Tomorrow's Organ Transplantation Program in China

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(The Madrid Conference on Organ Donation and Transplantation March 23-25, 2010)

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- 1. Problems exist amid the development of organ transplantation in China
- 2. Roadmap for future organ transplantation development

1. Problems exist amid the development of organ transplantation in China

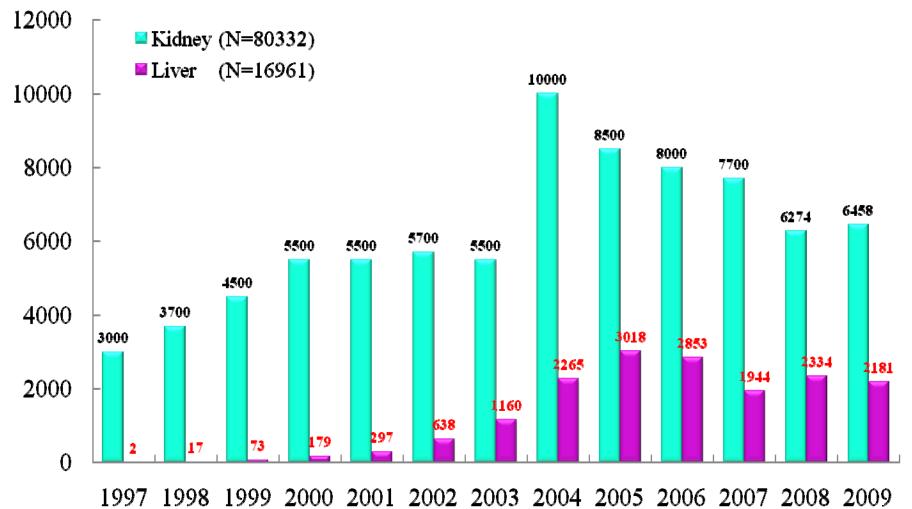
 Over half a century, China made arduous efforts in the development of organ transplantation with dedications from Chinese medical professionals spanning several generations.

 Today, China performs the second largest number of organ transplants in the world with a total number of 10,000 cases per year.



| | Туре | Number |
|-----------|-------------------|--------|
| 1969—2009 | Kidney | 93285 |
| 1993—2009 | Liver | 16961 |
| 2003—2008 | Heart | 717 |
| 2003—2008 | Lungs | 165 |
| 1994—2008 | Small intestine | 17 |
| 1989—2008 | Pancreas & Kidney | 219 |







- The total number of organ transplantation in China ranks the second in the world. Nearly all types of organ transplantation available internationally can be performed in China
- Development of basic and clinical research in transplantation
- Standardization of transplantation techniques
- Rapid expansion of clinical application
- Large number of new young experts
- Significant improvement of post-transplant survival rates and management
- International exchange and cooperation



- Use of organs from executed prisoners
- Commercialization of the services
- Transplant tourism
- Lack of a national system for organ donation and allocation
- Scarcity of organs for huge demands



Over-reliance on deceased organs from executed prisoners, a source that does not comply with international ethical and standard of practice.



Commercialization of the services

Illegal trading of human organs and organ intermediaries have emerged in China, forming a tremendous profit chain that is against the principle of equity and the goal of building a harmonious society.



- Some hospitals trade with illegal organ agencies and make false identifications for selling organs to foreigners for profit.
- Transplant tourism has made the sale of human organs even more lucrative.



Donation, use of organs and selection of recipients are currently hospital based without centralized standards and a transparent registry system for organ procurement, equitable organ allocation and selection of patients for transplantation.

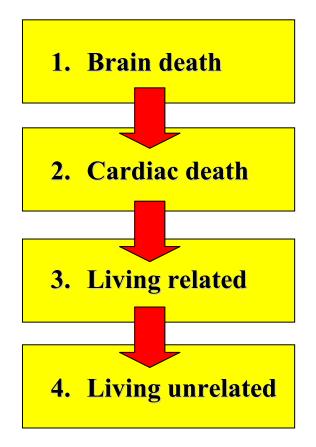


- There are about 1 million end-stage kidney disease patients on regular blood or peritoneal dialysis and around 300,000 terminal liver disease patients requiring organ transplantation in China.
- Lack of a legal, long-term and large-pool donor system is the greatest challenge in the development of organ transplantation in China.



