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Current Situation of Organ Donation in China

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Additional information is available at the end of the chapter

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Abstract

The shortage of organs is a worldwide challenge for transplantation. To alleviate such organ shortage and keep pace with the world's development and experience on organ transplantation, the pilot program of organ donation after citizen death (DCD) has been carried out in China, with support and attention from the Chinese government. From 2010, with the joint efforts of the government and medical workers for these years, a series of laws, regulations and related process management have been formulated, and great achievements have been made in DCD work. Currently, the main source of organs in China has come from DCD. However, some difficulties still restrict organ donation rates. Firstly, resistance to organ donation in China is often due to the conventional view among citizens. Secondly, some medical workers do not fully understand the definition and diagnosis criteria of brain death and therefore do not uphold and promote DCD work. Thirdly, the existing laws and institutions for organ transplantation fail to implement and remain defective. Nevertheless, China has made a firm and strong stride in DCD work. In order to carry out DCD work better, Chinese government, people and medical workers have to do much more.

Keywords: organ donation, transplantation, China, DCD, OPO

1. Introduction

Organ transplantation in China began in the 1960s and has gone through semicentennial of hard work and development [1]. With the continuous development of the technology in transplantation, we have made great progress in organ transplantation and have gradually improved and completed in aspects of operation technology, long-term patient maintenance, transplantation-related scientific research and transplant-related management. At the same time, more and more patients with end-stage organ failure get prompt treatment

and long-term survival. The curative effect has been recognized by the public. At present, it has become a routine treatment in our country.

However, from the 1960s to 2006, organ transplantation in China lacks supporting and supervision of specialized regulatory and law [2]. Due to the specificity of organ transplantation, which involves various of parts and links, it requires strict and orderly management of the identification, assessment, procurement, preservation, function maintenance, registration, distribution of organ resources and selection, evaluation, postoperative maintenance of recipient and other aspects. All these need to establish a scientific donation system at the national level to ensure the legal operation of organ transplantation, to guarantee the legal rights and benefits of the donor and the recipient, to ensure the quality of transplanted organs and the fair distribution and rational use of organs. The selection of recipient should also be based on the severity of illness rather than the other requirements. Meanwhile, strict control indications to ensure the quality of medical care and safety of recipients.

In 2007, our country promulgated “the Regulations on Human Organ Transplantation” (hereinafter referred to as “the Regulations”) [3], which marks that our organ transplantation has embarked on a legal track [4]. After the relevant departments took a series of positive measures, initial results were obtained. The objective of implementing the “the Regulations” is to establish an ethical and sustainable organ transplant system. In the past, there were some serious problems in organ transplantation in our country, such as organ trading, tourism transplanting, opaque distribution, and so on. In the meantime, due to the lack of voluntary organ donation, there had been a history of reliance on organs of deceased prisoners [5]. These are all serious mismatches with the development of our country’s modernization and seriously restrict the sustainable development of organ transplantation [6]. It is not only difficult to guarantee the quality and safety of transplantation but also undermine the image of our civilized power. With the rapid and steady development of all walks of life in our country, the firm establishment of legal system, the increasing emphasis on health of people and the increasing demands on the quality of life, the medical industry in our country has become the industry which needs more improvement. The development of organ transplantation in our country has entered a crucial stage.

Since the 1980s, China began to try organ donation-related work in the light of international advanced experience. In June 1986, experts from various disciplines in China drafted the first draft “Brain death criteria,” and in 1995 and 2003, they repeatedly modified and improved the draft. In July 1997, the first brain-dead organ was donated in Shanghai, and two cases of kidney transplantation were successfully performed. In February 2001, the second case of brain-dead organ donation and the first DBD liver transplantation were performed in Nanjing, China. In July 2005, the first case of donation after cardiac death (DCD) was successfully performed in Guangzhou, China. The first case of DBD heart transplantation in China was successfully performed in July 2006. The first DBD lung transplantation in China was obtained in March 2007. The successes of these attempts have also inspired our continued search [7].

In view of the declining source of cadaver donation in our country, living donors are in violation of the international principle of “no injury” to healthy people. In order to avoid the trade of organs, our country strictly investigates and limits the donor’s status and relatives’ scope [8]. Living donors cannot be the major source of organ transplantation. China urgently

needs to establish a sustainable organ donation and transplantation system in line with social ethics and China's national conditions. In August 2009, the Red Cross of China and the former Ministry of Health held a conference for human organ donation work in Shanghai to jointly announce the establishment of a human organ donation system and promote DCD across the country [9].

2. The gradual processing of DCD work in China

After a long period of deliberation and discussion by health authorities and scholars of transplantation and law, China started pilot work of organ donation and procurement in 2010, that is, donation of cardiac death (DCD). Chinese Red Cross, entrusted by the ministry of health, hosted the pilot work. Since then, China's organ transplantation has entered a new stage [10].

In March 2010, the Ministry of Health (now the China Health and Family Planning Commission) and the Red Cross Society issued a document to carry out organ donation pilot work in 10 provinces and cities in China. The 10 provinces and cities are Tianjin, Liaoning, Shanghai, Jiangsu, Zhejiang, Fujian, Jiangxi, Shandong, Hubei and Guangdong [11]. Since Hunan Province had begun organ donation work and made some achievements before that, in June 2010, the Ministry of Health and the Red Cross General Union jointly approved Hunan Province to join the pilot provinces for organ donation [12]. At the same time, a document was issued on the "Organ Donation Pilot Work Program." Several requirements were put forward in the work of the 11 provinces and cities: (1) to establish the organization structure and team of organ donation work; (2) do a good job of personnel training; (3) to ensure the start of this work and ensure the work funding; (4) attach great importance to propaganda work; (5) explore the establishment of compensation and relief mechanism and incentive mechanism to ensure the sustainable and healthy development of donations; and (6) on the basis of common goals and principles, explore the formulation of implementation rules in line with the actual conditions in the region. In July 2010, the "Guidance to Chinese Organ Donation after Cardiac Death pilot work," which was written by the former Ministry of Health and the Red Cross of China together with related experts, was published in "Chinese Journal of Organ Transplantation" and initiated the DCD pilot work in China [13]. At the same time, the "Organ Donation Pilot Work Program" has also been formulated, which specified the duties and institutional framework of organ donation system and preliminary scheme of donation work process (Figures 1 and 2).

2.1. The determination and classification of DCD

International classification of cardiac death organ donation is mainly based on the Maastricht standard established in 1995. In view of the immature conditions of legislation on brain death in our country, our country has formulated the DCD classification standard of China according to China's national conditions so that the combination of "brain death" and "cardiac death" is well applied, in which way can also avoid the misunderstanding in our country's cultural identity and make the donation procedure comply with the law. In 2011, the Ministry of Health issued

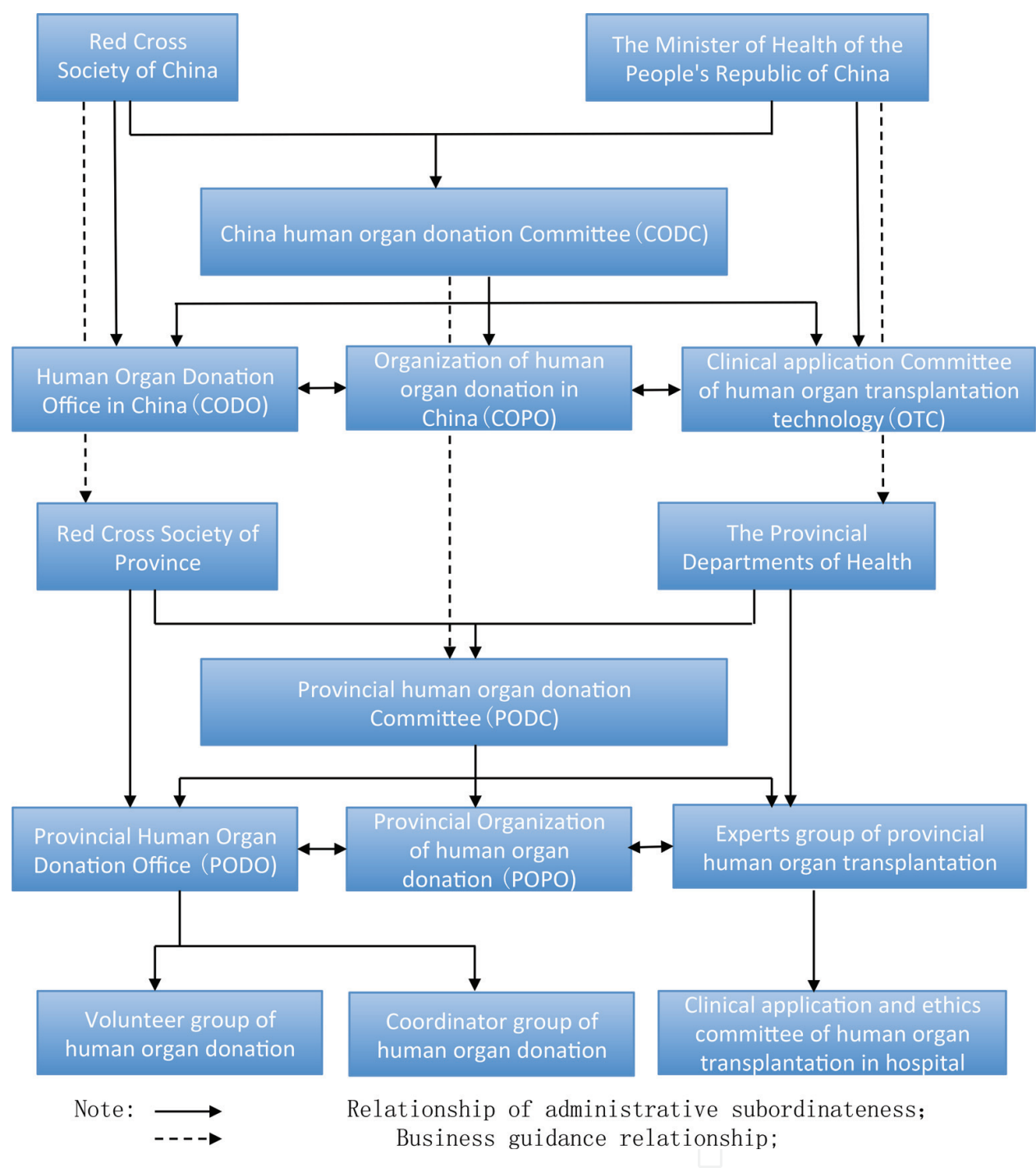


Figure 1. The structural chart of Chinese human organ donation system [11].

