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Reform Proceeding of Organ Donation and Transplantation System in China



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The first kidney transplantation in China was performed in 1960, which symbolized the start of transplantation exploration in China [1]. To facilitate understood, the organ transplantation development in China could be divided into in three phases: the initial exploration phase (1960–2005), development and construction phase (2005–2015) and scientific standardization phase (2015–). During the initial exploration phase, all activities related to organ donation and transplantation were explored. Although a few cases of transplant with organs donated after citizen's death has been performed, executed prisoners were the main source of organs donors. Neither norms and guidelines nor registration system were present in this period, as experiences accumulating and technique maturing, guidelines and regulations was in urgent need to safeguard the scientific and health development.

Huang Jiefu, the vice minister of the Ministry of Health, pledged that China would promote the reform of the organ transplan-

tation system, develop voluntary, no-paid organ donation by citizens at the World Health Organization (WHO) High-level meeting on health held in Philippines [2]. The development and construction phase started, and the reform proceeding to establish a legal and standardized system for organ transplantation began in China. The reform was initiated with promotion of the legislation in the field of organ transplantation in 2007, the State Council of China promulgated the *Regulations on Human Organ Transplantation* [3], which was implemented nationwide in May 2007. The administrative matters involved in the process of human organ transplantation were stipulated. It was reiterated in the regulations that organ transplantation in China must comply with the WHO guidelines on human organ transplantation and the international medical norms. In order to criminalize organ trafficking, the *Amendment (VIII) to The Criminal Law* was promulgated in 2011, making it punishable under criminal law, and the legal framework in the field of transplantation was strengthened [4]. The Law of The Red Cross Society of the People's Republic of China was revised in May 2017 [5], and it clearly stipulated that organ donation should be promoted and that humanitarian relief mechanisms should be explored by charities.

According to the regulations, the former Ministry of Health of china reviewed and approved organ transplant hospitals in 2008, thereby reducing the number of transplant-qualified medical institutions from >600 to 164 (in 2008), the hospitals were scrutinized and regulated strictly every year from then on. In the same year, a registration system for liver and kidney transplant recipients was established, the medical quality of the transplant hospitals was monitored. To standardize the clinical

transplant practice, the Chinese Medical Association developed serial clinical norms and guidelines about transplantation, A total of 23 guidelines, covered aspects like complications diagnosis, prevention and treatment, had been published and compiled in *The clinical guideline for organ transplantation (2010 version)*. At same times, the clinical practice regulations of kidney, liver, heart and lung were also developed and formed a *book on organ transplant clinical technique norms (2010 version)* [6, 7]. The application of this clinical norms and guidelines did improve the standardization and medical quality of the organ transplantation practice in China.

With the strengthening of the legal framework surrounding organ transplantation, deceased organ donation was explored in a three-year pilot program since 2010 [8], and then was officially promoted nationwide on February 25, 2013. The organ Procurement Organizations (OPOs) and organ donation offices were then established in various transplant medical institutions. According to China's socioeconomic development level and cultural background, the Red Cross Society of China (RCSC) was introduced to participate in propaganda, coordinate, and witness in organ donation as a third party [9]. The China Organ Donation Administrative Center (CODAC) was set up to take charge in the work related to human organ donation and promote the concept of organ donation. An efficient and professional team of organ donation coordinator is need to promote the deceased organ donation, and it was organized and trained by CODAC since 2011. So far, 34 training courses have been held, and 2,516 professional coordinators have been trained and certified. The coordinators are affirmed by 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, which has become the main force on the organ dona-

tion front. Organ donation involves social, religious, ethical, political, legal, etc. To better promote the deceased organ donation, a unique deceased donor classification system with three categories has been innovatively proposed [9]. Meanwhile, the criteria and clinical norms for brain death determination have been developed and updated, and the latest version (including adult and child version, respectively) was revised in 2013 [10, 11], and the national "Brain Injury Evaluation Quality Control Center" set in Xuanwu hospital is approved for training and certifying physicians and surgeons qualified to declare brain death. A total of 3,643 professionals qualified in brain death determination were trained from 2013 to 2019, who covered all regions in the mainland China. They are certified to create suitable conditions for organ donation based on brain death. In recent years, China has also explored and introduced regulations and mechanisms beneficial for organ donation and transplantation. 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 RCSC jointly established a green channel mechanism for organ transportation to ensure smooth transfer of donated organs in 2016 [12].

A scientific allocation system through which the organs donated could be allocated fairly and transparently is key characteristics to the scientific and ethical transplant system. The China Organ Transplant Response System (COTRS) was developed and put into operation in 2011, by which advanced international experience was referred to for determining the allocation priority. The *Management Regulations for Acquisition and Distribution of Human Donor Organs (Trial)* was issued in August 2013 as based on the experience with operation of COTRS [13]. It is mandatory that all donor organs must be allocated through the COTRS thereby ensuring that the processes are just, open, and traceable.