- Where do organs come from? Who are the donors?
- The demand for transplantable organs must be balanced against a framework of acceptable values based on the Chinese society.
- Ethical organ transplantation is not possible without organ donation and a regulated organ allocation system.







- Deceased organs: Dependent on the good will of individuals and families to provide access to the dead with informed consent (over 90% of grafts are from executed prisoners)
- Living related organs: Genetically related or kinship to the recipients.



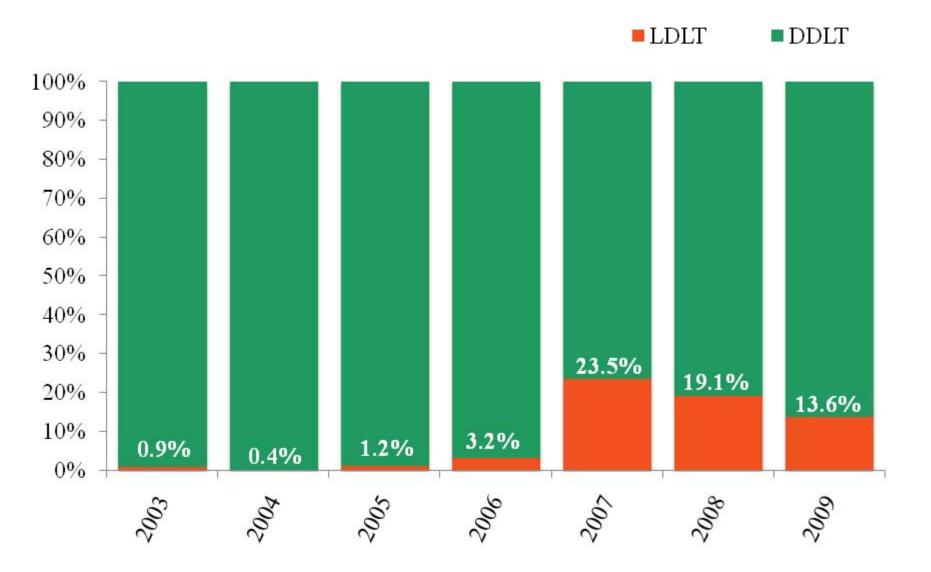
The additional safeguards have been established to ensure the individual rights of row inmates

- Re-examination of death sentences of a small number of extremely serious offenders by the Supreme People's Court
- Issues of balancing between society's need for justice and order and individuals' rights (legal philosophy)
- Requirement of written consent from organ donors (and/or their families) and bar of physicians from execution of the prisoners.
- Eventually abolishing the death penalty in the due time.



- Because of the reduction of the deceased organs, living-related organ transplants have been dramatically increased in the last 2-3 years, with roughly 3,000 cases annually.
- Driven by hunger for profit by organ brokers, some poor people are desperate in need to sell their organs for survival of the family. Some wealthy people are seeking organs at high prices, which is against justice and fairness of the society.

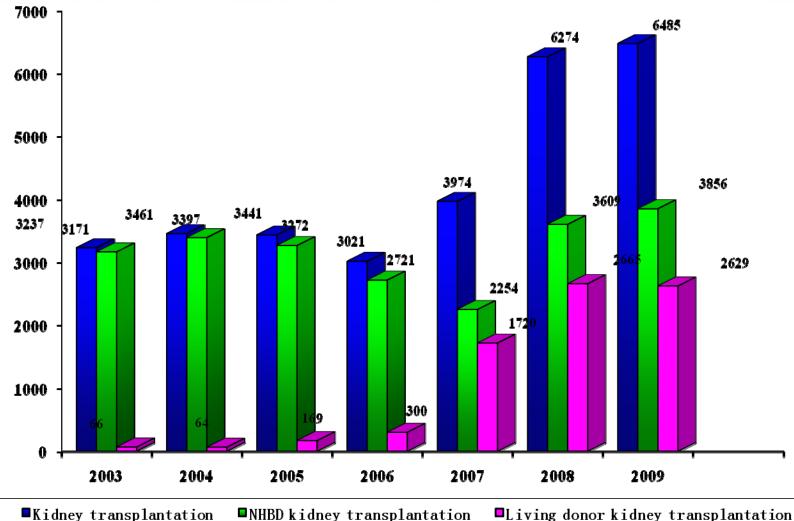
Living Donor vs. Deceased Donor Liver Transplantation 2003-2009







