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## Deceased organ donation in India: where do we go from here?

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### Abstract

*Transplantation represents one of the best examples of the scientific achievements of medical science. However, its success has also led to some of the fiercest ethical challenges in modern medicine. Partly as a response to the uncovering of a flourishing clandestine kidney trade, the Central government promulgated the Human Organs Transplant Act (HOTA) in 1994. HOTA, along with its amendments, was a step forward in recognising concepts such as brain death. Nevertheless, there are numerous ethical challenges still to be resolved, particularly with regard to consent, incentives to donors and families, and equitable distribution of donated organs.*

### Introduction

Transplantation represents one of the best examples of the scientific achievements of medical science. However, its success has also led to some of the fiercest ethical challenges in modern medicine. The number of patients desperately needing a transplant far outnumbers the available organs, leading to a competition for organs which severely tests the principles of transparency and distributive justice. Transplantation is also unique in that it needs public sanction without which it will collapse. Although living donation is an option for some organs, the main source of organs is deceased donation which hinges on consent from family members. This consent is shaped not only by the perceived credibility of the process but also by other cultural, religious and political factors. On the recipient side, the ethical challenge is how to ensure justice in

allocating the few available organs to someone from amongst a large pool of patients on a waiting list.

The discourse surrounding organ transplantation covers a wide sweep of disciplines like sociology, anthropology, culture studies, public health, economics and politics. Central to the discussion, however, is ethics. Over the years this discipline has engaged with these debates in an intense and rigorous manner. Since its inception the pages of this journal have carried a wide variety of writings on this topic, about its global overarching dimensions as well as the Indian context. South Asia in general, and India in particular, has had to grapple with the specific issue of the enticement of the desperately poor to sell their organ for a price (1). The recent increase in cadaveric or deceased donation in India has been acclaimed by many in the lay media. In certain states it has also been argued that this has led to a reduction in commercial transplantation (2). But there has been a paucity of the social and ethical analysis necessary in a field where so much is at stake.

Organ transplantation in India has a relatively short history compared to the developed world. India's conceptual and scientific contribution to this specialty has been limited even as it has been at the epicentre of one of the biggest ethical controversies concerning transplantation. Kidney transplants in India were first performed in the 1970s. Though transplant activity picked up in the 80s and early 90s, it was largely restricted to live donor kidney transplants in selected urban centres. In the 1990s the establishment of more centres and the availability of trained staff, led to an increase in kidney

transplants. Transplantation of other organs such as the liver is a very recent activity.

It is pertinent to note at the outset that the benefits of transplantation are still not available to a large proportion of India's population needing them. Many patients with end stage renal disease are on long-term dialysis and lead a very poor quality of life. Even dialysis facilities are limited, expensive and inaccessible. More than 90% of patients in South Asia die within months of diagnosis because they cannot afford treatment(3). It has been estimated that only 2.5% of patients with end stage renal disease in India actually end up getting a transplant (3). For the liver, this proportion would be an even more miniscule minority. There has been little substantial activity in transplantation of other organs like the heart and lungs.

### **The kidney trade in India**

Organ transplantation in India has received prominent coverage in the media, one major reason being the notorious kidney trade in the 1980s. Foreign patients flocked to India for transplants from paid "donors." These transplants were often performed clandestinely in small hospitals in substandard conditions, but some large private institutions tacitly participated in this activity. The results of these transplants were also poor (4). While the media reported on these scandals, medical bodies, including medical councils and other regulatory bodies, largely remained silent. This was not surprising considering that self-regulation of medical practice in India has historically been very weak. Also, the kidney trade earned huge monetary benefits for the rapidly expanding private sector. A significant section of the medical fraternity, including nephrologists and kidney transplant surgeons, was complicit in the kidney trade.

Attempts were made to offer an ideological rationale for this activity, seeking to justify paid-for donations as consistent with a libertarian and free market philosophy (5). Using the same logic, there were calls for a "regulated" market. It was, however, obvious on the ground level that the donors in this market had often been coerced and even been duped by middlemen of any monetary rewards. Also, follow-up studies of unrelated donors showed that their quality of life was poor (6). Countries like Iran have experimented with a state-sponsored regulated model and claimed some success (7). While the details of this debate do not belong in this paper, it is important to keep this bit of history in mind when addressing issues related to deceased donation.