As coordinators are growing and maturing with the construction and improvement of the organ donation system, the number of voluntary deceased organ donation has been increasing year by year, and gradually occupying an important part of transplant organs [14]. Based on these facts, The National Human Organ Donation and Transplantation Commission (NHODT) announced that executed prisoner organ donation should be terminated from January 1, 2015. From then on, citizen organ donation has become the only legitimate source of transplantable organ in China [15].

After 10 years of arduous reform, a fair, transparent, and open climate of voluntary citizen organ donation movement has gradually formed across the society. Organ donation reached 6,302 cases in China mainland in 2018. The number of organ donors ranked second worldwide, and the per-million-population (pmp) donation

rate rose to 4.53 (from 0.03 at the beginning of the pilot in 2010), thereby laying a solid foundation for high-speed development of organ donation and transplantation (Figure 1) [16]. More patients benefit from transplant surgery with the promotion of deceased organ donation. The quantity of solid organ transplantation was rapidly escalating, a total of 20,201 organ transplants were performed in 2018 (Figure 2). With the rapid increasing of the quantity of the solid organ transplantation recently, China now turns to pursue quality management and improvement in the transplantation field [16]. At present, the development targets of organ transplantation is undergoing a transition from fast growth of quantity and scale to promoting improvement of quality. China has set up organ transplant quality control centers based on the original transplant recipient clinical data registration systems in 2016, who are responsible for the national medical quality monitoring, supervision and inspection of specific

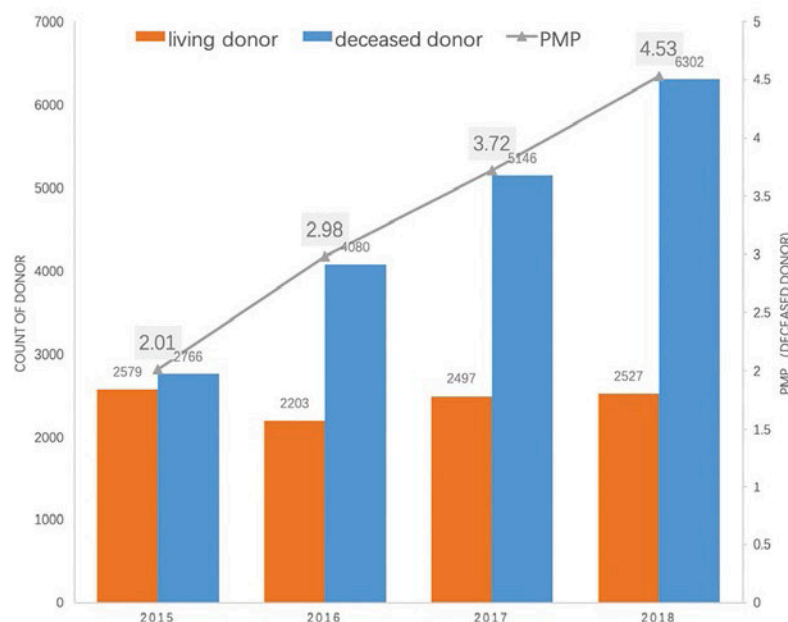


Figure 1. Counts of Deceased Donor, Living Donor and PMP, 2015–2018. PMP was calculated with the deceased donor. The Figure and data were obtained from the Report on Organ Transplantation Development in China (2015–2018), and authorized by the China Organ Transplantation Development Foundation