“Notice of the General Office of the Ministry of Health on Initiating Cardiac Death Donor Organ Transplantation” and proposed “China Classification Criteria” and related definitions:

1. Definition of DCD: DCD refers to the organ donation after the citizen’s death. In the past, it was also called non-heart beating donation (NHBD)
2. DCD classification: Currently, the DCD classification standard as defined by the 1995 Maas-tricht International Conference in Holland is adopted internationally. According to China’s national conditions combined with internationally accepted standards, in February 2011, the

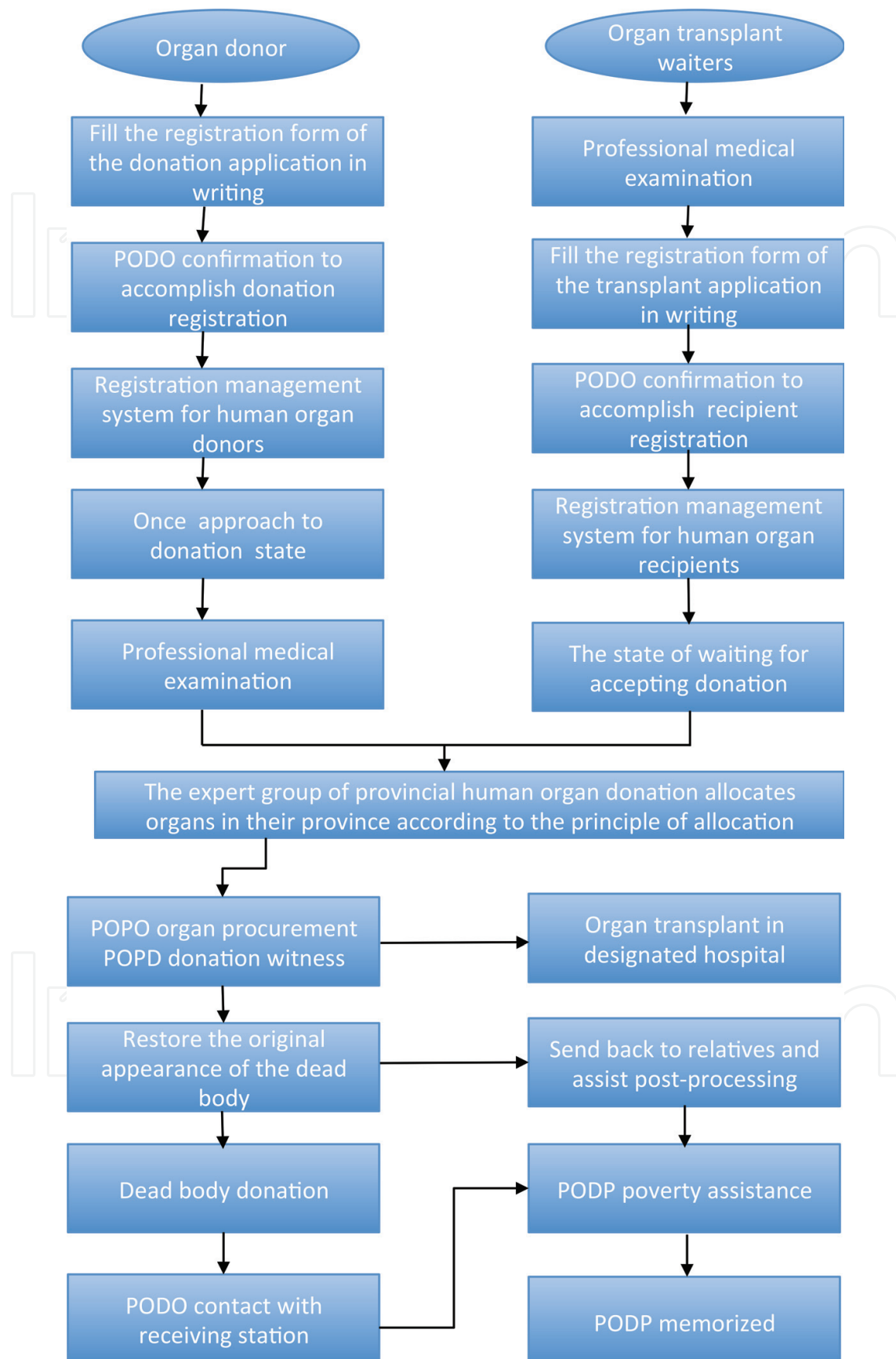


Figure 2. The process chart of Chinese human organ donation work [11].

China Human Organ Transplantation Technology Clinical Application Committee passed and announced the Chinese human organ donation classification standards, that is, the following three categories:

China Category I (C-I): This includes internationally standardized donation after brain death (DBD), that is, brain death cases. After rigorous medical examination, the indicators of potential donors are in line with the latest international and current domestic brain death standards (China Journal of Cerebrovascular Diseases, 2009 Volume 6, Issue 4), by the Ministry of Health commissioned by the agency-certified brain death experts who clearly identified it as brain death. Family members also come under this category, who fully understand the situation and choose to stop the treatment and donate organs, at the same time, having obtained the approval and support from the hospital and relevant leading departments.

China Category II (C-II): Internationally standardized cardiac death organ donation (DCD) includes the I–III case of the Maastricht standard classification.

China Category III (C-III): This includes donation after brain death awaiting cardiac death (DBCD). Similar to Maastricht's standard class IV, it is a controlled type and meets the diagnostic criteria for brain death. Since the brain death law has not yet been established, and family members cannot accept donations of organs under cardiac beating, donations should be made according to the DCD procedure, that is, life support should be removed, and donations should be made after cardiac arrest. The C-III is in line with China National conditions [14].

2.2. The pilot project of DCD has been carried out smoothly

In March 2012, the National Health and Family Planning Commission (formerly the Ministry of Health) and the Red Cross Society jointly held a wrap-up meeting on the organ donation pilot work throughout the country in Hangzhou, Zhejiang Province, and summarized their experience in organ donation work [15]. After 2 years of pilot work, under the joint promotion of the Red Cross and the National Health and Family Planning Commission, the Pilot Regions had to do a lot of work and achieved initial success in setting up sound organizations, applying for specialized agencies, revising of laws, exploring relief mechanisms, standardizing work processes and coordinating training, guiding the public in a scientific way and carrying out scientific assessments. As of March 15, 2012, the pilot completed a total of 207 donations, contributing 546 organs and saving more than 500 lives [16]. In August 2012, the National Health and Family Planning Commission and the Red Cross jointly issued the "Opinions on Further Promoting human organ donation work" (Zhonghong Zi, No. 39) in order to continue this steady progress. It specified the guiding ideology, basic principles, work objectives and specific measures for human organ donation. It also announced the organizational structure and responsibilities of the organ donation system and the organ donation process after the death of Chinese citizens, including eight important aspects, which are registration, donation evaluation, donation confirmation, organ acquisition, organ distribution, body processing, memory and humanitarian aid [17]. On March 25, 2013, the National Health and Family Planning Commission and the Red Cross jointly held a video conference on organ donation work throughout the country,

demanding to carry our organ donation work in the whole country this year [18]. As of August 14, 2014, 169 units completed 2107 human donations and 5787 organs were donated, saving the lives of more than 5000 patients by transplants [19].

3. Organ donation work procedure after Chinese citizens' death

On August 1, 2012, the Red Cross Society of China and the Ministry of Health published the "Opinion on Further Promoting human organ donation work (Zhonghong Zi, No. 39)," officially announcing the organ donation process after the death of Chinese citizens. The main contents include enrollment registration, donation evaluation, donation confirmation, organ acquisition, organ distribution, body processing, memory, humanitarian assistance, and so on (Figure 3).

DCD organ procurement process (Figures 4–7).

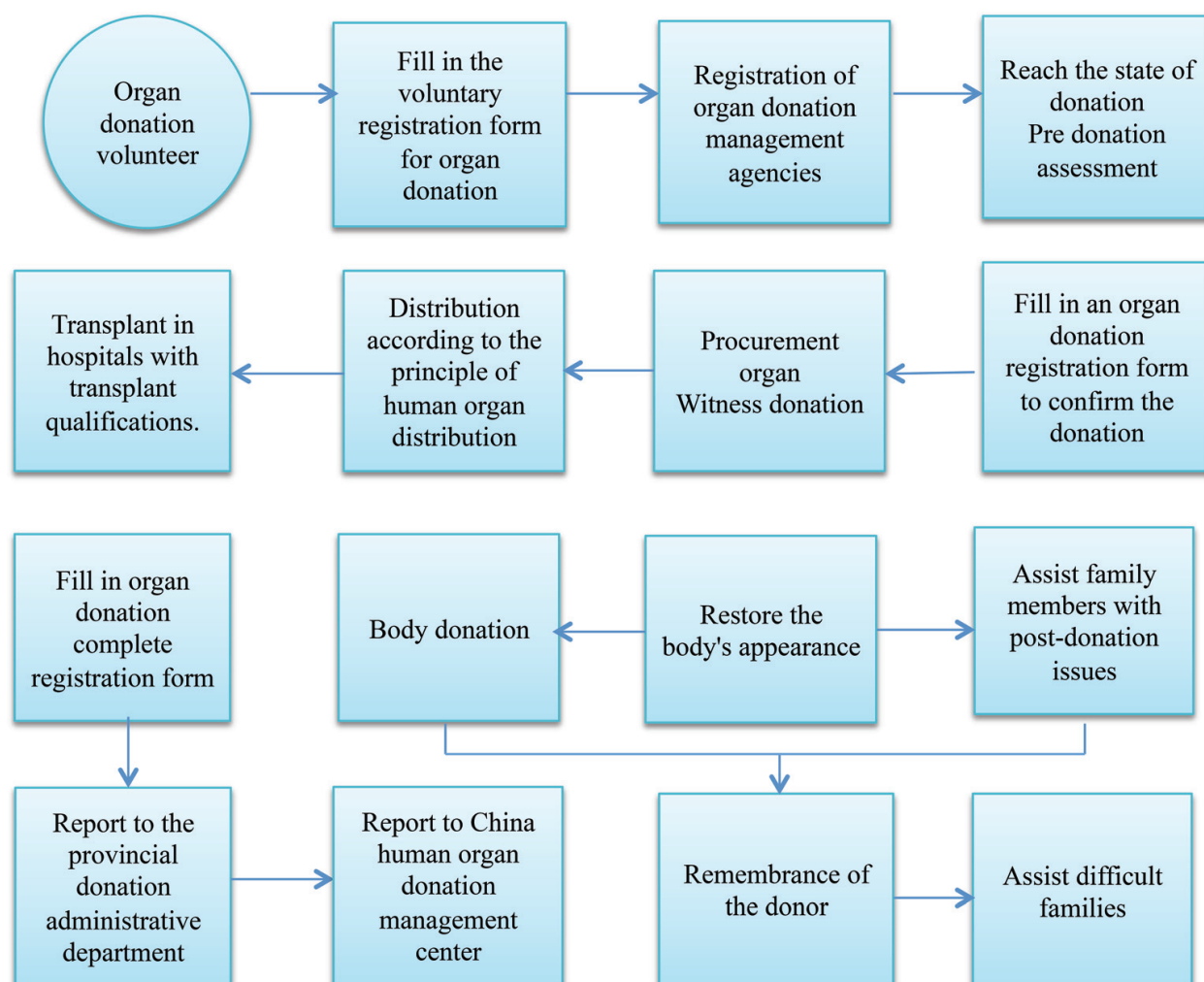


Figure 3. The process chart of Chinese DCD work [11].