### **The Transplantation of Human Organs Act**

Partly as a response to the kidney scams, the Central government in 1991 constituted a committee to prepare a report which could form a basis for all-India legislation governing organ transplantation. Although the main terms of reference of the committee were concerned with "brain death," it also recommended that trading in human organs be made a punishable offense. In 1994, the government of India promulgated the Transplantation of Human Organs Act (THOA)

(8). The Transplantation of Human Organs Rules followed in 1995. Subsequently the Rules alone were amended in 2008. Later, THOA itself was amended in 2011. The Rules for the amended Act have just been notified, in 2014. THOA of 1994 banned any form of "commercial trading" in organs. Unrelated donation was permitted on grounds of altruism but only with the sanction of an authorisation committee. The committee took a decision on the basis of documentation and interviews of both prospective donor and recipient.

Even after the promulgation of THOA, scandals involving unrelated donors continued to break out in the media. In the last few years there seems to have been a decrease in media exposes. This may reflect an overall reduction in what was once a thriving industry, but it is also believed that some of the activity has moved underground, and some has moved out of the country where the wealthy and influential have taken advantage of the apparently liberal laws in countries like Singapore and undergone live unrelated transplantation there (9).

Simultaneously, THOA also legalised brain death in India, paving the way for performing deceased donation by procuring organs from brain stem dead donors. The Act also laid down criteria for determining brain death. Safeguards against misuse were built into the rules. The tests for brain death had to be performed together by four individuals, none of whom had anything to do with the transplant. The tests were to be done twice, with a minimum gap of six hours. As per the law, brain death could be declared only in institutions recognised by the state appropriate authority. Written consent for donation of organs from the deceased person had to be obtained only from a close relative. The law and most of the scientific criteria and the methodology of diagnosing brain death were essentially derived from the British law.

### **Problematic interpretations of the law**

The law seemed to define brain death only in the context of organ transplantation, setting the stage for a peculiar situation. A disquieting and widely prevalent interpretation of the law by the medical community in India is that if brain death is diagnosed and the family refuses consent for donation, there is no legal sanction for disconnecting life support, including the ventilator. This has led to a major ethical predicament on the ground. The family is informed that their relative is "dead" and asked for consent for donation. But if they refuse and request that the body be handed over, their request to withdraw life support is turned down.

The law also identified only hospitals performing the transplant operation as recognised institutions where brain death could be declared. Thus in the large number of institutions where transplantation is not being performed, declaration of brain death was not possible. This led to bizarre situations where the cadaver donor had to be shifted to another recognised institution only for the purpose of organ retrieval. A recent amendment of the Act in 2011, and of the Rules in 2014, have created a category of institutions called "non-transplant organ

retrieval centres" where organs can be retrieved after consent and then transported to an institution where the recipient procedure is to be performed. However, a large number of institutions are still not recognised and prospective donors are often transferred to transplant recognised hospitals. This is an obvious conflict of interest scenario as the hospital can then use the organs as it gets priority as an "in house" donor. There is, therefore, the possibility of inducement to transfer potentially brain dead individuals with even "soft" incentives like fee waivers.

The question of whether brain death can be declared independent of organ donation is still an open question. In reality, brain dead individuals are still hooked on to intensive organ support measures (10). In a country where intensive care unit beds and ventilators are scarce, this often means denial of care to another patient with a serious illness.

For a long period after the Act was passed in 1994, there was little substantial activity in terms of declaration of brain death and donation after brain death. As of 2014, some 2,500 cadaver transplants have been performed in India, mainly in the last five years in the states of Tamil Nadu, Andhra Pradesh, Maharashtra, Kerala and Gujarat. Tamil Nadu, and the city of Chennai in particular, has seen significant success in cadaver donation with around 1,400 cadaver organs transplanted till date (11). Tamil Nadu's relative success has been ascribed to multiple reasons, including frequent interaction between the government and stakeholders, and provision of the necessary legal and administrative back-up through regular government orders facilitating the process. The Tamil Nadu programme has also attempted to maintain absolute transparency from its inception. Mumbai has witnessed an increased in cadaver donations in the last few years (12) and has already seen 15 donations in the first six months of 2014.

A closer look at donation patterns across the country reveals that deceased donation is largely driven by hospitals with active transplant programmes. These institutions directly benefit, monetarily or otherwise, from identifying brain death and promoting donation. These institutions are largely in the metros and often in the corporate sector.

### **Ground realities in India**

Problems peculiar to the Indian situation have come up in the practice of deceased donor transplantation. The diagnosis of brain death and subsequent donation is possible only in intensive care units (ICUs) which have the facilities for keeping a brain dead patient's organs working with mechanical ventilation, cardiac support and intensive monitoring. Such ICUs are few and are available only in big hospitals in major cities. They are often overloaded and understaffed and lack a central command structure. In this situation, the identification of brain death and requesting consent is often given low priority and brain dead patients are treated with "benign neglect". But if such patients become donors, they require the same attention as any other patient to keep the organs viable till they are removed. This requires a major attitudinal change and is resented by an already overburdened staff.

