Fokus

Steering between Humanitarian Medicine and the Commodity Market: China Sets Out to Govern Human Organ Transplants

Ole Döring

Abstract

China has enacted its *Provisional Regulations on Organ Transplantation*. This article outlines the content of this document in view of its historical context and discusses its implications with respect to social, ethical and cultural issues. It argues that the regulations are a significant step forward in aligning China's health-related ethics framework with international standards. The impact of the legislation will largely depend on compliance amongst health professionals and acceptance by the general public in China.

Keywords: China, Organ Transplantation, Ethics

Introduction

China has issued a new code of regulations concerned with organ transplantation, which has been effective since 1 July 2006: the "Provisional Regulations for the Administration of Clinically Applied Human Organ Transplantation Technology" (Chinese: *Renshen qiguan yizhi jishu linchuang yingyong guanli zanxing guiding*) (MOH 2006). National lawmakers, public opinion and a large fraction of medical ethicists have been heatedly debating and calling for a law to regulate the sector of human organ transplantation since 1986. During the National People's Congress's session in 2005, a group of about 100 deputies led by Chen Haixiao, a surgeon at Taizhou Hospital in East China's Zhejiang province, submitted three motions urging for legislation on organ donation, all of which were dismissed. A Chinese health authority has now set up a special committee for the first time and taken measures to help regulate organ transplants.

Sound procedure will become more important than the origin of the organs, marking a significant departure from the existing practice, in which donations were almost exclusively accepted from members of the patient's family. Thus it opens transplantation medicine for more options for organ procurement, while trying to counter the ethical and social risks of such a market with a strict political statement against commercialisation, such as prohibition of advertising, brokering and trading of donated organs, and establishing a rigorous system of oversight. The Chinese Ministry of Health issued these regulations in response to an urgent need to regulate the sector and with the aim to facilitate organ procurement. Up to now, Chinese transplant surgeons have tried to follow international practices, but complain that this is risky without adequate legal support. As such, they carry out their work in a grey area of the law (Li 2005).

The code includes guidelines for technical standards, administrative protocols and ethical criteria for the donation and processing of human organs in a systematically regulated manner. The code's status as "provisional" indicates that this draft is meant as a clear signal displaying the government's resolve to install normative orientation in a murky sector of medical practice. The regulations are now open to advice and suggestions from medical experts until they are submitted to the Legislative Affairs Office of the State Council for final approval.

Entering a murky field

Chinese doctors have already criticised the low normative status of the code, which, as yet, does not bear the full force of a law. Sensitive issues such as the origin of organs and the medical risks of transplantation for donors and recipients alike are not made entirely explicit (Erling 2006). The most imminent problem of human organ donation in China is that it is not organised as a transparent and rational system. Citizens are reluctant to donate organs for various reasons, including culturally grounded hesitation to remove an organ from an intact body and a deep mistrust of the medical departments in charge, which are often thought to have poor standards of proficiency and have an uncertain morality. Amongst other factors, the common practice of bribery combined with the fatal mismanagement of donated bio-products by private enterprises – which has resulted in blood contamination and led to the mass infection of citizens with HIV and hepatitis (Jia 2005) – plus poor documentation of the procurement protocols for organs and large-scale waste of medical resources have all created

a public image adverse to the official purpose of building a modern and healthy organ-donation system. Transparency and accountability have been made even more difficult because no national organ supply network administration exists.

