

The New Era of Organ Transplantation in China

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On June 13, 2016, the US congress passed the bill H. Res. 343 based on the false statements regarding organ transplantation in China, which indicated serious miscommunication and misjudgment between China and the US on the issue. The bill is preceded and followed by a series distorted media reports by the Cable News Network and the New York Times.^[1,2] It is a typical act of demonizing China with colored glasses that boldly ignored the facts and fabricated the evidence for political purposes.

In January 2015, we published a response article to the open letter from eight prominent overseas professors^[3] regarding the organ transplantation in China which clearly described the arduous 10 years' journey of the reform for organ transplantation and demonstrated the determination to change organ transplantation in China.^[4] Since the promulgation of "The Regulation on Human Organ Transplantation" by the State Council in 2007, remarkable progresses have been achieved by the joint efforts of the government and professional communities. We hereby laid out facts pertaining to the recent developments, as well as future roadmap of organ donation and transplantation in China to return the

discussion to the right track based on facts rather than wild political speculations.

THE HISTORICAL MOMENT OF THE TRANSITION FROM THE OLD PRACTICE TO THE NEW COMMUNITY-BASED DECEASED ORGAN DONATION IN CHINA

On December 4, 2014, professor Jie-Fu Huang, the director of National Organ Donation and Transplantation Committee (NODTC) of China made a public announcement that China will fully cease the use of the death penalty prisoners' organ for transplantation, with effective from January 1, 2015. The community-based organ donation has become the only legitimate source of transplantable organ in China since then.^[5-8] On March 11, 2015,

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professor Jie-Fu Huang responded to a question of a French reporter as the official speak person of the National Committee of the Chinese People's Political Consultative Conference (CPPCC) in front of the media from all over the world at a press conference on the sidelines of the annual session of the CPPCC in Beijing. He stated that the ending the use of death penalty prisoners' for transplantation and establishing a comprehensive and transparent voluntary organ donation system farewell to the undignified past and started a new hopeful chapter in the organ transplantation cause in China.^[9]

THE DATA OF COMMUNITY-BASED DECEASED ORGAN DONATION AND TRANSPLANTATION IN 2015

The China Organ Transplant Response System (COTRS, <http://www.cot.org.cn>) is the sole legitimate official organ allocation computer system in China. Starting from September 1, 2013, all community-based donated deceased organs are mandated to be allocated through COTRS.^[10] Out of COTRS allocation is forbidden and subjected to the revoke of license of organ transplantation and possible incrimination according to the Amendment VIII of Criminal Law.^[11] Thus, COTRS documented every legitimate organ donation and allocation since then. According to the COTRS and scientific registries' documentation (as of February 3, 2016), there were 2766 community-based deceased organ donations between January 1, 2015 and December 31, 2015, which accounted for 2150 liver, 4931 kidney, 279 heart, and 118 lung transplantations in the same period. With 470 living donor liver transplantations and 2109 living donor kidney transplantations, there were a total of 10,057 organ transplantations in China in 2015. The number of organ donation in China ranked as No. 3 in the world in 2015, marked the successful transition of China's organ transplantation system from the old practice to a brand-new alternative system that is consistent with the international standard.

THE ACTION PLAN FOR THE DEVELOPMENT OF BRAND-NEW ORGAN DONATION AND TRANSPLANTATION SYSTEM FOR CHINA

The NODTC is the highest policymaking body and accountable organization for organ donation and transplantation in China. The committee was jointly formed by the National Health and Family Planning Commission and the Red Cross Society of China (RCSC) on March 8, 2013, under the leadership of the State Council. The formal Vice Minister, professor Jie-Fu Huang was appointed as the director of NODTC then. On March 10, 2016, the NODTC was reconstructed with a group of new committee members focusing on the new organ donation program [Supplementary Material 1].^[12] Professor Zhu Chen, Vice-chairman of the Standing Committee of the National People's Congress and President of the RCSC, was appointed as the honorary director. Both Ms. Bin Li, the director of NHPFC, and professor Jie-Fu Huang were appointed as the dual directors of NODTC. The arrangement

illustrates the strong support and leadership on the work of NODTC from the central government. On May 14, 2016, the first work meeting of NODTC outlined the following 10 items as the official working plan to further construct the new organ donation and transplantation system in China. The current plan is focusing on infrastructure development and capacity building. The 10 items are:

1. To clarify the accountability and responsibility of the Health Authority and Red Cross Society in the process of organ donation; improve the third party witness mechanism and strength the building of organ donation coordinator system
2. Under the existing framework of universal humanitarian policy and regulations, study the humanitarian aid mechanism for the disadvantages of transplant candidate and donor family. The mechanism must be consistent with the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation
3. Develop the regulation on Organ Procurement Organizations
4. Entrust the China Organ Transplant Development Foundation to be responsible for operation, maintenance, and the upgradation of COTRS; to establish interlinked and unified technical and safety platform for COTRS and scientific registries, which include liver transplant registry, kidney transplant registry, heart transplant registry, and lung transplant registry
5. Initiate the revision process of "The Regulation on Human Organ Transplantation" that was promulgated by the State Council in 2007
6. Develop dynamic management regulation on transplant hospital licensing and promote the establishment of organ donation hospitals. The licenses of transplant hospitals that violated regulations, failed to develop deceased organ donation, or underperformed in terms of transplant service quality will be revoked. The hospitals that excel in the development of deceased organ donation program will have the opportunities to be accredited as transplant hospital with license after 2 years of construction and evaluation
7. Establish national organ transplant quality control centers to further ensure the quality of transplant service
8. Based on the existing national brain death quality control center, promote studies on brain death which focus on China Category III (organ donation after brain death followed by cardiac death)
9. Establish the training and accreditation system for transplant professionals
10. Prepare the participation on the 26th International Transplant Congress of The Transplant Society in August, 2016, in Hong Kong, and the China International Organ Donation Conference in October, 2016, in Beijing.

All the above reform measures signified the major first step of long marathon journey. The NODTC will work diligently with Chinese transplant professionals and international transplant

communities to stay true to the mission taken up by medical professionals, to implement and nurture the brand-new organ donation and transplantation system in China, and to provide high-quality and ethical lifesaving transplantation service to 1.3 billion Chinese people. With the delicate design of the new community-based deceased organ donation program, the Chinese traditional culture and virtue will play an essential positive role in the success of the program and contribute the rejuvenation of the nation under the new leadership of China.

Supplementary information is linked to the online version of the paper on the Chinese Medical Journal website.

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