

# Development of the organ donation and transplantation system in China

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Organ donation and transplantation in China has shown remarkable improvement through untiring efforts of several generations of transplant surgeons. Our work has been appreciated and recognized by the international community. However, misunderstandings and criticisms, even misinterpretations, and denigrations, have occurred. Therefore, this paper introduces the three evolutionary phases of development of organ transplantation in China: the initial exploration phase, development and construction phase, and scientific standardization phase.

## Initial exploration stage (1960–2005)

The first kidney transplantation in China was performed at the Peking University First Hospital in 1960, and the first successful living donor kidney transplantation was performed at the First Affiliated Hospital of the Sun Yat-Sen University in 1972. This marked the beginning of organ transplantation in China.<sup>[1]</sup> Many transplant surgeons, who were young at that time, went abroad to study and gained advanced experience from Europe and the United States. Several experiments and preliminary preparations for clinical transplantation were performed during this initial stage. All activities related to organ donation and transplantation were explored; neither norms and guidelines nor registration system were present in China during this period. As experiences were gained with advances in technique, guidelines and regulations were imperative to safeguard scientific and health development. Although donated organs were transplanted after death of civilians in some cases, executed prisoners were the main source of organs donors in this phase.

## Development and construction phase (2005–2015)

Jie-Fu Huang, the former Vice Minister of the former Ministry of Health of the People's Republic of China,

pledged on behalf of the Chinese Government at a World Health Organization (WHO) high-level meeting on health for the West Pacific region in 2005 that China would vigorously promote reform in the organ transplantation system; develop voluntary, no-paid organ donation by its citizens; and gradually reduce and eventually stop using organs donated by executed prisoners.<sup>[2]</sup> China began to establish a legal and standardized system for organ donation and transplantation, which was initiated with promotion of legislation in the field of organ transplantation. The former Ministry of Health of the People's Republic of China issued *Interim Provisions on the administration of Clinical Application of Human Transplant Techniques* in 2006, thereby establishing a technical accreditation system among organ transplantation institutions. The State Council promulgated the *Regulations on Human Organ Transplantation*,<sup>[3]</sup> which was implemented nationwide in May 2007. Suggestions were accepted from experts in the fields of medicine, law, ethics, sociology, human rights, and other areas during the legislation, and the WHO was consulted. The laws and regulations regarding human organ transplantation from 11 countries and regions worldwide were referenced in the regulations. The administrative matters involved in the process of human organ transplantation were stipulated. The regulations reiterated that organ transplantation in China must comply with the WHO guidelines on human organ transplantation; the will of the human organ donors must be respected; human organ trafficking must be forbidden; and sorting of patients applying for human organ transplant surgeries must be determined in a just, fair, and transparent manner. These regulations were consistent with the international medical norms. The promulgation and implementation of these regulations marked the legalization and standardization of organ transplantation in China. The former Ministry of Health of the People's Republic of China reviewed and approved organ transplant hospitals according to the regulations in

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2007, thereby reducing the number of transplant-qualified medical institutions from >600 to 164.<sup>[4]</sup> In 2008, a registration system for liver and kidney transplant recipients was established for registration and assessment of the medical quality of the transplant programs. To standardize the clinical transplant practice in China, the former Ministry of Health of the People's Republic of China authorized the Chinese Medical Association to organize the development of serial regulations and guidelines on the clinical practice of transplantation techniques. A total of 23 guidelines on organ transplantation techniques, including complications, diagnosis, prevention, and treatment have been published and compiled in *The clinical guidelines for organ transplantation (2010 version)*.<sup>[5]</sup> Simultaneously, clinical practice regulations for transplantation of kidney, liver, heart and lung were also developed and published as *A book on the clinical technique norms of organ transplantation (2010 version)*.<sup>[6]</sup> The application of these clinical and technical practice norms and guidelines improved the standardization and quality of organ transplantation practice in China. China further promulgated the *Amendment (VIII) to The Criminal Law* in 2011 to criminalize organ trading and make it punishable under criminal law, thereby strengthening the legal framework in the field of transplantation.<sup>[7]</sup>

With the strengthening of the legal framework surrounding organ donation, the Chinese government began to set up reforms in the organ donation system. In 2010, a pilot program of citizen-based deceased organ donation was started to fulfill the promise of discontinuation of the use of donor organs from executed prisoners.<sup>[8]</sup> A propaganda, coordination, and witness mechanism was established according to the level of socioeconomic development and cultural background of China, wherein the Red Cross Society of China participated in organ donation as a third party.<sup>[9]</sup> The Red Cross Society of China has set up the China Organ Donation Administrative Center (CODAC), which is responsible for participating in the work related to human organ donation and for promoting the concept of organ donation through various channels and means.