The overall image of poor medical practices in organ transplantation, including insufficient preparations and medical follow-ups for recipients and living donors, has not increased people's confidence and readiness to donate their organs. Micro-level surveys of hospital management reveal telling examples, such as Beijing Tongren Hospital, were it was found that 52% of those who had registered for post-mortem donation could not be traced in the event of death (Lin & Rui 2004). In addition, the qualification of institutions to offer transplantation services has become doubtful. Ordinary hospitals are reported to hire medical teams of transplantation experts from other places for short-term assignments in order to boost their reputation and profit, but are unable to offer comprehensive pre- and post-operational care. As a result, a disproportionately high number of hospitals in China – 500 or so – are currently listed as conducting liver transplants, compared with 100 hospitals performing the same operation in the highly developed United States. In response, government officials demand that recovery rates amongst transplant patients must be improved. China is the world's second-largest performer of organ transplants, but the overall recovery rates lag behind international levels, said Vice-minister of Health Huang Jiefu at a conference, according to *Xinhua*. He explicitly referred to concerns in the international community about poor management of organ sources and transplant patients (*Xinhua* 2006).

An estimated two million Chinese patients a year need to receive an organ. About 20 kinds of organs are involved, including kidneys, corneas, livers and hearts. However, far too few transplants can be conducted at present because of a shortage of donations. The example of kidney transplantation shows an increasing demand owing to the advancement of medical technology, such as through the development of anti-resistance drugs and sophisticated surgery. By the end of 2000, China had performed a total of 34,832 kidney transplantation operations since the operations started in the late 1980s. 5,561 transplantations were conducted in the year 2001 alone (Cao 2004). However, approximately 1.5 million Chinese patients are said to be suffering from kidney failure and would benefit from receiving a donor organ (Lin & Rui 2004). Owing to the shortage of donations, only between 50,000 and 60,000 of the 300,000 to 500,000 patients currently registered can hope for an operation (*China Daily*, 19 April 2006). The uncertainty about the exact figures is telling enough. Moreover, while waiting

for a donated kidney, the medical costs for dialysis exceed what many families can afford – reaching about 3,000 yuan (300 euros) per week. In addition, there are over four million Chinese patients waiting for a cornea transplant, but only 700 of them can receive matching cornea donations each year. The shortage of heart, liver and other organs is even more dramatic. Experts say that the liver shortage will be more serious in the near future because China has 120 million people carrying the hepatitis B virus, many of whom will eventually develop liver cancer (Hu 2005).

The allocation of organs in terms of fairness and management is a major issue here. In a situation where hospitals are almost entirely financially dependent on their own capabilities, this has led to several ethical issues. Chiefly, hospitals feel a strong incentive to assess organ allocation through economic criteria. It's an open secret that while many members of the general public are kept waiting and don't have a chance of getting an organ transplant, others, including foreigners and celebrities, receive organs due to other criteria than their position in the waiting list and medical urgency. Moreover, transplants are sometimes performed that are deemed medically futile, such as kidney implantation for a terminal cancer patient (McNeill and Coonan 2006, Hua 2006). As a Shanghai newspaper put it: "Driven by profit, hospitals will scramble for the limited organ supply and pay money to secure transplantable organs, which leads to high prices for the operation and almost ensures that poor patients aren't treated equally and fairly" (Hu 2005). To make matters worse, the allocating process encourages irregular practices by default. A medical ethicist recently reported the following: "Owing to the separation between organ acceptance and organ allocation, the allocation process may be very chaotic. Usually the hospital hastily looks for a patient in need of an organ when a cadaveric organ donor suddenly comes along" (Huang 2004). Typically, a liver must be transplanted within 12 hours of a donor's death, and a kidney in 24 to 36 hours. This might also be regarded by some as an incentive for seeking ways to procure organs under conditions that can be effectively organised beyond the control of the public, such as after executions. In fact, this line of argument is constantly being put forward by human rights advocates, who accumulate evidence for a link between the execution of prisoners and the instant removal of their organs for purposes of transplantation (Amnesty International 1998, China Intern 2006).