Living donor vs. deceased donor kidney transplantation from 2003 to 2009



2. Roadmap for future organ transplantation development

Great efforts must be made to increase the administrative efficiency to establish and oversee a national organ transplantation program



Human Organ Transplantation Regulation - March 21, 2007

中华人民共和国国务院令

第 491 号

《人体器官移植条例》已经2007年3月21日国务院 第171次常务会议通过,现予公布,自2007年5月1日 起施行。



China's organ transplantation system should be planned under the context of healthcare reform and development. The speed and scale of the program should be the results of taking considerations of realities such as level of medical services, the source of organs and socioeconomical status.

R H H M H

A systematic project (National Organ Transplantation Work Scheme)

Scientific Registries for Organ Transplantation

Accreditation System for Clinical Transplantation Service (163 certified hospitals)

> China Organ Allocation and Sharing System

Establish a scientific based policymaking process

Quality assurance for clinical service Accreditation system for hospitals and medical professionals Establish guidelines for clinical practice

Ensure equality, justice and transparency National Waiting List and Organ Matching System

National Organ Procurement Organization System (OPOs) Ensure effective use of transplantable organs

National Organ Donation Campaign Establish a donor registration system Promote organ donation rate Voluntarism



Scientific registries for organ transplantation will provide extensive scientific support to the policy-making process of the National Organ Transplantation Committee (OTC), which will ensure the highest professional standard of the transplant service.



National scientific registries for solid organ transplantation

- Liver Transplant Registry, <u>www.cltr.org</u>
 Queen Mary Hospital,
 The University of Hong Kong, Hong Kong
- Kidney Transplant Registry, <u>www.csrkt.org</u>
 PLA No. 309 Hospital, Beijing
- Heart Transplant Registry, <u>www.cotr.cn</u>, effective from April 2010 Fuwai Cardiovascular Hospital, Chinese Academy of Medical Sciences, Beijing
- Lung Transplant Registry, <u>www.cotr.cn</u>, effective from April 2010
 Wuxi People's Hospital, Wuxi



The system provides baseline requirements and guidelines for medical institutions. Currently, only 163 hospitals have been granted a license for performing organ transplantation in China.

Ban on transplants tourism

卫生部办公厅文件

卫办医发[2007]110号

卫生部办公厅关于境外人员申请人体器官移植有关问题的通知

各省、自治区、直辖市卫生厅局,新疆生产建设兵团卫生局,部直属 各单位:

为了认真贯彻《人体器官移植条例》,切实加强我国人体器官 移植管理,根据世界卫生组织人体器官移植指导原则,参照其他国 家和地区通行做法,现就境外人员申请实施人体器官移植有关事 官通知如下:

一、医疗机构及其医务人员不得为以旅游名义到我国的外国 公民实施人体器官移植。

医疗机构及其医务人员不得以旅游名义跨国境为外国居民实 施人体器官移植。

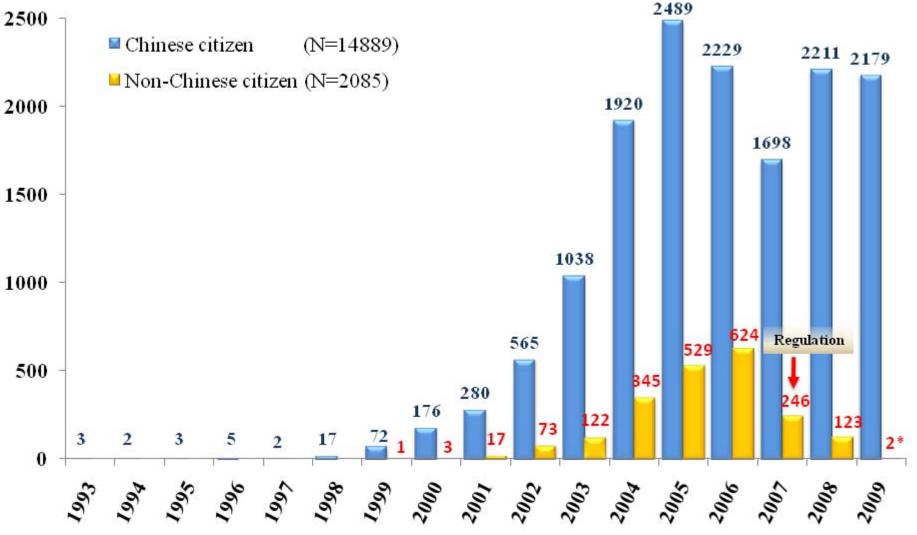
二、外国居民申请到我国实施人体器官移植的,医疗机构必须

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Since the enforcement of the Regulation in recent years, the certificates of 7 credited hospitals have been revoked, 8 physicians' licenses have been suspended, 3 of them are still in judicial custody, due to violation to the law.







* Living donor liver transplantation, approved by Ministry of Health, P. R. China





Ensure the equality, justice and transparency

National waiting list and organ matching system

Organ allocation and sharing policies



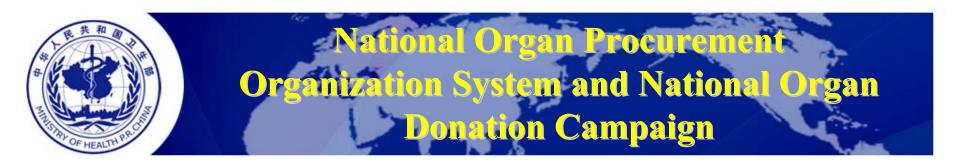
- Internationally recognized medical criteria regarding patient priority ranking, organ matching, allocation and sharing principles will be adopted by the China OTC and specialist committees.
- Chapter 4, Article 22: "National waiting list and organ allocation system shall be established to address medical needs of patients and ensure the principles of equality, justice and transparency."



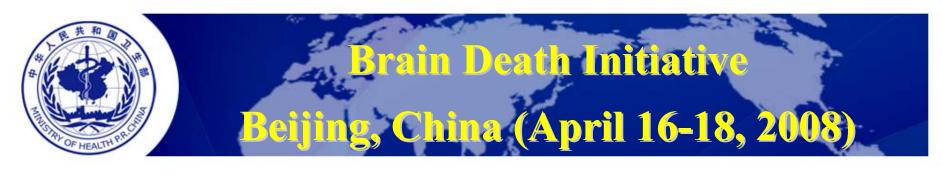
China Organ Allocation and Sharing Computer Network

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A sophisticated computer system has been developed by the MOH to implement policies and support the recently launched pilot project of organ donation program. The system will monitor and analyze the behaviors of participating parties and provide scientific reports to the OTC and Red Cross Society of China.



- Ensure efficient use of transplantable organs
- Establish a donor registration system that promotes the organ donation rate
- Voluntarism
- No payment for organs





Two criteria of judging standards for death co-exist and two autonomous options for both donors and recipients are implemented.

1.Accepting the concept of "brain death", putting brain death into the death category and making additions and amendments for the definition of death.

2.Implementing the objective of "Two standards co-exit and two autonomous options for stakeholders".



Organ donation initiative (Shanghai China, August 25th, 2009)



The National Human Organ Transplantation Working Conference, which was jointly sponsored by Red Cross Society of China and MOH, was successfully held in Shanghai on August 25, 2009. Some key issues on organ transplantation, such as the source of organs, establishment of an organ donation system and organ allocation mechanism, were constituted.



- Establish a human organ donation and allocation system independent of transplantation institutions,
 e.g. Red Cross Society of China.
- China's pilot program of organ donation from cardiac dead patients.



- High potential of organ donation from cardiac dead population in China
- Definition of organ donation from cardiac dead patients
- Medical and ethical standards of organ donation from cardiac dead patients
- Application of organs donated from cardiac dead patients.

