

Amendment of the Human Organ Transplant Act

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Abstract

On 6 January 2004, the Human Organ Transplant Act (HOTA) was amended to allow more Singaporeans to benefit from organ donation. The main amendments to HOTA were (a) to extend HOTA beyond kidneys to include livers, hearts and corneas; (b) to extend HOTA beyond deaths due to accidents to include all causes of deaths; and (c) to extend HOTA beyond cadaveric organ donation to also regulate living donor organ transplants. In this article, we review the amendments to HOTA and the Interpretation (Determination and Certification of Death) Regulations and examine the impact of HOTA on organ procurement and transplantation in Singapore.

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Key words: Kidney transplant, Organ procurement, Presumed consent, Transplant legislation

Introduction

Kidney transplants have been carried out in Singapore for more than 35 years, with the first cadaveric kidney transplant operation performed on 8 July 1970.¹ However, prior to the commencement of the Human Organ Transplant Act (HOTA) in 1988, there was only a small number of kidney transplants; between 1970 and 1987, only 85 cadaveric kidney transplants were carried out using kidneys procured from local donors in Singapore.²

There are 2 laws pertaining to organ donation in Singapore – the Medical (Therapy, Education and Research) Act (MTERA) and HOTA. A third set of legislation, the Interpretation Act, provides the criteria for determining death. It allows for death to be defined in terms of cardiac death or brain death. The Interpretation (Determination and Certification of Death) Regulations provide further conditions and criteria for the determination and certification of brain death.

MTERA was passed by Parliament in 1973. It provides for a person to pledge to donate his organs upon his death for the purposes of therapy (including transplant), education or research. Where a deceased person has not made any indication of his intent to donate, MTERA also provides for the relatives to donate the body or body parts of the deceased person for the above purposes. Between 1973 and 1987, cadaveric kidneys for transplant were obtained either under MTERA, or from overseas.

HOTA was introduced in 1987, as a presumed consent law that allowed for the removal of kidneys for the purpose of organ transplantation from those who died in a hospital as a result of accidents, and did not object to organ donation prior to their death. It applied to Singapore citizens and permanent residents between the ages of 21 and 60 years. Muslims were excluded from HOTA because of religious reasons. Persons who were of unsound mind were also excluded from HOTA. Persons who objected to organ donation could opt not to donate their organs by registering their objections with the National Organ Transplant Unit (NOTU), a central national registry overseen by the Director of Medical Services.

Several safeguards were provided for under HOTA. First, the designated officer of the hospital had to ensure that the necessary criteria required under HOTA were met and provide his written authorisation before the organs could be removed from a deceased person. The designated officer had to be a senior doctor appointed by the Director of Medical Services. Second, only medical practitioners who had been authorised by the Director of Medical Services could remove the organs from a deceased person under HOTA and transplant these organs. Third, organ trading was strictly prohibited.

Impact of HOTA

The introduction of HOTA resulted in more cadaveric

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kidneys being available for transplantation.³ Between 1970 and 1987, there was an average of 4.7 cadaveric kidney transplants per annum. Between 1988 and 30 June 2004, there was a total of 674 cadaveric kidney transplants or an average of 40.8 cadaveric kidney transplants per annum (Fig. 1). Of these, 13.5 cadaveric kidney transplants per annum were obtained through HOTA during this period.

Necessity for Amendments to HOTA

When HOTA was first introduced, a conservative approach was taken as Singaporeans were unfamiliar with the concept of organ donation and there was cultural reluctance to donate organs. HOTA was thus restricted to only kidneys and death due to accidents. In addition, the other types of organ transplant were not yet well developed in Singapore.