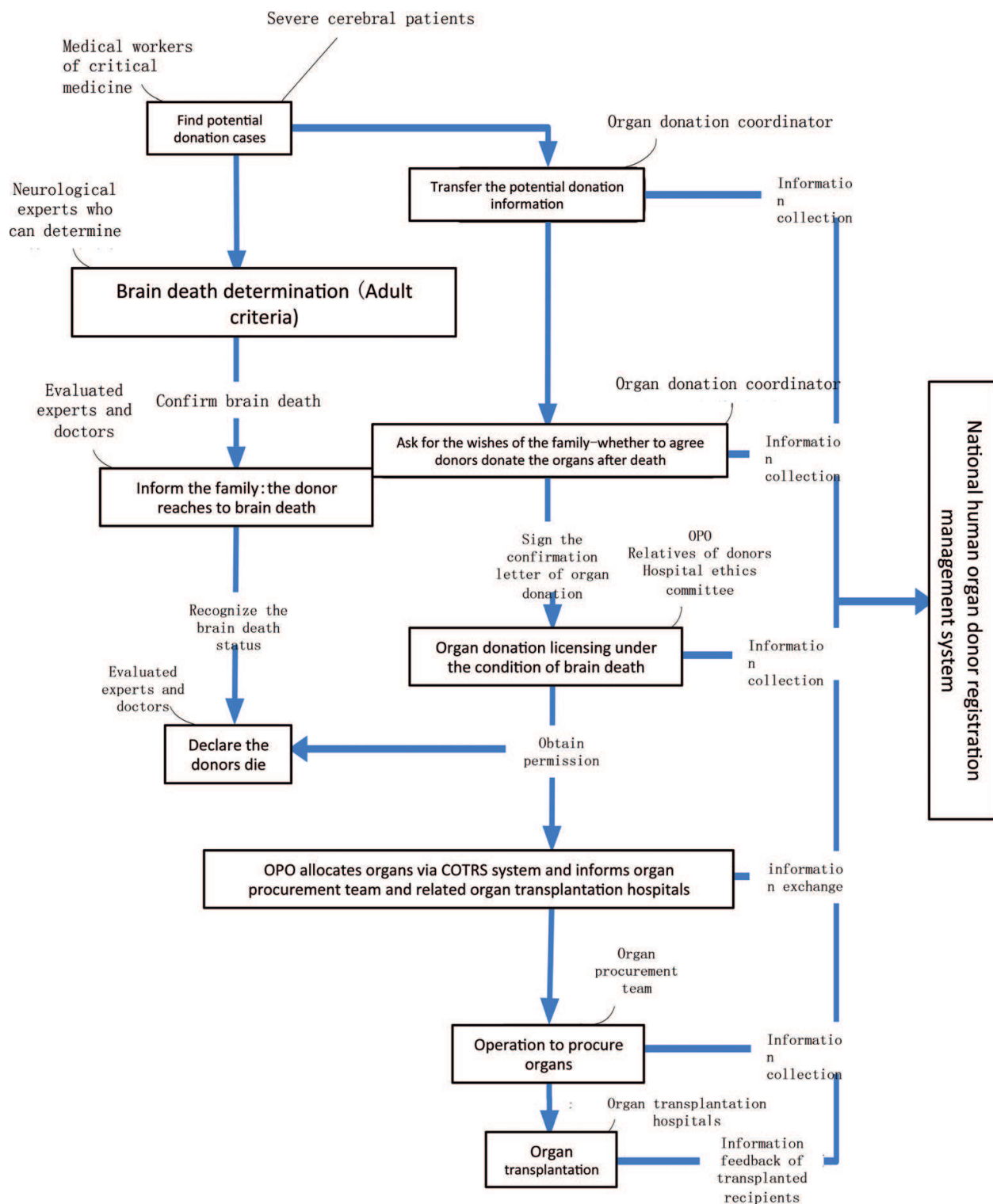


Figure 4. Flow chart of organ donation and procurement (C-I) [20].

The distribution of organs is based on the following seven basic principles of “Basic Principles for the Allocation and Sharing of Human Organs in China (2010 edition)” [21]:

1. The distribution and sharing of human organs should meet the medical needs.

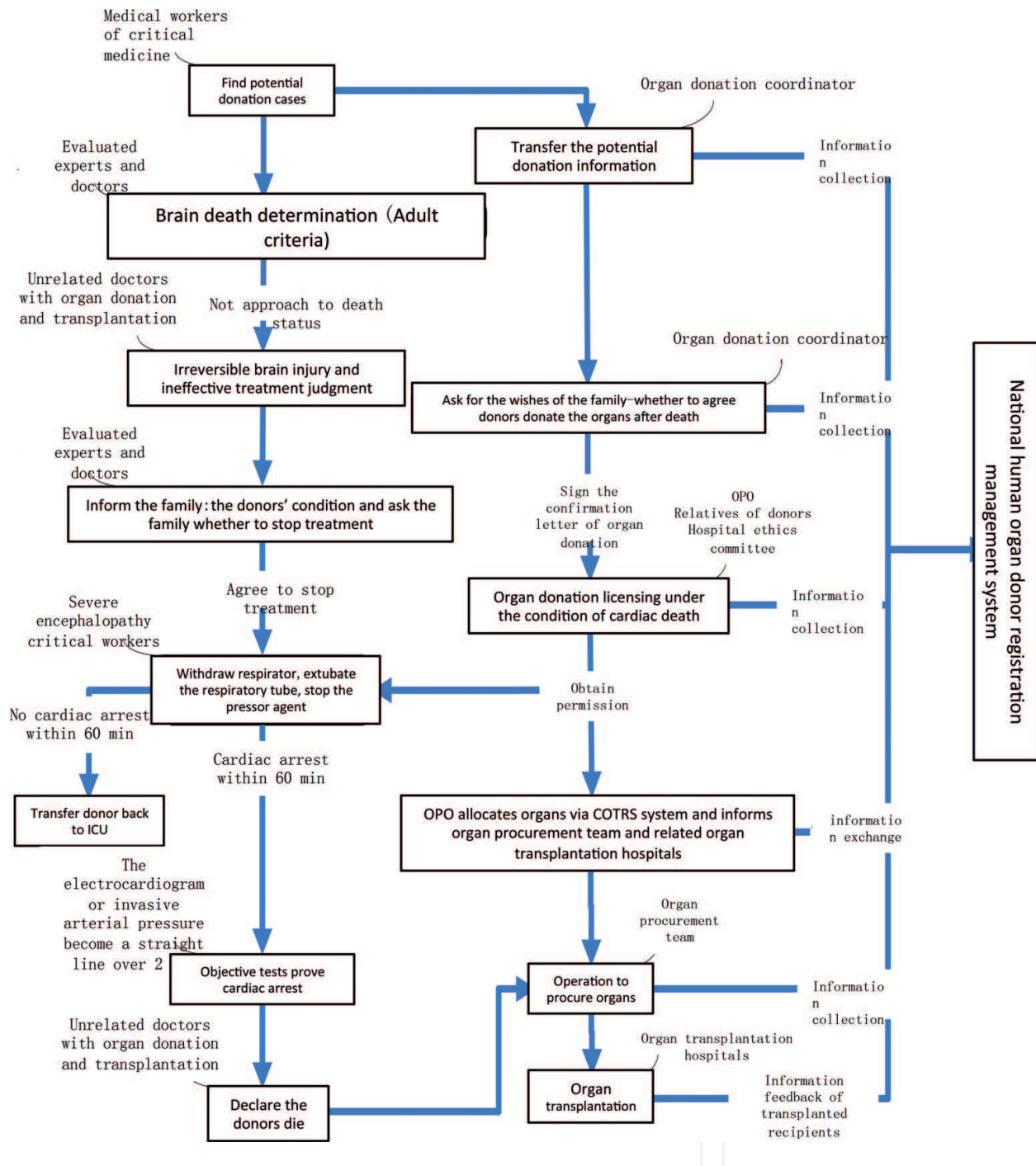


Figure 5. Flow chart of organ donation and procurement (C-II) [20].

2. The transplant hospital has the right, based on sound medical judgment, to refuse to accept unsuitable organs for transplant wait-ins.
3. Human organ distribution and sharing must take place according to the transplantation of hospitals, provinces (municipalities and autonomous regions), three levels of organ distribution and sharing level by level:

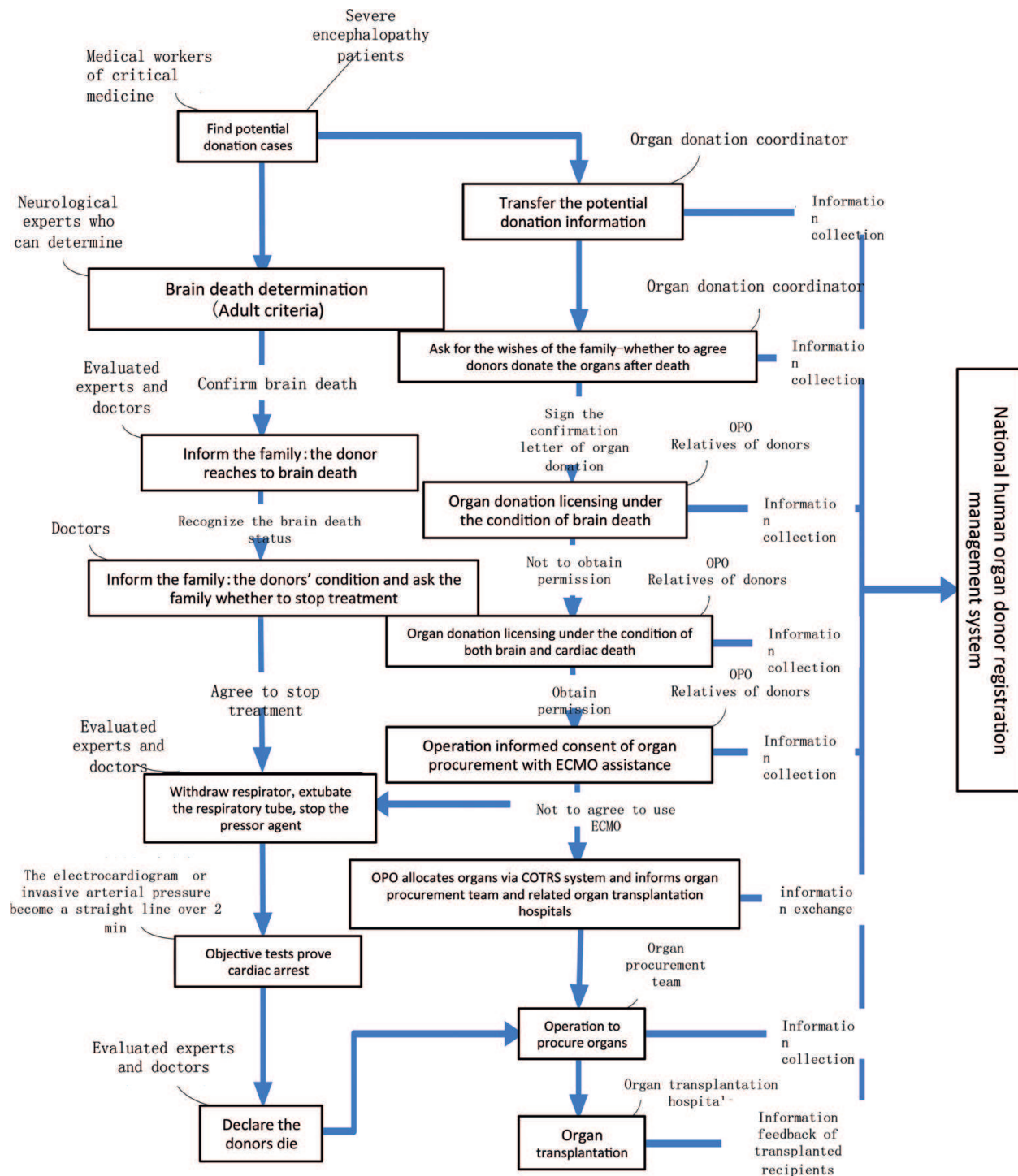


Figure 6. Flow chart of organ donation and procurement (C-III) without ECMO assistance [20].

- Human organ distribution and sharing process should avoid the waste of organs to maximize the patient's chance of receiving a transplant and improve the efficiency of organ distribution.