Responding to an unleashed market

This urge has increased the pressure already on doctors, administrators and policy-makers, especially because business has reacted by organising grey market organ sales that were not expressly forbidden or regulated until the *Provisional Regulations* were issued. Recently a series of reports have revealed a well organised practice of selling organs to wealthy foreigners (in Malaysia, Japan, the USA and other countries), which has added to the frustration felt by patients and doctors in China and stirred policy-makers to take action (Hua 2006). The continued flow of rumours about the alleged abuse of executed prisoners as organ sources has contributed to the damage of China's moral image. China's foreign ministry admitted that organs from prisoners were used, but said it was only in "a very few cases" and with the express permission of the convict. Foreign Ministry spokesman Qin Gang insisted that "It is a complete fabrication, a lie or slander to say that China forcibly takes organs from the people given the death penalty for the purpose of transplanting them" (BBC 2006). Experts have acknowledged the operation of illegal organ trade in some regions (Jiang 2006). The *China Daily* corroborated the fact that "executed criminals" could now legally be used as organ donors, given their explicit agreement (*China Daily*, 5 May 2006). The most obvious problem, however, is how to control the irregular commercial activities and ensure the fair allocation of organs.

Beyond this, BBC News and other international media have speculated that the sudden move to legislation could be related to the deaths or post-operational complications suffered by several foreigners who had travelled to China for transplants. Japanese authorities recently announced that they would investigate the cases of at least eight Japanese patients who fell ill or died after receiving organ transplants in China. China's Ministry of Health said the temporary ban on the sale and purchase of organs was being introduced to protect patients' health (BBC 2006, AFP 2006, Hua 2006).

For more than a decade, foreign media and human rights agencies have been reporting that organs are taken from executed criminals. In 2001, in a hearing before the US Subcommittee on International Operations and Human Rights, Michael E. Parmly (Principal Deputy Assistant Secretary of State) testified about the allegations of irregularities and human rights violations in the context of organ procurement from executed prisoners, covering two decades (Parmly 2001). Recently, members of the Falungong sect have published stories about a "death

camp" at Sujiatun in Northeast China, where inmates are said to be systematically slaughtered in order to extract their organs (Steketee 2006). The Ministry of Health explicitly denied this in April 2006, labelling the reports "malicious slander." As Ministry spokesman Mao Qun'an declared: "Most organs in China have been voluntarily donated by ordinary citizens on their deaths, and a small number from executed criminals who voluntarily signed donation approvals" (*China Daily*, 5 May 2006). Even so, he admitted that the government needed to enhance supervision and ban improper conduct related to human organ transplants. Moreover, Huang Jiefu bluntly told *Caijing* magazine that the government was keen to standardise the management of the supply of organs from executed prisoners (McNeill & Coonan 2006). A delegation of officers and staff from the US Embassy in Beijing and the US Consulate in Shenyang visited the area and the specific site on two separate occasions, but found no evidence to corroborate Falungong's claims (Bureau 2006).

Medical ethicists have been outspoken about what is often described as "the dilemma of organ extraction from executed prisoners" (Qiu 1999). There appears to be a consensus that in some cases prisoners' donations are not voluntary. One of the problems openly debated is that "they may be persuaded by their families to donate in atonement for their crime." However, Jiang observes with approval that "in academia, several papers have argued that the organ donation from the executed prisoners is not ethically justifiable" (Jiang 2006).

This agitated debate provided the backdrop for the *Provisional Regulations*, which were first made public on 27 March 2006 during the annual session of the National People's Congress (NPC). At the occasion, Minister of Health Gao Qiang explained the intention of the technical codes and criteria for human organ transplants: "It mainly aims to strengthen the regulation of organ transplants from the perspective of medical science and medical services" (Xing 2006).

The major ethical purpose of the *Regulations* is to protect the health of donors and recipients while increasing the organ procurement rates, namely through a ban on human organ sales. At the same time, they specify and elaborate earlier regulations that had been promulgated on 6 April 1996 and take up some of the provisions formulated in China's Medical Ethics Association's "Ethical Principles of Organ Transplantation," submitted in 1998 (Cong 2003). These older regulations already state (in very general terms) that "the buying or selling of human tissues and organs is not allowed. The donation or exchange of human tissue and organs with organizations or individuals outside national borders is not

allowed." Over the last ten years, however, the area of health care – and that of organ transplantation in particular – has grown into a political challenge calling for significantly more elaborate regulation.