However, with an increasing number of patients requiring transplants, there was a need to review and revise HOTA to alleviate the demand for more organs, including kidneys as well as other vital organs such as the heart and liver. At the same time, there was also a need to put in place an effective regulatory framework for living donor organ transplants, which till then had not been subject to any legislative purview, even though the first living donor kidney transplant in Singapore was carried out in 1976. Although the Ministry of Health had established professional guidelines stipulating that the social, psychological and emotional profile of the donor had to be assessed, a full medical examination carried out, and informed consent taken, there was no legislation supporting these requirements.

Demand for More Organs

Whilst the introduction of HOTA in 1987 had made more cadaveric kidneys available for transplantation, this effect was far outstripped by the growth in demand for kidneys, as evidenced by the continued growth of the kidney transplant waiting list. In 1988, there were 208 end-stage

renal failure patients on the kidney transplant waiting list. By end 2003, the waiting list had increased to 673 end-stage renal failure patients (Fig. 2).

Likewise, there was also a shortage of livers and hearts available for transplant. The first liver transplant and the first heart transplant were only carried out in Singapore in 1990,^{4,5} and hence liver and heart had not been included in HOTA when it was first introduced in 1987. The organ shortage resulted in a small number of liver and heart transplants being carried out in Singapore. Between 1998 and 2003, there was only an average of 7.3 liver transplants per annum and 1.8 heart transplants per annum. Due to the shortage of organs, an average of 14.7 patients per annum died while waiting for a liver transplant, and 2.7 patients per annum died while waiting for a heart transplant (Table 1).

With regard to cornea transplants, Singapore relied heavily on imported corneas, mainly from the United States of America. Between 1998 and 2002, there were 861 cornea transplants carried out in Singapore, of which 363 (42%) transplants involved imported corneas. As imported corneas might not be of optimal quality because of the long transit time between the country of origin and Singapore, there was a need to increase the local supply of corneas.

Amendments to HOTA

Following extensive public consultations spanning January to September 2003, the HOTA Amendment Bill was debated over 2 days in Parliament and passed unanimously on 6 January 2004. The amendments to HOTA were:

- a. to extend HOTA beyond kidneys to include the liver, heart and cornea;
- b. to extend HOTA beyond death due to accidents to all causes of death; and
- c. to extend HOTA beyond cadaveric organ donation to include living donor organ transplants.

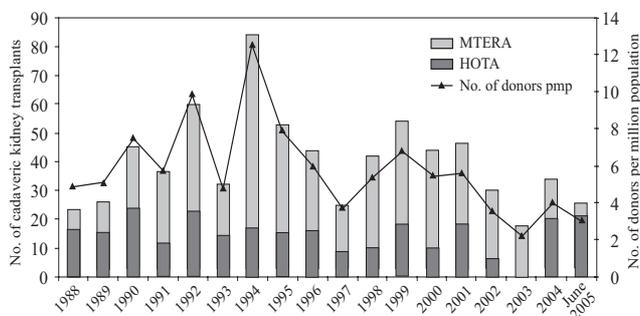


Fig. 1. Number of cadaveric kidney transplants and number of donors per million population, 1988 to June 2005. Source: Transplant data from NOTU Population data from the Singapore Department of Statistics

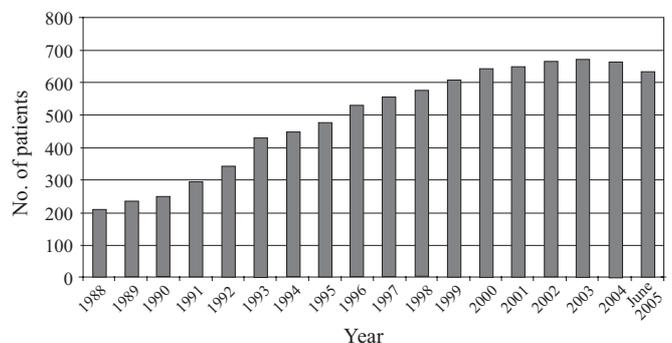


Fig. 2. Kidney transplant waiting list, 1988 to June 2005. Source: NOTU

Table 1. Number of Liver Transplants, Heart Transplants, and Cornea Transplants, 1998 to 2003

Year	1998	1999	2000	2001	2002	2003
Liver transplants						
Number of cadaveric liver transplants	7	13	10	7	5	2
Number of patients who died while waiting for liver transplant	18	21	12	8	14	15
Heart transplants						
Number of cadaveric heart transplants	1	5	1	2	2	0
Number of patients who died while waiting for heart transplant	5	1	3	1	3	3
Cornea transplants						
Number of cornea transplants*	34	30	25	28	18	16

* excludes corneas from cardiac dead donors.