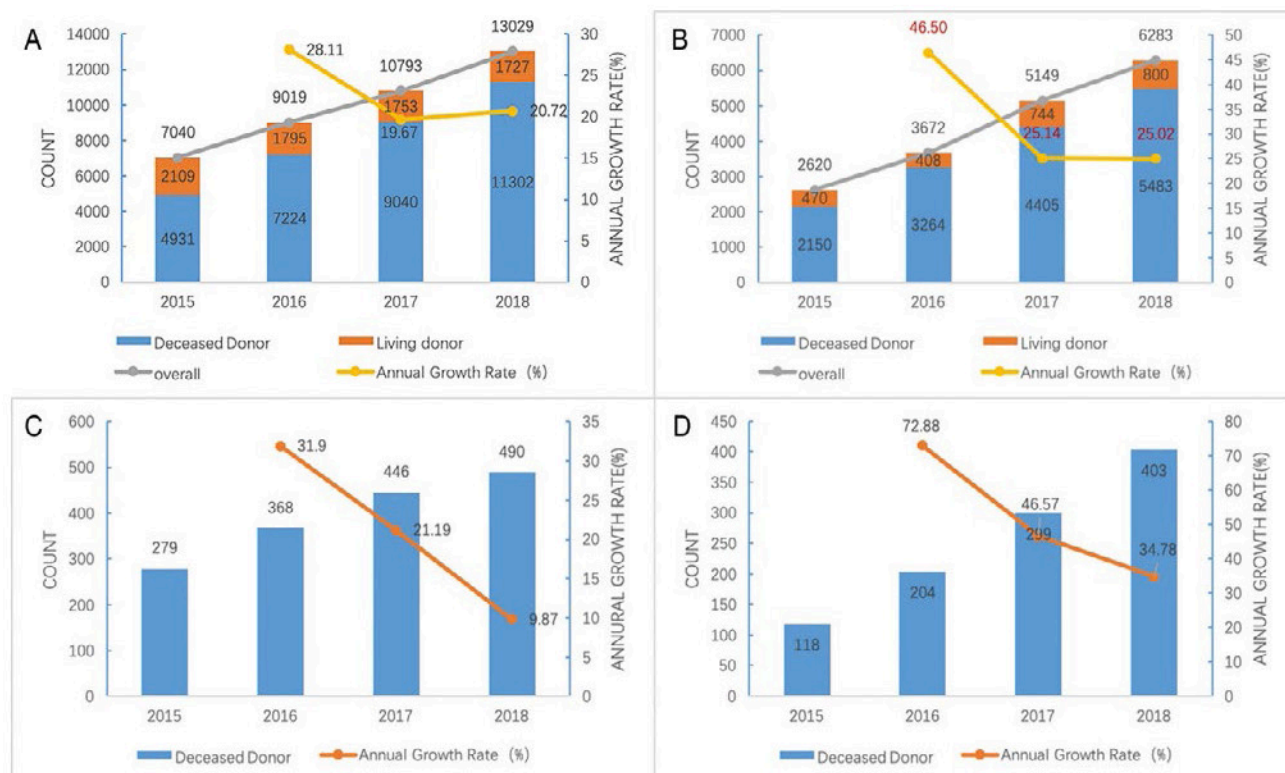


Figure 2. Counts of Transplantation Surgeries in China, 2015–2018. A: kidney Transplantation performed in china, and the annual growth rate calculated with the deceased donor Transplantation. B: Liver Transplantation performed in china, and the annual growth rate calculated with the deceased donor Transplantation. 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

transplant programs. The exploration of the quality improvement program began in 2017 by the Kidney Transplantation Quality Control Center of National Health commission [17], and it was introduced to other transplantation program in the 2019 Annual Congress of Chinese Society of Organ Transplantation [18]. The Chinese organ transplantation quality improvement program would establish statistic models based on clinical outcomes data of the Chinese recipients to set up scientific medical quality evaluation methods, and through refining of clinical practices guideline and norms to promotion standardized diagnosis and treatment procedures, thereby to promotion the quality improvement in organ

transplantation. The establishment of standardized diagnosis and treatment system was led by the Chinese Medical Association, which organize the experts from Chinese Society of Organ Transplantation to update and revise the clinical guideline and clinical norms for transplantation. *Clinical Guideline For Organ Transplantation in China (2017 version)* has been published in 2018, it has referred the latest clinical evidence and incorporated with the local experience about the Chinese patient clinical characteristics, a total of 27 guidelines had been revised or establish [19]. The updating and revising of the clinical norms has been ongoing since 2018, 57 clinical practice norms have been completed and published

[20–22]. The publication of guidelines and norms effectively improves the standardization of organ transplant diagnosis and treatment, and does promote the quality improvement of clinical care.

The organ donation and transplantation system in China was constructed with long-term support and assistance of the international transplant community. Since 2006, many international transplantation experts have visited China to provide assistance and guidance [8]. A jointly China-European Union (EU) education program named “knowledge Transfer and Leadership in Organ Donation, from Europe to China (KeTLOD)” has been carried out

since 2016. These efforts greatly increased awareness of organ donation among Chinese society [23, 24]. Since 2015, the China has invited international experts to personally witness the whole organ donation processes to confirm the facts. The organ donation work is transparent and open in China, and leaves a deep impression on the visiting experts. It has also prompted experts skeptical of the organ transplantation process to acknowledge the construction and reform of the organ transplantation system [2, 25]. The United Nations and the Vatican Pontifical Academy of Sciences jointly held a conference on "Ethics in Action" in March 2018 [26, 27]. For the first time, Huang Jiefu introduced the experience with organ transplantation reform and its practice to the world. It was referred to as the "China model" and well received by the participating experts [28]. 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 status [26, 29].

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 [30]. 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 criteria of WHO. It also provided the world transplant community with the "Chinese experience." China will actively promote international exchanges and cooperation in the cause of organ donation and transplantation in the field of humanities and health organ among countries along "The Belt and Road," thereby jointly addressing problems and challenges in human development [30].

We will make unremitting efforts to build a perfect organ donation and transplantation system that is consistent with the ethics and criteria of the WHO, 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".

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