To enhance organ donation, an efficient and professional team of organ donation coordinators is needed. The building of the professional coordinator team by CODAC started in 2011, and so far, 34 training courses have been conducted for organ donation coordinators, and 2516 professional coordinators have been trained and certified. The organ coordinator undergoes inspection, qualification, and certification every year to ensure strict implementation of the certification systems. This has gradually established an efficient and professional countrywide coordinator team for organ donation, which has become the main force on the organ donation front. Organ donation involves social, religious, ethical, political, legal, and other aspects. Organ donation not only conforms to the international principles but is also based on national conditions and cultural traditions. To better promote the development of organ donation in China, a unique Chinese donor classification system has been set up with three categories of standards for deceased organ donation, namely Category I (donation after brain death), Category II (donation after circulatory death), and Category III

(donation after brain death followed by cardiac death).<sup>[9]</sup> Meanwhile, the criteria and clinical norms for brain death determination have been developed, updated, and revised. The Criteria and Technical Specifications for Brain Death Determination (including adult and child versions) were issued in August 2013,<sup>[10,11]</sup> thereby promoting the regularized and standardized determination of brain death in China. The Xuanwu Hospital of the Capital Medical University was approved to set up the "Brain Injury Evaluation Quality Control Center," which is responsible for training and certifying physicians and surgeons qualified to declare brain death. A total of 3643 professionals qualified in brain death determination, who covered all regions in the mainland of China, were trained from 2013 to 2019. They are certified to create suitable conditions for organ donation, based on brain death. As the pilot program achieved great success, a well-developed working system was established, the voluntary organ donation was officially promoted nationwide on February 25, 2013. Organ procurement organizations (OPOs) and organ donation offices were set up in various transplant medical institutions.

The scientific and ethical organ transplant system is characterized by voluntary donation of organs by citizens and fair and transparent allocation to the transplant recipients through a scientific distribution system. The China Organ Transplant Response System (COTRS) was developed and put into service in 2011, through which organs were automatically allocated according to the national policies. Internationally recognized principles and experiences were referred to for determining the priority of allocation. The following priority principles were adopted: region, disease severity, blood type matching, tissue matching, rare opportunities, immediate family of the organ donors, etc. The former National Health and Family Planning Commission issued *Provisions on the Administration of Human Organ Procurement and Allocation (Interim)* in August 2013 based on the experience with the operation of the distribution system,<sup>[12]</sup> which mandated allocation of all donor organs through the COTRS. No organization or individual is allowed to randomly distribute donor organs outside the system, thereby ensuring that the donor organ allocation is fair, just, open, and traceable.

### Scientific standardization stage (2015–2019)

The team of transplant coordinators is growing and maturing with the construction and improvement of the organ donation system. Voluntary deceased organ donation has increased year by year since the pilot program initiated in 2010, reaching 1702 cases in 2014.<sup>[13]</sup> Deceased organ donation has become an important source of transplant organs. The China Human Organ Donation and Transplantation Committee officially announced that China would stop the use of organs from executed prisoners from January 1, 2015, and that voluntary organ donation by citizens would become the only legal source of deceased donor organ transplantation in China.<sup>[14-16]</sup> This received an enthusiastic response from the entire society and praise from the international transplant community.<sup>[13]</sup>

The organ donation and transplantation system in China was constructed with the long-term support and assistance of the international organ donation and transplantation community. Since 2006, many global experts on organ transplantation have visited China to provide assistance and guidance. Experts from Spain, France, Italy, Germany, the United States, and other countries have played an important role in the construction of the donation policy and propaganda, coordinator training, and OPO operation, among other aspects. They participated in organ transplant reform in China and jointly published a series of articles with Chinese experts in international journals on organ transplantation.<sup>[18]</sup> More than ten Chinese and European universities and many medical institutions jointly applied to the European Union the “Erasmus + Capacity Building in Higher Education” Program to carry out the “knowledge Transfer and Leadership in Organ Donation, from Europe to China (KeTLOD)” in 2016 under the guidance of the *Joint Statement of China–EU Education Cooperation*.<sup>[17]</sup> By 2019, the trained Chinese supervisors of organ donation conducted undergraduate awareness programs on organ donation in Chinese universities, thereby increasing awareness of organ donation among Chinese college students.<sup>[18,19]</sup>