Special characteristics of organ procurement in China

Criterion of death

One of the main political obstacles to making a law in the past was the issue of defining a concept of death, which is required for legal organ procurement. China hesitated to join the 189 United Nation member states that accept the "brain death" criterion as such a requirement. This practice has further decreased the quantity of potentially usable donations. The "irreversible loss of all functions of the brain" (including the brain stem) is regarded by many as insufficient and even counter-intuitive, since a body can feel "warm and alive" to the touch despite irreversible brain damage. Hence the traditional concept of cardiac death is regularly applied. Thus, a human being is only declared dead and eligible for transplantation once their heartbeat and breathing have irreversibly ceased. In such a condition, the deceased person's organs quickly become unfit for use after explantation due to the termination of the blood and oxygen supply.

There is a common speculation amongst medical ethicists that the emerging regulatory system will continue to respect the concept of cardiac death as it is widely upheld in the population, whereas at the same time, the concept of brain death will be promoted as being scientifically based. This implies a potential co-existence of both practices. The proper policy instruments to administer donation, such as the "opt-in" or "opt-out" models familiar from debates in Europe and North America, are under discussion in China (Xiao 2003). There is some hope on the part of modernisers that the experience of a more rational practice in the future will increase the general public's confidence and gradually enhance its willingness to donate organs for transplantation. Many transplant surgeons support the brain death concept. For example, Professor Gao Chenxin, a lung transplant expert at the Shanghai Chest Hospital who has witnessed four patients die while on a waiting list for matched lungs since 2002, strongly supports legislation based on the concept of brain death. "This would not only release important medical resources but also provide additional organs to save other patients" (Hu 2004).

Who shall provide organs for whom?

Chinese medical professionals disagree about the best policy, however. One of the most obvious differences between China and developed countries is that in the latter, 15 per cent of the organs for transplants come from altruistic none-related donors, whereas in China almost all the living organ donations take place between members of the same family.

The first kidney donation from non-related living donors was conducted at the largest organ transplant institute in China in April 2006. Before that, the Tongji Organ Transplant Institute had conducted 113 kidney transplants from close relatives. The innovative approach of cross-family donation goes beyond family bonds, but still binds the choice of donors and recipients to their relationship to the patient, maintaining a high degree of inter-personal commitment between donor and recipient that could boost the sense of altruism although it is not framed in traditional family terms. "The organ exchange between different families is a mode worthy of further spreading. It can increase total kidney transplants by 5 to 10 per cent," said Chen Zhonghua, the surgeon responsible for this operation. He argues that the matching probability between different families is high given the large pool of patients on the waiting list (Hu 2004).

Still, Zhu Tongyu, Director of the Organ Transplantation Centre of Shanghai's Fudan University, explains: "Low-cost, short-term waiting, as well as a better match rate are some of the advantages of living organ donations among relatives" (Hu 2005). In 2005, his hospital had performed about 20 living organ donations among close relatives. His colleague, Chen Zhonghua, supports this argument. "At present, increasing the percentage of relative organ donations is the most effective way to address the organ shortage problem," he said, offering three reasons in explanation. "First, there is no relative health-care security system to safeguard their rights if they develop donation-related diseases in the future. Second, at present, there are no rules to guide organ donation from non-relative donors and it will open the gate for organ sales. Third, the hospitals cannot get to know the real intention of the donors" (*China Daily*, 19 April 2006).

The last points allude to the widely spread practice of illegal off-the-record transactions between unclear sources of organ procurement and wealthy recipients arranged by professional brokers. According to a news report from Shanghai, a kidney transplant in a hospital generally costs about 50,000 yuan (about 5,000 euros). On the black market, a single kidney is traded for up to three times this

amount. In large local hospitals such as Huashan and the People's No. 1 Hospital, it is quite common to find notices such as "Donating a healthy kidney" or cornea, along with contact details (mobile phone numbers) on walls or toilets (Erling 2006, McNeill & Coonan 2006). The go-betweens linking the donor and recipient take the lion's share as their unaccounted profit (Hu 2004). Chen, who was a government consultant involved in the drafting of the new *Provisional Regulations*, has been one of the most outspoken critics of the outcome as it now stands. In an interview, he told the *South China Morning Post* in March 2006 that they had failed to properly address the origins of organs in the transplant market, which he called "messy and disordered" (McNeill & Coonan 2006).