Another conflict inevitable in this resource-constrained scenario concerns where to use inadequate resources: on sick patients who need life-saving care to save their lives or on care of the brain dead potential donor. Since most donors are in the private sector, the cost of their maintenance has also been an issue. How does one bill a family which has donated organs? And as common sense dictates, if the bill should be waived, from what point in the illness should it be done? And will waiving of the entire bill in the private sector be seen as inducement?

In the early years of deceased donation in India it was thought that cultural, religious and social beliefs, and lack of public awareness, prevented families from giving consent. The lack of progress in cadaver donation was often ascribed to lack of public awareness. However, it was soon obvious that there were other factors impeding donation and that the consent rate would go up significantly if institutions made systematic efforts to identify and approach family members of brain dead donors, the consent rate was likely to be significant. Cadaveric transplants were not being performed, not because of lack of awareness and refusal by families to donate, but because of absence of institutional mechanisms to approach the families of brain dead individuals. It has been the same story as in eye and blood donation, which has a much longer history in India.

Across the world, the form and method of obtaining consent for removal of organs from brain dead individuals has evolved over the years. The most common is "informed consent" in which close family members agree to donate organs after brain death has been certified. This is the form of consent that has been practised in India. However, "family consent" is a vague term, and, unlike in some countries, no hierarchy of relatives has been specified in the rules. There have been cases of differing views within the donor family. The ethical question here is: whether unanimity in concurrence is to be sought, and if not, whether one family member's views can override others.

### **Other forms of consent**

In the rest of the world, in an effort to increase the donor pool, other strategies are now being debated and implemented. The first area involves improving the consent rate for brain dead donors. This includes "donor cards" which citizens sign and keep during their lifetimes; "required request" where it is mandatory for a doctor to ask the relatives of a brain dead patient about organ donation, and, in some countries, "presumed consent" which grants authority to doctors to remove organs from brain dead individuals whenever usable organs are available, in the absence of objection from the deceased in his or her lifetime, or from the family members. Financial and other incentives to families of deceased donors have also been debated as an option.

Such strategies have also been proposed and debated in the public domain in India. The recent modification of THOA rules in 2014 seems to propose a "required request" strategy which makes it mandatory for the ICU doctor to identify brain death and ask the relatives of the brain dead patient about organ

donation. Such a strategy is debatable in the heterogeneous, unregulated and unstructured healthcare scenario in India. This partly coercive and top down approach is likely to lead to tensions and resistance from a medical fraternity unprepared for this paradigm shift. The actual impact of such strategies remains to be seen, but they have not been adequately debated in the public domain.

In some European countries, such as Austria, Belgium, Denmark, Finland and France, "presumed consent" has been legalised and is practised. This grants authority to doctors to remove organs from brain dead individuals whenever usable organs are available, in the absence of any objection from the deceased in his or her lifetime, or from family members. Presumed consent places the burden of opting out of organ donation on those who object to this procedure. This form of consent was introduced in these countries after a long history of cadaveric donation as well as public debate on the issue. The introduction of such a strategy is occasionally debated in the public domain in India as a knee jerk reaction to the poor progress in deceased donation (13). Such constructs have their origin in a developed and structured western Anglo Saxon society and need in-depth debate and discussion before being considered here. One shudders to think of the Pandora's box that such legislation would open in this completely unregulated healthcare system. The argument that individuals after their death should serve "the greater common good" brings up many questions (13). For one, what constitutes the "greater common good"? Can we, for example, use the common good argument to legislate to stop people in large cities using automobiles and instead use public transport to reduce pollution, which is a major silent killer?

### **Donation after cardiac death**

In an earlier issue of this journal, Bardale (14) discussed the relevance of an alternative form of cadaveric donor, the "non heart beating donor" (NHBD), otherwise called "donation after cardiac death". As opposed to the brain dead donor, whose brain is irreversibly damaged but whose heart is beating and circulation is intact, the heart of the NHBD has ceased to beat and circulation has ceased. In the NHBD the organs need to be removed instantly for them to be viable for transplantation. In the mid-1990s there was a resurgence of interest, and acceptance, in the West in using organs from NHBDs. In 1995 the Maastricht classification of NHBDs was put forward (15). However, the wider application of NHBD has brought up a number of complex ethical dilemmas, dealing essentially with the end of life.