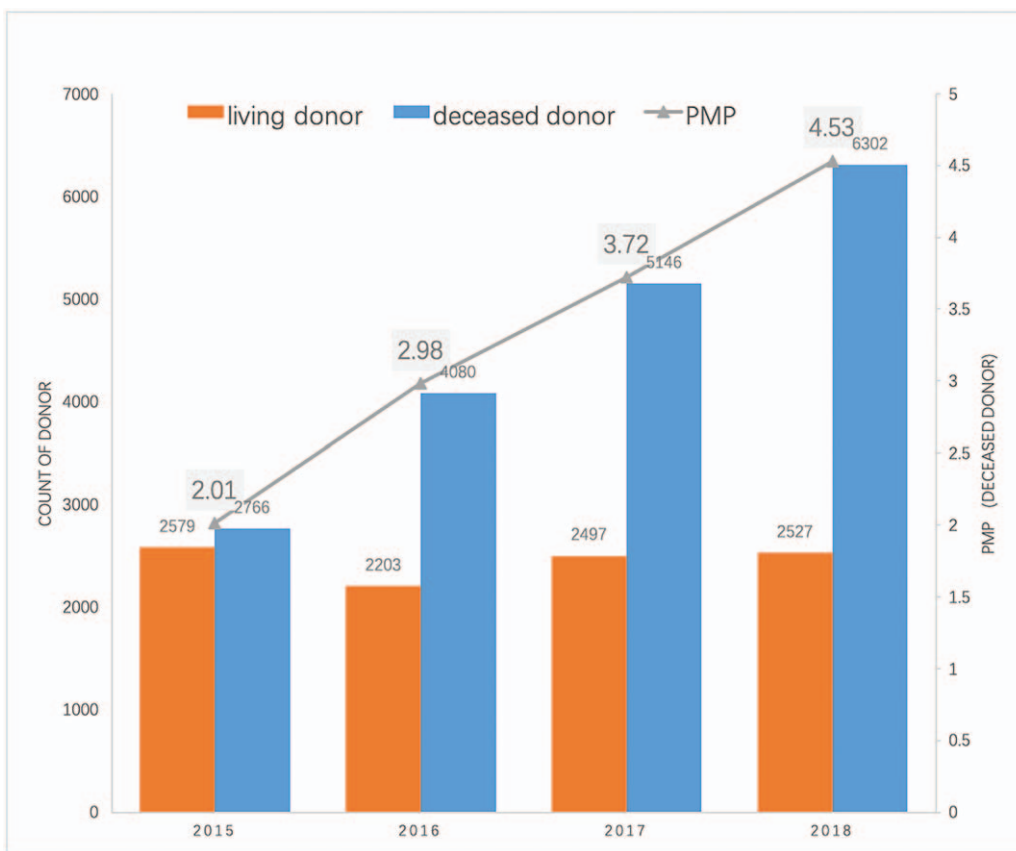
Organ transplantation in China has been criticized internationally because of the use of organs from executed prisoners.<sup>[20]</sup> Since 2015, the Chinese government has invited international experts to China to personally witness the entire organ donation process to confirm the facts. Organ donation is transparent and open in China, and it leaves a deep impression on the visiting experts; it has also prompted experts who were skeptical of the organ transplantation process to acknowledge the construction and reform of the Chinese organ transplantation system.<sup>[2,15]</sup> The United Nations and the Vatican Pontifical Academy of Sciences jointly held a conference on “Ethics in Action” in March 2018.<sup>[21,22]</sup> For the first time, Professor Jie-Fu Huang introduced the reform of organ transplantation and its practice in China to the world, and it was well received by the participating experts.<sup>[23]</sup> It is referred to as the “China model.” At the conference, it was concluded that the organ donation and transplantation reform experience in China may be adopted as a reference for countries with similar social and cultural backgrounds and socioeconomic development.<sup>[21,24]</sup>

The fourth China-International Conference on Organ Donation — ‘The Belt and Road’ Organ Donation International Cooperation Development Forum was held in Kunming, Yunnan, from December 6, 2019 to December 8, 2019.<sup>[25]</sup> Representatives from WHO, the International Association of Organ Transplantation (TTS), and transplant associations from 62 countries across all continents attended the forum. Experts at the conference praised China’s achievements in organ donation and transplantation reform, and they affirmed the important role of the “Chinese Experience” in the construction of the transplant system. The forum follows the principles of “extensive consultation, joint contribution, and shared benefits.” The *Kunming Consensus on International Cooperation Development of ‘The Belt and Road’ Organ Donation and Transplantation* was issued.