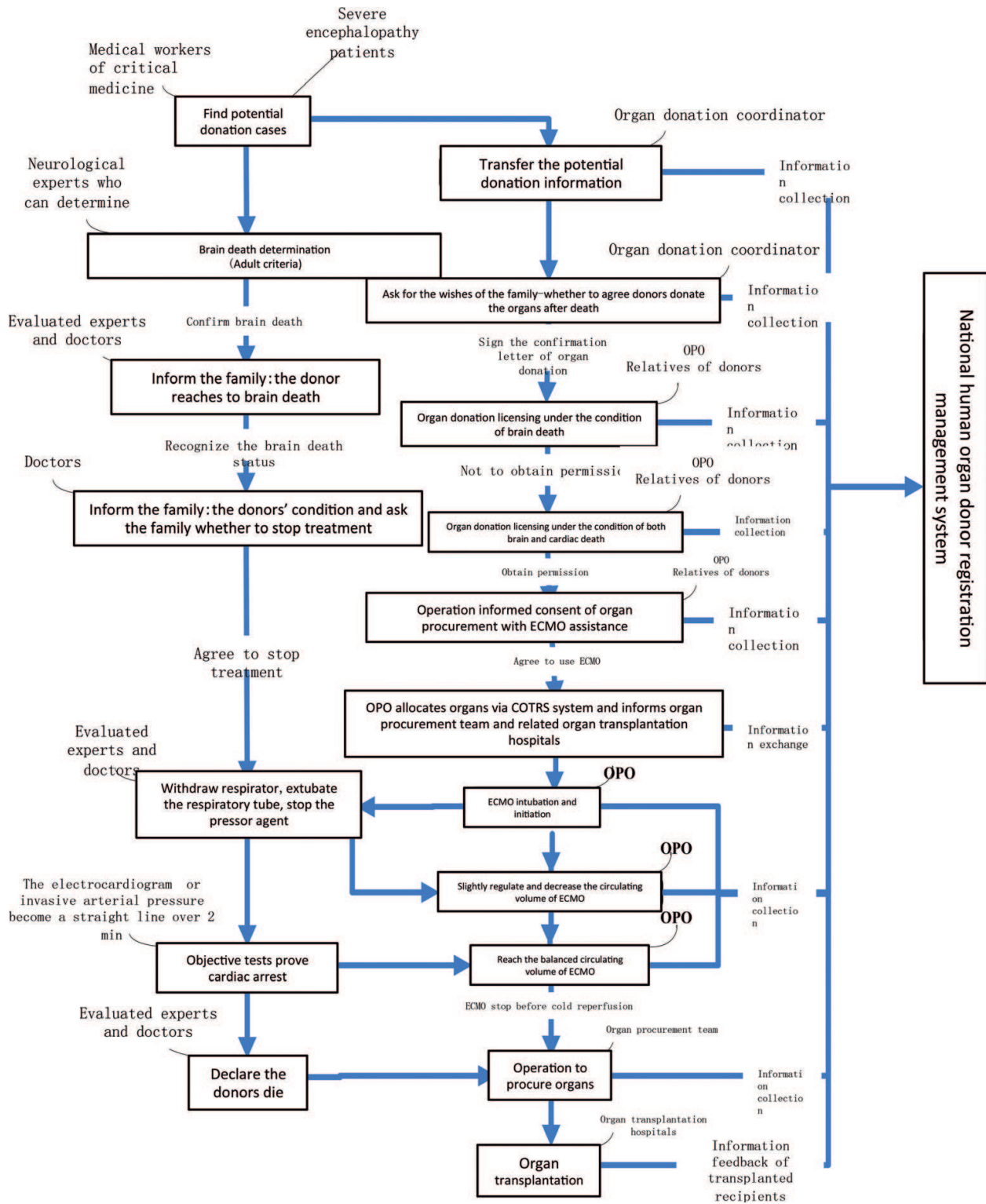


Figure 7. Flow chart of organ donation and procurement (C-III) with ECMO assistance [20].

5. To optimize the matching quality of organs and recipients and improve the postoperative survival rate and quality of life of transplant recipients, on the premise of ensuring the lowest possible death rate in the transplant waiting list.

6. To ensure the fairness of organ distribution and reduce the physical, pathological and geographical differences caused by uneven distribution of organs.
7. Regularly review and amend human organ distribution and sharing policies.

With the progress of the human organ donation pilot work in our country, in order to further standardize organ procurement, distribution and transplantation, the National Health and Family Planning Commission issued the “Regulation on the Administration and Accession of Human Donated Organs (Trial Implementation)” in 2013. The regulation further develops the organizational structure and normative process of organ procurement and distribution system. It also has consolidated the legal basis for the establishment of the organ procurement and distribution system in our country. Not only does it promote the birth of organ procurement organization (OPO) but it also empowers the China Organ Transplant Response Systems (CORS) (www.cot.org.cn) to exercise the power of organ distribution. The regulation compulsively demands that donated organ must be distributed through the organ distribution system, and organizations or individuals cannot allocate donated organs outside the organ distribution system to ensure the origin and fairness of organ donation. At the same time, it requires OPOs to obtain the organ according to the china organ donation after cardiac death classification standard [22].

In order to guarantee the implementation of laws, regulations and policies, the medical database associated with it has also been gradually improved in recent years. Following the establishment of the four major scientific systems of kidney, liver, heart and lung transplantation, the China Organ Transplant Response Systems (CORS), China Organ Transplant Surgeon Registration System and Human Organ Donation Coordinator Registration System have also been constructed and put into use one after another. Since the “Regulations” were implemented through April 30, 2015, the organ distribution system has performed a total of 6170 organ matches, including 1738 liver and 4432 kidneys. Among them, 83.2% (5136 cases) were assigned to wait in hospital and 16.8% (1034 cases) were shared with other transplant hospitals in and outside the province. According to the statistics, the organ distribution system calculates the matching list for no more than 8 s and takes an average of 1.2 h for organ sharing [23]. The organ distribution system operates efficiently without human intervention. Through the assistance and data exchange between the various systems, invisible monitoring network of Chinese organ procurement and transplant is formed, which means that China’s organ transplant, based on the legal management, further deepens scientific information management.

4. The composition and responsibilities of the DCD working group

The DCD team includes the donor’s responsible doctor, organ donation coordinator, member of human organ procurement organization (OPO), surgical group, anesthesiologist, organ donation management committee, organ transplantation ethics committee, and so on. The above members constitute the DCD working group to participate in the DCD implementation process, each of which does its job, divides the labor and cooperate and jointly decides the key procedures.

4.1. DCD working group

1. The donor's responsible doctor: the doctor participates in the entire donation process except for the removal of the organ. Major responsibilities: find potential donors, have a preliminary assessment of potential donors with donation conditions; responsible to inform the families of patients, after the family members express the intention to terminate treatment; contact the Provincial organ Donation Committee (PODC); submit the basic information of potential donors; assist in organ donation coordination and discuss organ donation matters with family members; consult with family members to decide to remove cardiopulmonary support treatment; responsible for the implementation of the removal; confirm and announce the death of the donor; carry out necessary medical intervention of donors before donation; fill DCD records; review the case and report to the hospital organ donation committee and hospital organ transplant ethics committee.
2. Organ donation coordinator: the main responsibility is to discuss the organ donation with the family members and obtain the legal documents such as the donation of informed consent and so on. The organ donation coordinator is trained and qualified by the Red Cross.
3. Organ donation evaluation expert: the team is composed of high-quantified chief physicians or above-ICU physicians, neurologists and surgeons and is mainly responsible for confirming whether the patient meets organ donation conditions.
4. OPO group: the team is mainly responsible for organ removal and not participating in the removal of cardiopulmonary support.
5. The Hospital Organ Donation Committee/The Hospital Organ Transplant Ethics Committee: the team checks whether the relevant legal documents for supervision and donation are perfect, whether the donation process accords with the informed consent principle and supervises the DCD reporting medical records and record management.
6. Other related members, including the anesthesiologist, operation staff, and so on, mainly assist the OPO team to complete the organ procurement [24].

4.2. Organ procurement organization

1. Constituent conditions: The Organ Organization (OPO) is established by provincial health administration department and comprises one or several human organs' organ transplant surgeons, neurologists, critical care physicians and nurses under the unified leadership of the Health and Family Planning Commission. The OPO must establish a team of human organ donation coordinators with specialized skills and qualifications. OPO also needs to formulate medical standards of identifying and screening potential donors, to establish standard human donation organs' procurement, technical specifications and provide specialized personnel and equipment to ensure the quality of organ procurement.

2. Responsibilities: (1) appropriate medical assessment of potential donors in their service area; (2) in accordance with the "Regulations," sign the human organ donation informed consent or other human organ donation legitimacy document with the donors or their spouse, adult children, parents (or other legal guardians), and so on. (3) maintenance of organ donation; (4) entry of clinical data and legal documents of potential donors and donated organs into CORT; (5) use of organ distribution system to start donation of organs; (6) acquire, save and deliver donated organs and confirm the transfer of donated organs according to the distribution result of the organ distribution system and the hospital with human organ transplantation qualification where the organ transplant recipients who obtained the organ are located; (7) carry out medical treatment on the remains of donors according to ethical principles and participate in the memory and condolences work; (8) protect the personal information of donors, recipients and waiters and protect their legal rights and interests; (9) organize relevant medical staff in medical institutions within the scope of their services to participate in professional training and assist the executive on the regular OPO coordinator training and assessment, conduct scientific research and academic exchanges; and (10) publicity and education on knowledge of human organ donation to the general public [25].

4.3. Division principle of OPO service areas

In order to encourage and promote effective DCD work in all the provinces and avoid unnecessary competition and looting, under the coordination of the health administrative departments, various provinces and cities established a number of independent OPO organizations and divided the service scope of OPO organizations at the same time. The OPO group must comply with the following principles [26]:

1. Provincial OPOs cannot procure organs across provinces.
2. Each OPO cannot procure organs across their own service area.
3. All organs must be assigned to the China Organ Transplant Response System for uniform distribution.
4. Each OPO has a priority in the allocation of its organs but should ensure that organs will be used effectively.

The number of OPOs varies from province to province. Most provinces adhere to the principle of free combination among transplant hospitals. For example, hospitals that are more advanced in DCD work and have a higher transplantation professional level and can carry out multiple organ transplants can form independent OPOs. A strong transplant center can lead a weaker transplant center to form an OPO. An experienced transplant center can lead an inexperienced transplant center to form an OPO. To avoid organ waste, centers that only can carry out one kind of transplantation can form an OPO with centers that can carry out multiple kinds of transplantation.

Taking Hunan as an example: With a population of 67.83 million (in 2015), Hunan Province has a total area of 211,800 km² and a total of 14 cities and 122 counties. There are eight

hospitals in the province that can carry out organ transplants, of which three hospitals can carry out a variety of organ transplants and the remaining five can only carry out kidney transplantation; there are a total of four existing OPOs in Hunan Province and under the joint consultation divided into four OPO service areas [27].

In order to carry out the work of DCD better, each transplantation hospital has set up some working groups: the OPO leadership group, the DCD ethics committee, the DCD work hospital coordination group, the full-time coordinator team, the OPO procurement group, the DCD work post-processing group, and so on. The composition and responsibilities of each group are as follows [28]:

1. OPO leadership group

Composition: includes the hospital main party and government leaders, functional departments and potential DCD clinical department leaders and transplant center responsible person.

Responsibilities:

1. to protect the development of DCD work and provide a good platform for collaboration;
 2. to carry out publicity work inside and outside the DCD and regularly report to the higher authorities;
 3. regular inspection, to grasp the legality of the DCD process;
 4. to give DCD work in financial support and financial supervision; and
 5. to protect, such as ambulances, equipment, care, medical, legal and other aspects of support to ensure the smooth flow of DCD work.
2. DCD Working Coordination Group: Composed of the Medical Services Department, the Department of Health, Propaganda Department, the vehicle team, the hospital legal adviser, potential DCD medical department director, nurse and coordinators.
3. DCD Ethics Committee

Composition: Includes the management, medical, psychological, nursing, pharmacy, law, ethics, community representatives and other aspects of the composition of the residents.

