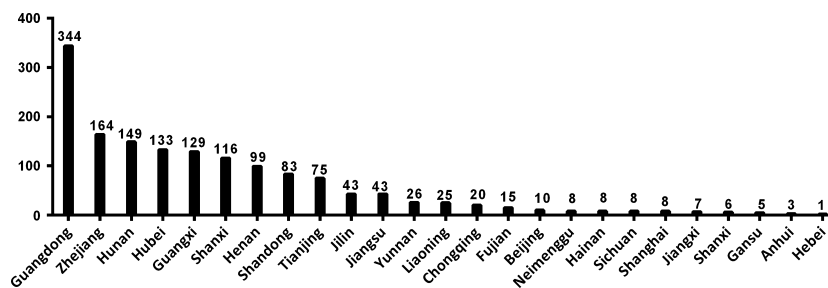
#### Constrains and solutions

There are still many difficulties in the development of organ donation in China, such as the imbalanced development of organ donation among regions and provinces (Fig. 3). There is also a lack of motivation and significant resistance.

The lack of motivation is revealed in two aspects: the public’s unwillingness to donate and the lack of motivation of some OPOs. As cremation is commonly practised today, the Chinese traditional views are no longer the major impedance to the public’s willingness to donate. The results of a survey conducted in Wuhan and Guangzhou showed that one-third of the people were willing to be organ donors [12]. There is still no reliable statistic report of the conversion rate in China. A recent survey carried out in India, in which some cultural similarities are shared with China, showed that family refusal accounted for their poor conversion rate [13]. This warrants the importance of public education. The key points for public education are illustrated by an Australian study, which shows that willingness



**Figure 2** Numbers and ratios of DCD or LD liver/kidney transplantation from 2010 to 2013. Data from the China Liver Transplant Registry and Chinese Scientific Registry of Kidney Transplantation. LD, living donation; DCD, donation after circulatory death.



**Figure 3** Statistics of organ donation in different regions of China. Data from the Chinese Organ Donation Management Center as of February 27, 2014.

to register as an organ donor is highly influenced by the altruistic motive of saving lives and improving lives for others [14]. So the future donation campaigns in China should better focus on appealing to the altruism spirit for saving lives for others. Such education programs should be held as long-standing campaigns, because their impact on community attitudes decreases over time [15]. The major concern of the public about the equitability of organ allocation after donation must also be well addressed in China.

In a nutshell, organ donation is a complex and difficult process. The quantity and quality of organ donation can only be ensured by efficient and professional OPOs. Currently, 165 hospitals in China have been accredited for organ transplantation and have their own OPOs. Among these 165 hospital affiliated OPOs, only 60 have established organ donation [11]. In 2013, only 20 OPOs achieved over 10 cases of organ donations. The total case number of these top 20 accounted for 63.5% (535/843) of the whole nation last year. It could be due to the fact that many OPOs remain unaware that the potential donors should be found by themselves rather than the Red Cross Society of China.

The impedance of organ donation exists in the actual processing procedure. The current three categories for organ donation after death lack clear operational guidance and sufficient legal support, thus increasing operational difficulties. It is stated in the regulation that if a citizen did not indicate an unwillingness to donate organs before death, his/her family members (parents, spouses, and adult children) may jointly agree to a donation with written consent. However, in reality, dilemmas arise, for example, a deceased organ is suitable for donation, but the donor's family members are not found, or the family members are not in town, then written consent cannot be obtained in a short time.

Recently, the National Health and Family Planning Committee has issued the *Interim Provisions on Human Organ Procurement and Allocation* [16], which states that the duties of an OPO encompass the entire process of organ donation, from identifying potential donors, obtaining informed consent, protecting the donors, procuring,

preserving, and transporting the organs, to condoling the families, educating, and mobilizing. In other words, every hospital's OPO should have the responsibility and capability to establish organ donation independently. The regulation also states that all organs recovered must be allocated automatically through the organ allocation system. The organ allocation system strictly follows *the Basic Principles of Chinese Human Organ Distribution and Sharing and the Core Policy of Liver and Kidney Transplantation* [17]. The geographical factor is the primary factor affecting organ matching, meaning that the region of the waiting list of an OPO is assumed to be the primary scope of organ allocation. This policy provides a hospital with an incentive to conduct more donations and transplants. This also serves to ensure equitable and transparent organ allocation in a hospital. It is believed that implementation of this regulation will further dispel public concerns, clarify the responsibilities of OPOs, and encourage organ donation.

The European experience demonstrated that the most significant factor influencing the donation rate from deceased donors and the success rate of subsequent transplants is legislative measures [18]. Our lawmakers should pay more attention to streamline the donation process and to provide the people with more possibilities in making organ donation. If the relevant standards are legalized and widely accepted, the efficiency of the organ donation work would be much increased. Thus, legislation of brain death and promulgation of guidelines for donation after circulatory death are significant for the development of organ donation in China.