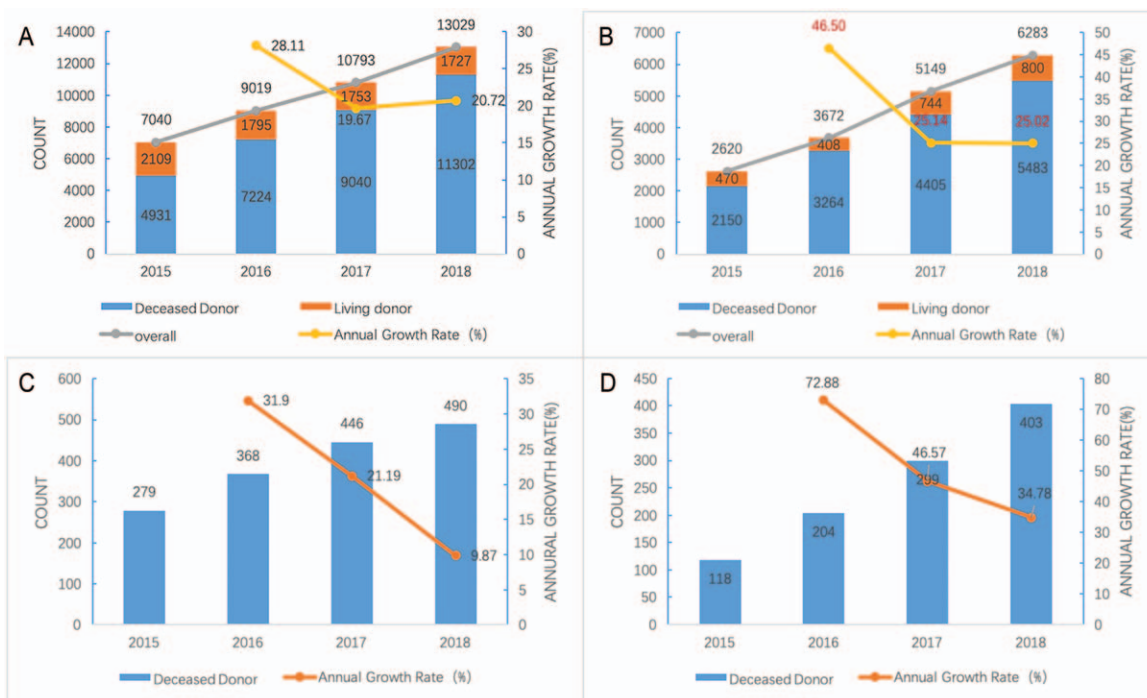
China conveyed to the world the belief of establishing an ethical organ transplant system consistent with the WHO criteria. It also provided the world transplant community with the “Chinese experience.” China will actively promote international exchanges and cooperation in organ donation and transplantation in the field of humanities and health among countries along “The Belt and Road,” thereby jointly addressing problems and challenges in human development.<sup>[25]</sup>

China has gradually established a complete system of organ donation and transplantation, including organ donation system, organ procurement and allocation system, organ transplantation medical service system, organ transplantation quality control system, and organ transplantation supervision system, after 10 years of arduous reform. Recently, China has introduced and established regulations and mechanisms beneficial for organ donation. For example, the former National Health and Family Planning Commission, Ministry of Public Security, Ministry of Transport, China Civil Aviation Administration, China Railway Corporation, and China Red Cross Federation jointly established a green channel mechanism for organ transportation to ensure smooth transfer of donated organs in 2016.<sup>[26,27]</sup> The Law of The Red Cross Society of China, revised in May 2017,<sup>[28]</sup> clearly stipulated that organ donation should be promoted and humanitarian relief mechanisms should be explored by charities. A fair, transparent, and open environment of voluntary citizen organ donation has gradually formed across the society. The annual growth rate of deceased organ donation was 20% to 34%, and it has reached 6302 cases in the mainland of China in 2018.<sup>[29]</sup> The number of organ donors reached second place worldwide, and the per-million-population donation rate rose to 4.53 (from 0.03 at the beginning of the pilot), thereby laying a solid foundation for high-speed development of organ donation and transplantation [Figure 1].<sup>[29]</sup>