Responsibilities:

1. confirming and identifying that medical institutions have the relevant qualifications and conditions;
2. discuss and approve DCD organ transplantation and confirm that the donor source is legitimate and matching type is reasonable;
3. to confirm that the donor and the recipient of the documents meet the requirements of legal documents, that there is no sale of human organs;

4. to confirm whether necessary inspections have been given to the donors and recipients to ensure clinical efficacy.

4. DCD determination group

Composition: Includes the brain death or DCD identification of neurological and surgical experts. Requirements:

1. experts in determination group at least are associated experts and
2. experts must undergo a specific brain death and DCD training.

5. OPO procurement group

Composition: Includes professional transplantation medical staff and related staff.

Responsibilities:

1. receive DCD-related information and DCD authentication written information;
2. evaluation of donor quality;
3. assess the recipient indications, contraindications, general condition and timing of surgery; and
4. being responsible for the acquisition, preservation and transshipment of organs.

6. DCD post-processing group

Composition: Formed by the Medical Department, the vehicle team, the Propaganda Department, logistics department, coordinators and Red Cross staff, and so on.

Responsibilities:

1. body maintenance;
2. coordinate with the relevant departments and arrange the cremation;
3. communicate and coordinate with relevant departments and arrange the implementation of the cemetery and the memory activities;
4. cooperate with the Red Cross in publicity; and
5. deal with other left-over issues after DCD work.

DCD work in Hunan Province has always been in a leading position in the country. The success of DCD work in Hunan Province is mainly attributed to the strong support and cooperation of the Provincial Health and Family Planning Commission, the Red Cross Society and the transplant hospitals. **Figure 1** shows DCD in eight hospitals in Hunan Province for 2010–2016 and **Figure 2** shows implementation of DCD in China. The work of organ transplantation in China is also known as the “Hospital president project” and all the transplant centers that have better development are fully supported by their presidents [29].

5. Chinese organ donation coordinator

5.1. Basic requirements of coordinator

“There is no organ transplant without organ donation, no organ donation without coordinator” [30]. This fully demonstrates the importance of coordinators in organ donation and transplantation. At present, there are two main types of coordinators in China: Red Cross Coordinator and OPO Coordinator.

Based on relevant regulations “Management of human organ donation coordinator” promulgated on June 1, 2013, the coordinator shall meet the following conditions [31]:

1. has good conduct and loves organ donation career
2. has medical and other related disciplines’ specialist qualifications
3. has at least 2 years of work experience
4. are formal or hired personnel of local regulatory agencies or persons recommended by medical institutions

According to the “Regulation on Procurement and Distribution of Human Donated Organs (Provisional)” issued by the National Health and Family Planning Commission, the OPO coordinator should meet one of the following conditions:

1. bachelor’s degree or above in medical college, holds a valid “People’s Republic of China physician practicing certificate”, with more than 2 years of clinical work experience and is a licensed doctor engaged in medical work in medical institutions.
2. has a college degree on nursing or above and has “People’s Republic of China nurse practicing certificate.” The person must have more than 2 years of clinical nursing experience and is a registered nurse engaged in clinical nursing activities in a medical institution.

In addition, the coordinator should also have a serious working attitude, a certain degree of communication skills and language skills as well as good psychological quality and psychological endurance. Only in this way can we properly handle the relationship with donors and their families, do a good job in organ donation coordination and push forward the donation of human organs [32].

5.2. Coordinator training in China at the current stage

From 2010 to 2012, the Chinese Red Cross is mainly responsible for the training of coordinators. After the establishment of China Organs Donation Administration Center after 2013, it specially undertook the training of coordinators and organized 4–5 training courses each year. It invited experts in medicine, law, ethics and psychology from all over the country to give lectures and organized domestic relevant experts who compiled the “Training Materials on Human Organ Donation Coordinator in China” (the first and second volumes) [33]. The coordinators were required to attend relevant studies and pass the qualification examination.

At present, a management system of coordinators with rigorous management, impartial examination and scientific training has been formed, which has delivered a large number of high-quality coordinators for the DCD work in China and, at this stage, and has made great contributions to the successful development and promotion of DCD work in China.

5.3. Organ donation coordinator working procedures in current China

1. discover potential DCD donors [31]
2. report the information and wait for evaluation
3. after the assessment team finds that it meets the conditions of donation, communicate with potential DCD family members
4. after donors' family members agree to donate, witness the completion of China organ donation registration form and family's informed consent
5. witness the work of the OPO team to ensure that all work is conducted in a reasonable and lawful manner
6. assist in the burial, memory and other post-processing work
7. assist the aftermath of the donors' family members
8. assist in completing legal instruments related to organ donation

6. China's current DCD work archives establishment and management

The organ donation archive is a strong evidence of DCD's legal compliance but also important information for late summing up experience and conducting scientific research. With the increasing number of DCDs, the management of donors' archives is becoming increasingly important. Establishing a set of scientific and standardized donor archive management standards is of great significance to promote the sustainable development of DCD [34].

Since the launch of the pilot DCD program in China in 2010, great attention has been paid to the collection of archives and data. All provinces and transplant hospitals have done a great deal of work and summed up some experience. For each case of donation, corresponding archives were set up and collected the important information. In the early stage, it is mainly the collection and preservation of paper materials; the project basically includes the following [35]:

1. China organ donation completion form
2. China organ donation registration form
3. donor and their relatives' ID cards
4. donor's basic information table

5. donor comprehensive evaluation table
6. potential organ donor's family informed consent
7. brain death determination family member's application form
8. brain death determination family's informed consent
9. brain death determination form
10. the donor electroencephalogram inspection report
11. DCD organ transplant ethics form
12. donor management form
13. organ procurement record form
14. the donor discharge diagnosis/patient history information
15. the HLA matching report
16. the recipient information
17. recording video or photo material throughout the process of organ donation
18. donor medical death certificate
19. cremation certificate
20. organ donation process record form

However, there are also some problems. For example, the standard norms are not uniform, and the paper materials are not conducive to long-term preservation; inspection and data statistics are inefficient. Through continuous discussion and exploration and the cooperation of various field experts, we have made use of information technology and Internet technology to develop an organ transplant file management system that is suitable for China. The

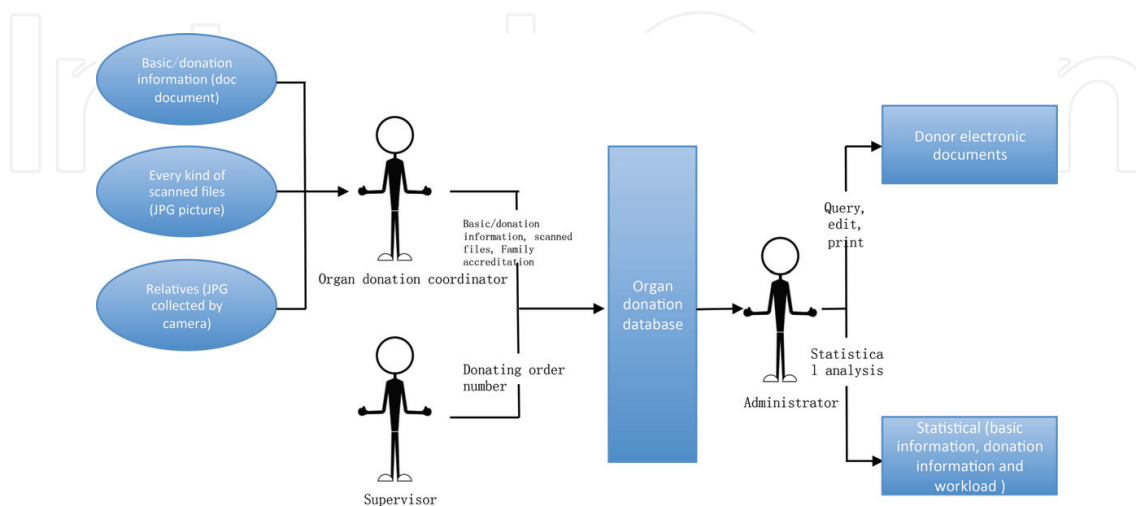


Figure 8. Flow chart of organ transplant file management system [33].

registration of this system basically covers all the information and data above. The process is as follows (**Figure 8**):

Real-time reporting, monitoring of implementation, data analysis and follow-up were conducted in every case of this organ donation database to ensure the regulation of DCD work and also accumulated a large amount of data and laid the foundation for the long-term development of DCD.

7. China's DCD organ donation problems

7.1. Organ donation and transplantation supply and demand situation is still grim

At present, great progress has been made in organ donation and transplantation in our country. With the continued development of our society and economy, especially the improvement of the levels of medical service, it is still a huge challenge to solve the contradiction between the rapid growth of people's health needs and the overall shortage of service provision. About 300,000 end-stage organ failure patients in our country need organ transplantation each year, yet the number of organ transplants is less than 20,000 each year. From a global perspective, the number of organ donations in our country is at the forefront, but the donation rate per million population needs to be improved. How to improve the organ donation rate so that more patients receive prompt treatment is still the long-term goal of our work.

7.2. Citizens lack the correct understanding of organ donation

First of all, under the influence of "maintaining the integrity of the body" and the wrong "death concept," Chinese citizens' willingness to organ donation is not strong, and due to the fact that the law relating to brain death is still lacking in our country, it also hinders the practice of "brain death" standard to a certain extent in our country. Secondly, the lack of social propaganda makes citizens lack the recognition of the donation process and give up donation. Coupled with the wrong public opinion, such as some exaggerated organ buying and selling speech, etc., also make citizens concern whether the use of donated organ is properly or not, which mislead citizens' cognition of organ donation, affecting their willingness to donate. At the same time, most medical workers have not been involved in organ donation and are not familiar with the criteria for determining brain death, the classification and conditions of organ donation and their reluctance to ask their patients' families' attitudes and wishes toward organ donation, which also hinder the discovery of potential organ donors.

7.3. Organ donation and transplantation-related systems still need to be sound

China's organ donation worked from scratch, achieved by leaps and bounds. At present, we have initially established a donation and transplantation system for human organs in line with China's national conditions, culture and social ethics. However, all aspects of system design and legal norms still need to be explored and developed in practice. To establish a sound organ donation and transplantation system that is compatible with the level of social-economic

development level, improve a more equitable and efficient organ distribution system and to scientifically plan the regional distribution of transplanted hospitals so as to ensure the equalization of organ transplant services for all citizens, we also need to keep it up.

For example, various provinces in China have formed an independent organ procurement organization (OPO) and delineated their corresponding service scope. Unlike other countries, most of the OPOs in China are composed of transplant medical teams in organ transplant hospitals. This form is advantageous in the initial stage of DCD work, but with the development of this work, some disadvantages are also exposed, such as the limitation of organ distribution and the irrational division of service areas, and so on, which all need to be constantly adjusted and improved in following-up work.

At present, there are two organ donation registration websites in China: organ donation administration center website by the Chinese Red Cross and “Shi and Suo” organ donation registration website administered by the National Health and Family Planning Commission. Current organ donation and transplantation network systems include the donor system, China organ transplant response system (CORTS). The use of websites is yet to be promoted, just as CORTS, a site that plays a major role in organ allocation, the number of patients who have registered on CORTS for transplantation has a large discrepancy from the actual number of 300,000 patients who are waiting for transplant. Compared with the UNOS website in the United States, the CORTS website in our country did not give full play to its functions, and lacked the legal effect and administrative system. Its authority and compulsion needed to be improved [36, 37].