Source: NOTU

Table 2. Number of Organ Donors and Cadaveric Organ Transplants, 1 July 2004 to 30 June 2005

	HOTA		MTERA	Total
	Death due to accidents	Death due to causes other than accidents		
No. of organ donors	5	16	3	24
No. of kidney transplants	10	31	6	47
No. of liver transplants	2	3	0	5
No. of heart transplants	2	0	1	3
No. of cornea transplants	7	26	0*	33

HOTA: Human Organ Transplant Act; MTERA: Medical (Therapy, Education and Research) Act

* excludes corneas from cardiac dead donors.

Source: NOTU

The regulation of living donor organ transplants was achieved through the addition of Sections 15A to 15D to HOTA. These provided for the appointments and functions of hospital Transplant Ethics Committees (TECs), and required all living (both related and unrelated) donor organ transplants to have prior written authorisation from the TEC. The considerations of the TEC, in deciding whether to approve an application of a living donor organ transplant were to include whether there was (a) informed consent from the donor, (b) presence of any form of organ trading, or (c) presence of any “fraud, duress or undue influence” when the informed consent was obtained from the donor. In addition, the TEC was to “have regard to the considerations of public interest and community values”, to allow the TEC the breadth to take into account the dynamic nature of societal expectations in a rapidly changing medical arena.

Amendments to the Interpretation (Certification and Determination of Death) Regulations

The Interpretation (Determination and Certification of Death) Regulations were also amended to allow for the use of supplementary tests in the determination of brain death. The supplementary tests provided for were: (a) cerebral

angiography to confirm that there was no intracranial blood flow; and (b) radionuclide scan to confirm that there was no intracranial perfusion.

Impact of the Amended Human Organ Transplant Act

The revised HOTA came into effect on 1 July 2004. Between 1 July 2004 and 30 June 2005, there was a total of 24 cadaveric organ donors, making available for transplantation a total of 47 kidneys, 5 livers, 3 hearts and 33 corneas. Twenty-one donors (87.5%) came under HOTA, while the other 3 donors came under MTERA. Among the 21 HOTA donors, 5 donors (23.8%) had deaths due to accidents, while 16 donors (76.2%) had non-accidental causes of death (Table 2). Supplementary tests were used during brain death certification for 6 cadaveric organ donors. Thus, the number of HOTA kidneys since the amendment of HOTA has risen to 41 over the preceding year. This compares to 13.5 cadaveric kidney transplants per annum obtained through HOTA prior to the amendments.

Discussion

The introduction of HOTA in 1988 led to an increase in the number of cadaveric kidneys available for transplant.

This was similar to the experience in other countries with presumed consent legislation.^{6,7} However, despite the increase in availability of organs, demand continued to outstrip supply, with the waiting list for cadaveric kidneys more than tripling between 1998 and 2003.

In the first year that it was implemented, the revised HOTA resulted in an increase in the number of cadaveric organs for transplant. Of the 21 cadaveric organ donors who came under HOTA, 16 donors died from non-accidental causes of death. Prior to the extension of HOTA beyond deaths due to accidents to include all causes of death, those who died from non-accidental causes of death would not have been included under HOTA. Instead, organ donation would have come under MTERA and would have required consent from the donor's family. Based on Sheehy et al's estimation of a consent rate of 54% for organ donation⁸ and NOTU's estimate of a consent rate of 30% to 35% in Singapore (personal communication with Ms Sally Kong, Senior Manager, NOTU), it can be estimated that the amended HOTA resulted in an additional 8 to 11 cadaveric donors in its first year of operation.