More patients benefit from transplant surgery with the promotion of organ donation by citizens. The quantity of solid organ transplantation is rapidly increasing, with the annual growth rate of the deceased organ transplantation around 20% for each organ transplantation program during the three years from 2015 to 2018 [Figure 2]. A total of 20,201 solid organ transplants were performed in 2018, ranking second in terms of numbers per country worldwide.<sup>[29]</sup> Meanwhile, the quality of organ transplant medical care is also improving in China, and the long-term survival rates have reached the advanced international level.<sup>[30]</sup> Innovative techniques for organ transplantation, such as non-ischemic liver transplantation,<sup>[31]</sup> and other liver transplantation techniques, are continuously developed and have reached advanced international levels. A breakthrough was made in ABO-incompatible kidney transplantation.<sup>[32,33]</sup> The clinical service capacity of single-center pediatric liver transplantation is in the advanced international level.<sup>[34]</sup> Organ preservation and donor organ maintenance technology are continuously improving.<sup>[35,36]</sup> The clinical experience of liver transplantation for liver cancer and hepatitis B has been gradually recognized by the international community.<sup>[37]</sup>



**Figure 1:** Counts of deceased donor, living donor, and PMP, 2015–2018. PMP was calculated with the deceased donor. The figure and data were obtained from *the Report on Organ Transplantation Development in China (2015-2018)* and authorized by the China Organ Transplantation Development Foundation. PMP: Annual donors per million population.



**Figure 2:** Counts of transplantation surgeries in China, 2015–2018. A: Kidney transplantation performed in China, and the annual growth rate calculated with the deceased donor transplantation. B: Liver transplantation performed in China, and the annual growth rate calculated with the deceased donor transplantation. C: Heart transplantation performed in China, and the annual growth rate. D: Lung transplantation performed in China, and the annual growth rate. All the data were obtained from *the Report on Organ Transplantation Development in China (2015-2018)*, and authorized by the China Organ Transplantation Development Foundation.

China is climbing to the peak of world transplantation technology.<sup>[29]</sup>

With rapid increase in the quantity of solid organ transplantation recently, China now turns to emphasize on quality management and improvement in the field of transplantation.<sup>[29]</sup> China has set up organ transplant quality control centers based on the original transplant recipient clinical data registration systems, which are responsible for the national medical quality monitoring, supervision, and inspection of specific transplant programs in 2016. The purpose of carrying out medical quality control is to reduce the gap in the curative effect among transplantation centers and improve the quality of transplantation. At present, the development of organ transplantation in China is undergoing a transition from fast growth in quantity and scale to promoting improvement in quality. Continuous improvement of medical quality is an inevitable demand for promoting the scientific, balanced, standardized, and high-quality healthy and orderly development of organ transplantation. The exploration of the quality improvement program began in 2017 by the Kidney Transplantation Quality Control Center of National Health Commission of the People's Republic of China,<sup>[38]</sup> and it was introduced to other transplantation program in the 2019 Annual Congress of Chinese Society of Organ Transplantation.<sup>[39]</sup> The Chinese organ transplantation quality improvement program would establish a statistical model based on the main outcomes data of the Chinese recipients to set up scientific medical quality evaluation methods, and through refining of the clinical practice guidelines and norms for promotion of standardized diagnosis and treatment procedures, thereby promoting quality improvement in organ transplantation. The establishment of standardized diagnosis and treatment system was led by the Chinese Medical Association, which organized the Chinese Society of Organ Transplantation to update and revise the clinical guidelines and norms for transplantation. *The Clinical Guideline for Organ Transplantation in China (2017 version)* has been published in 2018, and it has referred the latest clinical evidence and incorporated the local experience regarding the clinical characteristics of Chinese patients; the work began in 2015 and was completed in 2017. A total of 27 guidelines have been established or revised.<sup>[40]</sup> The updating and revising of the clinical norms has been ongoing since 2018, 57 clinical practice norms have been completed and published in three transplantation-associated Chinese medical journals.<sup>[41-43]</sup> The publication of guidelines and norms effectively improves the standardization of organ transplant diagnosis and treatment, and promotes improvement in quality of clinical care.

We will make unremitting efforts to build a perfect organ donation and transplantation system consistent with the ethics criteria and WHO guidelines. We will make efforts to climb to the peak of the science and technology in organ transplantation, thereby actively promoting international cooperation of "The Belt and Road" organ donation and transplantation, presenting the image of a responsible political power to the international community, and making our due contribution to the construction of the "human destiny community."

## Conflicts of interest

None.

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