8. The achievements and prospective of China’s DCD work

After several years of hard work, China has made gratifying achievements in the work of DCD. Some of the figures are shown in **Figures 9–19**:

China has successfully resumed the transition from relying on the judicial channels to procuring organs through the voluntary donation of citizens. The reform is the result of the concerted efforts of the top leadership of the country, relevant departments, social organizations, the vast majority of transplant medical personnel and Red Cross workers, who obtained the understanding of society and the recognition of the international community. Based on the guiding principles set by the relevant international organizations and based on the actual social and economic development and cultural traditions in China, we adopted methods suited to China’s national conditions and promoted the continuous progress of organ donation and transplantation in China. After several years of pilot research, the influence of organ donation after citizen death to our society has surpassed that of the transplant medical service itself. Such love charity is gradually becoming a common practice in China. With the joint efforts of the health administrative departments, the Red Cross Society and the transplant medical institutions, organ donation after citizen death has taken a solid first step. However, China has a large population, huge demand for organ transplants and some traditional concepts are still affecting us. In particular, we are still in the process of improving laws and regulations, strengthening government supervision and departmental coordination, clarifying responsibilities of all parties, refining work processes and strengthening international exchanges and cooperation. There is still a lot of work to do [38].

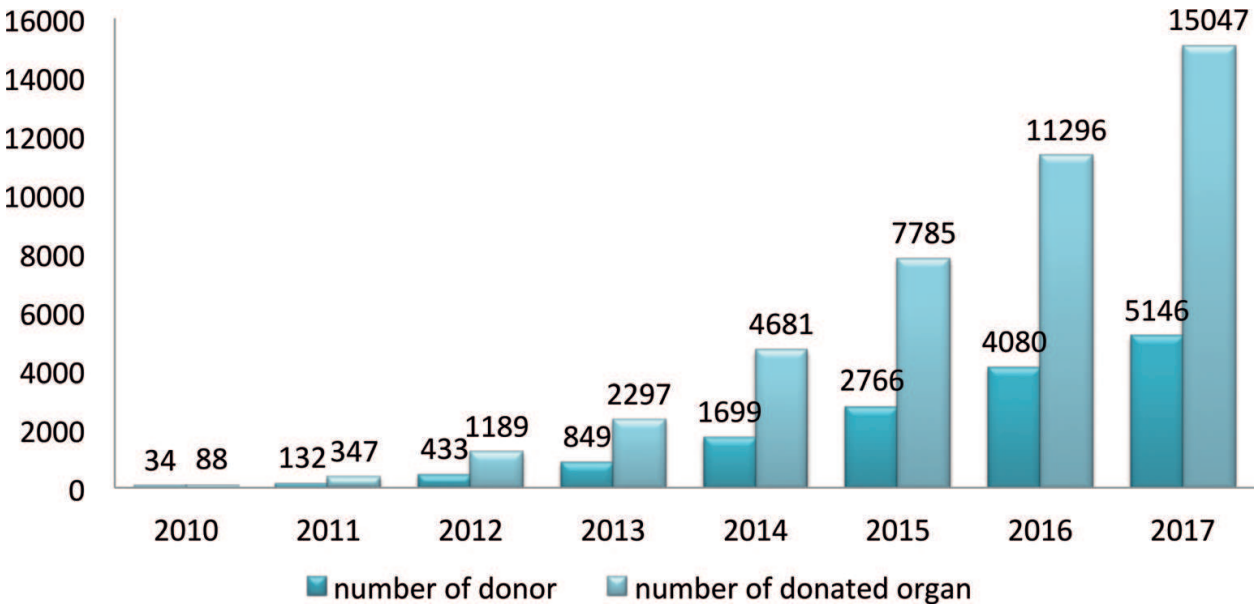


Figure 9. Overview of organ donation according to the data of China organ donation administrative center, by the end of 2017 [data from China organ donation administrative center].

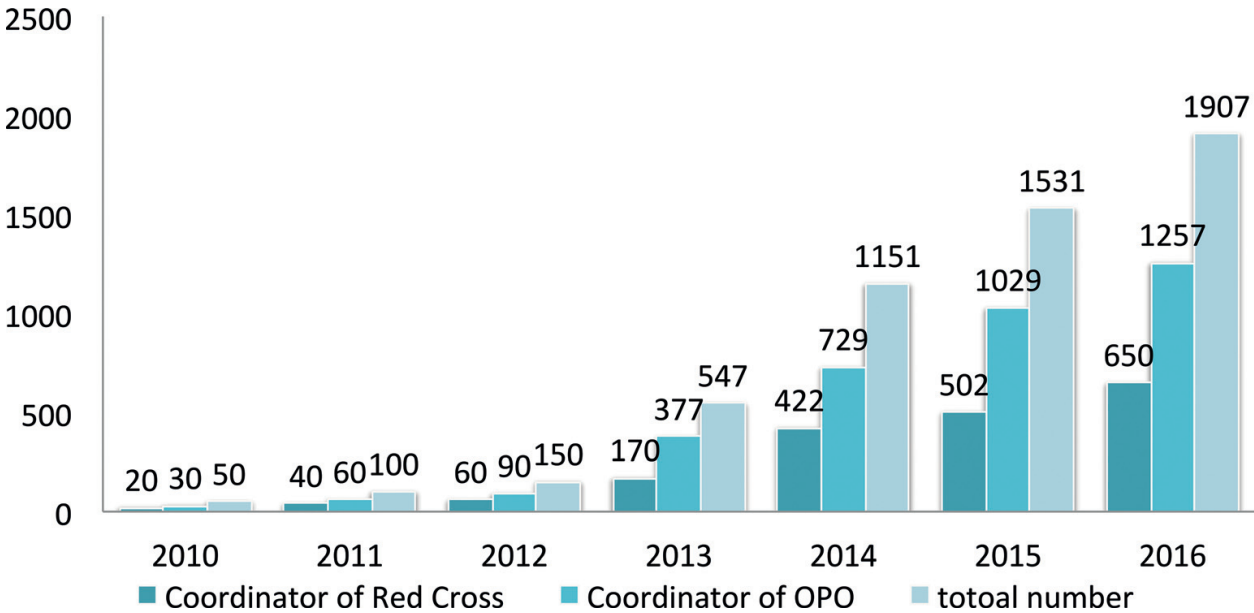


Figure 10. The change of the number of coordinators according to China organ donation administrative center [data from China organ donation administrative center].

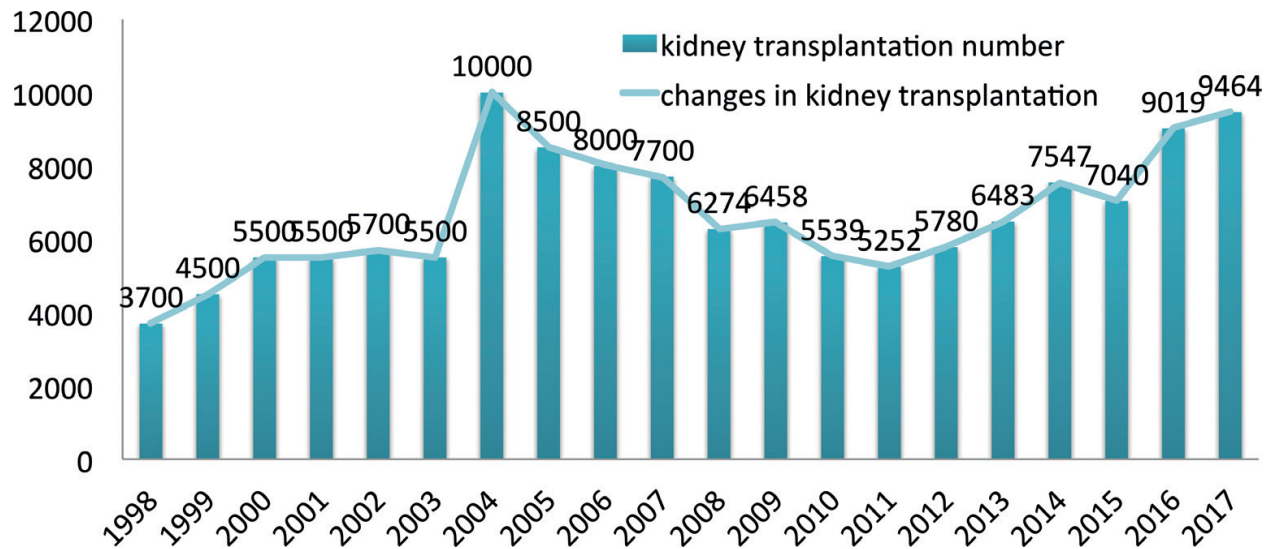


Figure 11. Annual data on kidney transplantation (20 years) [data from Chinese scientific registration of kidney transplantation (CSRKT)].

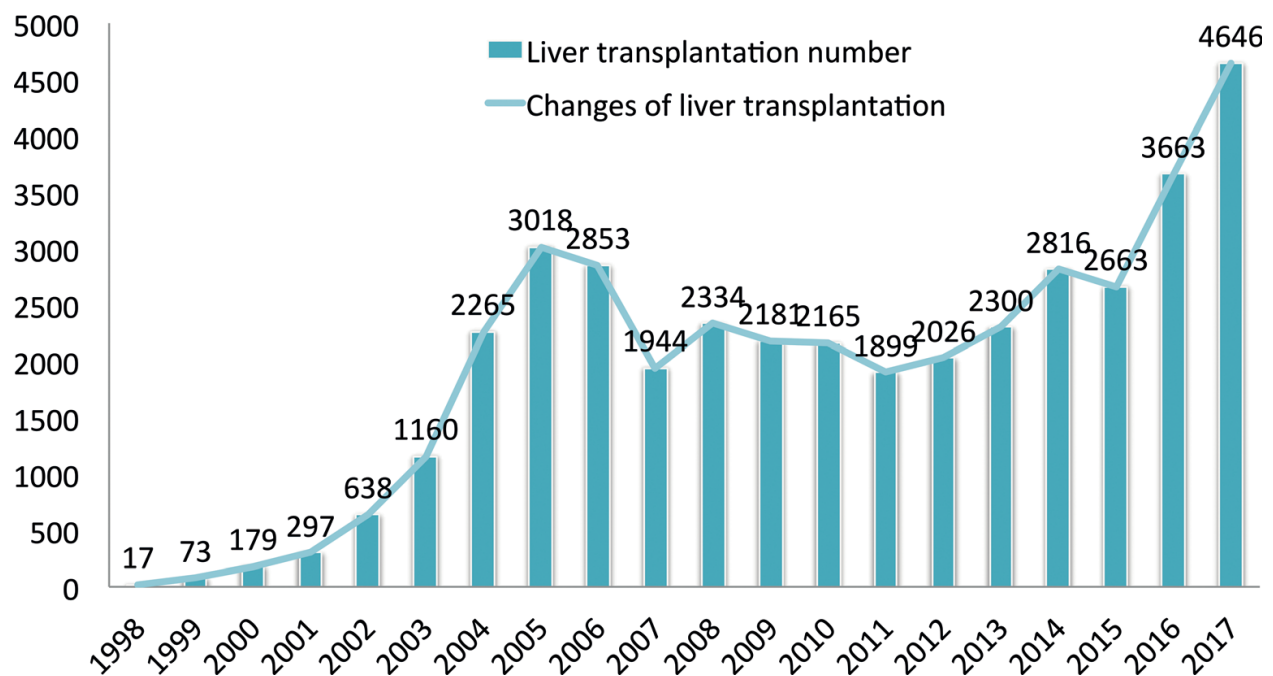


Figure 12. Annual data on liver transplantation (20 years) [data from Chinese liver transplantation registration].