Ambitious public campaigns, such as the first Organ Recipients Sports Games held in 2004, or electing a young man from Shandong as one of the "Ten People Who Moved China," because he had donated a kidney to his elderly mother, emphasize the resolve of the authorities to tackle the problem of insufficient numbers of organs for transplantation. However, the moral message of such propaganda is directed at the intra-family donation. This ambiguity goes hand in hand with another obvious compromise in the spirit of the regulations, namely the quandary about the death criterion. After all, it appears that in the intra-family context, cardiac death is easier to explain than the brain death concept.

There are more complications in view of the related economic issues. Donations between family members receive no financial compensation. The cost of the donation operation itself – from 20,000 to 40,000 yuan (2,000-4,000 euros) – is not covered by medical insurance. Jiang says it is "an interesting paradox" that arises from this economic disadvantage, especially in light of the proposed open-donation system, i.e. donating organs to recipients from outside the family. For many people, this seems to be a one-way street. Most peasants don't have the financial means to obtain an organ transplant if they need one. "It is arguably unfair to let this vulnerable population change their view of organ donation for (the) goal of repaying society" (Jiang 2006).

The current system seems designed to repel rather than to attract potential donors. To date, the regulation of cadaveric organ donation in China requires the potential donors to contact the local Red Cross or other related institutes by their own initiative and means in order to get registered. The application form is only effective when it is signed by the donor and all the members of his or her family who are directly related. The lack of public knowledge about the ways to register one's organs for donation causes many potential donors to abandon

their efforts. Ethicists complain that citizens need a great deal of determination in order to actually become registered donors.

Objectives and measures of the *Provisional Regulations*

The *Provisional Regulations* are highly elaborate in their attempt to cover the relevant issues comprehensively and thoroughly. They are composed of 47 articles that are structured into five chapters. Chapter 1, covering articles 1-6, explains the general purpose (*zengze*) of the *Regulations*. Articles 7-18 of Chapter 2 prescribe the registration of clinical and research applications (*zhenliao kemu dengji*). Chapter 3 (articles 19-36) stipulates the administration of clinical applications (*linchuang yingyong guanli*). Chapter 4 contains articles 37-45 on supervision (*jiandu guanli*), and articles 46-47 of Chapter 5, the final chapter, provide supplementary specifications (*fuze*).

Chief objectives

The chief objectives of the "Provisional Regulations for the Administration of Clinically Applied Human Organ Transplantation Technology" can be summarised as follows:

- The medical and administrative system is to provide the best medical standards possible and reduce the risks of all the parties involved. The health and economic concerns of donors and recipients and the legal concerns of medical professionals have to be particularly respected.
- The availability of organs for medical transplantation should be increased significantly in terms of procurement, management and advanced technological and professional standards.
- The system of allocation of human organs should be based on fairness, transparency and efficiency.
- All forms of commercial activity are to be banned from the area of human organ transplant medicine so as to strengthen its genuine health-related purpose and contain any influence from the economy.
- New infrastructures should be established in the form of institutional ethics committees, with the power and qualification to oversee the actual practice

of organ transplantation, regarding each individual process within a clearly regulated institutional and normative framework.

According to Chinese officials, these objectives are instrumental for implementing China's policy priorities, i.e. to guarantee medical safety and the health of patients (Chinese Embassy 2006). They insist that banning the sale of organs will make it easier to stop practices that violate the existing ethical and medical standards of organ transplants and boost compliance with the law.