The provision for supplementary tests under the Interpretation (Determination and Certification of Death) Regulations is likely to have also contributed to the increased number of organ donors. If supplementary tests were not available, the 6 donors where supplementary tests were used might not have actualised as it might not have been possible to perform some of the tests for brain death certification, or the potential donor's condition might have deteriorated while waiting for the drug titres of depressant drugs to go down.

Various factors have been suggested as possible determinants of the organ donation rate in a country.^{9,10} In carrying out our policy review, we considered the possible impact of these factors on the yield of organs. As HOTA was originally limited to deaths due to accidents, we examined the relationship between the number of deaths due to accidents among Singaporeans and permanent residents between the ages of 21 years and 60 years, and the number of cadaveric kidneys obtained through HOTA. We found no correlation between the number of accidents and the number of cadaveric kidney transplants (Fig. 3). Nonetheless, the lower yield of actualised donors over the years could have been due to more accident victims either dying at the site of the accident, or surviving due to better management in the intensive care units at the hospitals. With regard to the low organ donor rate in 2002, of the 8 potential HOTA donors identified, 5 potential donors could not be actualised because they were found to be medically unsuitable. The absence of any HOTA donors in 2003 is likely to be due to the impact of SARS and the related policies implemented for infection control purposes.

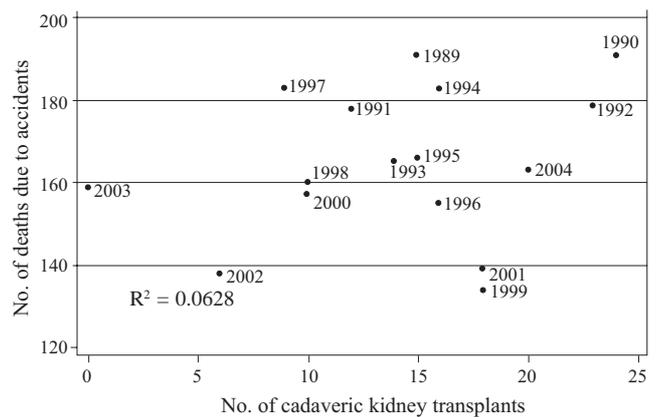


Fig. 3. Scatterplot of number of deaths due to accidents among Singaporeans and permanent residents aged 21 to 60 years, and the number of cadaveric kidney transplants obtained through HOTA, 1988-2004.

Source: Ministry of Health, Registry of Birth & Death and NOTU

There was extensive public consultation before we proceeded with the amendments to HOTA. There are many ethical and societal concerns with regard to presumed consent legislation for organ donation¹¹⁻¹⁴ and it was extremely important to take into consideration societal views on organ donation and presumed consent legislation. The public consultation on the proposed amendments to HOTA spanned 9 months and the views of all major religious groups, as well as various community and professional groups were sought before the HOTA amendment bill was presented and debated in Parliament. There were also extensive public education campaigns before and after the passage of the HOTA amendment bill to inform the public of the amendments to HOTA as well as organ donation.

In conclusion, based on the first-year experience, the amended HOTA has helped to increase the yield of cadaveric organs for transplantation. The kidney transplant waiting list has also begun to shorten. Nonetheless, the organ donation rates in Singapore still lag behind those in many countries such as Spain, the United States and the United Kingdom. The transplant community in Singapore will need to identify further avenues to enhance the organ transplant programme. In particular, we will need to explore how the number of living donor organ transplants can be enhanced to increase the supply of organs. The implementation of a robust regulatory framework for living donor organ transplants will thus allow us to move forward with greater confidence in promoting living organ transplants, thereby saving the lives of more patients.

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