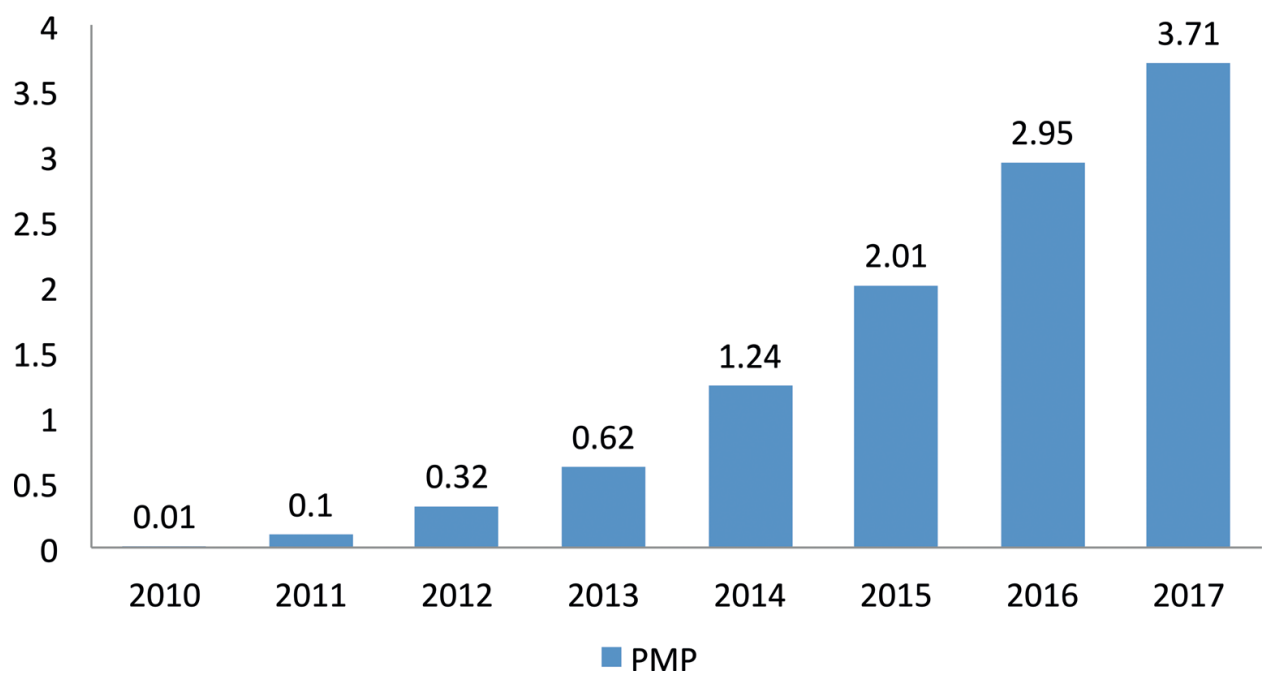


Figure 13. Annual data on organ donation PMP [data from China organ donation administrate center].

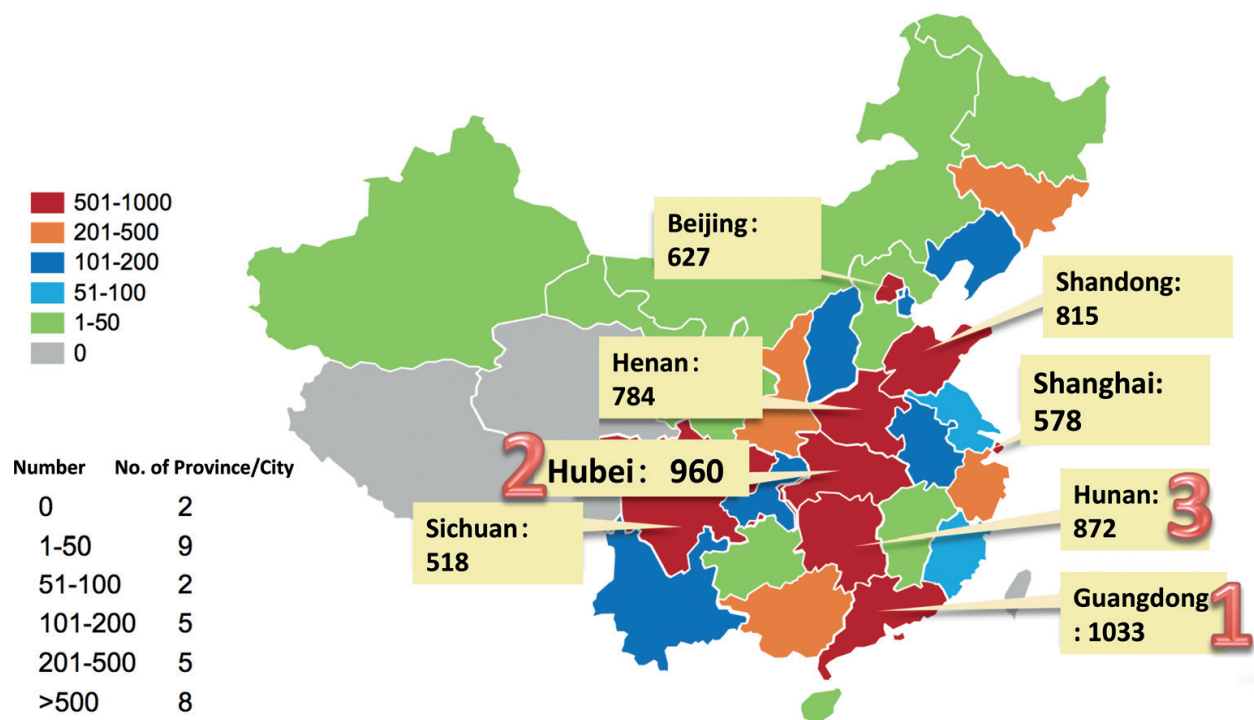


Figure 14. The overview of kidney transplant in 2016 [data from Chinese scientific registration of kidney transplantation (CSRKT)].

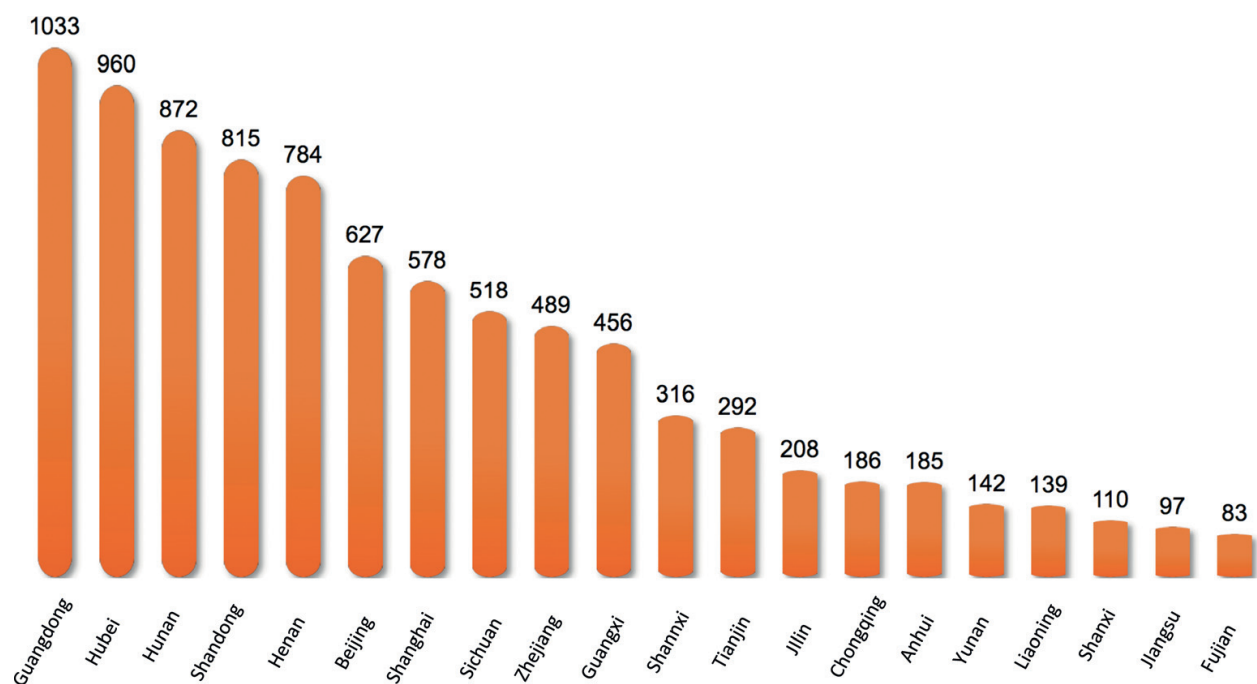


Figure 15. Number of kidney transplantations in each province in 2016 top 20 [data from Chinese scientific registration of kidney transplantation (CSRKT)].

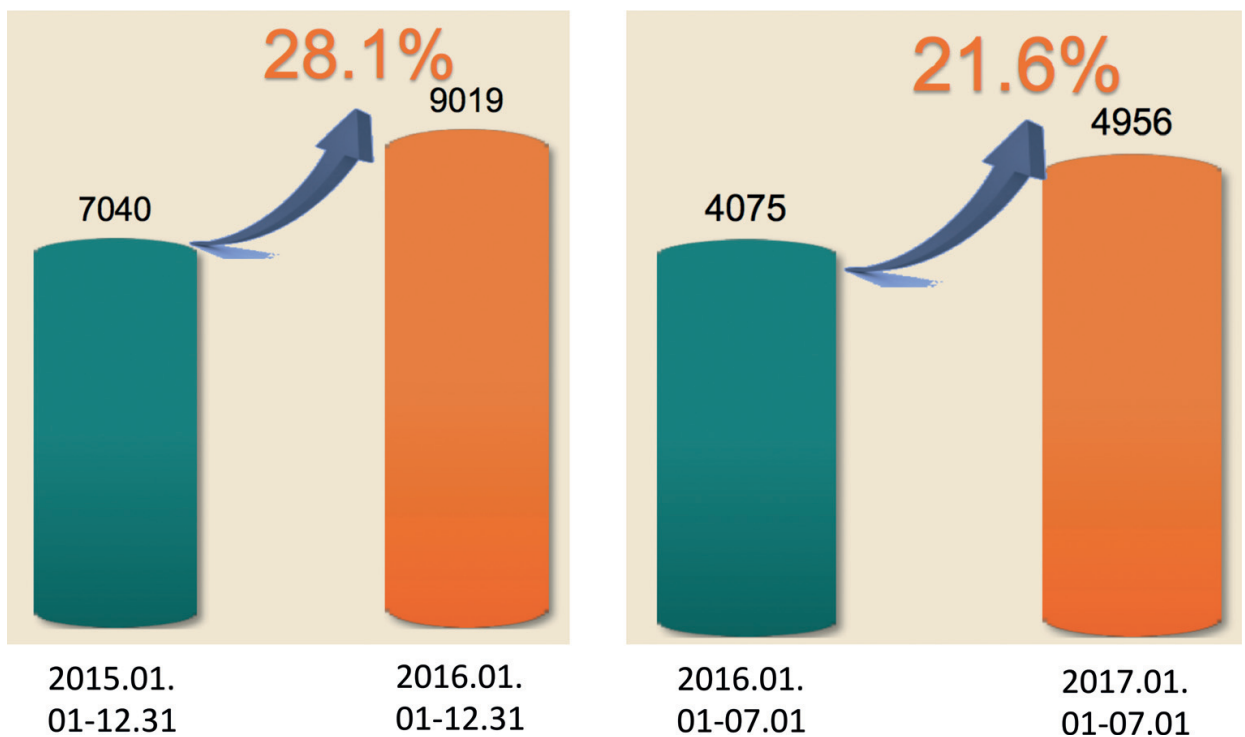


Figure 16. During the same time period, the number of kidney transplantations has been continuously increasing, that is, more than 20% [data from Chinese scientific registration of kidney transplantation (CSRKT)].