The implementation of such programmes in a scenario such as India's will need both social and cultural acceptance, and substantive regulatory mechanisms (16). It will also need the presence of trained medical teams who can conduct almost instantaneous removal of organs in a planned manner. But there is no reason to believe that families who would consent to organ donation after brain death would not do so after cardiac arrest. In fact, it is easier to understand and accept the concept of cardiac death. The scientific and legal base for

it has been prepared in the rest of the world. This could be an area for India to explore in an effort to increase the donor pool.

### **Incentives for deceased donation**

There has been much discussion in the recent transplant ethics discourse on offering some form of incentive to families of deceased donors (17). This is being tested in countries like China (18), and there have been calls by Western ethicists to consider limited incentives like payment of funeral expenses (17) to donor families. This has not as yet entered the realm of policy.

The idea of incentivising donor families has also been discussed in the public domain and transplant circles in India. The incentives discussed range from simple waivers of the donor's hospitalisation costs to various proposals to support the donor's family members, including preference in jobs, free lifelong railway passes, and support for children's education. Since the recipient and the hospital performing the transplant are beneficiaries of the donation, it has been argued that there is no reason why the act should not be acknowledged and compensated in some form. This idea may seem to have some merit, especially since the recipient is often a rich person. However, any form of compensation inevitably commodifies the act of donation. Also, in an intrinsically unequal society this could be the slippery slope to inducement and a soft form of trading even in deceased donation. The inevitable scandals and intrigue surrounding this will impact the small but significant altruistic cadaveric donation programme which is just taking off in major cities.

### **Who is getting the organs? Addressing inequity in the recipient pool**

The current allocation policies for deceased donor organs differ from state to state within India. There is no unanimity on whether the organs should be allocated based on severity of disease, waiting period or on an institutional rotation. There is an attempt to centralise the activity by the formation of a National Organ and Tissue Transplant Organisation (NOTTO) under the Ministry of Health and Family Welfare. One of the stated objectives of this organisation is to evolve a national network for organ sharing. However, given that India is a large and diverse country with regional variations and aspirations, a very centralised approach may not be appropriate, and the states must be allowed flexibility in approach as long as they meet basic ethical requirements.

THOA laid down elaborate criteria on who can donate organs, but did not elaborate on how the donated organs would be distributed. Conceptually, donated organs do not belong to the hospital or the city where the donor's death took place; all altruistic donations belong to society as a whole. Thus the state has a responsibility to ensure that such organs are distributed in a transparent and equitable manner to those who need them, and not to those who can afford them. If they leave the decision to market forces, the state and the transplant

community are breaching the trust placed in them by donor families.

Healthcare in India is dominated by the private sector. This domination is even starker in organ transplantation. Transplant programmes in public hospitals are restricted to a few large teaching hospitals in the metros. Even these are overburdened and often in disarray. Even a fairly standardised and straightforward procedure like kidney transplantation is performed in very small numbers in the public sector. For example, none of the Maharashtra government's large teaching hospitals currently conducts kidney transplants. I estimate that less than 1% of the liver transplants performed in India have been in the public sector. Partly because of the poor progress in deceased donation, a large proportion of these are living donor transplants. The rapid proliferation of live donor transplants has been accompanied by a worrying number of donor deaths in this complex procedure which involves a significant risk for the donor (19). The pressure for a transplant is much more since, unlike the kidney where there is a backup of dialysis, patients with end stage liver disease have no such option.

Transplantation is complex and costly and there is almost no state funding for this procedure. Most of the activity in deceased donation has been in the private sector. In addition, a significant number of donors and a large majority of recipients are from private hospitals. Any call for altruism from the public is undermined by the fact the large majority of the organs currently go to the rich. It is imperative for the state to remove this incongruity and make transplantation accessible and affordable to all, regardless of their ability to pay. This will need political will and the mechanisms to build in social equity into the current distribution systems. One method of doing this could be to mandatorily allocate a proportion of organs for public sector institutions. Of course, this will have to go along with development of transplant facilities in this sector, something that is currently severely lacking.

In its present form, cadaveric donation in India largely benefits the rich and serves a miniscule percentage of the patients who need it. Thus, whilst we must continuously strive towards increasing donation rates we must not lose sight of this big picture. Many of the ideas and concepts in modern deceased donor transplantation come from the developed West where both societal attitudes and health systems are different from those in India. We in India need to develop a system which is equitable and transparent and not coercive. This will be a slow and difficult process that may also require linking to the bigger

struggle for an advanced and yet affordable healthcare system for all.

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