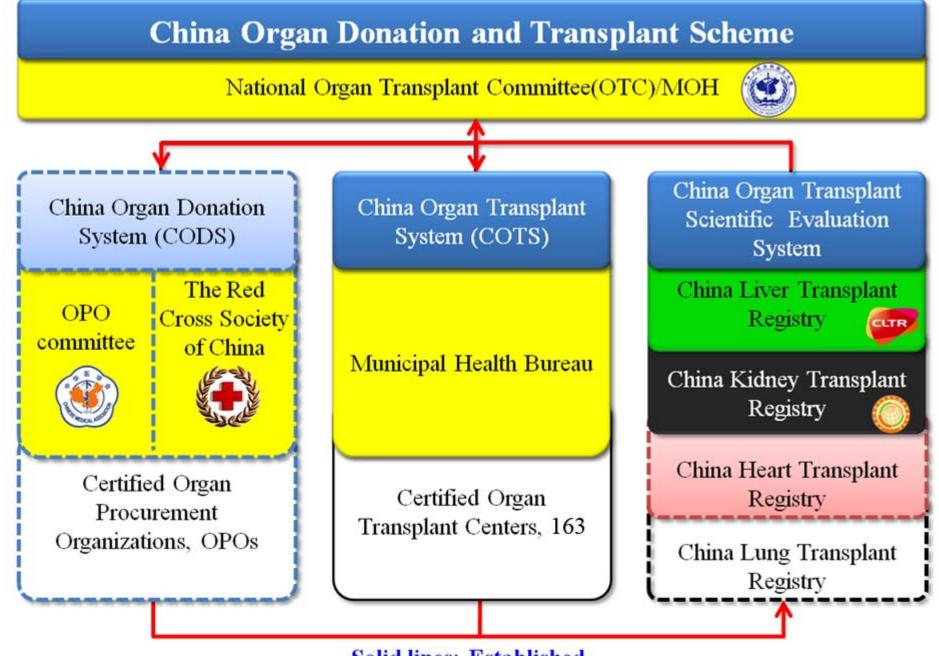


- Combine the appeals to altruism, community spirit and financial self-interest
- Role of "family consent" for donation
- Compensatory policies and responsibility of a third non-profit making party (Red Cross Society of China)
- Technical requirements (controlled organ donation from cardiac dead patients: linkage between brain dead and cardiac dead organs)



Significance of cardiac dead organs in the development of transplantation in China

- Expand the donor pool in a practical and ethical way
- Provide foundation for an organ allocation system
- Respect the desires and rights of individuals and their families
- Decrease illegal organ trades and trafficking
- Terminate the over-reliance on unethical organ sources



Solid lines: Established Dotted lines: In progress





National Organ Transplantation Committee (OTC)



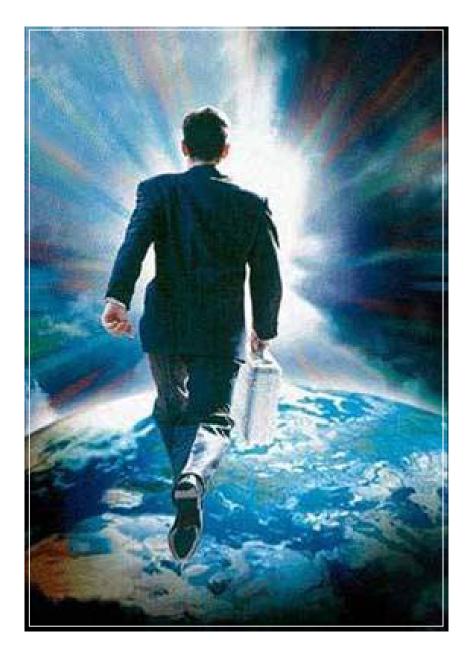
Launching Ceremony of Organ Donation from the Cardiac Dead in China March 2, 2010

全国人体器官捐献试点工作启动会 中华人民共和国卫生部 中国红十字会总会 2010. 2・天津

The 3rd Chinese Transplant Games Shanghai, China, June 13-15, 2008



Respect, help and love are the essence of the traditional Chinese culture. With support from the Red Cross Society of China, China will definitely set up a healthy and ethical organ donation and allocation system.



China should refer to the traditional Chinese culture and present socio-economic condition and learn from the internationally transplant community in establishing China's organ transplantation system and show "the responsible big country" image on the world stage.