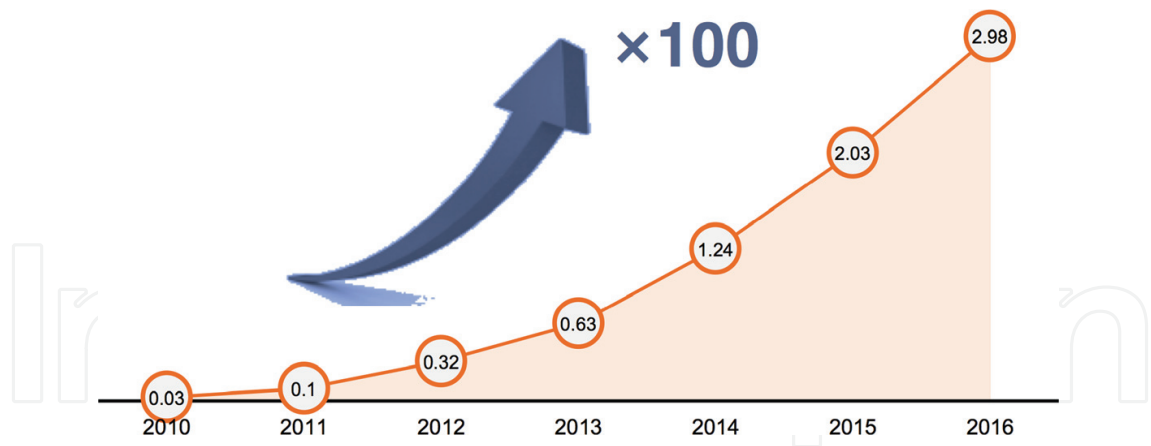


Figure 17. The increasing of donation rate [data from Chinese scientific registration of kidney transplantation (CSRKT)].

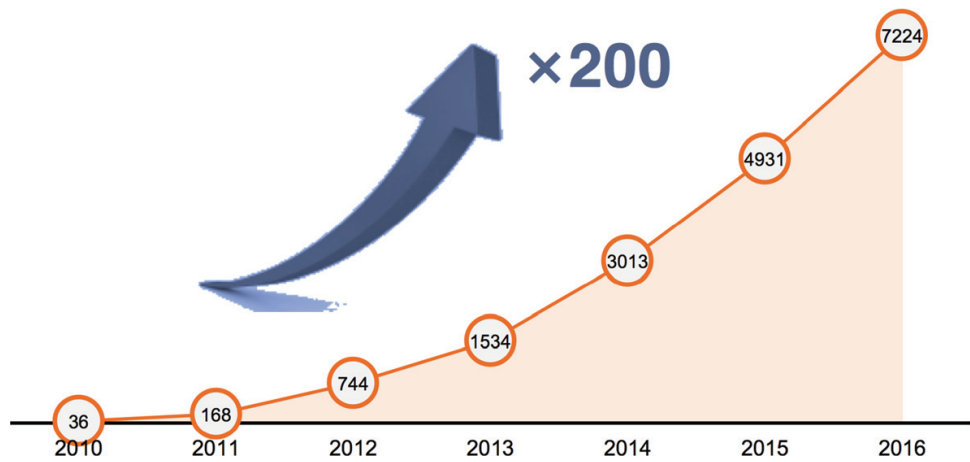


Figure 18. The increasing of DCD cases [data from Chinese scientific registration of kidney transplantation (CSRKT)].

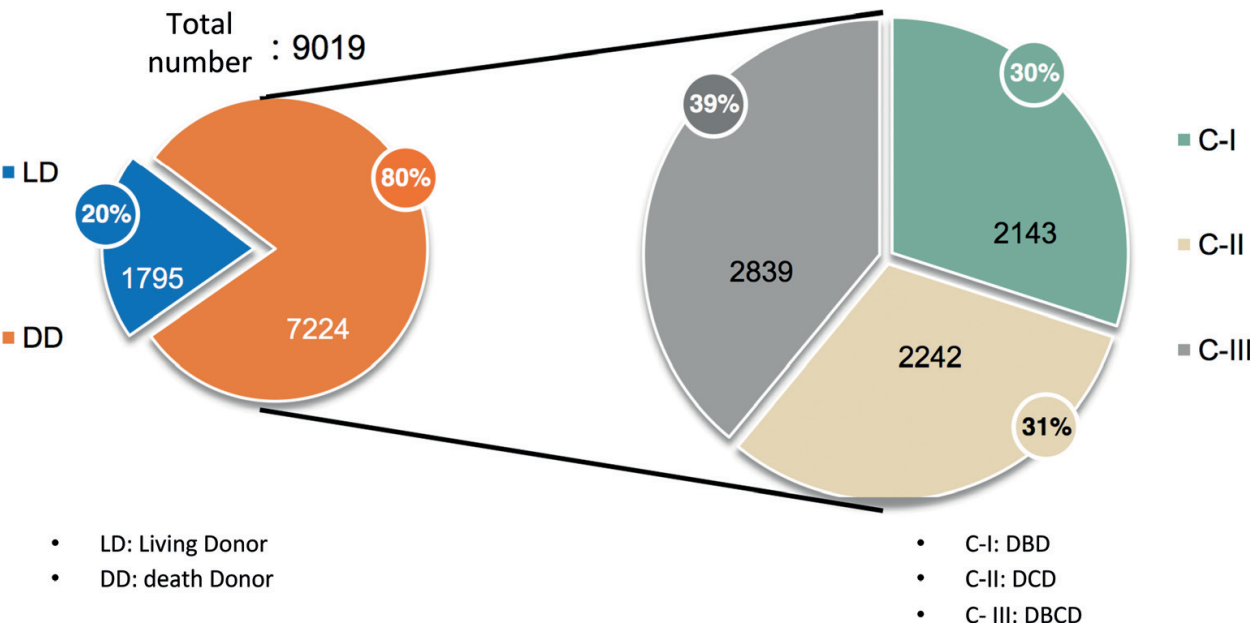


Figure 19. Organ donation in our country is based on death donors at current stage.

9. Conclusion

The shortage of organs was the bottleneck of transplantation. According to Chinese own features and the international development situation, China has carried out DCD work, which is fruitful, innovative and achievable. This has guaranteed the organ donation issue of China to develop healthily and sustainably. Although there is still some imperfection, Chinese DCD work will be better and better with our continuous promotion and international help.

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Conflict of interest

No conflict of interest.

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References

- [1] He X. To promote the orderly development of organ donation in China. Chinese Journal of Organ Transplantation (Electronic Edition). 2010;**4**(2):7-9
- [2] Huang J. Key initiatives to promote the healthy development of organ transplant in China. Chinese Journal of Organ Transplantation. January 2011;**32**(1)
- [3] Regulations on Organ Transplantation. State Council Order No. 491
- [4] Huang J. The development process of organ donation in China. Chinese Critical Care Medicine Intensive Case Med. May 2017;**3**(2)

- [5] Huang J. Speech at the national human organ donation pilot conference. 2010.3.2
- [6] Huang J. To create organ donation and transplantation system that is in line with China's national conditions. *Chinese Journal of Surgery*. January 2013;51(1)
- [7] Chen Z. Twenty five years wear a sword—Global organ shortage and transplant crisis and China's new road. *Chinese Journal of Organ Transplantation (Electronic Edition)*. November 2010;4(4)
- [8] Regulations on Regulating Living Organ Transplantation by The Ministry of Health. The Ministry of Health Order [2009] No. 126
- [9] Huang J. Speech at National Organ Donation Conference. 26 August 2009
- [10] Letter of the Ministry of Health on Entrusting the Red Cross Society of China to carry out Organ Donation Work. The Ministry of Health Order [2010] No. 25
- [11] Notice on Printing Organ Donation Pilot Work Program. The Red Cross of China Order [2010] No. 13
- [12] Approval on Including Hunan Province into Organ Donation Pilot Work. The Red Cross of China Order [2010] No.68
- [13] Chinese Medical Association Organ Transplantation Group. China organ donation after cardiac death work guidance. *Chinese Journal of Organ Transplantation*. July 2010;31(7)
- [14] Chinese Medical Association Transplantation Branch. China organ donation after cardiac death work guidance (the second version). *Chinese Journal of Organ Transplantation*. December 2011;32(12)
- [15] Declaration of China's human organ donation pilot work summary meeting. 23 March, 2012
- [16] Linna Hao. The Speech of Chinese Red Cross President on National Human Organ Donation Pilot Work Summary Meeting [Internet]. 2012. Available from: <http://www.chinanews.com/jk/2012/03-22/3764262.shtm> [Accessed: 2018-01-20]
- [17] Chinese Red Cross the Ministry of health Opinion on Continuing Promoting Organ Donation Work. The Red Cross of China Order [2012] No. 39
- [18] Huang J. Speech at a National Video Conference on Human Organ Donation. 25 February, 2013
- [19] Huang J, He X, editors. *Theory and Practice of Organ Donation after Citizens' Death*. ISBN: 978-7-117-20121-1
- [20] China Organ Donation Work Guidance (the fourth version)
- [21] Notice of the Ministry of Health on printing Fundamentals of Human Organ Distribution and Sharing in China and Core Policies of Liver and Kidney Transplantation. The Ministry of Health Order [2010] No. 113

- [22] Provisions on the Administration of the Procurement and Distribution of Donated Organs (trial). The Ministry of Health Order [2013] No. 11
- [23] China Organ Transplant Response System (COTRS). Available from: <https://www.cot.org.cn/>
- [24] China Organ Donation Work Guidance. August 2013;1:P55-P56
- [25] China Organ Donation Work Guidance (the fourth version). August 2015:P21-P22
- [26] New Regulations on the Administration of Organ Procurement Organization. China Hospital CEO. Sept 2013;17. ISSN 1674-3989
- [27] Ming Y. Speech on China-Beijing International Organ Donation Conference. Oct 2016
- [28] Ye Q. Speech on Chinese Medical Doctor Association Organ Transplant Annual Meeting. Dec 2015
- [29] Ming Y. Speech on 14th Congress of International Society for Organ Donation and Procurement (ISODP). Sept 2017
- [30] Gao X. Standardized training, strict management, law-based promoting human organ donation coordinator team building. *Prac International Journal of Organ Transplantation (Electronic Version)*. Mar 2015;3(2)
- [31] Notice on Printing The Management Method of Organ Donation Coordinator (trial). The Red Cross of China Order [2011] No.65
- [32] Ming Y. Discussion on the building of organ donation coordinator teams. *Organ Transplantation*. Sep 2014;5(5)
- [33] China Organ Donation Coordinator Training Material (two volumes)
- [34] Chen Yao, Bingyi Shi etc. Construction of organ donation files management system. *Hospital Administration Journal of PLA*. 30 Oct 2016;23(10)
- [35] Ye Q. The organizational construction of organ procurement organization. Speech on China Organ Donation Coordinator Training Session. 2015
- [36] Yu H. Rational thinking on increasing the donation rate of citizens' organ in our country. *Medicine and Philosophy*. Jun 2012;33(454)
- [37] Yu H. Countermeasures for the transplantation dilemma in China. *Medicine and Society*. Sept 2012;25(10)
- [38] Chen Z. Efforts to create a new situation of organ transplantation with Chinese characteristics. 21 Aug 2015