All of these measures will help China ameliorate the whole donation system and improve its efficiency. When this system meets the public demand for transplants, the controversial organ source from executed prisoners will naturally subside from the stage of history.

## Conclusion

Due to historical reasons, the development of the organ donation system in China has far lagged behind. In recent

years, regulations have been established to ensure fairness, impartiality, transparency, and respect for life throughout the process of organ donation. In a short period of time, the number of organ donations in China has upsurged to over 1000 cases and donation from condemned prisoners is no longer the main source of organs for transplantation. It has also been observed that the current donation practice still faces difficulties in many areas. The government is taking important measures to resolve problems such as a lack of motivation and significant resistance. Future work should be focused on the improvement of OPOs' professionalism, legislation of brain death, and promulgation of legally valid guidelines of donation after circulatory death.

### Authorship

LZ and LZ: participated in the data analysis and drafting of the article. They contributed equally to this paper. XG: contributed to the data collection. HW: contributed to the data collection and critical revision of the article. YZ: contributed to the design of the research and critical revision of the article.

### Funding

The work described in this article was supported by a grant from the Ministry of Health of China (grant no. 201002004).

### Acknowledgements

We thank Dr. Hanlan Lu for preparation of the graphs and Ms. Maggie Ho for editing of the text.

### References

- Huang J. Ethical and legislative perspectives on liver transplantation in the People's Republic of China. *Liver Transpl* 2007; **13**: 193.
- Caplan AL, Danovitch G, Shapiro M, *et al.* Time for a boycott of Chinese science and medicine pertaining to organ transplantation. *Lancet* 2011; **378**: 1218.
- China to end use of organs from executed prisoners for transplants in one to two years [Chinese]. Available at <http://finance.chinanews.com/jk/2012/11-21/4347626.shtml>. Accessed on March 17, 2014.
- Huang J, Mao Y, Millis JM. Government policy and organ transplantation in China. *Lancet* 2008; **372**: 1937.
- World Health Organization. WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. *Transplantation* 2010; **90**: 229.
- China Red Cross and Ministry of Health to launch organ donation system [Chinese]. Available at [http://www.gov.cn/jrzq/2009-08/25/content\\_1401158.htm](http://www.gov.cn/jrzq/2009-08/25/content_1401158.htm). Accessed on March 17, 2014.
- Liu YF. Chinese guidance of donation after cardiac death [Chinese]. *Chin J Organ Transplant* 2010; **31**: 436.
- Shi BY, Chen LP. Regulation of organ transplantation in China: difficult exploration and slow advance. *JAMA* 2011; **306**: 434.
- Huang J, Millis JM, Mao Y, *et al.* A pilot programme of organ donation after cardiac death in China. *Lancet* 2012; **379**: 862.
- Organ Donation to replace executed prisoners as source for transplants in China in two years [Chinese]. Available at [http://news.xinhuanet.com/health/2013-08/15/c\\_125173092.htm](http://news.xinhuanet.com/health/2013-08/15/c_125173092.htm). Accessed on March 17, 2014.
- China sees over a thousand voluntary organ donations. An organ transplant fund to be established [Chinese]. Available at <http://gb.cri.cn/42071/2013/08/16/6871s4220970.htm>. Accessed on March 17, 2014.
- Huang JF. The key measures promoting the development of organ transplantation projects in China: principal thinking about experimental units for heart death organ donation [Chinese]. *Chin J Organ Transplant* 2011; **32**: 1.
- Kumar V, Ahlawat R, Gupta AK, *et al.* Potential of organ donation from deceased donors: study from a public sector hospital in India. *Transpl Int* 2014; **27**: 1007.
- Irving MJ, Jan S, Tong A, *et al.* What factors influence people's decisions to register for organ donation? The results of a nominal group study. *Transpl Int* 2014; **27**: 617.
- Coppen R, Friele RD, Gevers SK, van der Zee J. Donor education campaigns since the introduction of the Dutch organ donation act: increased cohesion between campaigns has paid off. *Transpl Int* 2010; **23**: 1239.
- National Health and Family Planning Commission of the People's Republic of China Notice of the Interim Provisions on Human Organ Procurement and Allocation [Chinese]. Available at <http://www.chinapop.gov.cn/zhuzhan/wsbmgz/201308/f4ca93212984722b51c4684569e9917.shtml>. Accessed on March 17, 2014.
- MOH Notice of Issuing the Basic Principles of Chinese Human Organ Distribution and Sharing and the Core Policy of Liver and Kidney Transplantation [Chinese]. Available at <http://www.zhhealth.gov.cn:8080/tztg/4615.htm>. Accessed on March 17, 2014.
- Roels L, Rahmel A. The European experience. *Transpl Int* 2011; **24**: 350.