Administrative measures

- *Registration*: medical institutions have to register at provincial health departments. China's top-ranking comprehensive hospitals (referred to as 'Class Three A Hospitals') can register their services on the condition that they have doctors with clinical organ transplant qualifications, the relevant equipment, a good management system and a "medical science and ethics committee."
- *Qualification*: qualified doctors with clinical organ transplant training are only to practise in their assigned hospitals, which must be duly licensed. Unregistered medical institutions are strictly forbidden to carry out organ transplants.
- *Terms of probation*: registration will be cancelled if patients who receive a transplant fail to survive for a certain number of years due to causes related to the operation. If the Ministry of Health finds any registered institution to be unqualified, it can revoke the registration and put sanctions upon those responsible.
- *Institutional supervision*: the Ethics Committee must discuss every single organ transplant case. The legitimacy of the procedure and the organ/s in question has to be confirmed by the Committee. Operations can only be carried out with the Committee's approval. At the state level, the Ministry will set up a committee of experts in management, medical treatment, nursing, pharmacy, law and ethics.
- *Informed consent by donor*: medical institutions are required to obtain a written agreement from the donors and their family members after full and fair information has been provided by the surgeon in charge before the transplant. Donors may withdraw their consent at any time.

- *Non-specification of origin*: the regulations do not limit eligible donors to family members or exclude certain groups (e.g. prisoners). They do not exclude a legal criterion of death on the part of the donor (i.e. brain death or cardiac death).

In general, these measures are designed to implement basic standards of organ transplantation according to internationally accepted ethical codes and under the particular social conditions prevalent in China. The provision of informed consent (article 30) is explained in ways that might raise a few people's eyebrows: "Medical institutions must get written agreement from the donors or their relatives before the transplant, regardless of whether the donors are ordinary citizens or executed criminals." This clearly expresses an effort to acknowledge the moral, social and economic involvement of the family in any disease of a member. Yet at the same time, it seems to blur ethical and legal forms of representation of the relevant person's will, thus contradicting national and international standards of medical ethics. Legally, the person who is directly affected by an operation must be supported, protected and free to determine his or her will as an individual. Others who may be indirectly affected or in a position to support the patient should be involved by other means and at different stages of the process of determination in due manner, albeit not necessarily by signing the informed-consent form. Recently, in other areas of medicine, China has accepted the principle of "informed consent of the individual" (Döring 2004).

On the other hand, social practice in China suggests that the formal order of the process alone will not be regarded as adequate. In fact, the requirement of additional "family consent" could function as a precautionary provision for the potential donor, who might be in a vulnerable position, given that no interests but their well-being prevail on the family's part. For example, family members reportedly overrule the expressed wish of their relative to donate an organ upon their death; they will simply not let the Red Cross extract the deceased person's organs. This has led to new practices being established, such as extraction of the organ in question in the presence of a family member. Overall, the diversity of opinions within the family and "the lack of unanimity within is one of the obstacles of fulfilling one's will of cadaveric organ donation" (Yang et al. 2004). It will be interesting to see such practices develop in the course of time and how administrations establish protocols to deal with them.

Observations

This new legislation is part of a wave of laws and regulations that have been shaping almost the entire field of medicine and health care in China due to ethical, legal and political considerations since about 1998 (Döring 2003 NRG). It is a response to domestic needs as well as to China's integration into the international system of health governance and medical sciences. This historic process is currently in full swing, and quite a few urgent matters have not been precisely regulated yet even at the level of basic legislation. Moreover, the practical implementation of laws in this complicated area poses enormous challenges to China. One of the most controversial and under-regulated issues is how to deal with "euthanasia," i.e. with demands to allow assisted suicide upon request (Li 2005). Future experience with the elaboration and implementation of the regulations of the organ transplant system could serve as a test case for the maturity of China's emerging state of law, as will similar efforts in the areas of reproductive medicine and the life sciences. The country's health administration system was considerably re-organised under the impact of the SARS crisis, but it still faces many challenges, in particular the compliance of regional administrations and professionals (Döring 2003).

The *Provisional Regulations* might, intentionally or by default, help China's authorities ease some of the moral problems by clarifying doubtful sources of transplanted organs. In the past, international observers and human rights agencies have focused more on the issue of organ procurement from executed prisoners than on the irregularities in the general transplantation business. Lately, concern has been directed at the illegal international dealing in organs that are believed to come from these and other suspicious sources. The human rights issues raised every day by shortcomings in medical ethics in China's public health system have only recently attracted international attention.

Just when this article was finished, David Matas and David Kilgour published a „Report into Allegations of Organ Harvesting of Falungong Practitioners in China". It can be downloaded since 6 July 2006 from the Internet, at "http://investigation.redirectme.net". This hefty report of 66 pages includes a thoroughly documented investigation that suggests overwhelming evidence to substantiate at least the gist of the accusations. It concludes with a set of 17 recommendations for China's policy-making (pp. 40-43), arguing that if at least its second half were implemented the allegations considered could no longer be upheld. In fact, the principal target of the authors' argument is the practice

of organ trade in general, making China only one outstanding case within the global context. Parts of the recommendations, such as due informed consent of donors (recommendation number 13), full transparency and documentation of procedures (11), licensing and individual approval of transplantations (15), and non-commercialisation of organ transplants (17), seem to agree with the new regulations introduced above. The most controversial issue, shared with Chinese bioethicists, seems to be the non-eligibility of prisoners as donors (16). What seems to lend credibility to this report is an expressed sense of constructive support of the government's chosen principles of law reform. While explaining that all such practices would violate existing Chinese law, Matas and Kilgour maintain, "China is remarkably undefended to prevent the sorts of activities here alleged from happening". The authors are lawyers and members of a "Coalition to Investigate the Persecution of the Falun Gong in China" (CIPFG), a non-governmental organization registered in Washington, D.C.

The effectiveness of the *Provisional Regulations* will substantially depend on their robust and resolute implementation. In order to set up the required infrastructure of supervision, active co-operation and compliance on the part of the health profession is essential. Vice-minister Huang Jiefu has already called on major health associations like the China Medical Association to set up self-regulation mechanisms in order to help health departments govern transplants as a consequence of the *Provisional Regulations.* Moreover, the key role of ethics committees can only be ascertained if the training and selection of committee members and the fine tuning of protocols are all conducted in accordance with the highest possible standards. In particular, it is a substantial task to properly organise the work of ethics committees (e.g. so as to exclude any conflicting loyalties or partisan interests and make broad societal representation possible) and to train committee members for their difficult job.

On the larger scale of moral and ethical debate, the issue of human organ transplantation is still awaiting a fair public discussion in China. Many public opinion-makers, medical professionals and ethicists suggest that transplantation should be taken for granted. The underlying philosophical or religious concepts regarding the meaning of being human and the dignity of a human's life, with their diversity of views, tend to be either ignored or defamed as anti-modernist or mere superstition. The underlying message is that it is just a matter of time and the spreading of modern science and technology before "backward" scepticism will be overcome.

Initial surveys show that in China the rate of support for organ donation after death fades in correlation with increasing age and decreasing educational levels (Luo et al. 1998). Whether this is a result of "enlightenment" or a successful ideology of scientism is not discussed at all. On the other hand, the approval rates seem to indicate that it's probably not the frequently quoted "traditional value system" that stands in the way of more effective organ procurement, but rather the notorious shortcomings and scandals of the first few decades of poorly regulated transplantations in China. By reducing the mechanisms that currently discourage citizens from registering and donating their organs, the desired goal to increase procurement rates is likely to be achieved on the basis of medical altruism, disregarding reservations on moral grounds in sections of the population. Altogether, China seems eager to become a normal member of the global community in the area of human organ transplantation. For the time being, the ethical and administrative impact of the *Provisional Regulations* rests at the level of political intent.

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